

REPORT

Study Title:

Effects of AKPharma's Calcium Glycerophosphate

Nasal Spray wash (AkP 010112A) on Patient-Perceived

Breathing Comfort

LSR Protocol Number:

2749

Clinical Research Site:

Lovelace Scientific Resources, Inc.

2441 Ridgecrest Drive SE

Albuquerque, NM 87108

Study Director:

Darlene Harbour, BSN, RN, CCRC

Lovelace Respiratory Research Institute (LRRI)

2425 Ridgecrest Drive SE

Albuquerque, NM 87108

Senior Scientist:

10 NOV 2014

Edward G. Barrett, PhD

Director of Translational Research - Pharmacology

Sponsor:

AKPharma Inc.

PO Box 111

Pleasantville, NJ 08232



TABLE OF CONTENTS

| | | Page No. |
|-----|--------------------------------------|----------|
| 1.0 | EXECUTIVE SUMMARY | 3 |
| 2.0 | REGULATORY COMPLIANCE | 3 |
| 3.0 | KEY STUDY PERSONNEL | 3 |
| 4.0 | TEST ARTICLE | 4 |
| | 4.1 Identity | 4 |
| | 4.2 Description | 4 |
| | 4.5 Dispensing Instructions | 4 |
| 5.0 | STUDY DESIGN | 4 |
| | 5.1 Subject Eligibility Requirements | 5 |
| 6.0 | SAFETY MONITORING | 6 |
| 7.0 | OBSERVATIONS AND MEASUREMENTS | 6 |
| | 7.1 Blood Collection | 6 |
| | 7.2 Pulmonary Function Tests (PFT's) | 6 |
| | 7.3 Physical Examination | 6 |
| | 7.4 Results | 6 |
| 8.0 | DISCUSSION | 12 |
| APP | ENDIX 1 PROTOCOL | |

APPENDIX II INFORMED CONSENT FORM

APPENDIX III INSTRUCTIONS FOR SUBJECTS

APPENDIX IV SUBJECT DATA



1.0 EXECUTIVE SUMMARY

AkPharma Inc. has developed a calcium glycerophosphate (CGP) nasal spray wash for perceived rhinitis symptoms. The primary objective of the study is to assess subject nasal allergy symptoms. Also to be examined are changes in morning versus evening symptom scores and onset of the action of calcium glycerophosphate nasal spray, as well as changes observed in nasal eosinophil count and nasal histamine values. On study day 7, 14 and again at study day 21 subjects visit the study center where adherence to symptom diary and weight of the calcium glycerophosphate nasal spray wash is evaluated to confirm adherence. The secondary objective will include the changes observed in the FEV1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) on pulmonary function (spirometry) testing. Spirometry will be repeated on study day 7, 14 and again at study day 21.

In general, the subjects recruited into the study had persistent mild to moderate symptoms at baseline prior to the onset of treatment. Upon treatment with calcium glycerophosphate there was an immediate improvement in all symptom categories after the first week of treatment. Average daily symptoms scores over the three weeks of treatment with AKP010112A were significantly improved from baseline levels (Table 1). There was improvement in Respiratory symptoms. Respiratory function was evaluated (FEV and FVC; reported as % of predicted) at baseline and day 7, 14, and 21. There were no significant differences between baseline measures and anytime during the course of treatment.

In general, the reported adverse events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. These events were most likely associated with the initial delivery of the calcium glycerophosphate. The preponderance of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future, thus indicating that it was generally well tolerated and provided some noticeable benefit.

2.0 REGULATORY COMPLIANCE

This study was conducted in the spirit of U.S. FDA 21 CFR Part 56 (Good Clinical Practice).

3.0 KEY STUDY PERSONNEL

Study Director: Darlene Harbour, BSN, RN, CCRC

Principal Investigator: Jonny Salyer, MD

Clinical Principal Investigator

Senior Scientist Edward G. Barrett, PhD

Director of Translational Research - Pharmacology

Study Coordinator: Leslie Byatt, CCRC



4.0 TEST ARTICLE

4.1 Identity

Calcium Glycerophosphate (CGP)

4.2 Description

CGP is a calcium salt and an approved cosmetic component which has long been used as a food ingredient. CGP is a Dietary Supplement and is generally regarded as safe (GRAS). CGP is a normal cellular constituent, created de novo in the human body as an intermediate metabolite in the Krebs cycle of carbohydrate metabolism. As administered in this nasal rinsing-coating application, essentially all of the molecule that transits the nasal cavity and into the throat will be considered to be ingested, a safe and nutritional pathway for CGP. There are no known contraindications that pertain to ingestion of this molecule other than dietary preclusion of calcium or phosphorus/phosphate. Moreover, there are no known addiction, habituation, or dependency concerns; the molecule is devoid of psychotropic side effects, rebound effects, anticholinergic activity, etc.

4.3 Supplier

AKPharma, Inc.

4.4 Storage Conditions

Ambient temperature (59-86 degrees Farenheit)

4.5 Dispensing Instructions

Subjects will be instructed to deliver two sprays per nostril twelve hours apart, once in the morning and once in the evening for 21 days. Subjects will be allowed to take two sprays per nostril- four additional times as needed between the morning and evening dose to treat allergy symptoms.

5.0 STUDY DESIGN

The overall study design involved four weeks of study participation and recruited twenty (20) subjects. Subjects will be screened for eligibility at Visit 0/day -21 to day -10. Allergic sensitivities will be confirmed using Immunocap testing.

Days minus 7 to minus 1 was a run-in period during in which subjects with perennial allergic rhinitis maintained a rhinitis diary. Subjects returned for evaluation on Visit 2, day 1 (+/- 48 hours). If they qualified after the run in period, they had Pre-Treatment Baseline Assessments performed: spirometry, complete blood count, (CBC), comprehensive metabolic panel (CMP), phosphate level, histamine and eosinophil counts, adverse Event (AE) and concomitant medication review. On Visit 2, Day 1, subjects began to use topical nasal spray wash of calcium glycerophosphate, two sprays per nostril, twelve hours apart, a.m. and p.m. for the balance of the study. Subjects were allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. The subject received a demonstration application at enrollment prior to leaving the clinic and self-administered again that night, regardless of time of day demonstration dosage was taken.

The subject returned for study visits on days 7 (+/- 48 hours), 14 (+/- 48 hours) and day 21 (+/- 48 hours) at which time they presented their daily symptom score sheets and had a repeat spirometry performed. A nasal eosinophil test and nasal histamine assay were examined on visit days 1, 7, 14 and 21. On day 21 they had an additional CBC, CMP and phosphate lab test performed.

5.1 Subject Eligibility Requirements

The Clinical Research Site recruited and enrolled male and female subjects, ages 18-80 with a history of perennial allergic rhinitis symptoms for at least twelve months prior to entrance to the study. Subjects had to self-report a medical history of known sensitivities to the perennial aeroallergens which included, but was not limited to dust, mold, cat, dog and cockroach. Allergic (IgE) antibodies to perennial aeroallergens were confirmed by an Immunocap lab result.

Subject compliance with the Symptom Diary between visits 1 and 2 had to be 80% or greater in order for subjects to be considered for randomization.

Women of child bearing potential (WOCBP) and men had to agree to use an effective method of birth control during study participation, which may have included surgical sterilization, self-report of being post-menopausal for at least 12 months, double barrier method, or taking birth control pills.

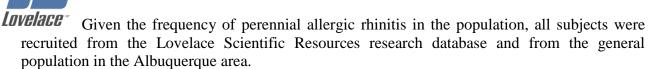
The Clinical Research Site excluded subjects if they did not agree to not wash out of excluded medications such as intranasal or systemic glucocorticosteroids for one month prior to enrollment, intranasal cromolyn for two weeks prior to enrollment, intranasal or systemic decongestants for three days prior to enrollment, and intranasal or systemic antihistamines for three days prior to enrollment, (Loratidine had to be washed out for ten (10) days prior to enrollment). Subjects were excluded if they were taking immunomodulatory or cytotoxic drugs.

General exclusions included a history of rhinitis medicamentosa (overuse of vasoconstrictor nasal sprays, e.g. Afrin®, producing rebound symptoms), planned travel outside the study area that would have precluded adequate follow up and the ability to comply with the visit schedule. Subjects with a diagnosis of asthma with more than two episodes per week or two nocturnal awakenings per month or if they had a known sensitivity to calcium or phosphorus supplements, were taking antihistamine treatment intermittently for atopic dermatitis, urticaria or any indication other than perennials allergic rhinitis, or if they were taking chronic, daily antihistamine treatment and planned to remain on that treatment for the duration of the study.

Subjects with a history of any clinically significant uncontrolled disease were excluded. Significant disease was defined as any disease that in the opinion of the investigator would put the safety of the subject at risk through study participation or would have confounded the interpretation of the study results should the disease/condition exacerbate during the study. Specifically, subjects were excluded if they had a diagnosis of hypercalcemia not limited to malignancy, sarcoidosis or hyperparathyroidism.

Subjects were excluded if they exhibited upon physical exam, nasal obstruction(s) sufficient enough to obstruct air flow that would interfere with study results.

Lastly, subjects were excluded if they were an employee of the clinical research site, an employee of the Sponsor or an immediate family member of the sponsor or the investigator(s). Immediate family was defined as spouse, parent, child and sibling.



6.0 SAFETY MONITORING

Adverse Events and/or Unanticipated Problems were monitored for safety, trends, issues that may require stopping the study. All adverse events were documented on an adverse event log in the subjects' individual research record. The Site was also maintained by one continuous running log of all adverse events for all subjects. The Investigator reviewed the adverse event and document severity and causality on the designated signature form. Any serious adverse event was recorded in subjects' research record as well as one continuous running log of serious adverse events at each site. Any serious adverse event were reported to the PI or Sub PI and to AK Pharma. The serious adverse event continuous log will be reviewed at the time of any and all serious adverse event and be documented with initials on the designated signature form. The PI's and/or sub PI's will call to order meetings if required to discuss any event or patient safety concerns. The protocol will be revised, put on hold or stopped if deemed necessary for patient safety. The PI and or Sub PI will report to regulatory agencies and IRBs in accordance with regulations. The PI will monitor vital signs and patient tolerability at each visit. The PI will make determinations regarding further subject assessment. If the patient cannot tolerate study drug due to side effects they will be withdrawn from the study.

7.0 OBSERVATIONS AND MEASUREMENTS

7.1 Blood Collection

Complete Blood Counts (CBC) and Chemistry Metabolic Panels (CMP) were collected at screening to determine subject safety for eligibility, and was collected at the final visit, again for subject safety. An Immunocap specimen was collected at screening to confirm perennial allergy eligibility. Phosphate levels were collected at screening and at the final visit to ensure subject safety. Nasal washings for eosinophil and histamine counts were collected at Day 1 (baseline), Day 7, 14, and 21 to show any changes while on treatment.

7.2 Pulmonary Function Tests (PFT's)

Basic Spirometry was performed on Day 1 for baseline measurement, and on Day 7, 14, and 21 to show any while on treatment. The specific tests recorded were Forced Vital Capacity (FVC), Forced Expiratory Volume in 1 second (FEV1), and the FVC/FEV1 ratio. Subjects did not undergo bronchodilator evaluation.

7.3 Physical Examination

A screening physical exam was conducted to determine eligibility and final visit physical exam to ensure subject safety.

7.4 Results

Symptom scores were collected over the course of the study on a daily basis in the morning (AM) and in the evening (PM). Six symptoms of twenty patients affected with allergy were recorded during their baseline period (7 days) and following 23-25 days of treatment. Their symptoms included "Runny Nose", "Itchy Nose", "Congestion", "Sneezing", "Hoarse Voice", and "Throat Clearing", with severity ranging from 0-3. We compared symptoms' difference of



the baseline VS 1st, 2nd, and 3rd, week after treatment (Table 1). Comparisons were based on the daily mean for each individual symptom score as well as a total symptom score over the course of the treatment week. Additionally, symptom score differences in the morning and afternoon were compared at baseline and after treatment.

Average daily symptoms scores over the three weeks of treatment with AKP010112A were significantly improved from baseline levels (Table 1). There was improvement in symptoms ("Runny Nose", "Itchy Nose", "Congestion", and "Throat Clearing") from week 1 to 2 of treatment. By the end of three weeks of treatment only the symptoms of "Itchy Nose" and "Throat Clearing" were further improved from the previous week, however, all symptoms remained significantly improved compared to baseline scores. Total mean daily symptom scores were reduced by 42% by the end of the study following treatment with AKP010112A (Figure 1).

There were differences in some symptom scores in the AM vs PM at baseline and during the treatment phase (Table 2). Total symptoms scores were worse in the AM as characterized by significant differences in "Hoarse Voice", and "Throat Clearing" at baseline. During the treatment phase while all symptoms improved over baseline they were again worse in the AM (Table 3: "Congestion", "Hoarse Voice", and "Throat Clearing").

Respiratory function was evaluated (FEV and FVC; reported as % of predicted) at baseline and day 7, 14, and 21. There were no significant differences between baseline measures and anytime during the course of treatment (Table 4).

At baseline (day 1 prior to first dose), day 7, day14, and 21 nasal lavages were performed in order to determine if histamine levels were altered by treatment with AKP010112A. Individual histamine levels are reported in figure 3 and there were varied levels even at baseline from individual to individual. Average levels did not change significantly following AKP010112A treatment (Figure 4). Additionally, nasal eosinophils were determined and reported as either not present (0) < rare (1) < few (2) < moderate (3) < many (4). There was no significant treatment effect with AKP010112A on numbers of eosinophils (figure 5 and 6).

Blood was collected at baseline (day 1 prior to first dose), day 7, day14, and 21 and lab CBC performed. There were no findings that were considered clinically significant. A total of 11 patients reported adverse effects of the treatment compared to 9 that did not. The reported events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. Other less frequently reported adverse events were nose bleeds, bad taste, watery eyes, nasal congestion, and headache. Fifteen of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future while 4 indicated they would not.

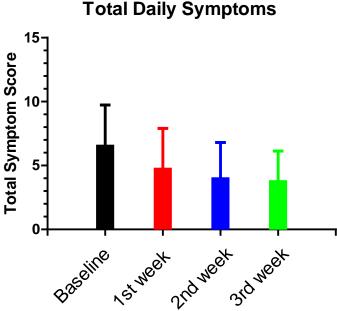


Table 1 Individual Symptom Scores.

| SYMPTOM | Baseline mean (+/-SD) | 1st Week mean (+/-SD) | 2nd Week mean (+/-SD) | 3rd Week mean (+/-SD) | Baseline VS 1st week after Treatment (p-value) | 1st VS 2nd week after Treatment (p-value) | 2nd VS 3rd week after Treatment (p-value) | Baseline VS 2nd week after Treatment (p-value) | Baseline VS 3rd week after Treatment (p-value) |
|----------------|--------------------------|--------------------------|--------------------------|--------------------------|--|---|---|--|--|
| Runny Nose | 1.601 (+/- 0.957) | 1.045 (+/- 0.937) | 0.873 (+/- 0.822) | 0.836 (+/- 0.726) | <0.0001 | 0.0063 | 0.3564 | <0.0001 | <0.0001 |
| Itchy Nose | 0.880 (+/- 0.922) | 0.557 (+/- 0.870) | 0.447 (+/- 0.803) | 0.341 (+/- 0.631) | <0.0001 | 0.0360 | 0.0068 | <0.0001 | <0.0001 |
| Congestion | 1.562 (+/- 0.965) | 1.207 (+/-0.852) | 0.917 (+/- 0.784) | 0.836 (+/- 0.812) | <0.0001 | <0.0001 | 0.2455 | <0.0001 | <0.0001 |
| Sneezing | 0.944 (+/- 1.034) | 0.672 (+/- 0.865) | 0.579 (+/-0.806) | 0.545 (+/- 0.717) | <0.0001 | 0.1179 | 0.3934 | <0.0001 | <0.0001 |
| Voice Hoarse | 0.338 (+/- 0.751) | 0.216 (+/- 0.621) | 0.288 (+/-0.704) | 0.207 (+/- 0.610) | 0.0154 | 0.1619 | 0.0906 | 0.3857 | 0.0064 |
| Thrt Clearing | 1.200 (+/- 0.981) | 1.075 (+/- 0.999) | 0.856 (+/-0.992) | 1.043 (+/-1.001) | 0.0564 | 0.0003 | 0.0148 | <0.0001 | 0.0017 |
| Total symptoms | 6.524 (+/-3.201) | 4.723 (+/- 3.184) | 3.965 (+/- 2.836) | 3.741 (+/- 2.386) | <0.0001 | <0.0001 | 0.1746 | <0.0001 | <0.0001 |

The mixed model with repeated measurements was used in analysis. Among the model to test symptoms' changes among different weeks, we consider patients as random effect and include morning / afternoon effect as covariates. Statistical calculations were performed using the SAS® software system, Version 9.3 (Cary, NC).

Figure 2. Average Daily Total Symptom Scores.



Daily symptom scores were averaged over the baseline period (day -7-0), first week of dosing (day 1-7), second week of dosing (day 8-14), and the third week of dosing (day 15-23(5)). Treatment with AKP010112A significantly improved symptom scores from baseline levels. Symptoms continued to improve over the duration of the study with a 42% improvement by the end of the study. Mean +/- SD.



Table 2. Average Daily AM vs PM Symptom Scores at Baseline

| SYMPTOM | AM mean (+/-SD) | PM mean (+/-SD) | Test Results (p-value) |
|----------------|--------------------|--------------------|---------------------------|
| Runny Nose | 1.603 (+/-0.917) | 1.600 (+/- 1.002) | 0.6404 |
| Itchy Nose | 0.907 (+/- 0.841) | 0.850 (+/- 0.905) | 0.3457 |
| Congestion | 1.556 (+/- 1.011) | 1.568 (+/- 0.917) | 0.5319 |
| Sneezing | 0.960 (+/- 0.999) | 0.928 (+/- 1.074) | 0.9856 |
| Voice Hoarse | 0.464 (+/- 0.847) | 0.201 (+/-0.604) | <0.0001 |
| Thrt Clearing | 1.351 (+/- 0.939) | 1.036 (+/-1.003) | <0.0001 |
| Total symptoms | 6.839 (+/- 3.274) | 6.187 (+/- 3.096) | 0.0315 |

Table 3. Average Daily AM vs PM Symptom Scores during Treatment

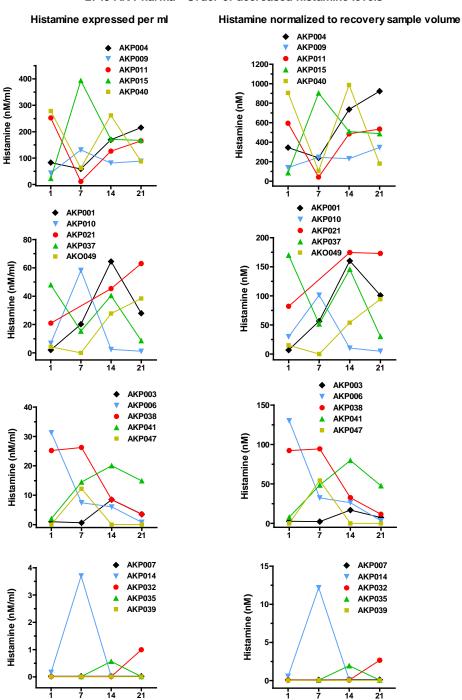
| SYMPTOM | AM mean (+/-SD) | PM mean (+/-SD) | Test Results (p-value) |
|----------------|--------------------|--------------------|---------------------------|
| Runny Nose | 0.957 (+/- 0.852) | 0.888 (+/- 0.825) | 0.0737 |
| Itchy Nose | 0.587 (+/- 0.868) | 0.533 (+/-0.807) | 0.0621 |
| Congestion | 1.181 (+/- 0.936) | 1.098 (+/- 0.871) | 0.0104 |
| Sneezing | 0.698 (+/- 0.883) | 0.679 (+/- 0.873) | 0.5796 |
| Voice Hoarse | 0.327 (+/-0.740) | 0.191 (+/-0.588) | <0.0001 |
| Thrt Clearing | 1.100 (+/-0.996) | 0.907 (+/- 0.997) | <0.0001 |
| Total symptoms | 4.400 (+/- 2.926) | 3.925 (+/- 2.760) | 0.0001 |

Scores average over the whole treatment period.

Table 4. FEV and FVC

| SYMPTOM | Baseline mean (+/-SD) | Day 7 mean (+/-SD) | Day 14 mean (+/-SD) | Day 21 mean (+/-SD) | Baseline VS Day 7 (p-value) | Day 7 VS 14 (p-value) | Day 14 VS 21 (p-value) | Baseline VS Day 14 (p-value) | Baseline VS Day 21 (p-value) |
|--------------|--------------------------|-----------------------|------------------------|------------------------|-----------------------------------|--------------------------|---------------------------|------------------------------------|------------------------------------|
| FEV (% Pred) | 97.70 (+/- 24.12) | 94.95 (+/- 25.26) | 95.95 (+/- 25.55) | 97.25 (+/- 23.68) | 1.5700 | 0.5709 | 0.7422 | 0.9991 | 0.2569 |
| FVC (% Pred) | 107.5 (+/- 23.6) | 103.9 (+/- 24.33) | 106.2 (+/- 22.86) | 108.0 (+/- 22.03) | 1.8320 | 1.1960 | 0.8905 | 0.6361 | 0.2544 |





2749 AK Pharma - Order of decreased histamine levels

Figure 3. Individual Histamine levels.

Time Point (days)

Time Point (days)

Histamine levels were determined in nasal lavage fluid at day 1 prior to first dose, day 7, day14, and 21.



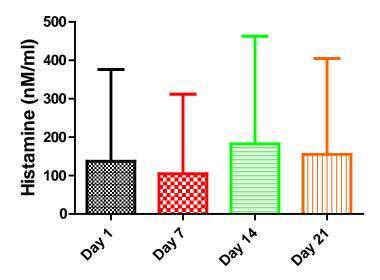


Figure 4. Average histamine levels.

Histamine levels were determined in nasal lavage fluid at day 1 prior to first dose, day 7, day14, and 21. Average levels did not change significantly following AKP010112A treatment. Mean +/- SD.

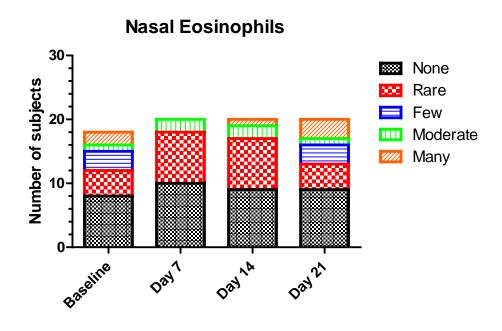


Figure 5. Relative numbers of eosinophils in nasal wash.

There was no apparent effect of treatment on eosinophils in the nasal wash. Graph represents the number of patients identified with a relative level of eosinophils. There was no data for two patients at baseline.



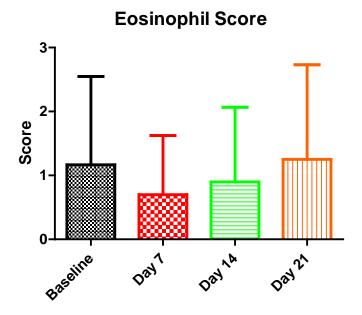


Figure 6. Relative numbers of eosinophils in nasal wash.

There was no significant effect of treatment on eosinophils in the nasal wash. Subjective scoring levels of eosinophils were assigned a value: not present (0) < rare (1) < few (2) < moderate (3) < many (4). There was no data for two patients at baseline. Mean +/- SD.

8.0 DISCUSSION

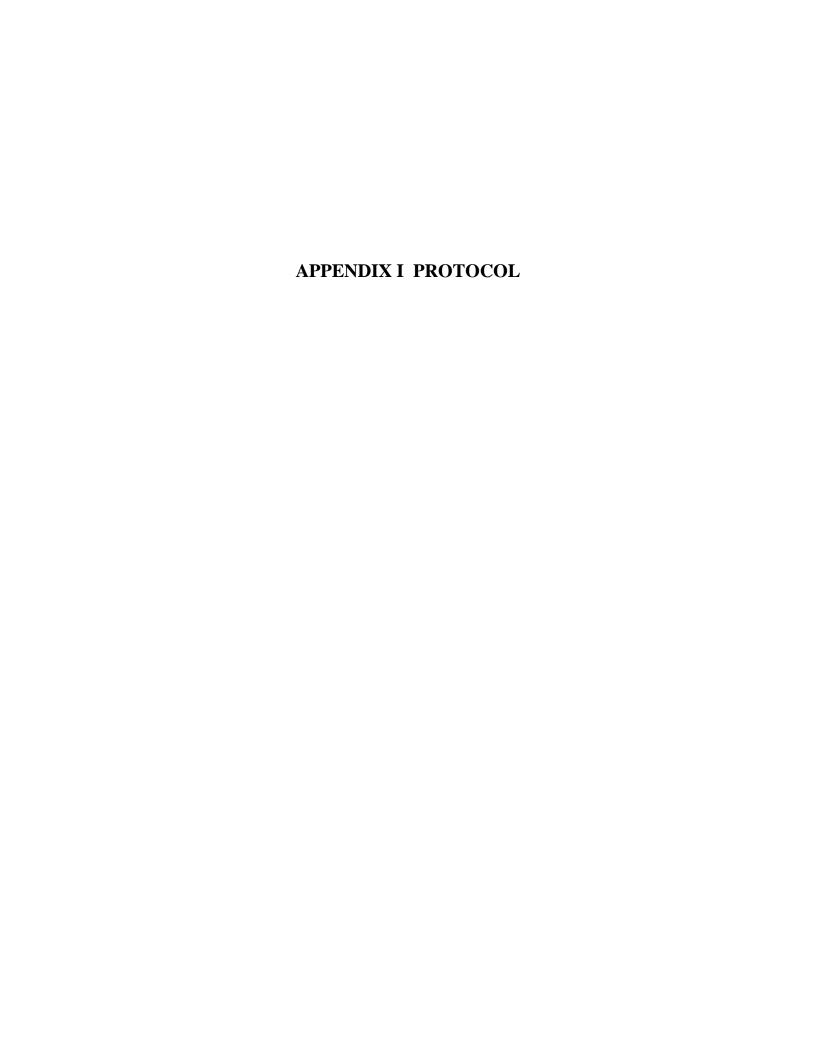
The primary objective of the study was to assess subject nasal allergy symptoms following treatment with calcium glycerophosphate. In general, the subjects recruited into the study had persistent mild to moderate symptoms at baseline prior to the onset of treatment. Upon treatment with calcium glycerophosphate there was an immediate improvement in all symptom categories after the first week of treatment. Further, there was improvement in symptoms ("Runny Nose", "Itchy Nose", "Congestion", and "Throat Clearing") from week 1 to 2 of treatment. By the end of three weeks of treatment only the symptoms of "Itchy Nose" and "Throat Clearing" were further improved from the previous week, however, all symptoms remained significantly improved compared to baseline scores. Interestingly, none of these symptom improvements were associated with changes in nasal histamine or eosinophil levels suggesting that mechanism of action may be independent of mast cell degranulation or the presence of allergic inflammation. Similar results were achieved, in a previous study, in which ragweed sensitized dogs were pretreated with calcium glycerophosphate prior to nasal challenge with allergen. In these preclinical dog studies there was a significant decrease in nasal congestion that was not associated with a decrease mast cell derived mediators or nasal inflammatory cells.

Typically, for individuals with mild to moderate persistent allergic rhinitis the first line of treatment is intranasal corticosteroids or treatment with an antihistamine with or without

maximum effect within 2 weeks with calcium glycerophosphate is most similar to the response profile of intranasal steroids (1). However, it appears that the mechanism of actions are likely different as intranasal steroids are typically most effective against late-phase mediators in eosinophilic-dominated inflammation with some effect on the acute phase of the allergic response (2). It is difficult to directly compare calcium glycerophosphate to other treatments as they were not compared head to head in the present study, however, it's interesting to note that the significant reduction in symptoms was achieved in the context of existing symptoms. Antihistamines and cromolyn are not as effective when given after the onset of symptoms (3).

In general, the reported adverse events were generally mild to moderate and did not require treatment. The most common adverse effects were stinging/burning immediately following treatment, nasal dryness, and sore throat. These events were most likely associated with the initial delivery of the calcium glycerophosphate. The preponderance of the subjects indicated on a satisfaction questionnaire that they would be willing to use/purchase this product in the future, thus indicating that it was generally well tolerated and provided some noticeable benefit.

- 1. Melvin TN and Patel AA. Pharmacotherapy for Allergic Rhinitis Otolaryngol Clin N Am 2011; 44; 727–739.
- 2. Mygind N. Local effect of intranasal beclomethasone dipropionate aerosol in hay fever. Br Med J 1973;4:464–6.
- 3. Krouse JH. Allergic rhinitis—current pharmacotherapy. Otolaryngol Clin North Am 2008;41(2):347–58.



Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

Original Protocol Date:

01 May 2013

APPROVED BY:

Jonny Salyer, MD Principal Investigator

Lovelace Scientific Resources, Inc.

Alan E. Kligerman

Chief Executive Officer

AKPharma, Inc.

Protocol Summary

5

Approximately 20-40 million Americans have allergic rhinitis, with direct and indirect costs ranging from \$1.2 billion to \$5.3 billion per year. Perennial allergic rhinitis is a common year round problem that is associated with sneezing, rhinorrhea and nasal congestion. Sneezing is induced by stimulation of nasal sensory nerves while congestion results from vasodilation. Rhinorrhea is associated with increased vascular permeability and granular secretion. A number of chemical mediators contribute to these symptoms including histamine, leukotrienes, interleukins and neuropeptides. A large number of drug interventions sold, including Rx and OTC, both inhaled and orally-taken, address this problem, with greater or lesser success, depending on the individual using them. A common problem with most or all of these drugs is their array of side effects, including addiction, habituation, rebound, dependency, anticholinergic effects, drowsiness - or its opposite, hyperactivity -, and psychotropic compromise of demanding activities such as driving or machinery operation.

AkPharma Inc. has developed preliminary data suggesting that calcium glycerophosphate (CGP), used as a nasal spray wash improves perceived rhinitis symptoms, and delivers none of the above named adverse symptoms linked with drugs. AkPharma has commissioned extensive study of this molecule which has a prior history of safe and effective therapeutic applications in other sectors of the body. CGP is a calcium salt and an approved cosmetic component and it has long been used as a food ingredient. CGP is a Dietary Supplement and is generally regarded as safe (GRAS). CGP is a normal cellular constituent, created de novo in the human body as an intermediate metabolite in the Krebs cycle of carbohydrate metabolism. As administered in this nasal rinsing-coating application, essentially all of the molecule that transits the nasal cavity and into the throat will be considered to be ingested, a safe and nutritional pathway for CGP. There is extensive information on its safety, including a recently concluded study conducted on ragweed-sensitized beagle dogs, which demonstrated proof of efficacy, with no untoward physiological or other adverse effects (Barrett, EG, Effects of inhaled calcium glycerophosphate on Rhinitis Responses in Ragweed Sensitized Dogs, Lovelace Respiratory Research Institute, Albuquerque, NM March, 2010). Further, in order to establish the systemic safety of this cosmetic-category product, a further terminal small animal study was conducted on inhalation of

nasally administered doses of CGP at levels proportionally comparable to expected human dosages (Brackee, G, Acoustic Rhinometry and Pathologic Analysis on Ovalbumin-Sensitized Guinea Pigs Treated with Calcium Glycerophosphate, Texas Tech Univ. Laboratory Animal Resources Center, Lubbock, TX). The study results demonstrated no discernable cellular effects in body tissue or in vital organs, including lungs, heart, brain or elsewhere in the study animals and no differences between test and control animals. There are no known contraindications that pertain to ingestion of this molecule other than dietary preclusion of calcium or phosphorus/phosphate. Moreover, there are no known addiction, habituation, or dependency concerns; the molecule is devoid of psychotropic side effects, rebound effects, anti-cholinergic activity, etc. We propose to evaluate subjects with perennial allergic rhinitis with or without lower respiratory tract asthma for potential beneficial effects of intranasal administration of CGP, primarily on their perceived and self-reported changes in respiratory comfort and feelings of breathing "well-being."

Study Design

The overall study design involves four weeks of study participation and will recruit twenty (20) subjects. Subjects will be screened for eligibility at Visit 0, Day minus 8 (-8). Allergic sensitivities will be confirmed using Immunocap testing.

Days minus 7 to minus 1 will be a run-in period during which subjects with perennial allergic rhinitis will maintain a rhinitis diary (see Diary). Subjects return for evaluation on Visit 2, day 1 (+/- 48 hours). If they qualify after the run in period, they will have Pre-Treatment Baseline Assessments performed: spirometry, complete blood count, (CBC), comprehensive metabolic panel (CMP), phosphate level, histamine and eosinophil counts, adverse Event (AE) and concomitant medication review. On Visit 2, Day 1 subjects will begin to use topical nasal spray wash of calcium glycerophosphate, two sprays per nostril twelve hours apart, a.m. and p.m. for the balance of the study. Subjects will be allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. The subject will receive a demonstration application at enrollment prior to leaving the clinic and will self-administer again that night, regardless of time of day demonstration dosage was taken.

The subject will return for study visits on days 7 (+/- 48 hours), 14 (+/- 48 hours) and day 21 (+/- 48 hours) at which time they will present their daily symptom score sheets and have a repeat spirometry performed. A nasal eosinophil test and nasal histamine assay will be examined on visit days 1, 7, 14 and 21. On day 21 they will have an additional CBC, CMP and phosphate lab test performed.

Inclusion Criteria

- 1. Male or female subjects ages 18-80
- 2. History of perennial allergic rhinitis symptoms for at least twelve months prior to entrance to the study. Subjects will self-report a medical history of known sensitivities to the perennial aeroallergens which include, but are not limited to dust, mold, cat, dog and cockroach. Allergic (IgE) antibodies to perennial aeroallergens will be confirmed from the Immunocap testing.
- 3. Compliance with the Respiratory Symptom Diary between visits 1 and 2 of 80% or greater.
- 4. Women of child Bearing Potential (WOCBP) must be taking an effective method of birth control, surgically sterile, or post-menopausal for at least 12 months. Men must use an effective birth control throughout the course of the study.

Exclusion Criteria

- 1. Intranasal or systemic glucocorticosteroids within one month of study initiation
 - i. Iintranasal cromolyn for two weeks prior to the enrollment
 - ii. Iintranasal or systemic decongestants for three days prior to enrollment
 - iii. Intranasal or systemic antihistamines for three days prior to enrollment: oratidine for ten (10) days prior to enrollment
- 2. A history of rhinitis medicamentosa (overuse of vasoconstrictor nasal sprays, e.g. Afrin®, producing rebound symptoms)
- 3. Planned travel outside the study area that will preclude adequate follow up and the ability to comply with the visit schedule
- 4. Subjects with a diagnosis of asthma with more than two episodes per week or two nocturnal awakenings per month.

- 5. Subjects with known sensitivity to calcium or phosphorus supplements.
- 6. Subjects who are taking antihistamine treatment intermittently for atopic dermatitis, urticaria or any indication other than perennials allergic rhinitis. Subjects will not be excluded if they are taking chronic, daily antihistamine treatment and plan to remain on that treatment for the duration of the study.
- 7. Subjects taking immunomodulatory or cytotoxic drugs.
 - a. Subjects who have a history of clinically significant uncontrolled disease, 'Significant' is defined as any disease that in the opinion of the investigator would put the safety of the subject at risk through study participation or would confound the interpretation of the study results if the disease/condition exacerbates during the study.
- 8. Subjects with a diagnosis of hypercalcemia not limited to malignancy, sarcoidosis or hyperparathyroidism.
- 9. Subjects with nasal obstruction(s) sufficient enough to obstruct air flow that would interfere with study results and could not be reliably extracted (e.g. polyps).
- 10. Subject is an investigator, employee of the Sponsor or an immediate family member of the sponsor or the investigator(s). Immediate family is defined as spouse, parent, child and sibling.

Subjects Study Protocol

Beginning on day minus 7 subjects who qualify will begin recording a diary in which they will self evaluate and score their symptoms. Scores will be recorded in both the a.m. and p.m. 12 hours apart at the expected dosing interval. The symptoms to be evaluated are rhinorrhea (runny nose), itching, congestion and sneezing. A 0-3 scale will be used in which 0 = absent symptoms (no sign/symptom evident), 1 = mild symptoms (sign/symptom clearly present, but minimal awareness; easily tolerated), 2 = moderate symptoms (definite awareness of sign/symptoms that is bothersome but tolerable), 3 = severe symptoms (sign/symptom that is hard to tolerate, causes interference with activities of daily living and/or sleep). To qualify, the subject will need to have completed at 80% of the required entries between visits 1 and 2 of the Respiratory Symptom Diary. The information from the diary collected at visit 2 will be considered the baseline nasal symptoms. Throat clearing (post-nasal drip) will also be evaluated. On Visit 2, Day 1, following baseline evaluations, calcium glycerophosphate nasal spray wash will be dispensed. Proper use will be demonstrated to and by the subject, including the appropriate way to squeeze bottle and

get bottle back to its normal ready for re-use dimensions. Subject will take actual dosage at this demonstration. Subject will then commence home usage, using two sprays in each nostril, twelve hours apart, a.m. and p.m. As noted above, subjects will be allowed to take two sprays per nostril- four additional times as needed between the a.m. and p.m. doses. On Day 1, the subject will self-administer again that evening, regardless of time of day that the demonstration dosage was taken. The subjects will record their symptoms scores one hour post-dose and again just prior to the next self-administration. The score recorded an hour after the dose is referred to as the "reflective" symptom score and the score recorded pre-next dose is referred to as "instantaneous" symptom score. A nasal eosinophil test and nasal histamine test is performed at Visit 2 (Day 1), Visit 3 (Day 7), Visit 4 (Day 14), and Visit 5 (Day 21

Primary and Secondary End Points

The primary end point will be the nasal diary score. The secondary end point will include the changes observed in the FEV1 (forced expiratory volume in 1 second) and FVC (forced vital capacity) on pulmonary function (spirometry) testing. Also to be examined as secondary end points are changes in AM versus PM symptom scores and onset of the action of calcium glycerophosphate nasal spray wash as well as changes observed in nasal eosinophil count and nasal histamine values. On study day 7, 14 and again at study day 21 subjects visit the study center where adherence to symptom diary and weight of the calcium glycerophosphate nasal spray wash is evaluated to confirm adherence. As mentioned above, spirometry will be repeated on each of those days. The subjects will also be questioned as to whether symptoms necessitated the use of any additional medications that are excluded above during the prior one-week period. They will also be questioned as to whether there have been any intercurrent infections such as an upper respiratory tract infection (such as the common cold) involving the nose or sinuses. If that proves to be the case, they will be disqualified from continuing in the study. Subjects will also be asked to evaluate quality of life on a 1-10 scale.

Statistical Analysis

Subject Recruitment

Given the frequency of perennial allergic rhinitis in the population, all subjects are expected to be recruited from the Lovelace Scientific Resources research database and the general population in the Albuquerque area. Screening will continue until the study enrolls 20 subjects.

Data Safety Monitoring Plan

Adverse Events/Unanticipated Problems will be monitored for safety, trends, issues that may require stopping the study. All adverse events will be documented on an adverse event record in the subjects' individual research record. The Site will also maintain one continuous running log of all adverse events for all subjects. The PI and/or Sub PI will review the adverse event continuous logs at the time of the event and on a quarterly basis and document severity and causality on the designated signature form. Any serious adverse event will be recorded in subjects' research record as well as one continuous running log of serious adverse events at each site. Any serious adverse event will be reported to the PI or Sub PI and to AK Pharma. The serious adverse event continuous log will be reviewed at the time of any and all serious adverse event and be documented with initials on the designated signature form. The PI's and/or sub PI's will call to order meetings if required to discuss any event or patient safety concerns. The protocol will be revised, put on hold or stopped if deemed necessary for patient safety. The PI and or Sub PI will report to regulatory agencies and IRBs in accordance with regulations.

The PI will monitor vital signs and patient tolerability at each visit. The PI will make determinations regarding further subject assessment. If the patient cannot tolerate study drug due to side effects they will be withdrawn from the study.

Quality Assurance/Monitoring

Quality reviews will be performed by Lovelace Scientific Resources, Inc., regulatory department personnel on a regular basis determined by the subject enrollment rate. Adherence to the protocol, ICH and GCP guidelines will be monitored.

Visit Schedule

| Assessments/Procedures | VO | V1 | V2 | V3 | V4 | V5 |
|------------------------|--------|-------|-------|----------|----------|----------|
| | Day -8 | Day-7 | Day 1 | Day 7 | Day 14 | Day 21 |
| Informed Consent | X | | | | | |
| Assess | X | X | X | | | <u> </u> |
| Inclusion/Exclusion | | | | | | |
| Medical History | X | | | | | |
| Concurrent Medication | X | X | X | X | X | X |
| Review | | | | | | - |
| Assess Adverse Events | X | X | X | X | X | X |
| Abbreviated Physical | X | | | | | X |
| Exam | | | | | | 1 |
| Lab: Immunocap | X | | | | | |
| Lab; CBC | | | X | | <u> </u> | X |
| Lab:CMP | | | X | | - | X |
| Lab: Phosphate | | | X | | | X |
| Lab: Nasal Eosinophil | | | X | X | X | X |
| Lab: Nasal Histamine | | | X | X | X | X |
| Patient Diary | | X | | <u> </u> | | |
| Symptoms Scores | | : | X | X | X | X |
| Satisfaction | | · | | | | X |
| Questionnaire | | | i | ļ | | |
| Pulmonary Function | | | X | X | X | X |
| Test (PFT) | : | | | | | 1 |
| IP Training | | | X | X | X | X |
| IP Dosing | | | X | X | X | X |
| IP Accountability | | | X | X | X | X |

APPENDIX II INFORMED CONSENT FORM

INFORMED CONSENT

TITLE: Effects of AkPharma's Calcium Glycerophosphate Nasal

Spray Wash (AkP010112A) on Patient-Perceived

Breathing Comfort

PROTOCOL NO.: N/A

SPONSOR: AkPharma, Inc

INVESTIGATOR: Jonny Salyer, MD

TELEPHONE: 505-348-9500

INTRODUCTION

Before agreeing to participate in this research study, it is important that you read and understand the following explanation of the proposed research study. This consent document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

If you are not completely truthful with your study doctor regarding your health history, you may harm yourself by participating in this study.

The study is being conducted for AkPharma Inc. Your study doctor is being paid by AkPharma to conduct this study.

You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

BACKGROUND AND PURPOSE

You are being asked to participate in this research study because you have recurring symptoms of nasal allergies and may meet study requirements. Possible causes of these allergy symptoms may include all allergens such as dust, pollen, mold, cat, dog dander or cockroach. Knowing the cause of your allergy symptoms is not required to be a part of the trial.

The study sponsor submitted a preliminary product label and application for approval for its Calcium Glycerophosphate (CGP) Nasal Spray Wash to the FDA in 2008 and in 2011. The FDA raised no objection to the cosmetic CGP nasal wash, its use or to the product label. The ingredients in Calcium Glycerophosphate Nasal Spray Wash are generally recognized as safe (GRAS).

The purpose of this research study is to look at the safety and effectiveness of the Calcium Glycerophosphate Nasal Spray Wash, how it affects your condition, and how well you tolerate Calcium Glycerophosphate Nasal Spray Wash.

NUMBER OF SUBJECTS / LENGTH OF PARTICIPATION

Up to forty (40) persons 18 to 80 years old with allergy symptoms in the past 12 months may take part in the study. The length of your participation in this study will be about 28 days.

PROCEDURES

Before any study-related tests and procedures are performed, you will be asked to read and sign this consent document. The following tests and procedures will be performed to determine if you qualify to take part in this study.

Screening (Visit 0):

- ♦ Informed Consent
- Assess Inclusion/Exclusion criteria (study plan requirements)
- ♦ Medical history (including demographic-personal information about yourself, such as date of birth, race, etc.)
- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- ♦ Limited physical exam
- ♦ Blood (about 2 tablespoons) collection for routine tests.

Visit 1: (7 days before receiving the nasal wash)

- Assess Inclusion/Exclusion criteria (study plan requirements)
- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- ◆ You will be required to keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray).

Visit 2: (Day 1 of Study)

- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- Blood (about 2 tablespoons) collection for routine tests.

- Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ♦ You will keep a daily diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray).
- ♦ You will be trained on the proper use of the nasal wash. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ♦ You will be given an appropriate amount of the nasal spray wash to take with you.

Visit 3: (Day 7 of Study)

- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- ♦ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- You will continue to keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray). Your diary will be reviewed for completeness.
- Your ability to use the nasal wash will be assessed. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ♦ You will return all unused nasal spray wash for weighing and be given new nasal spray wash to take with you.

Visit 4: (Day 14 of Study)

- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ◆ You will keep a diary of symptoms for 28 days (7 days before starting the spray and for 21 days on the spray). Your diary will be reviewed for completeness.

- ♦ Your ability to use the nasal wash will be assessed. Only you can take the study nasal spray wash. It must be kept out of the reach of children and persons who may not be able to read or understand the label.
- You will be asked to use the nasal wash, 2 sprays each nostril, every 12 hours every day for 21 days. You will be permitted an additional 4 doses per day if needed in-between the 12 hour scheduled doses.
- ♦ You will return all unused nasal spray wash for weighing and be given new nasal spray wash to take with you.

Visit 5: (Day 21 of Study/End of Study)

- Record recent and current medications (both over the counter and prescription)
- Assess for adverse events (any changes in your health you report after signing the informed consent)
- Limited physical exam
- Blood (about 2 tablespoons) collection for routine tests.
- ♦ Nasal sample (salt water rinse about 2 tablespoons) collection for routine tests
- Pulmonary Function Testing (PFT- measurement of breathing patterns measured from breathing through a hand held meter)
- ♦ Complete satisfaction questionnaire
- You will return the symptom diary and unused nasal spray wash for weighing.

EXPECTATIONS

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research participant when you are deciding to take part. If you participate in this study you will be expected to:

- Follow the instructions you are given.
- Come to the study center for all visits that are required.
- Tell the truth to the best of your knowledge about your medical history and current conditions as well as all medications, prescribed or over-the-counter; including vitamins and herbal supplements, you are taking.
- Tell the research staff if you have been in a research study in the last 30 days or if you are currently in another research study.

RISKS, SIDE EFFECTS AND/OR DISCOMFORTS

There are risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.

You may have side effects while participating in the study. Everyone taking part in the study will be followed carefully for any side effects. However, doctors do not know all the side effects that may happen. Side effects may be mild or very serious.

Nasal rinsing may cause nasal/oral discomfort such as dryness, gagging and cough.

Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.

No allergic reactions to Calcium Glycerophosphate are known in human experience or in animal studies. Allergic reaction to Calcium Glycerophosphate Nasal Spray Wash is possible. Serious allergic reactions can be life threatening. Persons who have been told not to take either calcium or phosphorus/phosphate should not participate in the study.

The use of Calcium Glycerophosphate Nasal Spray Wash can cause a slight drying of the nasal tissue in some persons.

To date there are no known risks taking Glycerophosphate Nasal Spray Wash.

UNFORESEEN RISKS

Since the study drug Calcium Glycerophosphate (CGP) Nasal Spray Wash is investigational when taken alone or in combination with other medications, there may be other risks that are unknown. All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening.

PREGNANCY / BIRTH CONTROL

Women who are pregnant or nursing a child may not participate in this study. If you are a woman of child bearing potential, you must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the study. We do not know what impact this drug will have on your fertility (your ability to conceive a child or impregnate a female). We also do not know what effects this drug will have on a pregnancy. You must use effective birth control throughout the course of this study. If female, you must avoid getting pregnant. If you become pregnant while in the study, you must tell the study doctor/staff as soon as possible. If male, you should avoid impregnating a female. You must use effective birth control throughout the course of this study. While you are in this study, if your partner becomes pregnant you must tell the study doctor/staff as soon as possible.

ALTERNATIVE TREATMENT

You do not have to be in this study to receive treatment for your nasal allergy symptoms. Other nasal rinses may be available. The study doctor will discuss with you the risks and benefits of the alternative treatments.

NEW FINDINGS

Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you.

BENEFITS

You may benefit as a result of your participation in this study. There is, however, no guarantee that you will benefit from your participation in this study. Results from this study may benefit others in the future.

COMPENSATION FOR PARTICIPATION

For your time and inconvenience related to your participation in this study, you will be paid for the study visits you complete according to the following schedule: \$50.00 for each of the following visits: Screening, Visit 2, Visit 3, Visit 4 and Visit 5 You will be paid \$20.00 for Visit 1. If you do not complete the study for any reason, you will only be paid for the study visits you do complete. Payment will be mailed at the end of each completed visit.

If you have any questions regarding your compensation for participation, please contact the study staff at the telephone number listed on page one of this consent document.

CONFIDENTIALITY

Records of your participation in this study will be held confidential except as disclosure is required by law or as described in this informed consent document (under "Confidentiality" or "Authorization to Use and Disclose Protected Health Information"). The study doctor, the sponsor or persons working on behalf of the sponsor (such as monitors or auditors), and under certain circumstances, the United States Food and Drug Administration (FDA) and the Institutional Review Board (IRB) will be able to inspect and copy confidential study-related records which identify you by name. Therefore, absolute confidentiality cannot be guaranteed. If the results of this study are published or presented at meetings, you will not be identified.

COMPENSATION FOR INJURY

If you are injured as a result of taking the study drug(s) or from procedures done for the purpose of this study, the sponsor will pay for those medical expenses necessary to treat your injury that are not covered by your medical insurance or any other third party coverage. There are no plans to provide other compensation beyond that which is

listed in this informed consent document. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are injured during this study, your study doctor will discuss with you the available medical treatment options.

COSTS

There will be no charge to you for your participation in this study. The study drug, study-related procedures, and study visits will be provided at no charge to you or your insurance company.

EMERGENCY CONTACT / IRB CONTACT

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the study doctor at the telephone number listed on page one of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in a research study being conducted by the study doctor listed on page one of this document.

Liberty IRB, Inc. has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not mean the IRB has approved your participation in the study. It also does not mean the study is without risks.

If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, you should write to Liberty IRB at Liberty IRB, 1450 S. Woodland Blvd, Suite 300A, Deland, Florida 32720 or call 386-279-4318 during business hours Monday - Friday 8:00 a.m. to 5:00 p.m. EST.

VOLUNTARY PARTICIPATION / WITHDRAWAL

Your decision to participate in this study is voluntary. You may choose to not participate or you may withdraw from the study for any reason without penalty or loss of benefits to which you are otherwise entitled and without any effect on your future medical care. Investigator or the sponsor can stop your participation at any time without your consent for the following reasons:

- If it appears to be medically harmful to you;
- If you fail to follow directions for participating in the study;
- If it is discovered that you do not meet the study requirements;
- For administrative reasons, including the target number of subjects have entered the treatment phase;

- A change in your medical condition;
- Other reasons, including new information available to the investigator or harmful reactions experienced by you or other subjects in this study;
- If the study is canceled.

If you leave the study before the final regularly scheduled visit, the study doctor may ask you to complete an end-of-study visit for your safety.

PRIMARY CARE PHYSICIAN / SPECIALIST NOTIFICATION OPTION

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

| (initials) | Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study. |
|------------------------|--|
| (initials) | No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study. |
| (initiala) | I do not have a primary care physician/specialist. |
| (initials) (initials) | The study doctor is my primary care physician/specialist. |

The remainder of the page left blank intentionally

CONSENT

I have read and understand the information in this informed consent document. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I voluntarily agree to participate in this study until I decide otherwise. I do not give up any of my legal rights by signing this consent document. I will receive a copy of this signed consent document.

| Subject's Printed Name | |
|--|------|
| Subject's Signature | Date |
| Printed Name of the Person Conducting the Consent Discussion | |
| Signature of the Person Conducting the Consent Discussion | Date |

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

During your participation in this research study, the study doctor, Dr. Jonny Salyer and study staff will collect or create personal health information about you (for example, medical histories and results of any tests, examinations or procedures you undergo while in the study) and record it on study documents. The study doctor will keep this personal health information in your study-related records (that we will refer to as "your study records"). In addition, the study doctor may obtain, and include in your records, information regarding your past, present and/or future physical or mental health and/or condition. Your study doctor may ask you to sign a separate authorization to obtain some or all of your medical records from your doctor. Your study records may include other personal information (such as social security number, medical record numbers, date of birth, etc.), which could be used to identify you. Health information that could identify you is called "Protected Health Information" (or "PHI").

Under federal law (the "Privacy Rule"), your PHI that is created or obtained during this research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization." Therefore, you may not participate in this study unless you give your permission to use and disclose your PHI by signing this Authorization. By signing, you are agreeing to allow the study doctor and staff to use your PHI to conduct this study.

By signing this Authorization, you also are agreeing to allow the study doctor to disclose PHI as described below:

• The sponsor of this study and anyone working on behalf of the sponsor to conduct this study (referred to as "the sponsor"). The sponsor will analyze and evaluate the PHI and may use it to develop new tests, procedures and commercial products. The study staff will assign a code number and/or letters to your records, which means that you will not ordinarily be identified in the records sent to the sponsor. The sponsor may, however, look at your complete study records that identify you. In addition, the sponsor may visit the study site to oversee the way the study is being conducted and may review your PHI during these visits to

make sure the information is correct.

• The Institutional Review Board ("IRB") may have access to your PHI in relation to its responsibilities as an Institutional Review Board.

The study doctor or sponsor may disclose your PHI to the United States Food and Drug Administration ("FDA") or similar regulatory agencies in the United States and/or foreign countries.

These disclosures also help ensure that the information related to the research is available to all parties who may need it for research purposes.

Except for the disclosures described above, your PHI will not be shared with others unless required by law. If your PHI is given to the parties listed above and/or to others who are not required to comply with the federal law, your PHI will no longer be protected by this law and could possibly be used or disclosed in ways other than those listed here.

You have a right to see and make copies of your PHI. You are agreeing, however, by signing this document, not to see or copy some or all of your PHI until the sponsor has completed all work related to this study. At that time, you may ask to see your records.

This Authorization will expire 50 years from the date you sign it unless you revoke (cancel or withdraw) it sooner.

You have a right to revoke your Authorization at any time. If you revoke it, your PHI will no longer be used for this study, except to the extent the parties to the research have already taken action based upon your Authorization or need the information to complete analysis and reports for this research. To revoke your Authorization, you must write to the study doctor, stating that you are revoking your Authorization to Use and Disclose Protected Health Information. If you revoke this Authorization, you will not be allowed to continue to be in this study.

You will receive a copy of this Authorization after you have signed it.

| Version Date: 20 May 2013 Lovelace Scientific Resources, Inc. | | 13.06.0012 |
|--|----------|------------|
| Signature of Subject | Date | |
| Printed Name of Subject | | |

Signature of the Person Obtaining the Authorization

Printed Name of the Person Obtaining the Authorization

APPENDIX III INSTRUCTIONS FOR SUBJECTS

<u>Instructions for Subjects - Nasal Spray Wash Study</u>

CGP Nasal Spray Wash Self-Administration

- 1. Blow your nose gently before using CGP Nasal Spray Wash.
- 2. Shake bottle slightly before using spray.
- 3. Gently insert the bottle tip into your left nostril while using your thumb or finger of your right hand to close off the right nostril. Keep your head upright.
- 4. Squeeze the bottle fully while at the same time inhaling all the spray through your left nostril. (Quickly remove bottle after spraying to minimize drawback into bottle.)
- 5. Repeat steps 3 and 4 with bottle nozzle in your right nostril, closing your left nostril with your left hand.
- 6. Do this procedure twice so you have taken two sprays in each nostril, alternately.
- 7. Avoid blowing your nose for at least 10 minutes after application.
- 8. Excess moisture may be sniffed upwards and either swallowed or spit out.

<u>Minimum</u> required dosage, 2 sprays per nostril in the morning and 2 sprays per nostril in the evening, approximately 12 hours apart.

Note: You may take additional sprays besides the morning and evening double sprays. You can take these any time of day or night, as needed or desired. Single sprays per nostril may suffice at such times, although 2 sprays are permitted. Do not take spray more than four additional times per 24-hour period. *Record all doses you take, including when and how many sprays are taken.*

Jonny Salver, MD, Lovelace Scientific Resources, Inc. Emergency Phone: (505) 348-9500

APPENDIX IV SUBJECT DATA

AKP-001

2,49 AKPharma PERENNIAL ALLERSIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| ent Demographics of Birth: 25 Jw 1948 (dd/mmm/yyyy) der: Male Female |
|--|
| |
| of Birth: 25 / Jun / 1948 (dd/mmm/yyyy) |
| |
| ier: Male Emale |
| male, Indicate Childbearing Potential |
| ☐ Childbearing ☐ Surgically sterilized ☐ Post-Menopausal |
| icity: Hispanic Non Hispanic |
| : Asian Black Caucasian American Indian |
| |
| Pacific Islander Other, Specify |
| |
| |
| king History |
| king Status: None (smoked less than 100 cigarettes in lifetime) |
| Former (previously smoked more than 100 cigarettes in lifetime) |
| Current (smokes now) |
| |
| pject is a <i>former</i> or <i>current</i> smoker, please indicate: |
| goot is a joi mer of current smoker, prease malence. |
| |

Version: 02 September 2013

Page 3 of 5 Screening/V1



Lovelace Sc. lfic Resources Clin TrialsLesire Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME BLS, BLS

PATIENT ID **AAGG3648**

COLLECT DATE & TIME

DOB 06/25/1948 SEX М

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

10/18/2013 15:00 (a) PT. PHONE NO.

RECEIVE DATE & TIME 10/18/2013 19:47 PRINT DATE & TIME 10/24/2013 06:05

30920906

0

PATIENT NO.

COMMENTS:

AKP001

| | | Result | | | |
|---|---------------------|--|--------------|-----------------|-----------|
| Test | in Range | Out of Range | Units | Reference Range | Site Code |
| Footnotes | | | | | |
| (a) Duplicate tests are printed on | this report | and the same of th | | | |
| Allerg, Panel 18 Collected on: 10/18/20 Allerg, Juniper | 13 15:00 | 9.80 H | kU/L | <0.35 | |
| Allerg, Cottonwood | ≤0.10 | | kU/L | <0.35 | |
| Allerg,West.Ragweed | 0.20 | | kU/L | <0.35 | |
| Allerg,Russian This | <0.10 | The state of the s | kU/L | <0.35 | |
| Allerg,Bermuda Grass | <0.10 | | kU/L | <0.35 | |
| Allerg, Alternaria | <0.10 | | kU/L | <0.35 | |
| Allerg, Mesquite | <0.10 | | kU/L | <0.35 | |
| Allerg,Cockroach | <0.10 | | kU/L | <0.35 | |
| Allerg,Derm. pter. | ntity not sufficien | - | kU/L | <0.35 | |
| | • | credited, please resubmit. | | | |
| | ore to assay, test | crearced, prease resubility | 1.110 | | |
| Allerg,Derm. farinae | ntity not sufficien | l | kU/L | <0.35 | |
| | _ | credited, please resubmit | | | |
| Allerg,Clad. herb. | <0.10 | crearecu, prease resubilita | 1.118 | | |
| Allerg, Firebush | <0.10 <0.10 | | kU/L | <0.35 | · |
| Allerg,Cat Dander Ep | ~0.10 | | kU/L kU/L | <0.35 | |
| Qua | ntity not sufficien | t | KQ/L | <0.35 | |
| | - | credited, please resubmit. | <i>‡</i> | | |
| Allerg, Dog Dander | ,, | 10.70 H | kU/L | <0.35 | |
| The | standard classific | ation system utilizes the i | followina c | lass cutoffs. | |
| Cla | | Interpretation | | | |
| 0 | <0. 35 | Negative for Allergen | | | LAI |
| <u> </u> | 0. 35-0. 69 | Positive for Allergen | · · · · · | MM | - 713 |
| II | 0. 70-3. 49 | Strongly Positive | | MM | 20. |
| III | 3. 5-17. 49 | Strongly Positive | | W. | |
| īv | 17. 5-52. 49 | Strongly Positive | | | |
| v | 52. 5-99. 99 | Strongly Positive | | | |
| VI | >100 | Strongly Positive | | | |
| Res | ults with allergens | scoring in Class 1 should | be consider | red weakly | · |

Allerg, Bluegrass Allerg, Pigweed Allerg, Mulberry

positive or equivocal. Class 2 and higher should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy. <0.10 kU/L < 0.35 <0.10 kU/L < 0.35 kU/L < 0.35 Quantity not sufficient

Continued on next page



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: BLS,

Gender: Male

Age: 65

Race: Caucasian

Height(in): 74.0

Weight(lb): 270

Any Info:

Id: AKP-001 Date: 11/06/13

Temp: 19

PBar: 637

Physician:

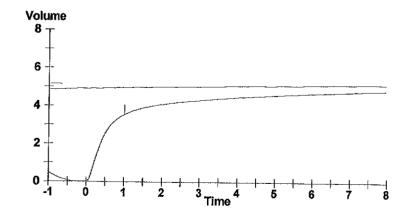
Technician do

| , tily 11110. | | | | | | | rechnicia | an: ag |
|---|--|---|-----|--|------|--------------|-----------|------------------------|
| Spirome | etry (E | Ref | Pre | E-RX Pre | | T-RX Post | Post | Flow |
| FVC FEV1/FV FEF25-75 FEF50% FEF75% IC VC PEF MVV PIF FEV1/FEV | 5%L/sec L/sec L/sec Liters Liters L/sec L/min L/sec | 5.15 4.09 78 4.01 4.94 1.85 5.15 9.40 148 | | % Ref 100 88 89 52 78 27 | Meas | | % Chg | 12 8 4 |
| | Volumes/f | Plethysm | | ohy | (B | TPS) | | 0 |
| Vtg VC TLC RV RV/TLC FRC PL ERV | Liters Liters Liters Liters % Liters Liters | 5.15 7.54 2.73 39 3.71 | | Í | | | | -8 |
| DIFFUS DICO DL Adj DLCO/VA VA BHT | mL/mmHg/min mL/mmHg/min | 29.6 | | | | | | -12 1 2 2 4 6 8 Volume |

Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec Raw cmH2O/L/sec 1.20 Gaw L/sec/cmH2O 0.890 sRaw cmH2O/L/s/L sGaw L/s/cmH2O/L 0.225 Vtg (Raw) Liters

Comments:



Version: IVS-0101-20-5B

Interpretation:



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: BLS. Gender: Male

Age: 65

Race: Caucasian

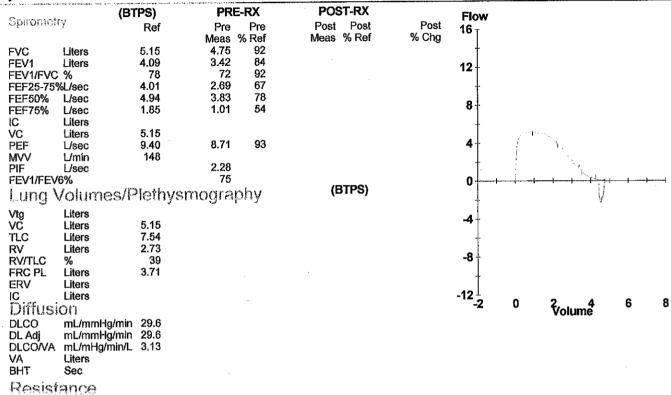
Weight/lh): 270

ld: AKP-001 Date: 11/13/13

Temp: 19

PBar: 640

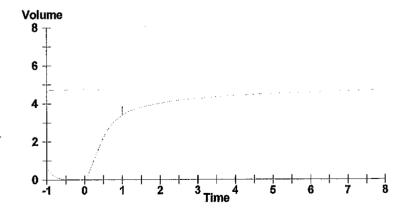
| granging and project to provide a manifestation of the control and | /DTDQ\ | DDE-BX | POST-RX | |
|--|------------|--------|---------|----------------|
| Any Info: | | | | Technician: VL |
| Height(in): 74.0 | Weight(lb) | : 270 | | Physician: |



Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec 1.20 Raw cmH2O/L/sec Gaw L/sec/cmH2O 0.890 sRaw cmH2O/L/s/L 4.44 sGaw L/s/cmH2O/L 0.225

Vtg (Raw) Liters

Comments:



Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: BLS,

Gender: Male Age: 65

Race: Caucasian

Height(in): 74.0

Weight(lb): 278

Id: akp-001 Date: 11/20/13

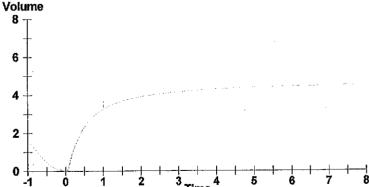
Temp: 20

PBar: 628

Physician:

Technician: VL

| А | ny inio: | | | | | | T CONTINUE | A11. V L | |
|---|--------------|----------------|-------------|-------------|--------------|-----------------------|------------|-----------------|--|
| J | | (B1 | rps) | PR | E-RX | POST-R | (| Flow | |
| | Spirometr | у , | Ref | Pre Meas | Pre % Ref | Post Pos Meas % Ro | | 16 | |
| | FVC | Liters | 5.15 | 4.51 | 88 | | | † | |
| | FEV1 | Liters | 4.09 | 3.31 | 81 | | | 12 - | |
| | FEV1/FVC | | 78 | 73 | 94 | | | '~" | |
| | FEF25-75% | 6L/sec | 4.01 | 2.44 | 61 | | | + | |
| | FEF50% | L/sec | 4.94 | 3.31 | 67 | | | 8 + | \wedge |
| | FEF75% | L/sec | 1.85 | 1.01 | 55 | | | 0 | |
| | IC | Liters | E 4E | | | | | † | |
| | VC | Liters | 5.15 | 8.85 | 94 | | | 4 - | The Artist Control of the Control of |
| | PEF | L/sec | 9.40 148 | 0.00 | 34 | | • | 7 | $\mathbf{P}_{\mathbf{q}_{i_1}}$ |
| | MVV PIF | L/min L/sec | 140 | 4.82 | | | | t | |
| | FEV1/FEV | | • | 75 | | | | o — | 1 |
| | 1 LV IN LV | m Jahrman/E | Matheren | | nhu | (BTPS |) | • | |
| | rang v | /olumes/F | пендан | indica | bity | • | • | + | <i>\</i> |
| | Vtg | Liters | | | | | | -4 | men. |
| | VČ | Liters | 5.15 | | | | | • | Maria de |
| | TLC | Liters | 7.54 | | | | | + | |
| | RV | Liters | 2.73 | | | | | -8 | |
| | RV/TLC | % | 39 | | | | | -0 | |
| | FRC PL | Liters | 3.65 | | | | | + | |
| | ERV | Liters | | | | | | _12 | |
| | IC Committee | Liters | | | | | | -12 -2 | 0 2 4 6 8 Volume |
| | Diffusi | UII. | | | | | | | volume |
| | DLCO | m∐/mmHg/min | 30.1 | | | | | | |
| | DL Adj | mL/mmHg/min | 30.1 | | | | | | |
| | DLCO/VA | mL/mHg/min/L | 3.07 | | | | | | |
| | VA BHT | Liters Sec | | | | | | | |
| | | | | | | | | | |
| | Resist | ance | | | | | | | |
| | Raw Total | cmH2O/L/sec | | | | | | | |
| | Raw Insp | cmH2O/L/sec | | | | | | | |
| | Raw Exp | cmH2O/L/sec | | | | | | | |
| | Raw | cmH2O/L/sec | 1.22 | | | | | | |
| | Gaw | L/sec/cmH2O | | | | | | | |
| | sRaw | cmH2O/L/s/L | 4.46 | | | | | | |
| | sGaw | L/s/cmH2O/L | 0.224 | | | | | | |
| | Vtg (Raw) | Liters | | | | Volume | | | |
| | | | | | | | | | |
| | Commen | ts: | | | | 8 T | | | |
| | | | | | | | | | |



Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: BLS, Gender: Male

Age: 65

Race: Caucasian

Id: AKP-001 Date: 11/27/13

Temp: 19

PBar: 637

Physician:

16

12

8

4

0

-8

-12

| Height(in): 74.0 Any Info: | vveignt(i | D): 270 | | Technician: | VL |
|-----------------------------|-----------|---------|---------|-------------|------|
| | (BTPS) | PRE-RX | POST-RX | | Flow |

| | | (B152) | PKE | :-KA | FUSI | -L/V | |
|---------|----------|---|--------------------|-------|--------|-------|--------|
| Spirom | etry | Ref | Pre | Pre | Post | Post | ` Post |
| | | • | Meas ' | % Ref | Meas % | 6 Ref | % Chg |
| FVC | Liters | 5.15 | 4.89 | 95 | | | |
| FEV1 | Liters | 4.09 | 3.66 | 89 | | | |
| FEV1/F\ | /C % | 78 | 75 | 96 | | | |
| FEF25-7 | 75%L/sec | 4.01 | 2.80 | 70 | | | |
| FEF50% | L/sec | 4.94 | 3.89 | 79 | | | |
| FEF75% | L/sec | 1.85 | 0.98 | 53 | | | |
| IC | Liters | | | | | | |
| VC | Liters | 5.15 | | | | | |
| PEF | L/sec | 9.40 | 11. 4 1 | 121 | | | |
| MVV | L/min | 1 4 8 | | | | | |
| PIF | L/sec | | 4.00 | | | | |
| FEV1/FI | | | 77 | | | | |
| Lung | Volum | ies/Plethys | mogra | ohy | (BI | 'PS) | |
| Vtg | Liters | | | | | | |
| vč | Liters | 5.15 | | | | | |

7.54 TLC Liters RV Liters 2.73 RV/TLC 39 3.65

Liters FRC PL **ERV** Liters Liters Diffusion

mL/mmHg/min 30.1 mL/mmHg/min 30.1 DLCO DL Adj DLCO/VA mL/mHg/min/L 3.11

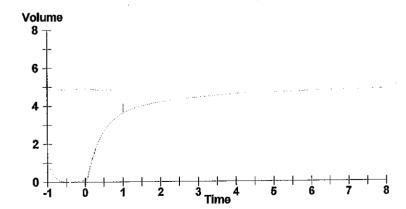
Liters V٨ BHT Sec

Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec Raw Exp Raw cmH2O/L/sec L/sec/cmH2O 0.877 Gaw 4.46 cmH2O/L/s/L sRaw L/s/cmH2O/L 0.224 sGaw

Vtg (Raw) Liters

Comments:



Intermetation

‱ Volume

8/ 11/ W/13

Coottop EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY) CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | 1 } | 2 3 | 2 3 | 2 3 | 2 3 | ON ON | NO | | 2 3 | 2 3 | 2 3 | 2 3 | NO | NO |
|----------|------------|-----------------------|----------------------|----------------------|--------------------|---------------------|---------------------|--------|----------------------|----------------------|----------------------|---------|---------------------|------------------------|
| (O. | 111 | 0 1 | 0 7 | 0 1 | 0 1 | YES | YES | 0 | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES |
| | <i></i> | 2 3 | 2 3 | 2 3 | 2 3 | (3/8 | 3 | | 2 3 | 2 3 | 2 3 | 2 3 | ON ON | ON |
| . | 13/2° | 6/1 | Ø 1 | Do. | 9 | YES (| YES | 0 | 0 1 | 0 1 | 10 | н О, | YES | YES |
| | ••• | 2 3 | 2 3 | 2 3 | 2 3 (| 30 | \$ | | 2 3 | 2 3 | 2.3 | 2.3 | (B)(| \$\ \$\ |
| ᅻ. | 2/11 | | | 0 | | YES (| YES (| 0 178 | (S) | 9 | 0 | Ø | YES (| YES (|
| | | 2 3 | 2 3 | 2 3 | 2 3 | 2) (2) | <u>0</u> | | 2 3 | 2 3 | е Ø | 2 3 | | (S) |
| 7, | 11/11 | (| © | 00 | 0 1 | YES (| YES | -2 | (f) o | 9 | 0 1(| 0 | YES (| YES |
| | | 3 | 2 3 | Ø3 | 2 3 | | NO) | | © 3 | 2 3 | © 3 | 2 3 | | |
| ιὑ | 2/3 | 0 1 | <u></u> | 0 1 (| @ 0 | YES | YES | ကို | 0 1 (| 9 | 0 1 (| 0 | YES | YES |
| | 7 | 2 3 | 2 3 | 2 3 | 2 3 | 9 | ON) | (| E (2) | 2 3 | 3 | 2.3 | <u>ي</u> (| S |
| 9- | 11 | 0 | (B) | (1) | Q | YES | YES (| 4- | 0 1(| 0 | 0 1 (| <u></u> | YES | YES |
| | | 2 3 | 2 3 | 2 3 | 2 3 | (<u>P</u>) | (S) | | 2 3 | 2 3 | (g) 3 | 2 3 | g (| ON) |
| ľν'. | 21 11 | \mathcal{O}_{\circ} | 0 | 0 1 | | YES (| YES (| τ̈́ | ⊕ 0 | 0 | 0 1 (| 9 | YES | YES |
| | 5/ | 2 3 | 2 3 | 2 3 | 2 3 | | MO) | | 2 3 | 2 3 | 2) 3 | 2 3 | M | |
| ٩٠ | 10/ | Q 0 | 0 | Θ_{\circ} | (D) | YES | YES | 9 | (I) o | (O) | 0 1 | | YES | YES |
| | 2 | 2 3 | 2/3 | 2 3 | 2 3 | 9 8 | SN SN | | 2 3 | 2 3 | 3 | 2 3 | ON | |
| 1.7 | 10/20 | 0 1 | 0 | 0 1/ | 1 0 | ×¥× | ∤ ⁄ES | (| 0 (10 3 | Ø 1 2 3 | 0 1 (2) 3 | O1 2 3 | YES (| YEŚ (|
| DAY | | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | | Voice Hoarse Y/N | Throat Clearing Y/N |
| | | R 0 | <u>¥</u> 5 | 0.5 | S. O. | >> | <u></u> | | <u> </u> | ≚ 5 | ة <u>ت</u> | y o | >> | 🗕 🍃 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER ALPO 3/

DATE COMPLETED: 11/6/13

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace S. itific Resources Leslie Byatt, wiln Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME X, BLS

PATIENT ID **AAGH2825** DÖB 06/25/1948 SEX REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME

Result

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

11/06/2013 16:32 (a)

11/07/2013 00:06

11/08/2013 15:32

30920949

0

PATIENT NO.

COMMENTS:

AKP001

| | | _ |
|--|----------|---|
| | In Danas | |

| Test | In Range | Out of Ran | ge | Units | Reference Range | Site Code |
|-----------------------------------|--|---------------------------|-----------|--|-----------------|-------------|
| Footnotes | | | | | | |
| (a) Duplicate tests are printed | d on this report | | | | | |
| Comp Metabolic Panel Collected of | • | | | | | |
| Sodium | 142 | | | mmol/L | 134-144 | |
| Potassium | 4.5 | | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | | mmol/L | 98-111 | |
| CO2 | 25 | | | mmol/L | 20-30 | |
| Anion Gap | 10 | | | | 6-14 | |
| Glucose | 88 | | | mg/dL | 60-100 | |
| BUN | 20 | | | mg/dL | 7-31 | |
| Creatinine | 1.13 | | _ | mg/dL | 0,62-1.66 | |
| | Creatinine method is IDMS t | | | | en adjusted. | |
| | Please note new reference r | ange effecti | ve 5/23/2 | 013. | | |
| eGFR non-African Am | >60 | | n | nL/min/1.73m2 | >60 | |
| GFR Comment | | _ | | | | |
| | Estimated GFR values are no | t accurate i | n acute k | idney failure, | inpatients | |
| | the very old or very young | or underwe races other | ignt (BMI | <zυ) peopιe,<br="">rasian or Δfr</zυ)> | ican American | |
| | on IV fluids, obese (BMI>34 the very old or very young, people with acute illnesses, | , or amputat | ions. | castall of All | rean conerreant | |
| Calcium | 10.1 | · | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.3 | | | gm/dL | 6.1-8.2 | |
| A!bumin | 4.6 | | | gm/dL | 3.4-4.7 | |
| Globulin | 2.7 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.9 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 79 . | | | U/L | 38-150 | |
| AST(SGOT) | 20 | | | U/L | 6-58 | |
| ALT(SGPT) | 35 | | | U/L | 14-67 | |
| Collected on: 11/06/2013 16:32 | • | | | | | |
| Fasting | NO | | | | | |
| CBC Collected on: 11/06/2013 16 | 9:20 | | | | | |
| WBC | 6.8 | | | x10E3 | 4.0-10.6 | |
| RBC | 5.79 | | | x10E6 | 4.64-6.00 / | 2 Nov 13 |
| Hgb | * | 18.5 | н | gm/dL | 14.5-17.7 N & | 5 Warn |
| Hčt | | 55 | H | % | 42-53 NC | é nam |
| MCV | 95 | | • • | fL | | 2 Nov 13 |
| MCHC | 33.8 | | | gm/dL | 31.2-35.2 | - IVO V · Z |
| RDW | 12.7 | | | ~ | 11.0-14.5 | |
| Platelets | 168 | | | x10E3 | 150-400 | |

16:32 Collected on: 11/06/2013

Phys, Addr, Phone

NO PHYSICIAN LISTED

Collected on: 11/06/2013

Phys, Addr, Phone

16:32

NOT GIVEN

Collected on: 11/06/2013

16:32

Important Info

Client notified that no specimen(s) were received for the following tests: A specimen for CMP was received and per client the slides were sent for Eosinophil Count.

When the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the slides were sent for the following tests:

A specimen for CMP was received and per client the following tests:

A specimen for CMP was received the following tests:

A specimen for CMP

End of Report

FAX24664

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

| DAILY SYMPTOMS SCORE CIRCLE APPROXIMATE RESPON | OMS SCOR | | SHEET (RHINITIS DIARY) SE EVERY 12 HOURS 1 | RY) | 5 | E | 1 | 3 | | |
|--|---|-----------------|---|-----------|-----------|-----------|-----------|----------|--------|----|
| DAY | 11/0/0/2 | 2 (1/0,7) | 7,80,00 | 4/2 | 45/11 | 9/4 | 7 | 48 | 6 | Ç |
| AIVI | Y 1 2 3 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 | 511157 5 | , | 511.01 | 51/01/ | 11/11/13 | 11/12/15 | 1715/15 | 011411 | 0 |
| Runny Nose | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0/1/2 3 | 0 Th 2 3 | 0 1723 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | | > | > | > |) |) | ٥ | <u>.</u> | | • |
| Itchy Nose | d 123 | (0)123 | 0123 | (f) 123 | 60123 | 70) 1 2 3 | 10/123 | 0 1 2 3 | 0 1 2 | က |
| 0 to 3 | _ |) | 2 | 2 | |) | 7 | | | |
| Congestion | 0 1/23 | 0 (1) 2 3 | 0 1 (2) 3 | 0(T)23 | 0 1 (2) 3 | 0/1)23 | 0(I)2 3 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | | د |) | > |) |) |) | | | |
| Sneezing | 0 1 12 3 | 0 1 2 3 | 00123 | 0)123 | Ø1 2 3 | 0123 | (6)123 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | |)) |) > |) | · > |) (|) | | | |
| Voice Hoarse | YES NO | YES (NO | VES (NO) | YES (ND | YES (NG) | YES (NO) | YES (NQ) | YES NO | YES N | Q. |
| N/Y | |) (| (| (|)(|) (|) (| | | |
| Throat Clearing | YES NÒ | YES (NO) | YES (NO) | (ON) SEX | VES (No | YES /NO) | YES (NO) | YES NO | YES NO | 0 |
| Y/N | |) |) |) |) | <u></u> |) | | | |
| DAY PM | 14) | 2 8 | <i>†</i> 7 € | 74 | h s + | 9 T | 177 | ∞ | 6 | |
| Runny Nose | 0 (1) 2 3 | 00 2 3 | 0/R23 | 0 (1) 2 3 | 0 1 1233 | 0 1/2/3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | ო |
| 0 to 3 | > | ٠, | 2 |) | > |) | ۲ | | | |
| Itchy Nose | 0 1 2 3 | 0 1 2 3 | Ph 1 2 3 (| 10123 | 10,123 | 60123 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 |) |) と | | ~ | |) | | | | • |
| Congestion | 0(1)23 | 0 1/(2)/3 | 0 1 2 3 | 0623 | 0 1 1/273 | 0 1/2)3 | 0 1/2/3 | 0 1 2 3 | 0 1 2 | ന |
| 0 to 3 |) |) | 2 | |) |) |) | | | |
| Jg. | 0 123 | 0 (1) 2 3 | 0/11/23 | 0 1723 | 0 (T) 2 3 | 0/10/23 | 0/5/23 | 0 1 2 3 | 0 1 2 | 3 |
| 0 to 3 | | (|) | (| \ > | (| S | | | |
| Voice Hoarse | YES KID | YES (NÓ | YES NO | YES CAID | (ON) SEA | (ON) SEA | YES /NO | YES NO | YES NO | 0 |
| N/N | (|) ⁽⁽ | | (|) |) (|) (| | | |
| Throat Clearing Y/N | YES (NO | YES (NO | YES (N <i>Q</i>) | YES (NÓ) | YES (MÔ) | NES (NO) | YES 🐠 | YES NO | YES NO | 0 |
| C | | | | | | | | | | 7 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

おしい Y=Yes N= No

SUBJECT NUMBER:

DATE COMPLETED:

3

SUBJECT INITIALS AND DATE:_

TriCore

Fax Number

Thu Nov 14 07:06:10 2013 Page 3 of 3



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc: fic Resources Leslie Byatt, ∪ı(n Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Cilent Nbr

24664

PATIENT NAME BLS, BLS

PATIENT ID **AAGH6054** DOB 06/25/1948

REPORT STATUS SEX Final М

PAGE

PHYSICIAN

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

11/13/2013 15:10

11/13/2013 20:27

11/14/2013 06:10

30920935

Test

O

PATIENT NO.

COMMENTS:

AKP001

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen

NO PHYSICIAN INDICATED

In Range

NCS Jelyn PI 18 Mov 2013

End of Report

BLS, BLS

11/14/2013 06:10

FAX24664

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

ON PATIENT-PERCEIVED BREATHING COMFORT

| • | 1 | | | | T | | E | \neg | | | | | _ | | | | | | |
|---|--|--------|--|------------|------------------------------|----------|----------------------|----------|----------|---------------------|------------------------|--------|------------|-----------------------------|-----------------|------------|--------------|--------------|---------------------|
| ` | N | 6/1 | / / / / / / / / / / | 1) | 2 3 | | 2 3 | 2 3 | | 9 | N N | 6 | 2 3 | | 2 3 | 2 3 | 2 3 | NO NO | NO No |
| ** | t | 3// | \ \ \ \ \ | i > | 0 1 | | 0 1 | 0 1 | | YES | YES | 01 | 0 1 | | 0 1 | 0 1 | 0 1 | YES | YES |
| \ | _ | 0/12 | ٦ |) | 2 3 | | Ø 3 | 2 3 | (| | <u></u> | | 2 3 | | 2 3 | 2 3 | 2 3 | ON | ON. |
| معت | | 8/1/ | | | 9 1 |) | 0 1 | (T)0 |) | YES | YES (| 00 | 0 1 | | 0 1 | 0 1 | 0 1 | YES | YES |
| \. | | 72 | ر ر ک |) 1 | 2 3 | | E)3 | 2 3 | (| E)(| 2 | | £ 2/ | | 2 3 | 8 | 2 3 | (2) | (2) |
| 1 | | 75 | | D. | 0) 1 | > | 0 1 (| 0 (1)2 |) | YES | YES | 17 | 0 1 |) | 9,1 | 0 1(| 9 | YES | YES |
| Ĩ | \leq | 7 | 3 6 |) | 2 3 | | Ø 3 | 2 3 | | Q (| 2 | 7 | 2 3 | | 2 3 | 12 3 | 2 3 | (2) | () |
| | \$ T | 1 | | C_{i} | Ø 1 |) | 0 1 | 0 1 | > | YES | YES | 97 | 0 (T)2 |) (| S | 0 | (D) o | YES | YES |
| 0 | • | /[2 | ر ا د |) I | 2 3 | | 1 🙆 3 | m | (| (<u>s</u>) | S | 7 | 2 3 | | 2 3 | 1(2)3 | 2 3 | | (2) |
| " | ') | 7 2 | 5 | 9 | 0)1 |) | 0 1(| 0/1/2 |) | YES (| YES | 77 | Ó. |) | \bigcirc 1 | 0 1(| O_1 | YES | YES |
| () | $^{\circ}$ | 1/4 | ر ا در | 1 | 2 3 | : | 2 | 2 3 | 4 | (N) | 2 | | 2 3 | | 2 3 | Ø3 | 2 3 | (8) | (2) |
| × € | -t.) | 1/4 | _ = _ = _ |) | 1 |) | 0 1 | 0 |) | YES | YES | 4 4 | (I) |) | | 0 1 (| 00 | YES | YES |
| DIAF | iai | 3 | 1 |) | 2 3 | | 12 3 | 2 3 | (| (S) | (ON) | | 2 3 | | 2 3 | (Z) 3 | 2 3 | | (2) |
| SITINI | HOUR | 43 | |) D | 6)1 |) | o (D2 | 0)1 |) | YES (| YES (| 4 3 | 0 (ft) 2 |) | Ø 1 | 0 1 (| () 0 | YES | YES |
| ĭ (RH | ERY 12 | 7.7 |) v | | 2 3 | | © 3 | m | | (2) | <u>S</u> | | 2 3 | | 2 3 | 2 3 | 2 3 | (5) | (2) |
| SHE | VSE EV | 2/1/ | | 5 | 01 | | 0 1 | 0 172 | <u>ک</u> | YES | YES | 7 | OA | $\mathcal{L}_{\mathcal{L}}$ | 6/1 | 0 @2 | 01 | YES (| YES (|
| SCORI | RESPO | 1/2/13 | 5 6 | - | 2/3 | / | (2 3 | 8 3 | | <u>e</u> | <u>Q</u> | | 2 3 | | 2 3 | 0 1 🗗 | 2 3 | 8 | (2) |
| OMS | MATE | = /// | 7 | | $\overset{\Diamond}{\wedge}$ | / | $\langle 1 \rangle$ | 0 1 | _ | X I | χŧs | t | |) | \mathcal{O}_1 | 0 1 | 0 🖒 2 | YES | YES |
| DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) | CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS | | Se | | d) | | <u></u> | | | ırse | saring | Σ | Se | | | Ę | | rse | saring |
| ILY S | CLE AF | DAY | Runny Nose | 0 to 3 | Itchy Nose | 0 to 3 | Congestion 0 to 3 | Sneezing | 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose | 0 to 3 | Itchy Nose | Congestion | Sneezing | Voice Hoarse | Throat Clearing Y/N |
| 7 | Ch | | 7 | 0 | Itcl | 0 t | 0 5 | Š | 0 t | Voic Y/N | Thro | | S. | 0 ţ | it c | 3 3 | Sir | | ĮĒ\$ |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No (2.1.5)

SUBJECT NUMBER: AL

DATE COMPLETED:

SUBJECT INITIALS AND DATE:

11-20-12



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace S ific Resources Leslie Byatt, cin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Cilent Nbr 24864

PATIENT NAME BLS, BLS

PATIENT ID **AAGG3648** DOB 06/25/1948

REPORT STATUS SEX Final М

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 11/20/2013 15:30

RECEIVE DATE & TIME

PRINT DATE & TIME

PATIENT NO.

11/20/2013 20:12

11/21/2013 06:06

30920939

0

AKP001

COMMENTS:

Test

In Range

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory

Phys, Addr, Phone

NO PHYSICIAN GIVEN

NS

End of Report

Rare NCS JUNES Jalyer-PI 219002013

| 744 Style alsolly BLS | | Jnvestigator Initials/Date | | | | | 1 | | | ble** | 216 | | PAGE: (of |
|--|-------------------|---|--|---|------|---|---|---|--|---|---|---------------------------------|--|
| LSR Study #: Subject Initials: | | Action Taken | | | | | | | | e as specific as poss | Date: 27 Nov 2013 | | |
| SI Su | g | ** End Date (DD/MMM/YYYY) | | | | | | / | | hould be made to b | | Date: | |
| | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | | 2 | 18 / | / | | | | space provided, but every effort should be made to be as specific as possible** | W Milning no | In Bat | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| 1 m.) | | SEVERITY | | / | | | | | | | :() | V): | 9 |
| Arthur Co See Co | | ** Start Date (DD/MMM/YYYY) | | | | | | | | ** If day is <u>unknown</u> , write UNK in | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: Subject Number: | | Adverse Event | | , | | | | | | ** | Investigator Signa | SC Sign | |

: 1

ì

2749 AKPharma PERENNIAL ALLERGIES V6/DAY 21 SOURCE DOCUMENTS

| Initials: | Site #: | Subject #: | 01_ |
|--|-----------------------------|--|------------------|
| CONCURRENT MI | EDICATION (See L | SR Worksheet) | |
| LSR Concurrent Medicat If, no please comment: | tion Worksheet Complete | d: YES NO | reported |
| Note: Review Medicatio Windows. | ons regarding Disallowe | d Medications and for | Specific Washout |
| Adverse Events (<i>Upa</i> | ···· | | |
| Did the patient experience If, yes please comment: | e a new adverse event: | YES NO | health |
| Did the patient experience If, yes please comment: | e have a change to an exi | sting AE: YES | NO N/-A |
| URINE PREGNANCY T | EST (Please attach results | () | . LA |
| Date Collected: | (dd | '/mmm/yy) | Male |
| Panel | Please circle on | sample Ti | |
| - | | and the second s | Positive* |
| Pregnancy Test β-HCG | Serum Ur | ine | ☐ Negative |
| | | :_ | D N/A |
| · · · · · · · · · · · · · · · · · · · | / | | |
| *If test returns a <u>Positive</u> r | result, the patient can not | be enrolled. | |

Version: 02 September 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

| DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) | OMS SCOR | E SHEET (I | RHINITIS DIA | RY) | Ç | 4 4 | ` | ` | |
|---|------------|------------|--------------|-------------|----------------|---------------|---------------------|--------------|---------|
| CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS | MATE RESPO | NSE EVERY. | 12 HOURS | ^ | 7 | \ | 7 | } | |
| DAY | 114 | 7 75 | 7 16 | 4 17 | 7 18 | 1, 19 | 27 | 7 27 | 22 |
| AM | 11120 | | 72/11 | 4/23 | 11/24 | 11/25 | T 11/2 ia | 11112+ | |
| Runny Nose | 0123 | 0 (1)2 | 3 0 D)2 3 | 0 17 3 | 0.1/2)3 | 0 1 2 3 | 0 6 2 3 | 0 (272 3 | 0 1 2 3 |
| 0 to 3 | | (|) | > |) |) |) | > (| |
| Itchy Nose | 0 1 2 3 | 01 2 | 3/6/123 | O1 2 3 | O(T) 2 3 | 0123 | (0)123 | O 123 | 0 1 2 3 |
| 0 to 3 | |) |) |) |) |) |) | Ç | |
| Congestion | 0 1 2 3 | 0 (T)2 | 3 0 (1) 2 3 | 0.1(2)3 | 0 1 (2) 3 | 0 1(2)3 | 0 (1) 2 3 | 0(1) 2 3 | 0 1 2 3 |
| 0 to 3 | |) | > |) |) |) |) |) | |
| Sneezing | 0 1 2 3 | 0)12 | 3 0 (1) 2 3 | $(0)_{123}$ | 0 (1) 2 3 | 0 (1) 2 3 | (d) 1 2 3 | 0 (1) 2 3 | 0 1 2 3 |
| 0 to 3 | | 2 |) |)) |) | (|) | | |
| Voice Hoarse | YES NO | YES NO | YES (NO) | YES (NO) | YES (NÔ | YES (NO | YES (NO) | YES (NG | YES NO |
| N/N | | ڒ | X(| | | |) ((| | |
| Throat Clearing | YES NO | YES (V) | YES (NO) | YES (NO | YES (NO) | YES (NG | YES (NO) | YES (NĢ | YES NO |
| Y/N | |) |) |) |) |) |) | ļ | |
| → DAY PM | 414 | 15 | 7 16 | 4-17 | 4 18 | 4 €19 | 20 | 21 | 22 |
| Runny Nose | 0 A52 3 | 0 (11)2 | 3 0 (17)2 3 | (b)1 2 3 | 0 (F)2 3 | 0 (17)2 3 | 6 (D ₂ 3 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 |) | > |) | (د | ۱ |) | , | | |
| Itchy Nose | 00123 | 01 2 | 3 001 2 3 | (b) 1 2 3 | $\bigcirc 123$ | Ø123 | 0123 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 |) | |) |) | | | | | |
| Congestion | 0(17)2 3 | 0 (1/2 | 3 0 1 2/3 | 0 1 (2)3 | 0 1 (2) 3 | 0 1 23 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 |) | , (| • | > | | |) | | ٠ |
| Sneezing | Ø123 | 0 (5/2 | 3 0 602 3 | 0 Ø 2 3 | 0 (1)2 3 | 0 10 2 3 | 0 (1/2 3 | 0 1 2 3 | 0 1 2 3 |
| 0 10 0 | - 1 | 1 | | | | | | 1 | |
| Voice Hoarse Y/N | YES (NQ | YES (NO | YES NO | VES (NO) | YES ₩ Ø | YES NO | YES (NO | YES NO | YES NO |
| Throat Clearing | VES (NG) | YES NO | y YES (U) | YES (NG) | YES (NQ | YES (V) | YES (VO) | YES NO | YES NO |
| n. / ; | | | | | | | | | |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: HWDD)

DATE COMPLETED:

11/20/13-

SUBJECT INITIALS AND DATE:_



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Leslie Byatt, Urin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME X, BL\$

PATIENT ID **AAGH2825** DOB 06/25/1948

REPORT STATUS SEX Final М

mg/dL

x10E3

x10E6

gm/dL

%

fL

gm/dL

%

x10E3

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 11/27/2013 15:03 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

11/27/2013 18:42

11/28/2013 06:11

2.3-5.6

4.0-10.6

4.64-6.00

14.5-17.7

42-53

81-98

31,2-35,2

11.0-14.5

150-400

NS

30920955

COMMENTS:

AKP001

| U92U900 | v | 17A |
|--|---|-----|
| A SECTION OF THE PARTY OF THE P | | |

| COMMENTO: | | | | | |
|------------------------------------|--|--|------------------|-----------------|--------------|
| | ı | Result | | | |
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Södium | 140 | | mmol/L | 134-144 | |
| Potassium | 3.8 | | mmol/L | 3.5-5.1 | |
| Chloride | 105 | | mmol/L | 98-111 | |
| CO2 | 28 | | mmol/L | 20-30 | |
| Anion Gap | 7 | | | 6-14 | |
| Glucose | | 109 (H) | mg/dL | 60-100 / | ሬ ያ _ |
| | Impaired fasting glucose 100-126 mg/dl (ADA Guidel | (IFG) is defined as a ines Diabetes Care 26 | . fasting glucos | e level of | 12Dec2013 |
| BUN | 13 | | mg/dL | 7-31 | |
| Creatinine | 1.05 | | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDMS | | | een adjusted. | |
| | Please лоте new reference | range effective 5/23 | 3/2013. | | |
| eGFR пол-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | |
| | Estimated GFR values are on IV fluids, obese (BMI> the yery old or very youn | 34) or underweight (B g. races other than C | MI<20) people. | • | |
| Calcium | people with acute illness 9.2 | es, or amputations. | | | |
| Total Protein | 6.9 | | mg/dL | 8.4-10.4 | |
| Albumin | 4.3 | | gm/dl. | 6.1-8.2 | |
| Globulin | 4.3 2.6 | | gm/dL | 3.4-4.7 | |
| Bilirubin, total | 0.9 | | gm/dL | 2.4-4.2 | |
| Alk Phos | 68 | | mg/dL U/L | 0.3-1.2 | |
| AST(SGOT) | 21 | | | 38-150 | |
| ALT(SGPT) | 38 | | U/L | 6-58 | |
| • | NO | | U/L | 14-67 | |
| Fasting | NO | | | | |

End of Report

Phys, Addr, Phone

Phosphorus

CBC WBC

RBC

Hgb

Hct

MCV

MCHC

Platelets

Eos, Respiratory

RDW

Halyer PI 2 Dec 2013

2.7

6.2

5.64

17.5

53

94

33.1

12.6

168

Not given

BL5/AKP,

Study Staff Initials and Date_____

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE: Would you use / purchase this nasal wash product in the future?" ☐YES ☒NO You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

[Type text]

Subject initials and Date

AKP-003

2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PAT | IENT DEMOGRAPHICS |
|--------|---|
| Pati | ient Demographics |
| Date | e of Birth: 23 / 17 49/1944 (dd/mmm/yyyy) |
| Gen | der: $\frac{23}{H}$ Male \Box Female |
| If fe | male, Indicate Childbearing Potential $\mathcal{N}\mathcal{P}$ |
| | Childbearing Surgically sterilized Post-Menopausal |
| Etho | nicity: Hispanic Non Hispanic |
| Race | e: Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| Smo | oking History |
| Smo | king Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| If sul | bject is a former or current smoker, please indicate: |
| | Years smoked: <u>28'</u> Cigarettes per day: <u>10'</u> |

Version: 02 September 2013

Page 3 of 5



Result

Lovelace Sci fic Resources Clin TrialsLeshe Byatt 2441 Ridgecrest Dr SE

Client Nbr 24664

REFERENCE LABORATORIES

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID **AAGF0188**

08/23/1944

SEX

Albuquerque, NM87108

REPORT STATUS Final

PAGE 1

X, MJC **PHYSICIAN**

Unlisted Physician.

COLLECT DATE & TIME 09/23/2013 08:20 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PATIENT NAME

PT. PHONE NO.

09/23/2013 19:01

09/25/2013 06:07

<0.35

<0.35

< 0.35

PATIENT NO.

30920879

0

AKP003

| COMMENTS | ; |
|----------|---|
| | |

| | _ | | Nosul | | | |
|---|----------|---------------------------------------|--|--|--|-----------|
| Test | | in Range | Out of Range | Units | Reference Range | Site Code |
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West,Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach Allerg,Derm. pter. | The stan | NCS 36 <0.10 0.30 dard classific | 23.10 H 15.20 H 16.60 H 10/18/19 16.60 H 9.20 H 14.20 H 0.60 H | kU/L kU/L kU/L kU/L kU/L kU/L kU/L kU/L | <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 lass cutoffs. | |
| | Class | ku/L | Interpretation | _ | | |
| | 0 | <0. 35 | Negative for Allergen | | | |
| | I | 0. 35-0. 69 | Positive for Allergen | | | |
| | rx | 0. 70-3. 49 | Strongly Positive | | | |
| | III | 3. 5-17. 49 | Strongly Positive | | | |
| | IV | 17. 5-52. 49 | Strongly Positive | | | |
| • | v | 52, 5-99, 99 | Strongly Positive | • | | |
| | VI | >100 | Strongly Positive | | | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

0.40

8.70

Allerg, Derm. farinae Allerg, Clad. herb. Allerg, Firebush Allerg, Cat Dander Ep Allerg, Dog Dander Allerg, Bluegrass Allerg Pigweed Allerg Mulberry Allerg, Helminth

<0.10

0.30

< 0.10 kU/L < 0.35 kU/L < 0.35 Н kU/L 7.80 <0.35 Н 15.70 kU/L < 0.35 Н 9.20 н kU/L < 0.35 kU/L < 0.35 **NOT GIVEN**

Н

kU/L

kŲ/L

End of Report

Phys, Addr, Phone

09/25/2013 06:07

FAX24864



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

(BTPS)

Name: MJC,

Gender: Male Age: 69

Race: Caucasian

Height(in): 72.0

Weight(lb): 187

Id: AKP-003 Date: 10/09/13

> Flow 16

12

8

4

0

-8

-12

Temp: 20

PBar: 628

Physician: ian:

| Any Info: | i i | | | | | | Technici |
|-----------|---------------------------------|--------|-------------|--------------|--------------|---------------|---------------|
| | garant tradició de la sente can | (BTPS) | PRE | E-RX | POS | T-RX | |
| Spirom | etry | Ref | Pre Meas | Pre % Ref | Post Meas | Post % Ref | Post % Chg |
| FVC | Liters | 4.61 | 4.69 | 102 | | | J |
| FEV1 | Liters | 3.64 | 3.35 | 92 | | | |
| | | =-0 | | 0.4 | | | |

FEV1/FVC % FEF25-75%L/sec 3.57 1.94 54 3.50 79 FEF50% L/sec 4.45 1.60 0.49 FEF75% L/sec Liters VC Liters 4.61 PEF L/sec 8.78 9.23 105 MVV L/min 136 2.32 PIF L/sec FEV1/FEV6%

Lung Volumes/Plethysmography

| Vtg | Liters | |
|-----------|----------|------|
| VČ | Liters | 4.61 |
| TLC | Liters | 7.00 |
| RV | Liters | 2.66 |
| RV/TLC | % | 40 |
| FRC PL | Liters - | 4.01 |
| ERV | Liters | |
| IC | Liters | |
| Triblian. | r s in | |

Diffusion DLCO mL/mmHg/min 22.5 DL Adj mL/mmHg/min 22.5 DLCO/VA mL/mHg/min/L 2.98

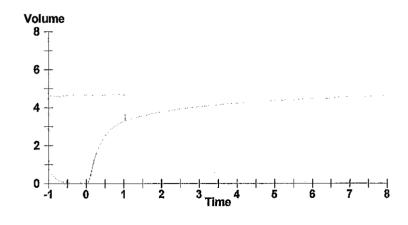
Liters VA BHT Sec Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec cmH2O/L/sec 1.09 Raw Gaw L/sec/cmH2O 0.963 cmH2O/L/s/L sRaw 4.36 L/s/cmH2O/L 0.229 sGaw

Vtg (Raw) Liters

Comments:

Intermetation



Norm Set: Knudson (1983)

Version: IVS-0101-20-5B

8

2 Volume



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: MJC, Gender: Male

Age: 69 Height(in): 72.0

Race: Caucasian

Any Info

Weight(lb): 180

ld: AKP-003 Date: 10/16/13

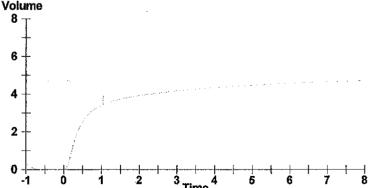
Temp: 19

PBar: 631

Physician:

Technician: VI

| Spirometry Ref | |
|--|---|
| FVC Liters 4.61 4.77 103 FEV1 Liters 3.64 3.45 95 FEV1/FVC % 78 72 93 FEF25-75%L/sec 3.57 2.50 70 FEF50% L/sec 4.45 4.10 92 FEF75% L/sec 1.60 0.77 48 IC Liters VC Liters 4.61 PEF L/sec 8.78 9.22 105 MVV L/min 136 PIF L/sec 3.78 FEV1/FEV6% 75 Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 PEFS L/sec 3.78 FEV1/FEV6% 75 Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 | |
| FEF50% L/sec 4.45 4.10 92 FEF75% L/sec 1.60 0.77 48 IC Liters VC Liters 4.61 PEF L/sec 8.78 9.22 105 MVV L/min 136 PIF L/sec 3.78 FEV1/FEV6% 75 Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 4 BEFF 1/sec 3.78 FEV1/FEV6% 75 Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 | |
| PEF L/sec 8.78 9.22 105 MVV L/min 136 PIF L/sec 3.78 FEV1/FEV6% 75 Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 4 | |
| Lung Volumes/Plethysmography Vtg Liters VC Liters 4.61 (BTPS) 4 | |
| VC Liters 4.61 | |
| RV Liters 2.66 RV/TLC % 40 FRC PL Liters 4.07 ERV Liters IC Liters -12 | 8 |
| DLCO mL/mmHg/min 22.0 DL Adj mL/mmHg/min 22.0 DLCO/VA mL/mHg/min/L 3.00 VA Liters BHT Sec | |
| Resistance Raw Total cmH2O/L/sec | |
| Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec Raw cmH2O/L/sec 1.07 Gaw L/sec/cmH2O 0.977 sRaw cmH2O/L/s/L 4.35 sGaw L/s/cmH2O/L 0.230 Vtg (Raw) Liters | |
| Comments: Volume 8 T | |



Version: IVS-0101-20-5B

Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: MJC,

Gender: Male

Age: 69

Race: Caucasian

Height(in): 72.0

Weight(lb): 187

Any Info:

Id: AKP-003 Date: 10/23/13

Temp: 20

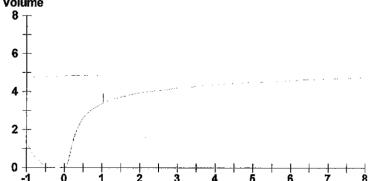
PBar: 634

Physician:

Technician: VL

| ally lillo. | | | | | · . | Commona | 11. V I | | | | | |
|-------------|--------------|--------|-------------|--------------|-------------------------|---------------|------------------|-----|-------------|--------------|---------------|--|
| Colombia | (B | TPS) | PR | E-RX | POST-RX | | Flow | | | | | |
| Spiromet | 3 y | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 _T | | | | | |
| FVC | Liters | 4.61 | 4.85 | 105 | | | + | | | | | |
| FEV1 | Liters | 3.64 | 3.42 | 94 | | | | | | | | |
| FEV1/FVC | : % | 78 | 70 | 90 | | | 12 | | | | | |
| FEF25-759 | | 3.57 | 2.11 | 59 | | | 1 | | | | | |
| FEF50% | L/sec | 4.45 | 3.63 | 82 | | | ŀ | | | | | |
| FEF75% | L/sec | 1.60 | 0.58 | 36 | | | 8+ | , i | <u>,</u> | | | |
| IC | Liters | | | | | | | - [| 1 | | | |
| VC | Liters | 4.61 | | | | | 1 | - 1 | , | | | |
| PEF | L/sec | 8.78 | 10.33 | 118 | | | 4 + | ĺ | `\ | | | |
| MVV | L/min | 136 | | | | | • | 1 | 1 | | | |
| PIF | L/sec | | | | | | + | ! | . | | | |
| FEV1/FEV | | | 74 | | | | 0 | |]Y>/\$-&. | | | |
| | /olumes/l | Plethy | | phy | (BTPS) | | U T | | | | 1 | |
| Vta | Liters | | | | | | İ | | | | | |
| Vtg VC | Liters | 4.61 | | | | | -4 | | | | | |
| TLC | Liters | 7.00 | | | | | - | | | | | |
| RV | Liters | 2.66 | | | | | Ŧ | | | | | |
| RV/TLC | % | 40 | | | | | -8∔ | | | | | |
| FRC PL | Liters | 4.01 | | | | | İ | | | | | |
| ERV | Liters | | | | | | † | | | | | |
| IC | Liters | | | | | | -12 [⊥] | | | | | |
| Diffusi | on | | | | | | -12 -2 | 0 | 2 Volume | 6 | 8 | |
| DLCO | mL/mmHg/min | 22.5 | | | | | | | Volume | | | |
| DL Adj | mĽ/mmHg/min | | | | | | | | | | | |
| DLCOVA | mL/mHg/min/L | 2 02 | | | | | | | | | | |
| VA | Liters | 3.02 | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | |
| Resist | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | | |
| Raw Insp | | | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | 4.00 | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.09 | | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | • | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.36 | | | | | | | | | | |
| \$Gaw | L/s/cmH2O/L | 0.229 | | | | | | | | | | |
| Vtg (Raw) | Liters | | | | | | | | | | | |
| | | | | | Volume | | | | | | | |
| Commen | fiai | | | | 8 T | | | | | | | |

Comments:



Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: MJC, Gender: Male

Age: 69

Race: Caucasian

Height(in): 72.0

Weight(lb): 183

Any Info:

Id: AKP-003 Date: 10/30/13

Temp: 21

PBar: 629

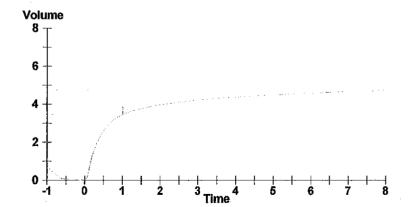
Physician: Technician: VL

| (Nairean east | (B | TPS) | PR | E-RX | POST-RX | | Flow | | | | |
|---------------|--------------|---------|-------------|--------------|-------------------------|---------------|-----------------|------------------------|----------------|-----|----------|
| Spiromet | iy . | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 _T | | | | |
| FVC | Liters | 4.61 | 4.76 | | | J | + | | | | |
| FEV1 | Liters | 3.64 | 3.48 | 95 | | | 40 | | | | |
| FEV1/FVC | % | 78 | 73 | 94 | | | 12 🕂 | | | | |
| FEF25-75 | %L/sec | 3.57 | 2.40 | 67 | | | 1 | | | | |
| FEF50% | L/séc | 4.45 | 3.64 | 82 | | | | I^{\bullet}_{Δ} | | | |
| FEF75% | L/sec | 1.60 | 0.66 | 41 | | | 8+ | -1 λ | | | |
| IC | Liters | | | | | |] | | | | |
| VC | Liters | 4.61 | | | | | | | | | |
| PEF | L/sec | 8.78 | 9.85 | 112 | | | 4 + | 1. | | | |
| MVV | L∕min | 136 | | | | | j | 4 | | | |
| PIF | L/sec | | 1.09 | | | | Ť | | N _q | | |
| FEV1/FEV | /6% | | 76 | | | | 0 ↓ | | The state of | 1 1 | - |
| Lung \ | Volumes/I | Plethys | smogra | phy | (BTPS) | | 1 | | Ų | | |
| Vtg | Liters | | | | | | | | | | |
| νč | Liters | 4,61 | | | | | -4 | | | | |
| TL.C | Liters | 7.00 | | | | | 1 | | | | |
| RV | Liters | 2.66 | | | | | | | | | |
| RV/TLC | % | 40 | | | | | -8 + | | | | |
| FRC PL | Liters | 4.04 | | | | | l | | | | |
| ERV | Liters | | | | | | 1 | | | | |
| IC | Liters | | | | | | -12 | | | | |
| Diffusi | on | | | | | | -12 -2 | 0 Z _{Volu} | 4 | 6 | 8 |
| DLCO | mL/mmHg/min | 999 | | | | | | VOIL | me | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | |
| DLCOMA | mL/mHg/min/L | | | | | | | | | | |
| VA | Liters | . 2.00 | | | | | | | | | |
| вĤТ | Sec | | | | | | | | | | |
| Resist | | | | | | | | | | | |
| | | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | 4.00 | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.08 | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | • | | | | | |
| sRaw | cmH2O/L/s/L | 4.36 | | | | | | | | | |

Comments:

Vtg (Raw) Liters

sGaw



Version: IVS-0101-20-5B

Intermetation:

cmH2O/L/s/L L/s/cmH2O/L 0.230

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| SCALE 0 to 3 | Throat Clearing Y/N | | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | O to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | 0 to 3 | DAY AM |
|--------------|---------------------|----------|--------------------|----------------------|----------------------|---------|----------------|---------------------|---------------------|--------------------|----------------------|----------------------|---------------------------------|-------------------|
| | YES NO | S | 0 (1) 2 3 | 0 1 👸 | 0 (1) 2 3 | 0 1(2)3 | ,7 | (YES) NO | YES (NO) YES | 0 1(2)3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2(3) | 19/2 |
| | (YES) NO | YES AND | 0 1 (2)3 | 0 1 2 3 | 0 (1) 2 3 | 0 1(2)3 |) ₆ | (ES) NO | (ð) | 0 (1) 2 3 | 0 1 🕄 3 | 0 (1) 2 3 | 0 1 2 3 | 10/3 |
| | YES NO | (§) | 0 1 3 3 | 0 1(2)3 | 0(1)2 3 | 0 1(2)3 | Ь Э | (ES) NO | YES (NO) | 0 (1)2 3 | 0 1 (2)3 | 0(1)2 3 | $0 \ 1 \ 2 \ 3 \ 0 \ 1 \ 2 \ 3$ | 10/4 |
| | (YES) NO | YES (NO) | 0 1 (2) 3 | 0 1 2 3 | 0 (1)2 3 | 0 1(2)3 | -4 | (YES) NO | YES (NO) YES | 0 (1)2 3 | 0 1(2)3 | 0 (L) 2 3 | | 10/5 |
| | YES) NO | YES (NO) | 0 1 (2)3 | 0 1 (2) 3 | $\bigcirc 1 \ 2 \ 3$ | 0 1 ②3 | -3 | YES) NO | (No) | 0 (1)2 3 | 0 1 2 3 | 0 2 3 | 0 1/2)8 | 10/4 |
| | (YES) NO | YES | 0 1 2 3 | 0 1 2 3 | 0)1 2 3 | 0 1 🛭 3 | -2 | YES NO | YES (NO | 0 (1)2 3 | 0 1 2 3 | 0123 | 0 🗓 2 3 | 10/7 |
| | (YES) NO | YES (NO) | 0 1(2)3 | 0 1 2 3 | 0123 | 0 🖒 2 3 | 4 | (YES) NO | YES (10) | 0 🛱 2 3 | 0 1 🖉 3 | Q1 2 3 ₀ | | 10/P |
| | YES | YES | 0 1 2 | 0 1 2 | 0 1 2 | 0 1 2 | 0 | (3) | YES (| 0(1)2 | 0 1(2) | 0 | Ö | \ \(\frac{1}{2}\) |
| | O | O | ω | 2 3 | ω | ω | | O | (3) | 2 3 | 2)3 | ν ω | 2 3 | 0 |
| | YES | YES | 0 | 0 1 | 0 1 | 0 | 0 | YES | YES | 0 | 0 1 | 0 | 0 | 0 |
| | 0 | O | 2 3 | 2 3 | 2 3 | 2 3 | | S | O | 2 3 | 2 | 2 3 | 2 3 | |

CALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ACP-OCS. DATE COMPLETED: 10-2-13 CAM)

SUBJECT INITIALS AND DATE:

10/2/1



Lovelace Scie p Resources Clin Trials-Lesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME MJC, MJC

PATIENT ID **AAGF8916**

08/23/1944

REPORT STATUS Final

PAGE 1

PHYSICIAN Unlisted Physician, **COLLECT DATE & TIME**

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

10/09/2013 10:26

10/09/2013 20:52

SEX

М

10/11/2013 06:10

30920909

0

PATIENT NO.

COMMENTS .

AKP003

| OMMEN 19: | | |
|-----------|--|--|
| | | |

| | R | esult | | | | |
|-------------------------------------|--|--|---|--|----------------------------------|-----------|
| Test | In Range | Out of Ran | ige | Units | Reference Range | Site Code |
| Eos, Respiratory | | Rare | * | | NS | |
| Comp Metabolic Panel | 407 | | | | 404.444 | |
| Södium Potassium | 137 4.2 | | | mmol/L mmol/L | 134-14 4 3.5-5.1 | |
| Chloride | 104 | | | mmol/L | 3.5-5.1 98-111 | |
| CO2 | 23 | | | mmol/L | 20-30 | |
| Anion Gap | 10 | | | *************************************** | 6-14 | |
| Glucose | | 116 | Н | mg/dL | 60-100 NC | s dover |
| | Impaired fasting glucose (100-126 mg/dl (ADA Guideli | (IFG) is defir nes Diabetes | ed as a Care 26: | fasting gluco. (3160-3167)20 | se level of //6 | QUT 13 |
| BUN | 20 | | | mg/dL | 7-31 | |
| Creatinine | 1.10 Creatinine method is IDMS | traceable Fo | tGER Cal | mg/dL culation has l | 0.62-1.66 been adjusted | |
| | Please note new reference | | | | Joen dajasoda | |
| eGFR non-African Am GFR Comment | >60 | _ | | mL/min/1.73m2 | >60 | |
| Of it Common | Estimated GFR values are ron IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | ot accurate i 4) or underwe , races other s, or amputat | n acute right (BM r than Ca rions. | kidney failur II<20) people, ucasian or Af | e, inpatients rican American, | |
| Calcium | 8.9 | | | mg/dL | 8.4-10.4 | |
| Total Protein | 6.9 | | | gm/dL | 6.1-8.2 | |
| Albumin | 4.4 | | | gm/dL | 3.4-4.7 | |
| Globulin | 2.5 | 4.0 | | gm/dL | 2.4-4.2 | cet 13 |
| Bilirubin, total Alk Phos | 94 | 1.3 | Н | mg/dL U/L | 0.3-1.2 / | 00515 |
| AST(SGOT) | 23 | | | U/L | 36-150 // 6-58 | |
| ALT(SGPT) | 41 | | | U/L | 14-67 | |
| Fasting | NO | | | 0,1 | 14-01 | |
| CBC | | | | | | |
| УЙВС | 4.1 | | | x10E3 | 4.0-10.6 | |
| RBC | 4.83 | | | x10E6 | 4.64-6.00 | |
| Hgb | 16.0 | | | gm/dL | 14.5-17.7 | |
| Hct | 47 | | | ~ % | 42-53 | |
| MCV | 96 | | | fL | 81-98 | |
| MCHC | 34.4 | | | gm/dl. | 31.2-35.2 | |
| RDW | 12.3 | | | % | 11.0-14.5 | |
| Platelets | 179 | | | x10E3 | 150-400 | |
| Phys, Addr, Phone Important Info | Not given | | | | | |
| πηροκατικ πτιο | Client contacted for clari | fication of t | est orde | rs Per clien | r's request. | |

Client contacted for clarification of test orders. Per client's request, the following test(s) will be performed: Eosinophils, Respiratory

End of Report



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci ∄c Resources Clin TrialsLesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

PATIENT NAME TGC, TGC

PATIENT ID **AAGF9554** DOB 04/30/1946 SEX REPORT STATUS M Final

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO. COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

10/10/2013 08:00 PATIENT NO.

10/10/2013 19:16

10/11/2013 06:10

30920910

Test

0

AKP006

COMMENTS:

In Range

Result

Out of Range

Moderate

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone

NO ORDERING PHYSICIAN

NS

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| HOLIRS | |
|----------|--|
| FRY 12 | |
| NSE FIVI | |
| RESPO | |
| MATE | |
| PROXII | |
| CLEAP | |
| S | |

3

| DAY | ₩. | . 2 | ന | 4 | Ŋ | 9 | 7 | 00 | σ | |
|------------------------|------------|----------------------|------------------|-------------------|---|------------------|-------------------|----------|--------|---|
| AM | 10/0/13 | 51/01/ ₀₁ | 9/10/13/10/11/13 | 10/14 | 10/12/13 10/13/13 / 0/15/13 10/10/13 / 0/10/1 | 10/14/13 | 10/143 | 10/14/13 | 1 200 | 2 |
| Runny Nose | 70 1 2 3 | 0 (1) 2 3 | 0 (1)2 3 | 0 17 3 | 0(1)2 3 | 0 1(2)3 | 01)2 3 | 0(1) 2 3 | 0 1 2 | |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0/123 | (g) 1 2 3 | O >1 2 3 | (O)1 2 3 | 0123 | <u>(0)</u> 1 2 3(| 0 1 2 3 | 0 1 2 | m |
| Congestion | 0 1 2 3 | 0 1 (2)3 | 0 1(2)3 | 0 (1)2 3 | 0(1)2 3 | 0 \bigcirc 3 | 0(1)2 3 | 0 1 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1/2 3 | 0123 | (0)123 | 0)123 | 0 \$723 | 0(1)2 3 | 0(1)23 | 0(1)2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES NO | YES (NO | y YES (NO) | YES (NO) | YES (NO | YES (NO | YES (MO) | YES (NO) | YES NO | 0 |
| Throat Clearing Y/N | YES NO | YES) NO | VES (NO) | YES (NO) | YES (NO) | VES (NO) | YES (400) | YES (NO) | YES NO | 0 |
| DAY PM | н | 2 | . 3 | 4 | 5 | 9 | 7 | 8 | 6 | |
| Runny Nose 0 to 3 | 0 12 3 | (g) 1 2 3 | (O)1 2 3 | 0(1)2 3 | 0 1 3 | 0(1)2 3 | 0(1) 2 3 | 0 1 2 3 | 0 1 2 | m |
| Itchy Nose 0 to 3 | (0)1 2 3 | (0) 1 2 3 (| (0) 1 2 3 (| (<u>0</u>)1 2 3 | (<u>O</u> 1 2 3 | (O)123(| (b) 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 04)23 | 0 1(2) | 0 🖒 3 | 0(1/2 3 | 0(1)2 3 | $0(1)^2$ 3 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | Q 13 2 3 (| (0)123 | 0(1)2 3 | 0 (1)2 3 | 0(1)2 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES NO | VES (NO) | YES NO | YES NO | YES NO | 0 |
| Throat Clearing Y/N | (YES NO | YES NO | YES (NO | YES (NO) | VES (NO) | VES (NO) | VES (NO) | YES NO | YES NO | 0 |
| 0 040 11000 | | | | | | | | | |] |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: PAL 2003 DATE COMPLETED: 10/9/13-10/16/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

fic Resources Lovelace Sc Clin TrialsLessie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

MJC, MJC

PATIENT ID **AAGF8916** DOB 08/23/1944 SEX REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

30920908 COMMENTS:

REQUISITION NO.

O

10/16/2013 10:15

10/16/2013 20:38

10/17/2013 06:08

NS

PT. PHONE NO.

PATIENT NO.

AKP003

Result

Test

In Range

Out of Range

Units Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Not given

NCS JS 10/18/13

End of Report

NOS JSalyer PI 18 Oct 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | | | | | ~ | | | | | | | | _ |
|---------------------|---------------------|--------------------|----------------------|----------------------|----------------------|------------|------------------------|---------------------|-----------------------|-------------------|----------------------|----------------------|---------|----------|
| Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing // (| Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | AM | אַר |
| YES NO | YES (NO) | 0(1)2 3 | 0 (1) 3 | 0)123 | 0 (1)2 3 | 7 | YES \ NO | Vis (Mg) | 0(1)23 | 1900) 3 | 2/3 | φ(<u>1</u>)2/8 | (oliue | 7 |
| YES (NO) | YES MO | 0 (1)2 3 | 0/1)2 3 | $\bigcirc 1 2 3$ | 0 (1) 2 3 | ∞ | YES (NO) | YES (NO) | 0 1 (2)3 | 0(1)23 | 9123(| 0/1/2 3 | 12/17 | ٥ |
| YES (NO) | YES (NO) | 0 🛈 2 3 | 0 (1) 2 3 | (9)1 2 3 (| 0 (1) 2 3 | 9 | YES (NO) | YES (NO) | 0 1(2)3 | 0(1)23 | 0)123 | Q ₁)23 | 10/F | 5 |
| YES (NO) | YES (NO) | 0(1)23 | 2 Z | O1 2 3 | 0 (1)2 3 | 10 | AES YOU | YES MO | 0 1(2)3 | 0 (1) 2 3 | 0123 | 0 (1)2 3 0 1 (2)3 | 10/19 | 3 |
| YES (NO) | ON SIA | 0 (1) 2 3 | 0 (<u>f</u>)2 3 | (v) 1 2 3 | 0 H)2 3 | 11 | YES MO | VES (NO) | 0 1 (2) 3 0 (1) 2 3 | 0 🗇 2 3 | ①1 2 3 | 0 1 ②3 | 10/20 | 7 |
| YES (NO) | YES (NO) | 0 (1) 2 3 | 0 (1)2 3 | (0) 1 2 3 | 0(1)23 | 12 | YES (NO) | YES (NO) | 0 🗇 2 3 | 0 1 D3 | (0)123 | 3 | 10/21 | . |
| YES (NO) | YES 🔞 | 0 🗓 2 3 | 0 (1) 2 3 | 0123 | 0 \$\)2 3 | 1 3 | YES NO | YES (NO), | 0 (1) 2 3 | 0 1 (2) 3 | (4)1 2 3 | 0/1)2 3 | 10/22 | , |
| YES NO | YES NO | 0 1 2 3 | 0123 | 0123 | 0 1 2 3 | 14 | YES (NO) | AES ₩ | 0 (1)23 | ε(ζ) ř o | 8219 | 0 (1) 2 3 | 10/25 | 4 |
| YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0123 | 15 | YES NO | YES NO | 0123 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 10/24 | 1 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ALPOIS DATE COMPLETED: (0/23/13

2nd 10-25-13

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci fic Resources Leslie Byatt, Ciin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME MJC, MJC

PHYSICIAN

Unlisted Physician, PT. PHONE NO.

REQUISITION NO.

30920972

COMMENTS:

Test

0

PATIENT ID

AAGF8916

OOB 08/23/1944 SEX М

REPORT STATUS Final

PAGE

COLLECT DATE & TIME 10/23/2013 10:30

RECEIVE DATE & TIME

PRINT DATE & TIME

10/24/2013 17:48

10/25/2013 06:09

PATIENT NO.

AKP003

Result

paper SubI

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone None seen Not given

In Range

NS

End of Report

| Study Identification: 2749 | 7 | | LSR | LSR Study #: | |
|---|-------------------|---|---------------------------|--------------------------|----------------------------|
| Subject Number: AKPOOS | 60 | | Sub | Subject Initials: MJQ | |
| | | ADVERSE EVENT LOG | 9 | | |
| Adverse Event (DD/MMM/YYYY) | SEVERITY | Relationship to Study Drug (Suspected/Not Suspected) | ** End Date (DD/MMM/yyyy) | Action Taken | Investigator initials/Date |
| | | | | | |
| | | | | | |
| - | * | | | | |
| | 3/ | | | | |
| | | 4/ | | | |
| | | | | | |
| | | | | | |
| | | | __\ | | |
| | | | J/. | | |
| | | | as | | |
| | | | | () | |
| | | | | 3) | |
| ** If day is unknown, w | vrite UNK in spac | ** If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible ** | hould be made to be | as specific as poseble** | * |
| Investigator Signature (at end of study): | dy): | 18Mu Luies | // C Date: | Date: 30 00 2015 | |
| SC Signature (at end of study): (| | ta march | 3 | Date: 10/30/13 | |
| | | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 | | PAGE: | SE: \ \ \ of \ \ |

:



Lovelace Scientific Resources Leslie Byatt, Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID **AAGF8916** DOB 08/23/1944 REPORT STATUS Final

PAGE 1

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 10/30/2013 10:23

M RECEIVE DATE & TIME 10/30/2013 19:48

SEX

PRINT DATE & TIME

REQUISITION NO.

PATIENT NAME MJC, MJC

PT. PHONE NO.

PATIENT NO.

10/31/2013 06:06

NS

30920966

0

AKP003

| CO | MM | EN | TS | ; |
|----|----|----|----|---|
| | | | | |

| | 1 | Result | | | |
|----------------------|---|-----------------------|------------------------------------|---------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 138 | | mmol/L | 134-14 4 | |
| Potassium | 4.5 | | mmol/L | 3,5-5,1 | |
| Chloride | 106 | | mmol/L | 98-111 | |
| CO2 | 26 | | mmol/L | 20-30 | |
| Anion Gap | 6 | | | 6-14 | |
| Glucose | 92 | | mg/dL | 60-100 | |
| BUN | 14 | | mg/dL | 7-31 | |
| Creatinine | 1.16 | | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDMS | | | een adjusted | |
| | Please note new reference | range effective 5/23 | 3/2013. | | |
| eGFR non-African Am | >60 | | mL/min/1.73m2 | >60 | |
| GFR Comment | | _ | | _ | |
| | Estimated GFR values are on IV fluids, obese (BMI>the yery old or very youn | not accurate in acute | kidney failure | , inpatients | |
| | on IV Tiglos, obese (BMI> | 54) or underweight (b | mikzuj peopie, Saucasian or Afr | ican American. | |
| | people with acute illness | es, or amputations. | MANUAL OF THE | Town Tally | |
| Calcium | 8.8 | · | mg/dL | 8.4-10.4 | |
| Total Protein | 7.0 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.4 | | gm/dL | 3.4-4.7 | |
| Globulin | 2.6 | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | | 1.6 H | mg/dL | 0.3-1.2 | |
| Alk Phos | 107 | 4.40 | Ú/L | 38-150 | |
| AST(SGOT) | 21 | NGS | U/L | 6-58 | |
| ALT(SGPT) | 34 | Olaku P | T U/L | 14-67 | |
| Fasting | Not given | Salyer P | | | |
| CBC | | 1110 - 201 | 13 | | |
| WBC | 5.3 | 1970000 | ×10E3 | 4.0-10.6 | |
| RBC | 4.74 | | x10E6 | 4.64-6.00 | |
| Hgb | 15.9 | | gm/dL | 14.5-17.7 | |
| Hct | 46 | | - % | 42-53 | |
| MCV | 97 | | fL | 81-98 | |
| MCHC | 34.6 | | gm/dL | 31.2-35.2 | |
| RDW | 12.6 | | % | 11.0-14.5 | |
| Platelets | 164 | | x10E3 | 150-400 | |
| | | | | 110 | |

End of Report

Eos, Respiratory Phys, Addr, Phone None seen

Not given

| 9749 | itials: \mathcal{M} | ements. | Ongoing at EOS (for Clinicuse) | | K | 1 | | 43 25 25 | | Z0/3 | | | | | | , | PAGE. 2 of |
|-----------------------|-----------------------|---|--------------------------------------|---------------------|--------------|-----------------------|----------------|-----------------|-----------|-----------------|----------------|---|--|---|---|---------------------------------|--|
| LSR#: | Subject Initials:, | s and supple | Stop Date | | | June, | | 9/2/6 | 23 | 1/83/5c | | | | | 4.02.77 | 1/14 | |
| | | .OG r medications, vitamin | * Start Date (Day/Month/Year) | _UNK/AUG/1999 | -66111 | 1-7-1/997 | //200 | 861//- | 964/ | | 5000//- | | | * If day or month of medication date is <u>unknown,</u> write UNK in space provided | Date: 26 F | Date: 2/2 | |
| | | CATION L | Route | Oral | oral | HT NO | 913313 Oral | on | praj | oral | Ora/ | | | <u>wn,</u> write L | | | nMeds 04/201 |
| | | CONCOMITANT MEDICATION LOGre taking. Also include over-the-counter me | Frequency | 2 Tabs per Poday | 90 | 19067 | CO San | OD | 00 | PRN | PRN | | | ate is <u>unkno</u> | wille | Heller | Lovelace Scientific Resources, Inc - ConMeds 04/2013 |
| 93/13 | 1 | COMITA | Unit | MG | ma | mcg | ng | mg | ma | D/Kg | is | 1 | | lication d | Marky | Ĭ. | e Scientific R |
| 6 | | CONC | Dose | 500 | 70 | 50 | 0/ | 10 | 0.4 | 53 4 | 82 3823 800 | | | nth of mec | 1880 | 11/2 | Lovelac |
| m3 bttc | AKPOO3 | CONCOMITANT MEDICATION LOG | Indication (What you take it for) | Diabetes | BPH | Seasonal allocales | 1 1 | 3. 3.42.50.00S. | BPH ' | ur) Seasonal | Osteoarthritis | | | * If day or mo | Investigator Signature (at end of study): | SC Signature (at end of study); | |
| Study Identification: | Subject Number: AK | List all <u>p</u> | Name of Medication | EXAMPLE | Finasteriale | FILHI CASONE | Lismoprii | Loratadin | Tamusosin | GOLS Misasellee | Thuprofon | : | | | Investigator Signatu | SC Signatu | • |

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | | | | | | | | | ſ |
|----------------------|----------|-----------|-------------------|-----------|-----------|-------------------|-----------|----------|--------|---|
| DAY | , , 14 | | 16 | 17 | | 19 | 20 | | 22 | |
| AM | 10/23/13 | 1,294/13 | 1925/13 | 19/36/13 | | 19/27/13/19/98/13 | 10/04/13 | 193913 | | |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 (1) 3 | 0(1)2 3 | 0 (1) 3 | 0 \$ 2 3 | 0 (1) 2 3 | e Z(T) o | 0(1)2 3 | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0 1 2 3 | () 1 2 3< | 0 2 3 | (g)1 2 3 | O123(| 9123 | (D) 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0 1 2 3 | 0 1(2)B | 0 1 (2)3 | 0(1)2 3 | 0 (1) 3 | 0 (1)2 3 | 0(1)2 3 | 0(1)2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1 2 3 | 0 (1)2 3 | 0 (1)2 3 | 0(1) 3 | 0 (1)2 3 | Q1)2 3 | $(1)^2$ 3 | 0 ① 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES NÓ | YES (NO | YES (NO) | YES (10) | YES MO | YES (NO) | YES (NO) | YES (NO) | YES NO | |
| Throat Clearing Y/N | VES NO | YES (NO) | (YES (NO) | VES (NO | YES MO | (NO) sak | YES (NO | YES (NO) | YES NO | 0 |
| DAY PM | ŤŤ | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | |
| Runny Nose 0 to 3 | ε z(Î) ο | 0 (Ī) z 3 | 0 🗓 2 3 | 0(1)23 | 0 🐧 2 3 | 0 🖒 2 3 | 0 🕦 3 | 0 1 2 3 | 0 1 2 | m |
| ose | (D)1 2 3 | Di 2 3 | Ø1 2 3 | Ø123 | Ø123 | Ø1 2 3< | 0)123 | 0 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | e z(T) o | 0 🕏 2 3 | 0 \$23 | 0 🗓 2 3 | 0 (1) 2 3 | 0 \$\mathcal{G}23 | 0(1)23 | 0 1 2 3 | 0 1 2 | т |
| Sneezing 0 to 3 | 0 1 🔘 3 | 0 (1)2 3 | 0 (1)2 3 | 0 (1) 2 3 | 0 (1) 2 3 | ε z Q o | 0 (5)2 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (VO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | W YES | YES (NO | YES NO | YES NO | 0 |
| Throat Clearing Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES AND | YES (NO | YES NO | YES NO | 0 |
| | | | | | | | | | |] |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N≃ No

ALLOGO DATE COMPLETED: SUBJECT NUMBER:

SUBJECT INITIALS AND DATE: $\frac{10/3a}{1}$

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort MJC/AKP-003

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" TYES NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| Trouble Free Experience |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

[Type text] Subject initials and Date Study Staff Initials and Dat

AKP-004

2,49 AKPharma PERENNIAL ALLER JES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIEN' | <u> T DEMOGRAPHICS</u> |
|------------|---|
| Patient | <u>Demographics</u> |
| Date of E | Birth: 10 / Jun / 1942 (dd/mmm/yyyy) |
| Gender: | Male Female |
| If female | , Indicate Childbearing Potential N/A |
| | Childbearing Surgically sterilized Post-Menopausal |
| Ethnicity | Hispanic Non Hispanic |
| Race: [| Asian 🔲 Black Caucasian 🗌 American Indian |
| | Pacific Islander Other, Specify |
| | |
| Smoking | History |
| Smoking | Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| If subject | is a former or current smoker, please indicate: |
| | |

Version: 02 September 2013



Lovelace Scie **Resources** Clin Trials-Leshe Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME X, RJE

PATIENT ID **AAGF0190** DÖB 06/10/1942 REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician. **COLLECT DATE & TIME**

RECEIVE DATE & TIME 09/23/2013 19:02

SEX

М

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

09/23/2013 11:00

09/26/2013 06:06

30920880

0

PATIENT NO.

COMMENTS:

AKP004

| | _ | |
|--|---|--|

| | | | Result | | | | | |
|----------------------|------------|---|------------|-----------|------------|--|---|-----------|
| Test | • | In Range | 0 | ut of Rai | nge | Units | Reference Range | Site Code |
| Allerg.Panel 18 | | | | | | | | |
| Allerg, Juniper | | | 9 | .20 | Н | kU/L | < 0.35 | |
| Allerg,Cottonwood | | | (|).40 | H | kU/L | < 0.35 | |
| Allerg,West.Ragweed | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Russian This | | | 7 | 7.30 | H | kU/L | <0.35 | |
| Allerg,Bermuda Grass | | 0.20 | | | | kU/L | <0.35 | |
| Allerg,Alternaria | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Mesquite | | | 0 | 7.70 | Н | kU/L | < 0.35 | |
| Allerg,Cockroach | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Derm. pter. | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Derm. farinae | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Clad. herb. | | <0.10 | | | | kU/L | <0.35 | |
| Allerg,Firebush | • | | | 1.10 | Н | kU/L | <0.35 | |
| Allerg,Cat Dander Ep | | | | 1.20 | , Н, | kU/L | <0.35 | |
| | | dard classifica | | | lizes the | tollowing c | lass cutoffs. | |
| | Class | .ku/L | Interpre | tation | | | | |
| | 0 | <0. 35 | Negative | for A | llergen | | | |
| | Ī | 0. 35-0. 69 | Positive | for A | llergen | | | |
| | II | 0. 70-3. 49 | Strongly | Posit | ive | | | |
| | III | 3. 5-17. 49 | Strongly | Posit | ive | | | |
| | IV | 17. 5-52. 49 | Strongly | Posit | īve | | | |
| | v | 52. 5-99. 99 | Strongly | Posit | ive | | | |
| | VI | >100 | Strongly | Posit | īve | | | |
| | A l though | with allergens or equivocal. increasing cla | ass ranges | (0-VI |) are refl | d be conside d be conside dective of i | red weakly red positive ncreasing | |

concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Dog Dander Allerg, Bluegrass Allerg, Pigweed Allerg, Mulberry Allerg, Helminth

<0.10

0.20

< 0.35 1.60 kU/L <0,35 1.90 kU/L Н < 0.35 2.70 Н kU/L < 0.35 kU/L < 0.35

Allerg, Helminth
Phys, Addr, Phone

End of Report Voluntur demonstrates reactivity to Revenue of

Allergens Cat Dander & epethelium and

Russian Trust Le. Meets inclusion Criteria

X, RJE

09/26/2013 06:06

Salyer

FA)

FAX24664



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: RJE, Gender: Male

Age: 71 Race: Height(in): 67.0

Race: Caucasian

Weight(lb): 208

Any Info:

ld: AKP-004 Date: 10/08/13

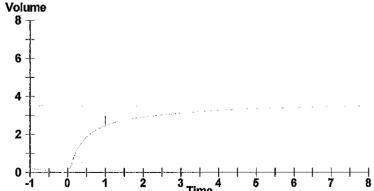
Temp: 21

PBar: 632

Physician:

Technician: VL

| Any into: | | | | | 100 | chilician | I. VL | |
|---|--|----------------------|----------------------------|----------------|------------------------------|---------------|----------------------------------|--|
| Spirometry | (BTI | Ref | PRE-R Pre F Meas % F | Pre I | POST-RX Post Post leas % Ref | Post % Chg | Flow 8 _T | |
| FVC Lite FEV1 Lite FEV1/FVC % | ers | 3.45 2.72 79 | 3.51 1 2.48 70 | 02 91 89 | icas 70 NGI | 70 Ong | 6 | |
| FEF25-75%L/s FEF50% L/s FEF75% L/s IÇ Lite | ec ec | 3.49 | 2.16 | 57 62 45 | | | 4 | |
| VC Lite PEF L/s MVV L/n | ers sec nin | 3.45 7.51 116 | 6.96 | 93 | | | 2 | |
| ••• | lumes/P | lethysmo | 73 graph | У | (BTPS) | | 0 | |
| Vtg Lite VC Lite TLC Lite RV Lite | ers ers | 3.45 5.78 2.35 | | | | | -2 | |
| RV/TLC % FRC PL Lite ERV Lite IC Lite | ers ers | 41 3.01 | | | | | -4 -6 | |
| Diffusion DLCO mL | ors _/mmHg/min _/mmHg/min | 21.7 | | | | ÷ | -6-1 0 1 _{Volume} 2 3 4 | |
| DL Adj mL DLCO/VA mL VA Lite BHT Se | ./mHg/min/L ers | 2.97 | | | | | | |
| Registan | co | | | | | | | |
| Raw Total cm Raw Insp cm Raw Exp cm Raw cm Gaw L/s sRaw cm | nH2O/L/sec nH2O/L/sec nH2O/L/sec nH2O/L/sec sec/cmH2O 0 nH2O/L/s/L n/cmH2O/L 0 | 4.71 | | | | | | |
| - | | | | 1 | /olume | | | |
| Comments: | | | | | 8 | | | |



Version: IVS-0101-20-5B

interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: RJE, Gender: Male

Age: 71 Race: Caucasian Height(in): 67.0 Weight(lb): 206

Any Info:

ld: AKP-004 Date: 10/15/13

Temp: 20

PBar: 631

Physician:

| | (DTDO) | DDE DV | DOST DY | |
|---------------|-----------------|--------|---------|---------------|
| Info: | | | Т | echnician: VL |
| 9111(111). 01 | .o vroigint(io) | . 200 | | , |

| any into: | | | | | | | i Guilliula | II. V C. | | | | |
|--|---|---|--|---|------|----------------|-------------|------------------------|---|-------------|-------|---|
| Spiratos | (B * | TPS) Ref | Pre | E-RX Pre | Post | Post | Post | Flow 8 _T | | | | |
| FVC FEV1/FVC FEF25-75 FEF50% FEF75% IC VC PEF MVV PIF FEV1/FEV | %L/sec L/sec L/sec Liters Liters L/sec L/min L/sec | 3.45 2.72 79 2.75 3.49 1.15 3.45 7.51 116 | 3.29 2.38 72 1.68 2.13 0.67 7.37 | % Ref 95 88 92 61 61 58 | | % Ref BTPS) | % Chg | 4 | | | 1-1-1 | |
| Vtg VC TLC RV RV/TLC FRC PL ERV IC Difffus DLCO DL Adj DLCO/VA VA BHT | Liters Liters Liters % Liters Liters Liters Liters Liters LITERS | 3.45 5.78 2.35 41 3.03 | | <i>y</i> 3 | | | | -2 -4 -6_1 | 0 | 1 Volume | 3 | 4 |
| Raw Insp | cmH2O/L/sec cmH2O/L/sec | | | | | | | | | | | |

Norm Set: Knudson (1983)

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 sRaw
 cmH2O/L/s/L

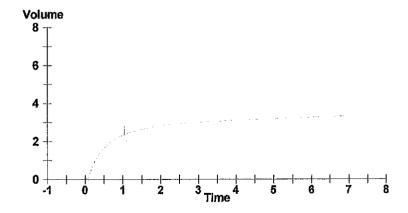
 4.70

 sGaw
 L/s/cmH2O/L

 0.213

Vtg (Raw) Liters

Comments:



internectation:



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: RJE, Gender: Male

Age: 71 Race: Caucasian Height(in): 67.0 Weight(lb): 205

Any Info:

Id: AKP-004 Date: 10/22/13

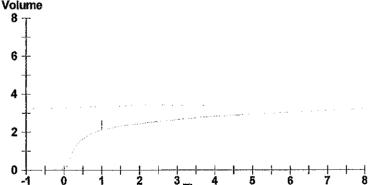
Temp: 21

PBar: 635

Physician: Technician:

| u., | د در د در د در د در درور سر معاود | | | | DOOT DY | | | |
|--------------|--------------------------------------|------------|--------|--------------|-------------------------|---------------|-----------------|---------------------------------------|
| Spirometr | . (B | TPS) | | E-RX | POST-RX | | Flow | |
| CAN CHEIST | , | Ref | Pre | Pre % Ref | Post Post Meas % Ref | Post % Chg | 8 T | |
| FVC | Liters | 3.45 | 3,44 | 100 | INICOS 70 IVCI | 70 Ong | 1 | |
| FEV1 | Liters | 2.72 | 2,13 | 78 | | | | r. |
| FEV1/FVC | | 79 | 62 | 79 | | | 6 🕂 | <i>f</i> ', |
| FEF25-759 | | 2.75 | 0.69 | 25 | | | 1 | |
| FEF50% | L/sec | 3.49 | 1.59 | 45 | | | | |
| FEF75% | L/sec | 1.15 | 0.08 | 7 | | | 4+ | |
| IC | Liters | | | | | | 1 | 1 |
| VC | Liters | 3.45 | | | | | T | λ |
| PEF | L/sec | 7.51 | 6.98 | 93 | | | 2 ∤ | <u> </u> |
| MVV | L/min | 116 | | | | | | 1 |
| PIF | L/sec | | | | | | Ť | N. |
| FEV1/FEV | | | 70 | | | | 0 | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| l una \ | /olumes/I | Plethy | smodra | ohv | (BTPS) | | - | |
| | | | | | | | † | |
| Vtg | Liters | 0.45 | | | | | -2∤ | |
| VC TLC | Liters | 3.45 | | | | | - | |
| TLC | Liters | 5.78 | | | | | † | |
| RV RV/TLC | Liters % | 2.35 41 | | | | | -4 | |
| FRC PL | Liters | 3.03 | | | | | • | |
| ERV | Liters | 3.00 | | | | | + | |
| IC | Liters | | | | | | -6 [⊥] | |
| | | | | | | | -o_ -1 | 0 1 2 3 4 |
| Diffusi | | 04.0 | | | | | | Volume |
| DLCO | mL/mmHg/min | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | |
| | | 2,98 | | | | | | |
| VA | Liters | | | | | | | |
| BHT | Sec | | | | | | | |
| Pegist | ance | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | |
| Raw | cmH2O/L/sec | 1.55 | | | | | | |
| Gaw | L/sec/cmH2O | 0.728 | | | | | | |
| sRaw | cmH2O/L/s/L | 4.70 | | | | | | |
| sGaw | L/s/cmH2O/L | 0.213 | | | | | | |
| Vtg (Raw) | Liters | | | | | | | |
| | | | | | Volume | | | |

Comments:



Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: RJE, Gender: Male

Age: 71 Race: Caucasian Height(in): 67.0 Weight(lb): 201

Any Info:

Id: AKP-004 Date: 10/29/13

Temp: 20

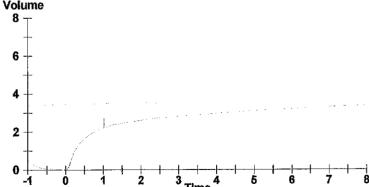
PBar: 630

Physician:

Technician: VL

| any inio. | | | | | | 00111110101 | — | |
|--|--------------|------------|---------|----------------|------------|-------------|-------------------|--|
| er i jamen i i i i i i i i i i i i i i i i i i i | (E | TPS) | PRE | -RX | POST-RX | | Flow | |
| Spiromet | ry . | Ref | Pre | Pre | Post Post | Post | 8 - | |
| | | | Meas | | Meas % Ref | % Chg | ٠, | |
| FVC | Liters | 3.45 | 3.53 | 102 | | | † | |
| FEV1 | Liters | 2.72 | 2.25 | 83 | | | 6∮ | $f \setminus X$ |
| FEV1/FVC | | 79 | 64 | 81 | | | ٠, | / \ |
| FEF25-75 | %L/sec | 2.75 | 0.89 | 32 | | | + | A North Control of the Control of th |
| FEF50% | L/sec | 3.49 | 1.53 | 44 | | | 4 - | |
| FEF75% | ∐/sec | 1.15 | 0.30 | 26 | | | ~ T | |
| IC | Liters | | | | | | + | · . |
| VC | Liters | 3.45 | | | | | | |
| PEF | L/sec | 7.51 | 7.02 | 93 | | | 2 ∱ | M _i |
| MVV | Ľ/min | 116 | | | | | 1 | · 1 |
| PIF | L/sec | | 1.58 | | | | | V. Ade warms |
| FEV1/FEV | /6% | | 70 | | (0700) | | 0 ++ | The state of the s |
| Luna \ | Volumes/ | Plethv | smodrat | ohy | (BTPS) | | | $\frac{1}{2} \sum_{i \in \mathcal{I}_{i}} \frac{1}{2} \sum_{i \in \mathcal{I}$ |
| | | J | Tree 7 | w ^p | | | Ī | 10 to 12 feet 1 |
| Vtg | Liters | 0.45 | | | | | -2 | |
| VČ | Liters | 3.45 | | | | | | |
| TLC | Liters | 5.78 | | | | | † | |
| RV | Liters | 2.35 | | | | | -4 | |
| RV/TLC | % | 41 3.06 | | | | | • | |
| FRC PL | Liters | 3.00 | | | | | † | |
| ERV | Liters | | | | | | | • |
| IC | Liters | | | | | | -6 <u>↓</u> -1 | 0 1. 2 3 4 |
| Diffus | | | | | | | • | 0 1 _{Volume} 2 3 4 |
| DLÇÖ | mL/mmHg/mii | | | | | | | |
| DL Adj | mL/mmHg/mir | ո 21.3 | | | | | | |
| DLCO/VA | mL/mHg/min/l | 2.95 | | | | | | |
| ·VA | Liters | | | | | | | |
| BHT | Sec | | | | | | | |
| Poele | ianca | | | | | | | |
| · · | | | | | | | | |
| | cmH2O/L/sec | | | | | | | |
| Raw Insp | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | |
| Raw | cmH2O/L/sec | 1.53 | | | | | | |
| Gaw | L/sec/cmH2O | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.69 | | | | | | |
| sGaw | L/s/cmH2O/L | 0.213 | | | | | | |
| Vtg (Raw) | Liters | | | | | | | |
| | | | | | Volume | | | |

Comments:



interpretation



Lovelace Scie Resources Clin Trials-Leslie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME RJE, RJE

PATIENT ID **AAGF8237** DOB 06/10/1942

REPORT STATUS \$EX М Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 10/08/2013 10:05 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

10/08/2013 20:16

10/09/2013 06:05

30920926

0

AKP-004

| | F | Resu it | | | | |
|------------------------------------|---|---|---------------------------|---|----------------------------|-----------|
| Test | In Range | Out of Ran | iãe | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 135 | | | mmol/L | 134-144 | |
| Potassium | | 3.1 | L | mmol/L | 3,5-5.1 | |
| Chloride | 101 | | | mmoi/L | 98-111 | |
| CO2 | 26 | | | mmo!/L | 20-30 | |
| Anion Gap | 8 | | | - 11 | 6-14 | |
| Glucose | Impaired fasting glucose (100-126 mg/dl.(ADA Guidel | 121 (IFG) is defir ines Diabetes | H led as a Care 26: | mg/dL fasting glucos (3160-3167)200 | 60-100 e level of 3) | |
| BUN | 24 | | | mg/dL | 7-31 | |
| Creatinine | 0.88 | | _ | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDMS | traceable. Es | tGFR Cal | culation has b | een adjusted. | |
| | Please note new reference | range effecti | ve 5/23/ | 2013. | | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| | Estimated GFR values are mon IV fluids, obese (BMI): | not accurate i 34) or underwe | n acute eight (BM | kidney failure, II<20) people, | inpatients | |
| | the very old or very young people with acute illness | es, or amputat | ions. | acastan of All | real paid really | |
| Calcium | 9.5 | , , | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.3 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.9 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.4 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.9 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 66 | | | U/L | 38-150 | |
| AST(SGOT) | 25 | | | U/L | 6-58 | |
| ALT(SGPT) | 51 | | | U/L | 14-67 | |
| Fasting | NO | | | • | | |
| Phosphorus | 2.8 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | | | |
| WBC | 4.6 | | | x10E3 | 4.0-10.6 | |
| RBC | | 4.35 | L | x10E6 | 4.64-6.00 | |
| Hgb | 15.5 | | | gm/dL | 14.5-17.7 | |
| Hct | 44 | | | % | 42-53 | |
| MCV | | 102 | Н | fL | 81-98 | |
| MCHC | 35.1 | | | gm/dL | 31.2-35.2 | |
| RDW | 11.8 | | | % | 11.0-14.5 | |
| Platelets | 203 | _ | | x10E3 | 150 -4 00 | |
| Eos, Respiratory | | Rare | * | | NS | |
| Phys, Addr, Phone | Not given | | | | | |

End of Report

April Sub I 09 Oct 2013

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY) CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

Newt Wed

| | - | 77 | 20207 | | | | | ₹ | |
|---|-------------|----------------------|-----------|-----------|----------------------|----------|--------------------|----------------|---------|
| DAY | -1/- | φ- | rγ | 4 | ကု | 7, | 7 | 0 | C |
| AM | 10/1/13 | 7/0/ | 10/3 | 10/4 | 10/5 | 7.0/1 | (/2/ | € € | 13/9 |
| Runny Nose O to 3 | 0 1(2) 3 | 0 🔘 2 3 | 0 0 2 3 | 0 🗘 2 3 | 0 (1)2 3 | 0 (1)2 3 | (<u>0</u>) 1 2 3 | O 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 Ø 2 3 | 01 2 3 | 0123 | 0123 | O 123 | 0123 | 0123 | 01 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | Q1 2 3 | 0(1)2 3 | 0 (1) 2 3 | 0(1)2 3 | 0 1 3 | 0 (1) 2 3 | 0(1)2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 10 2 3 | 0 1 2 3 | 0 (1) 2 3 | Q123 | O1 2 3 | 0123 | Ø123 | 01 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO | YES (NO) | VES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (10) | YES (NO) | YES NO |
| Throat Clearing Y/N | (YES) NO | YES (NO | (YES) NO | (YES) NO | SES) NO | (YES) NO | YES (NO) | (YES) NO | YES NO |
| DAY PM | -7 | 9- | 5- | 4- | -3 | -2 | -1 | 0 | 0 |
| Runny Nose 0 to 3 | (0) 1 2 3 | O 1 2 3 | 6123 | 0123 | $\bigcirc 1 \ 2 \ 3$ | 9123 | (O)1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0123 | (O)1 2 3 | 0123 | 0123 | 0 1 2 3 | QQ 2 3 | 0123 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0123 | 0123 | 0 1 (2)3 | 0 (1)2 3 | ØØ2 3 | 0 (1)2 3 | 0 (1)2 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0123 | $\bigcirc 1 \ 2 \ 3$ | 0123 | 0(1)2 3 | (9)123 | O1 2 3 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO | YES (NO) | YES (NO) | YES NO | YES NO |
| Throat Clearing Y/N | YES (NO) | YES (NO) | (YES) NO. | YES NO | YES) NO | YES (MO) | YES (NO) | YES NO | YES NO |
| SCALE 0 to 3 0= No symptoms (no symptoms detected) | (no sympton | os detected) | 0 | Itchy E. | res | 3 |) | | |
| 1) | | מ תרונוניים | | • | | | | | |

 $\mathbb{1}=Mild$ symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ALP-004 DATE COMPLETED: 10/1/13 - 10/8/13

SUBJECT INITIALS AND DATE:

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| > 0 | * | • | • | • | L | | r | • | • |
|---|----------------|------------------|--------------------|---------------|------------|------------------|-------------------|-----------|---------|
| DAY | - C | 7 | n_(| 4 | U ~ | ~و | • | xo | מס |
| AM | & / C / | 5/Q/ | 0//07 | 11/0/ | 70//0.1 | 10/13 | 10/14. | 10/15. | |
| Runny Nose | 0 1 2 3 | (0)i23 | (0)123 | 0)1 2 3 | 0 1 2 3 | 0(T)2 3 | 0)123 | (0)123 | 0 1 2 3 |
| 0 to 3 | |) (|) (| <u></u> | |) | |) (| |
| Itchy Nose 0 to 3 | 0 1 2 3 | (9)123 | (O) 2 3 (O) 2 3 | Ø1 2 3 | 0 1 2 3 | Q1 2 3. | (<u>0</u>)1 2 3 | (0)1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0(1)2 3 | 0 1 2 3 | 0 (1)2 3 | 0 1 2 3 | 01 2 3 | 01 2 3 | 0123 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0(1)2 3 | (0)123 | 0123 | 0 1 2 3 | Q 123 | 0123 | 0)123 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO | YES (NO) | YES (NO | YES NO | YES (10) | YES (M) | YES (NO) | YES NO |
| Throat Clearing Y/N | YES NO | (YES) NO | YES (MO) | YES (NO) | YES NO | YES (MO) | YES (NO) | YES (MO | YES NO |
| DAY PM | 1 | 2 | 3 | 4 | 5 | 9 | 7 | 8 | 6 |
| Runny Nose 0 to 3 | (0) 2 3 | (6) 123 | (<u>0</u>)1 2 3 | ()123 | 0123 | 0123 | 01 2 3 | 0 1 2 3 | 0 1 2 3 |
|) eso | 0)123 | (b) 1 2 3 | (0)1 2 3 $($ | O 123 | 0 1 2 3 | Ø 1 2 3 | 01 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1(2)3 | Ø123 | 0(1)23 | o Ø5 3 | 0 1 2 3 | (0) 1 2 3 | 01 2 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0) 123 | 0123 | 0/123 | 0 (1)2 3 | 0 1 2 3 | Ø123 | 0/1/2/3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse | YES (NO | YES (NO | YES (NO) | YES (NO) | YES NO | YES (10) | YES (NO | YES NO | YES NO |
| Throat Clearing Y/N | YES (NO | YES (NO) | YES (NO) | YES (MO) | YES NO | YES (NO) | YES (NO) | YES NO | YES NO |
| C 0 1 C C C C C C C C C C C C C C C C C | 103 | | | | | | | | |

SCALE 0 to 3 · 5-P.1

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

DATE COMPLETED: $\frac{1}{2}\frac{O|\mathcal{L}|}{2}$ $\frac{10|I|I}{3}$ SUBJECT NUMBER: #KP 004

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Clin Trials-Lesue Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME RJE, RJE

PATIENT ID **AAGF8237** DOB 06/10/1942

REPORT STATUS SEX М Final

PAGE

PHYSICIAN

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

Unlisted Physician,

PT. PHONE NO.

10/15/2013 10:00

10/15/2013 20:47

REQUISITION NO.

PATIENT NO.

10/16/2013 06:08

30920914

Ω

COMMENTS:

AKP-004

Result

Test

In Range

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory

None seen

NS

Phys. Addr. Phone

NO PHYSICIAN GIVEN

Caliback Accession Comments:

T3392344

EOSR, UNKPHY

0/15/2013 10:32 pmFAXED TO 3488546

NCCS1685

End of Report

Man Sub I 16 Oct 2013

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | | | | | | | , | |
|---|-------------|---------------------------|------------------|--------------|-----------|--------------------|----------------|---------------|----------|
| DAY | \ | ~~ | m | | M. | u. | | ∞ , | o |
| AM | 10/13 | 19/1u | 10/17 | 10/18 | 10/19 | 10/20 | 10/21 | 10/22 | |
| Runny Nose 0 to 3 | 0 1 2 3 | O123 | $\bigcirc 1 2 3$ | 1 2 3 | (O) 1 2 3 | (O)1 2 3 | 0 1 2 3 | (O)1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | $\bigcirc 1 \ 2 \ 3$ | <u>(9</u> /1 2 3 | Ø123 | 0123 | 0123 | 01 2 3 | 0123 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 (1) 2 3 | 0/123 | Ø123 | 0 (22 3 | 0 (1) 2 3 | <u>6</u> 1 2 3 | O 123 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0 (1)2 3 | (g) 1 2 3 | 9123 | 0)123 | (2) 1 2 3 | 01 2 3 | ()123 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO | YES (NO) | YES (NO) | YES (NO | YES (NO | YES (MO) | YES (NO | YES NO |
| Throat Clearing Y/N | YES NO | YES (NO | YES (NO | YES (NO) | YES (NO) | YES (NO) | YES (NO | YES (NO | YES NO |
| > DAY PM | 1 | 2 | 3 | 4 | 5 | 9 | 7 | 8 | 6 |
| Runny Nose 0 to 3 | (0)1 2 3(| 0)123 | E Z V 0 | (0)123 | (0)123 | (<u>0</u>) 1 2 3 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | (0) 1 2 3 (| 0123 | (0)123(| 0 1 2 3 | 0123 | (0)1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | (0)123 | 0(1)2 3 | 0(1)2 3 | (6)123 | 0123 | (<u>O</u>)1 2 3 | 0(1)2 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0)123 | (0)123 | (0/123) | (0) 23 | (0)123 |) E Z I(0) | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO | YES (NO) | YES (NO) | YES (NO) | YES (NO | YES NO | YES NO |
| Throat Clearing Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (C NO | YES NO | YES NO |
| SCALE 0 to 3 0= No symptoms (no symptor | (no sympton | M-1/2-1/2 ns detected) | 1-0-7 | | 1-0-01 | 11-21-11 | 2-0-2 | | |

SCALE 0 to 3 0= No symptoms (no symptoms detected)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

DATE COMPLETED: SUBJECT NUMBER ACT 004

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci ic Resources Clin Trials-Lesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME RJE, RJE

PATIENT ID

AAGF8237

06/10/1942

SEX REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO. COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

10/22/2013 10:32 PATIENT NO.

10/22/2013 19:42

10/23/2013 06:06

30920973

0

AKP-004

COMMENTS:

Result

Test In Range Out of Range

14Dr 2013

DOB

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen

NS

NO PHYSICIAN GIVEN

End of Report

FAX24664

| 6 | | | Investigator | | | | | | | | *** | | | PAGE: 1 of |
|-------------------------|-----------------------|-------------------|---|--|---|-----|--|--|--|---|--|---|---------------------------------|---------------|
| LSR Study #: 2749 | Subject Initials: RJE | | Action Taken | | | | | | | THE REAL PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY AND ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS OF THE PROPERTY ADDRESS | as specific as possible | 24 FM-2014 | 2 | |
| LSR | gns | 90 | ** End Date (DD/MIMM/YYYY) | | | | | | | | should be made to be |) Date: 2% | B.oate. | |
| R | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | | 2 | 28/ | | | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | 100 Montainers | ole Ball | ace Scientifi |
| na Allen | 400 | | SEVERITY | | | / | | | | | ite UNK in spac | (A): | 7 | |
| Alphame | X ALP DOL | | ** Start Date (DD/MMM/YYYY) | | | | | | | | ʻday is <u>unknown,</u> wr | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: _ | Subject Number: | | Adverse Event | | | | | | | | ** | Investigator Signa | SC Sign | |

. 1

for Clinic use) Ongoing at EOS List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. Subject Initials: 1206 12 12 1012012 Jul 130 G 87 2012 Cart Stop Date られた Cont 13/24/13 Date: 26 February LSR#: t) 0e/---1990 8000 8008 Toral UNK/AUG/1999 1106/--* If day or month of medication date is unknown, write UNK in space provided 1001-(Day/Month/Year) * Start Date 10/24/13 0/2/ |--/ CONCOMITANT MEDICATION LOG mar(| --Lovelace Scientific Resources, Inc - ConMeds 04/2013 orai Brai Sign 3 Route 920 925 Ĭ MG 2Tabs per Frequency 0 0 0 0 19 TH BID 9 00 Z (br 200 8 5 200 300 <u>ξ</u> 30 Unit 21 500 150 n O Dose 300 R \sim Amlopidine Hypertension 10 TUDGATENSION 211010 Hyperthologiesia-Hypertension Hypertension seasona (What you take it for) AKP OOU Indication Diabetes SC Signature (at end of study): Investigator Signature (at end of study): 5 た し な Caraiae Chlorothiazide FexoRenadure Hadra lazune J. M. C. L. C. Study Identification: _ Name of Medication DSartan Subject Number: EXAMPLE ASDILL A

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | W | t m | m | <u></u> | <u></u> | I | 1_ | | <u></u> | | 00 | ~ | 1 | <u> </u> | 1 |
|--------|-------------------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|--------|----------------------|----------------------|----------------------|--------------------|---------------------|---------------------|--------------|
| 2 | 30 | 2 3 | 2 3 | 2 3 | 2 3 | 8 | 2 | 22 | 2 3 | 2 3 | 2 3 | 2 3 | 9 | 2 | |
| 5 . | 59/13 10/3d | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES | 7 | 0 1 | 0 1 | 0 | 0 1 | YES | YES | |
| | 9/13 | 2 3 | 2 3 | 2 3 | 2 3 | 2 | (2) | | 2 3 | 2 3 | 2 3 | 2 3 | NO No | ON | |
| 10,21 | 12 | (O) | (O) | (Ī) o | 0 | YES | YES | 21 | 0 | 0 7 | 0 1 | 0 1 | YES | YES | |
| _ | 413 | 2 3 | 2 3 | 2 3 | 2 3 | (2) | (g) | | 2 3 | 2 3 | 2 3 | 2 3 | (S) | (S) | |
| 72′ | 727/13/92413 | \bigcirc_1 | (G) | 0 0 2 | (<u>1</u>) | YES | YES | 20 | $\bigcirc 1$ | 0 | 0 | 0 | YES (| YES (| 010 |
| 6 | 27/13 | 2 3 | 2 3 | 2 3 | 2 3 | (2) | (§) | _ | 2 3 | 2 3 | 2 3 | 2 3(| (g) | | - (|
| 10,16 | 5 | \bigcirc_1 | 01 | 0(1)2 | 6 | YES | YES (| 19 | 50 | 2) | 0 (1)2 | 3 | YES | YES | 200 |
| 00 | 413 | 2 3 | 2 3 | 2 3 | 2 3 | (2) | (S) | 00 | 2 3 | 2 3 | 2 3 | 2 3 | (2) (| (§) | 5 |
| 1, , 1 | 17/25/13 10/24/13 | [O | (S) | 0(<u>C</u>)2 | | YES | YES | 18 | \bigcirc_1 | 0 | o D | (O) | YES | YES | 11-9-2 |
| 7 | 5113 | 2 3 | 2 3 | 2 3 | 2 3 (| © (| <u>Q</u> | 7 | 2 3 | 2 3 | 2 3 | 2 3 (| 2)(| S) | |
| 1,0,1 | 17/2 | \bigcirc_1 | Q | (O) | 60 1 | YES | YES | 17 | (6) 1 | Ø | 2 1 1 | 0/1 | YES | ŸES | |
| 9 | 4(13 | 2 3 | 2 3 | 2 3 | 2 3 | (2) | | į, | 2 3 | 2 3 | 2 3 | 2 3 | ON) | ON | |
| 16 | <u>전</u> 의 | 01 | 001 | 01 | 0 1 | YES (|) XES | 16 | | 601 | \bigcirc_1 | <u>(</u>) | YES (| YES | |
| 15 | ગાર | 2 3 | 2 3 | 2 3 | 2 3 | <u>S</u>)(| (NO) | 10 | 2 3 | 2 3 | 2 3 | 2 3 | (S) | (M) | |
| ₹~ | 2 | (g) | 9 | 0 1 | 6 | YES (| YES | 15 | (0) | 0/1 | 0(1) | (0)1 | YES (| YES | 4-0-1 |
| 14 | 10/22/13 | 123 | 2/3 | /2 3 | 2 3 | ON ON | ON | 4 | 2 3 | 2 3 (| 2 3 | | (ON) | | 7 |
| 1 | 10/2 | 0 1 | 0 1 | 0^{1} | 0 | Yets | √ĘS | 14 | O 1 2 | <u>©</u> | \bigcirc_1 | 0 1 2 3 | YES | YES | |
| DAY | AM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | SCALE 0 to 3 |
| | | ~ 0 | = 0 | ပဝ | ω o | > | F > | L.,, | 8 O | _ _ _ 0 | 00 | S | > > | ⊢ ≻ | Ü |

0= No symptoms (no symptoms detected)

1-8-8

;

1= Mild symptoms (symptoms present but easily tolerated)

2≈ Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

400 du SUBJECT NUMBER: スカ

DATE COMPLETED:

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scir ic Resources Leslie Byatt, C....'Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME X, RJE

PATIENT ID **AAGF0190** DOB 06/10/1942

REPORT STATUS SEX Finai M

PAGE

PHYSICIAN Unlisted Physician. COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

10/29/2013 10:05

10/29/2013 19:10

10/30/2013 06:09

30920919

0

PATIENT NO.

COMMENTS:

AKP004

| | ••• | 004,1 | | | | |
|----------------------|--|---------------|----------|----------------------------|-----------------|-------------|
| Test | In Range | Out of Rar | iãe | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 134 | | | mmol/L | 134-144 | |
| Potassium | | 3.2 | L | mmol/L | 3.5-5.1 UC | S RAD |
| Chloride | | 97 | Ĺ. | mmol/L | 98-111 NC | - Le 1811 = |
| CO2 | 27 | | | mmol/L | 20-30 | |
| Anion Gap | 10 | | | | 6-14 NC | , main |
| Glucose | | 112 | Н | mg/dL | 60-100 | |
| | Impaired fasting glucose (100-126 mg/dl.(ADA Guideli | IFG) is defin | ned as a | fasting glucose | level of | |
| BUN | 100-126 mg/d1. (ADA GU1del1 25 | nes Diabetes | Care 26 | % (3160~316/)200: ma/d! | | |
| Creatinine | 0.83 | | | mg/dL mg/dL | 7-31 | |
| Orealinine | Creatinine method is IDMS | traceable Fo | etGER Ca | nigrui. Iculation has b | 0.62-1.66 | |
| | Please note new reference | | | | sen aujusteu. | |
| eGFR non-African Am | >60 | range errect | 146 3/23 | • | | |
| GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| Of it Comment | Estimated GER values are n | ot accurate i | in acute | kidnev failure | innationts | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | 4) or underwe | eight (B | MI<20) people. | inpaciones | |
| | the very old or very young | , races other | ' than C | aucasian or Afr | ican American, | |
| Calcium | people with acute illnesse | s, or amputat | cions. | /all | | |
| Total Protein | 6.9 | | | mg/dL | 8.4-10.4 | |
| Albumin | 3.8 | | | gm/dL gm/dL | 6.1-8.2 | |
| Globulin | 3.1 | | | gm/dL | 3.4-4.7 | |
| Bilirubin, total | 0.8 | | | • | 2.4-4.2 | |
| Alk Phos | 65 | | | mg/dL U/L | 0.3-1.2 | |
| AST(SGOT) | 23 | | | · U/L | 38-150 6-58 | |
| ALT(SGPT) | 40 | | | Ü/L | | |
| Fasting | NO | | | O/L | 14-67 | |
| Phosphorus | 3.0 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | III SI GE | 2.0-0.0 | |
| WBC | 5.9 | | | x10E3 | 4.0-10.6 | |
| RBC | 010 | 4.37 | L | x10E6 | 4.64-6.00 | - mmer |
| Hgb | 15.3 | 1107 | L | gm/dL | 14.5-17.7 | - |
| Hct | 43 | | | % | 42-53 | ~ |
| MCV | • • | 99 | Н | fL | 81-98 NC. | S MARIN |
| MCHC | | 35.3 | H | gm/dL | 31.2-35.2 | e nor |
| RDW | 11.5 | | • • • | % | 11.0-14.5 | 77 0000 |
| Platelets | 185 | | | x10E3 | 150-400 | |
| Eos, Respiratory | None seen | | | ******* | NS | |
| Phys, Addr, Phone | Unknown | | | | 110 | |

Callback Accession Comments:

T3427418

AGAP, ALB, ALKP, ALT, AST, BUN, CA, CL, CO2, CREA, EOSR, FAST, GFRCOM, GFRW, GLOB, GLU, HCT, HGB, K, MCHC, MCV, NA, PLT, PO4, RBC, RDW, TBIL, TP, UNKPHY, WBC

10/29/2013 09:28 pmFAXED TO

3488546 NC CS1685

End of Report

MM Sob I 30 lst 2013

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" ☑YES ☐NO. |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| nostries consistantly, this product has been wonderful During the trial period I have been breathing through my nose better than I can remember during |
| my adult life. |
| |
| |
| |

[Type text]
Subject initials and Date 10/29/13 Study Staff Initials and Date____

AKP-006

2/49 AKPharma PERENNIAL ALLERJIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| <u>PATIENT D</u> | EMOGRAPHICS | |
|------------------|----------------------------|--|
| Patient Den | nographics | |
| Date of Birth | : 30 / Apr / | 1946 (dd/mmm/yyyy) |
| | Male | |
| If female, Inc | dicate Childbearing Potent | ial |
| | Childbearing | Surgically sterilized Post-Menopausal |
| Ethnicity: |] Hispanic Non Hi | ispanic Caucasian |
| Race: | Asian 🗌 Black 💢 | Caucasian |
| F | acific Islander Othe | er, Specify |
| | | |
| Smoking Hi | story | |
| Smoking Stat | tus: None (smoked le. | ss than 100 cigarettes in lifetime) |
| | Former (previous | sly smoked more than 100 cigarettes in lifetime) |
| | Current (smokes i | now) |
| If subject is a | former or current smoker | ; please indicate: |
| 5 | | |

Version: 02 September 2013



⊭ Resources Lovelace Scio Clin Trials-Lesile Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr

24664

PATIENT NAME TGC, TGC

PATIENT ID **AAGF0173**

DOB 04/30/1946

REPORT STATUS SEX Final

PAGE

Unlisted Physician.

PHYSICIAN

COLLECT DATE & TIME 09/23/2013 15:10

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

09/23/2013 18:39

09/25/2013 06:07

PATIENT NO.

30920882 COMMENTS:

006

| Test |
|--|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Alierg,Alternaria Allerg,Mesquite Allerg,Cockroach |
| Allerg, Derm. pter. |

| | Result | | | | |
|----------|------------|-----|-------|-----------------|-----------|
| In Range | Out of Rai | nge | Units | Reference Range | Site Code |
| | 3.40 | H | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| | 5,70 | Н | kU/L | <0.35 | |
| | 0.40 | FD | kU/L | < 0.35 | |
| <0.10 | - | | kU/L | < 0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |

The standard classification system utilizes the following class cutoffs. Interpretation Clace ku/L

| Class | KO/ L | Eller production |
|----------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| <u>v</u> | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| | ciinical allergy. | | | | |
|----------------------|-------------------|------|---|------|--------|
| Allerg,Derm. farinae | <0.10 | | | kU/L | <0.35 |
| Allerg, Clad. herb. | <0.10 | | | kU/L | <0.35 |
| Allerg, Firebush | <0.10 | | | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | | 0.50 | H | kU/L | <0.35 |
| Allerg, Dog Dander | 0.10 | | | kŲ/L | <0.35 |
| Allerg, Bluegrass | | 1.80 | Н | kU/L | <0.35 |
| Allerg, Pigweed | <0.10 | | | kU/L | <0.35 |
| Allerg, Mulberry | <0.10 | | | kU/L | <0.35 |
| Allerg, Helminth | <0.10 | | | kU/L | <0.35 |
| Phys. Addr. Phone | NOT GIVEN | | | | |

End of Report

Archeson Creteria

Positive for Atternea alternaria

positive for Cat darder 4 epithelium

09/25/2013 06:07 Salyer 9/25/13 FAX24664

TGC, TGC



t avelace Scientific Resources 2441 Ridgecrest Dr SF Albuquerque, NM 87108

(BTPS)

Name: TGC, Gender: Male

Age: 67 Race: Caucasian Height(in): 74.0 Weight(lb): 196

Any Info:

ld: AKP-006 Date: 10/03/13

> Flow 16 _T

12

8

4

0

-8

-12

0

2 Volume

Temp: 22

PBar: 630

Physician: Technician: VL

| ty milo. | | | | | | | |
|----------|------------|--------|------|-------|-----------|-------------|---------------|
| | ., | (BTPS) | PR | E-RX | POST- | RХ | |
| ន់ដែលបាន | Alfry - | Ref | Pre | Pre | | Post Ref | Post % Chg |
| | | | weas | % Ref | ivieas 70 | Kei | 76 Oily |
| FVC | Liters | 5.09 | 4.62 | 91 | | | |
| FEV1 | Liters | 4.03 | 2.82 | 70 | | | |
| | 10.01 | 70 | 0.4 | 70 | | | |

FEV1/FVC % 3.94 32 1.24 FEF25-75%L/sec ** 37 FEF50% L/sec 4.87 1.82 1.80 0.36 20 FEF75% L/sec IC Liters VC Liters 5.09 9.33 8.99 96 PEF L/sec 145 MVV L/min 0.95 L/sec FEV1/FEV6% 68

Lung Volumes/Plethysmography

| Vtg | Liters | |
|--------|--------|------|
| VČ | Liters | 5.09 |
| TLC | Liters | 7.51 |
| RV | Liters | 2.77 |
| RV/TLC | % | 40 |
| FRC PL | Liters | 4.27 |
| ERV | Liters | |
| IC | Liters | |
| Diffus | Off | |

DLCO mL/mmHg/min 24.3
DL Adj mL/mmHg/min 24.3
DLCO/VA mL/mHg/min/L 3.04
VA Liters

BHT Sec

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

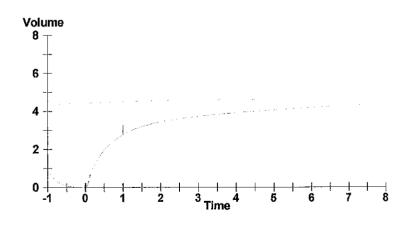
 sRaw
 cmH2O/L/s/L
 4.31

 sGaw
 L/s/cmH2O/L
 0.232

 Vtg (Raw)
 Lifers









Lovelace Scientific Resources 2441 Ridgecrest Dr SF Albuquerque, blië 57108

Name: TGC, Gender: Male

Age: 67 Race: Caucasian Height(in): 74.0 Weight(lb): 196

Any Info:

ld: AKP-006 Date: 10/10/13

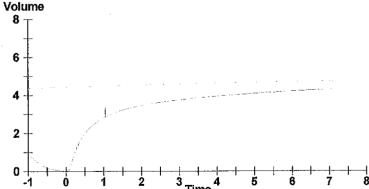
Temp: 21

PBar: 627

Physician: Technician: vl

| e Tan e e e e e e e e e e e e e e e e e e e | (B | TPS) | PR | E-RX | POST-RX | | Flow | | | | |
|---|--------------|--------|-------------|--------------|-------------------------|---------------|--------------------|-----------------|------------------|---|---------------|
| Spinara t | i y | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | |
| FVC | Liters | 5.09 | 4.72 | 93 | | | † | | | | |
| FEV1 | Liters | 4.03 | 2.92 | 72 | | | 12 | | | | |
| FEV1/FVC | : % | 78 | 62 | 79 | | | · - | | | | |
| FEF25-75 | %L/sec | 3.94 | 1.17 | 30 | | | + | | | | |
| FEF50% | L/sec | 4.87 | ** 1.87 | ** 38 | | | 8 | | | | |
| FEF75% | L/sec | 1.80 | ** 0.32 | ** 18 | | | o † | $I \setminus I$ | | | |
| IC | Liters | | | | | | + | -1 | | | |
| VC | Liters | 5.09 | | | | | اما | · · | | | |
| PEF | L/sec | 9.33 | 8.78 | 94 | | | 4 🕂 | į | ١. | | |
| MVV | L/min | 145 | | | | | ļ | } | N ₁ . | | |
| PIF | L/sec | | 4.11 | | | | _ | | Marie 1 | | |
| FEV1/FEV | 6% | | 70 | | (DTDC) | | 0 1 | + + | | | |
| | Volumes/I | Plethy | /smogra | bhy | (BTPS) | | + | | | | |
| Vtg | Liters | | | | | | -4 | | the second | | |
| VČ | Liters | 5.09 | | | | | - 1 | | | | |
| TLC | Liters | 7.51 | | | | | t | | | | |
| RV | Liters | 2.77 | | | | | -8↓ | | | | |
| RV/TLC | % | 40 | | | | | -0 T | | | | |
| FRC PL | Liters | 4.27 | | | | | 1 | | | | |
| ERV | Liters | | | | | | امما | | | | |
| IC | Liters | | | | | | -12 <u> </u> -2 | 0 | 2 1 | 6 | 8 |
| Diffus | 1001 | | | | | | -2 | U | Volume 4 | U | v |
| DLCO | mL/mmHg/min | 24.3 | | | | | | | | | |
| DL Adj | mL/mmHg/min | 24.3 | | | | | | | | | |
| DLCO/VA | mL/mHg/min/L | 3.02 | | | | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| (Inche) | MACO | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.01 | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | | | | | | |
| sRaw | cmH2O/L/s/L. | 4.31 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | 0.232 | • | | | | | | | | |
| Vtg (Raw) | Liters | | | | | | | | | | |
| | | | | | Volume | | | | | | |

Comments:



 $\log tr \cos r s^{2} s ((ww))$



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NN 87108

Name: TGC, Gender: Male

Age: 67 Race: Caucasian Height(in): 74.0 Weight(lb): 196

Any Info:

ld: AKP-006 Date: 10/17/13

Temp: 19

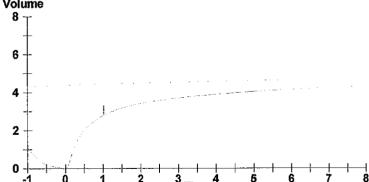
PBar: 631

Physician:

Technician: VL

| | (E | TPS) | PR | E-RX | POST-RX | | Flow | | | | |
|------------------|----------------------------|--------------|-------------|--------------|-------------------------|---------------|-----------|---------------------------|----------------|---|---|
| Spiromat | ry | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | |
| FVC | Liters | 5.09 | 4.63 | 91 | | | † | | | | |
| FEV1 | Liters | 4.03 | 2.89 | 72 | | | 12 | | | | |
| FEV1/FVC | | 78 | 62 | 80 | | | ·~ | | | | |
| FEF25-759 | | 3.94 | 1.19 | 30 | | | † | | | | |
| FEF50% | L/sec | 4.87 | ** 1.76 | ** 36 | | | 8 + | | | | |
| FEF75% | L/sec | 1.80 | ** 0.34 | ** 19 | | | • [| Λ | | | |
| IC | Liters | | | | | | ŧ | / \ | | | |
| VC_ | Liters | 5.09 | 0.50 | 00 | | | 4 | | | | |
| PEF | L/sec | 9.33 | 8.59 | 92 | | | 4 | | | | |
| MVV | L/min | 145 | 4.38 | | | | + | | | | |
| PIF FEV1/FEV | L/sec | | 70 | | | | | | 5.a. 1 4 | | |
| | | | | un land | (BTPS) | | 0 | - - - | 71.77 | | |
| | /olumes/l | Mem | /smogra | pny | (51, 0) | | + | | 1 | | |
| Vtg | Liters | E 00 | | | | | -4 ∤ | | V | | |
| VC | Liters | 5.09 | | | | | | | | | |
| TLC | Liters Liters | 7.51 2.77 | | | | | † | | | | |
| RV | % | 40 | | | | | -8∤ | | | | |
| RV/TLC FRC PL | Liters | 4.27 | | | | | T | | | | |
| ERV | Liters | 7.21 | | | | | t | | | | |
| IC | Liters | | | | | | -12 İ | | | | |
| Ďiffusi | | | | | | | -12 -2 | 0 Z Volum | 4 6 | 3 | 8 |
| | | 242 | | | | | | VOIUIT | I U | | |
| DLCO DL Adj | mL/mmHg/mir mL/mmHg/mir | | | | | | | | | | |
| | mL/mHg/min/l | | | | | | | | | | |
| VA | Liters | _ 0.04 | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| | | | | | | | | | | | |
| Regist | | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | |
| Raw Insp | | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.31 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | 0.232 | | | | | | | | | |
| Vtg (Raw) | LICETS | | | | | | | | | | |
| | | | | | Volume | | | | | | |
| | | | | | 8 | | | | | | |

Comments:



Interpretation



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: TGC, Gender: Male

Age: 67 Race: Caucasian Height(in): 74.0 Weight(lb): 196

Any Info:

ld: AKP-006 Date: 10/24/13

Temp: 20

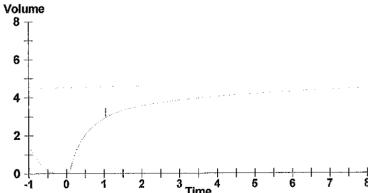
PBar: 634

Physician:

Technician: VL

| | (B | TPS) | PR | E-RX | POST-RX | | Flow | | | | |
|---------------|---------------|----------------|-------------|--------------|-------------------------|---------------|------------|-----|----------------|---|---|
| Spirametr | y · | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | |
| FVC | Liters | 5.09 | 4.61 | 91 | | | † | | | | |
| FEV1 | Liters | 4.03 | 2.96 | 73 | | | 12 - | | | | |
| FEV1/FVC | | 78 | 64 | 82 | | | '- | | | | |
| FEF25-75% | &L/sec | 3.94 | 1.49 | 38 | | | + | | | | |
| | L/sec | 4.87 | ** 2.15 | ** 44 | | | 8 | 15 | | | |
| | L/sec | 1.80 | 0.46 | 26 | | | O T | 13 | | | |
| | Liters | | | | | | + | `i. | | | |
| | Liters | 5.09 | | | | | | ! | · · | | |
| PEF | L/sec | 9.33 | 8.72 | 94 | | | 4 † | ! | N _a | | |
| MVV | L/min | 145 | 4.00 | | | | 1 | ; | E. | | |
| PIF | L/sec | | 4.66 | | | | | 1 | ye. J | | |
| FEV1/FEV | | Box 5 . 3 | 69 | * | (BTPS) | | 0 | | | | |
| 744* | /olumes/l | Plethy | /smogra | phy | (6173) | | + | | Λ - 1 | | |
| Vtg VC | Liters | | | | | | - 4 | | | | |
| | Liters | 5.09 | | | | | • | | 50 to 1 | | |
| TLC | Liters | 7.51 | | | | | † | | | | |
| RV | Liters | 2.77 | | | | | -8 ∤ | | | | |
| RV/TLC | % | 40 | | | | | -0 | | | | |
| FRC PL | Liters | 4.27 | | | | | + | | | | |
| ERV | Liters | | | | | | 40 | | | | |
| ic Diffusi | Liters | | | | | | -12 -2 | 0 | 2 4 | 6 | 8 |
| Ulitusi | on - | | | | | | | • | Volume 4 | • | • |
| DLCO | mL/mmHg/mir | 1 24.3 | | | | | | | | | |
| DL Adj | mL/mmHg/mir | n 24 .3 | | | | | | | | | |
| | mL/mHg/min/l | _ 3.06 | | | | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| (Cegaria | జర్మన్స్ - | | | | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.31 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | 0.232 | | | | | | | | | |
| Vtg (Raw) | Liters | | | | | | | | | | |
| | | | | | Volume | | | | | | |
| Pomonon | | | | | 8 T | | | | | | |

Comments:



National States

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505)938-8922 Patient Name: Medical Record: DOB:04/30/1946 Account Number: TGC,TGC AAGF0173

Age: 67Y Sex:M

30920928

Unlisted Physician

Attending MD: Patient ID:006 Patient Phone:0

H3250423 COLL: 10/03/2013 08:45 REC: 10/04/2013 19:41 PHYS: Unlisted Physician Req#: 30920928

10/04/2013 11:23 pm FAXED TO 5053458546 NC CS10030

| Comp Metabolic Panel 143 [134-144] mmol/L Potassium 4.4 [3.5-5.1] mmol/L Chloride 109 [98-111] mmol/L CO2 26 [20-30] mmol/L Anion Gap 8 [6-14] Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am >60 [>60] mL/min/1.73m2 Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
|---|
| Potassium 4.4 [3.5-5.1] mmol/L Chloride 109 [98-111] mmol/L CO2 26 [20-30] mmol/L Anion Gap 8 [6-14] Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Setimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Chloride 109 [98-111] mmol/L CO2 26 [20-30] mmol/L Anion Gap 8 [6-14] Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment |
| CO2 26 [20-30] mmol/L Anion Gap 8 [6-14] Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Anion Gap Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Glucose 90 [60-100] mg/dL BUN 18 [7-31] mg/dL Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment |
| BUN Creatinine 18 [7-31] mg/dL 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Setimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Creatinine 1.13 [0.62-1.66] mg/dL Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted. Please note new reference range effective 5/23/2013. eGFR non-African Am GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| Please note new reference range effective 5/23/2013. eGFR non-African Am >60 [>60] mL/min/1.73m2 GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| eGFR non-African Am >60 [>60] mL/min/1.73m2 GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| GFR Comment Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, |
| |
| the very old or very young, races other than Caucasian or |
| African American, people with acute illnesses, or |
| amputations. |
| Calcium 9.1 [8.4-10.4] mg/dL |
| Total Protein 6.9 [6.1-8.2] qm/dL |
| Albumin 3.9 [3.4-4.7] gm/dL |
| Globulin 3.0 [2.4-4.2] qm/dL |
| Bilirubin, total 0.5 [0.3-1.2] mg/dL |
| Alk Phos 138 [38-150] U/L |
| AST(SGOT) 17 [6-58] U/L |
| ALT(SGPT) 24 [14-67] U/L |
| |
| Fasting NO |
| |
| Phosphorus 2.7 [2.3-5.6] mg/dL |
| CBC |
| |
| RBC 5.11 [4.64-6.00] x10E6 , Ann 1 (1.1) 3 |
| Hgb L 12.9 [14.5-17.7] gm/dL NC4/W/M/ |
| Hct 42 [42-53] % |
| MCV 83 $[81-98]$ fL $\sqrt{3}$ |
| MCHC L 30.4 [31.2-35.2] gm/dL NOC MAPA // CA |
| RDW H 15.3 [11.0-14.5] % 1/0 C MAPA 11 Oct 15 |
| WBC 4.7 [4.0-10.6] x10E3 RBC 5.11 [4.64-6.00] x10E6 Hgb L 12.9 [14.5-17.7] gm/dL VC4 WMM // Out /3 Hct 42 [42-53] % MCV 83 [81-98] fL MCHC L 30.4 [31.2-35.2] gm/dL VC4 MMM // Out /3 RDW H 15.3 [11.0-14.5] % VC5 MMM // Out /3 Platelets 211 [150-400] x10E3 |

CONTINUED

Printed: 10/09/2013 15:57

Patient Name: TGC, TGC

Medical Record #: AAGF0173

INTERIM REPORT

Location: CORE

Page: 1

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505)938-8922 Patient Name: Medical Record: DOB:04/30/1946 Account Number: TGC, TGC AAGF0173

AAGEU173 Aqe:67Y Sex:M

30920928

Unlisted Physician

Attending MD: Patient ID:006 Patient Phone:0

H3250423 COLL: 10/03/2013 08:45 REC: 10/04/2013 19:41 PHYS: Unlisted Physician Req#: 30920928

10/04/2013 11:23 pm FAXED TO 5053458546 NC CS10030

Eos, Respiratory

* Rare

[NS]

Phys, Addr, Phone

NOT GIVEN

MM 2013

END OF REPORT

Printed: 10/09/2013 15:57

INTERIM REPORT

Patient Name: TGC, TGC

Medical Record #: AAGF0173

Location: CORE

Page: 2

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| NO (Say |
|---------------------------|
| YES NO YES NO |
| 0(1) 2 3 (5) 1 2 3 0 10 2 |
| (3)01/2/3 012(3)016 |
| 0 2 3 0 0 2 3 0 1 2 |
| 0 1(2) 3 0 1 2(3) 0 (1) 2 |
| -3 -2 -1 |
| (ES) NO (YES) NO |
| YES NO YES NO |
| 0 \$ 2 3 0 0 2 3 0 1 (2) |
| 0126/0126)0126 |
| 002300230103 |
| 01/63016/3016 |
| 9/32/10/1/10/2 |
| |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ACC DO LE DATE COMPLETED: DE 2013

SUBJECT INITIALS AND DATE:_

E/150 M

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| PPROXIN | NAIE KESPU | CIRCLE APPROXIMA I E RESPONSE EVERY 12 HOURS | HOUKS | | | 1 | ,,,, | 1.00 | | |
|-------------------|------------|--|--------------|----------|----------------|----------------|---|----------|---------|------|
| | 7 7 | 7 | بري ع | | No 5 | ِ س | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | 8 | ì | |
| | 5/03/13 | 5) \$ /010 | 0 | 10/06/13 | 10/07/13 | 19/08/13 | 1909/13 | 17/19/13 | 3 12/18 | (3 |
| | V 123 | 0 1/20 3 | 0 1 🖉 3 | 0 1 🖉 3 | 0 (2) 2 3 | 0 🗘 2 3 | 0.023 | 0 Ø 2 | 3 0 1 | 2,3 |
| 1 | 0 1 2 3 | 0 (1) 2 3 | Q 123 | 0 1 🕲 3 | 1 2 3 | Ø1 2 3 | 0/1 2 3 | Ø1 2 | 0 8 | ½ 3 |
| | 0 1 2 3 | 0 1 2 | 0 1 2 | 0 1 2 3 | 0 1 🖉 3 | 0 1 (2) 3 | 0 (02 3 | 0 1 2 | 3 0 1 | 2 3 |
| | 0 1 2 3 | 0 (1) 2 3 | 0 🕲 2 3 | 0 (D)2 3 | 1 2 3 (| 9123 | Ø1 2 3 | 0 1 0 | 3 0 1 | 2 3 |
| ···· | YES NO | YES (G) | YES (ND) | YES (NO) | YES (LO) | YES (NO | YES (O) | YES (MO) |) YES | 9 |
| | YES NO | YES NO | YES) NO | YES NO | ON (S) | YES NO | (YES/ NO | SES) | YES | 9 |
| | н | 2 | က | 4 | 5 | 9 | 7 | ∞, | | 6 |
| <u> </u> | 0 Ø23 | 0. 1 3 | 0128 | 0 Ø 2 3 | 0 723 | 0 🗘 2 3 | ε <i>[</i> ŷ τ΄ ο | 0 1/2 | 3 0 1 | ,2 3 |
| | 0 (1) 2 3 | 0 (1) 2 3 | 0 \$ 2(3) | 0 3 2 3 | 0,123 | O 1 2 3 | 9 123 | 0 1 2 | 3 0 1 | 2 3 |
| t | 0 1 2 🕄 | 0123 | 0 1 2(3) | 0 🖤 2 3 | 0 1 🕲 3 | 0 1(2)/3 | 0 1 🖉 3 | 0 1/ 2 | 3 0/1 | 2 3 |
| | 0 Ø2 3 | Ø1 2 3 | 0①23 | 0(1) 2 3 | © 1 2 3 | 0123 | 0,4023 | 3 V 0 | 3 0 1 | 2 3 |
| | YES (MO) | YES KO | YES MO | YES (NQ) | YES (NQ) | YES (NO) | YES (NO) | YES NO |) YES | NO |
| Throat Clearing (| YES NO | (YES) NO | YES NO | YES NO | (YES/ NO | (YES) NO | VES NO | YES NO |) YES | NO |
| | - 0110 m | | | | | | | | | |

SCALE 0 to 3

SCALE U to 3 706/1 n 0= No symptoms (no symptoms detected)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

DATE COMPLETED: SUBJECT NUMBER:

SUBJECT INITIALS AND DATE:_

TriCore

Fax Number

Fri Oct 11 09:24:42 2013 Page 2 of 2

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: Medical Record: DOB: 04/30/1946

TGC, TGC AAGF9554

Account Number:

Age: 67Y Sex:M 30920910

Unlisted Physician

Attending MD:

Patient ID:AKP006 Patient Phone:0

H3265159 COLL: 10/10/2013 08:00 REC: 10/10/2013 19:16 PHYS: Unlisted Physician Req#: 30920910

120 Janie 180 15 Oct 2013

10/11/2013 09:24 am FAXED TO 3488546 NC CS11533

Eos, Respiratory

* Moderate

[NS]

Phys, Addr, Phone

NO ORDERING PHYSICIAN

END OF REPORT

Printed: 10/11/2013 09:24

Patient Name: TGC, TGC Medical Record #: AAGF9554

INTERIM REPORT

Location: CORE

Page: 1

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| J. | 14 1 | 10/16 10/11 10/10 | £23 0(1)23 0 1 23 | 0123 6123 0123 |) | 0 (1)2 3 0 (1) 2 3 0 1 2 3 | | 0(1/2 3 0 1 2 3 0 1 2 3 | | YES (NO) YES (NO) YES NO | | (ES) NO (YES) NO YES NO |) | 13 14 15 | 0.6/23 0 1 2 3 0 1 2 3 | | 0 1 2 3 0 1 2 3 0 1 2 3 | | 01(2/3 0123 0123 | , | 01/23/01/23/01/23 | | YES NO YES NO YES NO | | MES) NO YES NO YES NO |
|---------------------------|------|-------------------|-------------------|----------------|------|----------------------------|----------|-------------------------|------------|--------------------------|-----|-------------------------|----------|----------|------------------------|------------|-----------------------------|--------|----------------------|--------|-------------------|-------------|----------------------|-----|-----------------------|
| | 27 | d/0,7 | 0 (1/2 3 0 | 0)123 (| | 0 (1)2 3 (| + | 0(1/2 3 (| 1 | (YES) NO |) | XES) NO | 1) | 12 | 0 1(2) 3 | į | \bigcirc 1 2 3 \bigcirc | | 0 1 2 3 | (| $0 \frac{1}{2}$ | | VES (NO | | YES) NO |
| | Ħ | 10/14 | 0 🗘 2 3 | 0 2 2 3/ | | 0 1(2/3 | \ | 0 1(2) 3 | - 1 | YES (NO) | (| YES NO |) | 11 | (0)123 | | Q123 | | 0 (1)2 3 | _ | 0 (1/2 3 | L | SS) | 1 | YES NO |
| , | 10 | 10113 | o Ø2 3 | 0 (1)2 3 | K | 0 1 🔘 3 | | 0 1 3 | _ | (ES) NO | (| YES NO | | 10 | 0(1)23 |) * | 0123 | | 0 1(2) 3 | | 0 1 3 | | YES (NO | | ON (SA) |
| HOURS | 6 | 10/12 | 0(1)2 3 | 0123 | ` | 0.123 |) | 0 (2)2 3 | | YES (SO | (| VES NO |) | 6 | 0 1 2 3 | , | Q 2 2 3 | | 0 1 2 3 | |)0 (()2 3 | | YES (NO) |)(| (YES) NO |
| NSE EVERY 12 HOURS | ∞ | 10/01 | 0 1 2 3 | 0 (1) 2 3 / |) | 0 1 2 (3) |) | 0 1 2 (3) |) (| YES (NO) | ĺ | YES) NO |) | φ (| 0 1 (2)3 |) | $(0)_{123}$ |) | 0 1(2)3 |) | 0 1 2(3) | <i>j</i>)X | YES (80 | | (YES NO |
| 1ATE RESPON | 7 | 10/10 | 0 1 2 3 | 0 1 2 3 | | 0 1 2 3 | | 0 1 2 3 | | YES NO | | YES NO | <i>J</i> | 7 | 0(1)23 |) - | 0/1)23 | צ | 0 1 2 3 |) | 0 1 2(3) | (| YES (MG) | | (YES / NO |
| CIRCLE APPROXIMATE RESPO | DAY | AM | Runny Nose | lose | | Congestion | 0 to 3 | Bu | 0 to 3 | Voice Hoarse | N/Y | Throat Clearing | | DAY PM | Runny Nose | 0 to 3 | ose | 0 to 3 | Congestion | 0 to 3 | Sneezing | 0 to 3 | Voice Hoarse | N/N | Throat Clearing |
| | L | | J | | | 1 | | 1 | | L | | | | 1 | \ | | 1 | | | | | | | | |

SUBJECT NUMBER: AKP DOLL

Y=Yes N= No

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

1= Mild symptoms (symptoms present but easily tolerated)

0= No symptoms (no symptoms detected)

SCALE 0 to 3

DATE COMPLETED: 10/10/13 - 10/17/13

SUBJECT INITIALS AND DATE:

tax Number

Fri Oct 18 07:05:36 2013 Page 1 of 2

RICORE REFERENCE LABORATORIES

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scie, Resources Clin Trials-Leslie Byatt 2441 Ridgecrest Dr SE

Client Nbr 24664

PAGE

Albuquerque, NM 87108

Final

REPORT STATUS

PATIENT NAME TGC, TGC

PHYSICIAN

Unlisted Physician,

REQUISITION NO. PT. PHONE NO.

30920916

0

006

COLLECT DATE & TIME 10/17/2013 08:05

AAGF0173

PATIENT ID

RECEIVE DATE & TIME 10/17/2013 19:35

ŞEX

М

PRINT DATE & TIME 10/18/2013 06:07

PATIENT NO.

COMMENTS:

Test

Result

In Range

Out of Range

DOB

04/30/1946

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

Not given

Rare

NS

End of Report

NCS Salyer 18 Oct 2013

| | 9 | | Investigator Initials/Date | | MM. What | KITH WELLY | | | | | * | | PAGE: 6 of |
|----------------------------------|-------------------|-------------------|---|-----------|---------------|------------|--|--|--|--|--|---|--|
| LSR Study #: 2749 | Subject Initials: | | Action Taken | Non retes | NONB | None | | | | | as specific as possible* | | 12/14 |
| LSR | qnS | g | ** End Date (DD/MMM/YYYY) | 12/11/13 | 0/NOV/13 | 25/NON/13 | | | | | hould be made to be | Date: | Events 04/2013 |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Susperted | Susperted | Suspected | | | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | Most Line var | Lovelace Scientific Resolutes, Inc - AdverseEvents 04/2013 |
| | | | SEVERITY | mld. | mod | misd | | | | | ite UNK in spac | :(8 | (h) |
| 9x Pharma | ALP 000 | | ** Start Date (DD/MMM/YYYY) | 12/04/13 | 0 12/001/13 | 19/001/13 | | | | | f day is <u>unknown,</u> wr | Investigator Signature (at end of study): | SC Signature (at end of study): |
| Study Identification; ALP MOTONE | Subject Number: | | Adverse Event | no bled | Idsal Passage | NOSP bleed | | | | | ** | Investigator Sign: | SC Sign |

Cife on



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Leslie Byatt, Crin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME TGC, TGC

PATIENT ID **AAGF0173**

04/30/1946

SEX REPORT STATUS Final

PAGE 1

Site Code

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 10/24/2013 08:37

М RECEIVE DATE & TIME 10/24/2013 21:13

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

10/29/2013 06:03

30920970

006

COMMENTS:

| | | (CODE II | | |
|----------------------|----------|--------------|--------|---------------------|
| Test | In Range | Out of Range | Units | Reference Range |
| Comp Metabolic Panel | | | | |
| Sodium | 139 | | mmol/L | 134-14 4 |
| Potassium | 4.1 | | mmol/L | 3.5-5.1 |
| Chloride | 107 | | mmol/L | 98-111 |
| CO2 | 26 | | mmol/L | 20-30 |
| Anion Gap | 6 | | | 6-14 |
| Glucose | 85 | | mg/dL | 60-100 |
| BUN | 16 | | mg/dL | 7-31 |
| Creatinine | 1,23 | | mg/dL | 0.62-1.66 |

Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

Please note new reference range effective 5/23/2013.

Requit

eGFR non-African Am **GFR Comment**

mL/min/1.73m2

>60

NCS MAN

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American,

рe

| Calcium Total Protein |
|-----------------------------------|
| Albumin |
| Globulin |
| Bilirubin, total |
| Alk Phos |
| AST(SGOT) |
| ALT(SGPT) |
| Fasting |
| CBC |
| WBC RBC |
| Hgb |
| Hct |
| MCV |
| MCHC |
| RDW |
| Platelets |
| Eos, Respiratory |
| Phys, Addr, Phone |
| Allerg,Panel 18 Allerg,Juniper |
| |
| Allerg,Cottonwood |
| Allerg,West.Ragweed |

Allerg, Russian This Allerg, Bermuda Grass Allerg, Alternaria Allerg, Mesquite Allerg, Cockroach

Allerg, Derm. pter.

| he very old or very young, eople with acute illnesses, | races othe | r than | Caucasian or Afr | ıcan American, | |
|---|------------|------------|------------------|----------------------------------|----------------------------|
| 9.8 | Or ampaca | C (G) (S) | rng/dL | 8.4-10.4 | |
| 7.2 | | | gm/dL | 6.1-8.2 | |
| 4.2 | | | gm/dL | 3.4-4.7 | |
| 3.0 | | | gm/dL | 2.4-4.2 | |
| 0.5 | | | mg/dL | 0.3-1.2 | |
| 147 | | | Ű/L | 38-150 | |
| 18 | | | U/L | 6-58 | |
| 26 | | | U/L | 14-67 | |
| NO NO | | | O/L | 14-07 | |
| 110 | | | | | |
| 5.1 | | | x10E3 | 4.0-10.6 | a Ostzona |
| 5.28 | | | x10E6 | 4.64-6.00 | 7020 |
| | 13.4 | L | gm/dL | 14.5-17.7 N | g Octross 15 napri |
| 44 | | | % | 42-53 | 5WI |
| 84 | | | fL | 81-98 | <u> </u> |
| | 30.4 | L | gm/dL | 31.2-35.2 NC | cmm |
| | 14.9 | Н | % | 11.0-14.5 1/0 | i mann |
| 206 | | | x10E3 | 150-400 | 00 |
| | Few | * | | NS //6 | S MOON 1 |
| Not given | | | | 11.0-14.5 NO 150-400 NS NG | |
| | | | | 0/1 | e name 1 |
| .= 4= | 3.60 | H | kU/L | <0.35 /VV | > 1000. |
| <0.10 | | | kU/L | <0.35 | 1 |
| <0.10 | | | kU/L | <0.35 | _ 1 |
| <0.10 | | | kU/L | <0.35 | Mary \ |
| | 9.30 | Н | kU/L | <0.35 NC? | More , more Oct 2013 |
| - 4- | 0.40 | Н | kU/L | <0,35 NC6 | ; NXPU |
| <0.10 | | | kU/L | <0.35 | 142017 |
| <0.10 | | | kU/L | <0.35 | eur cars 1 |

kU/L

The standard classification system utilizes the following class cutoffs.

Interpretation **Class** kU/L

< 0.10

| 0 | <0. 35 | Negative for Allergen |
|---|-------------|-----------------------|
| ī | 0. 35-0. 69 | Positive for Allergen |

| Study Identification: | BUCE | | | | | | LSR#: | |
|-----------------------|--|-------------|----------------|--|--------------------|---|-------------------|---------------------------------|
| Subject Number: | 9006 | | 1 | | | · | Subject Initials: | ls: 76 L |
| List all | List all <u>prescription</u> medications you | | OMITA | CONCOMITANT MEDICATION LOG | ATION L | CONCOMITANT MEDICATION LOG are taking. Also include over-the-counter medications, vitamins and supplements. | s and supplem | ents. |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency (VIV) | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS (for Clinic use) |
| EXAMPLE | Diabetes | 200 | MG | 2 Tabs per | Oral | | | |
| yn. hr | Khon | B5 |), | 李 | 60 | un/4/1838 | | |
| Whitenes | Mhobon Syphing | , , , , | 794 | QQ | CJ | 111 | | |
| ×. | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or moi | nth of medi | ication da | ite is <u>unknow</u> | <u>m</u> , write U | * If day or month of medication date is <u>unknown</u> , write UNK in space provided | | |
| Investigator Signati | Investigator Signature (at end of study): | | Man | istair | Un | Date: 26 Fel | 1-2014 | |
| SC Signat | SC Signature (at end of study): | lah | Q | MA | | Date: 2/2/ | 2 | • |
| | | Lovelace | Scientific Res | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | Meds 04/2013 | | - a- | PAGE: \big of \frac{1}{2} |

1 1

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| r- | | | | | | | Τ | | | Τ- | | _ | , c | ^ | ~ | | ന | | ~ | , 1 | | 1 | | |
|--|------------------|-------------|-------------------|-------------|----------|-----------------|---------|----------------|------------------------|--------------|----------------|-----|------------|------------------|--------|----------------|--------|-------------|--------|-----------------------|---|--------------|-----------------|-------|
| | | 7 | ر س_ | 2/3 | 7 | ი ქ | 2 3 | | 2 | 2 | | 22 | 5 | _ | -c | , | , 5 | | 6 | - 1 | 9 | | ON ON | |
| ć | 77 | | - 1 | 0 1 | - 1 | 7 0 | _ _ | | YES | , | YES | 2 | 6 | | < | | 0 | - | U | <u></u> | YES | | YES | |
| 1 | · '' | (| n | m | ا | ربر د | 2 3 | | (S) | 9 | <u> </u> | | | ر م | 0 / 0 | 0 | 2 3 | | 7 3 | | 8 | | O N | |
| č | 21/ | 2/4 |) () | 0/1 2 | 7 | (2) 1 0 | (F) (J | <i>አ</i> | YES (| | YES | 21 | , | - - - - | - | н Э | 0 | | 1 | | YE§ | | YES | |
| , , , | ?_ | | - n | 3 | , | ຠ | ۳ | ר , | 8) | + | 2/_ 2 | | ١. | ر ا ا | 1 | ر د د | 2 3 | | , | _ \ | /ON) | <u> </u> | 9 | |
| | , , , , | 3 | 2 / | 0)1 2 | | <u>}</u> \ □ | 0 | Ð ₁ | YES | \downarrow | YES/ | 20 | í, | 7. | , | ` ∃ ∑> | 0 | Ŋ | 1 | 1) | YES (| | YES | |
| 1 | | 1 | m | 3 | | m m | 'n | | 2 | | <u>/</u> 9 | - | ١. |) 2 | 1 | n 7 | | | 1 | n (| NO |) | ON | |
| ָ ֓֞֞֜֞֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֡֓֓֓֓֡֓֡֓֓֡֓֡֓֡ | 19/ | <u>`</u> | o (<u>1</u> /2 2 | <u>V</u> 12 | | 0 1 | 7 | | YES | Ĺ | (KES | 10 |] | <u></u> | 1 |) - - | 5 | | , | | YES / | | YES | |
| \$ | ~ | | m | 3 | - | m | ٦ |) c 7 | 8 | \dashv | Š O | | - | | | 2 3 | 2 | | | n , | SN SN | | ON | 1 |
| | 1 - | 200 | Q1 2 | 27 | | 22 | 7 | 7 7 | YES (| | | 10 | ř | D | | 0) | 6 | _ | (| 3 | (ES) | | (KES) | , |
| - | | | 3 | 3 | _ | <u></u> | 6 | O | (2) | | g. | 1 | 1 | 2 3 | | 2 3 | 7, | | ı | 2 3 | (og | 1 | SN S | ٦ |
| . | 17 | 3 | 0 1 (2) | 0 1 (2 | ^ | 0 1 2 | , | 0 1 2 | YES (| | (KES) | 7 | 7 | (6) [] | - I | Q | | 7 | | 5 | YES | } | (ES) |) |
| | ~ | | m | m | - | m | , | m | (2) | | <u>9</u> | | 1 | m | + | m | | ر د د | 1 | 2 3 | (<u>§</u> | <u> </u> | S S | 7 |
| URS | 16 | <u>E</u> | Ø 2 | 1 2 | - 1 | 1.0 | | 0((2) | YES (| (| YES) | , | 1.5 | 0 (D) 2 | ł | 017 | , | 7, T | ٠. | (E) | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | | (VES) | |
| 12 HC | 7 | , | 3 | 3 | | 3 | | 0 E | | | | + | _ | <u>ო</u> | | <u>س</u> | , | n | + | m | | _ |) Q | |
| E EVERY 12 HOURS | 13. | 4 | ý 2 | 7 2 | | 10 | ١. | (F) | S S |) | S) NO | ; | 12 | ₹ | | 1 2 | | E T | | ⊕ ² | ` | \smile_{l} | | l |
| NSE E | ļ | درج دیست | 20 | 9 |) | 0 | | $\frac{9}{2}$ | YES | · | /ES | | | 0 | 1 | C | | <u> </u> | _ | 0 | VEC / | | |) |
| ESPO | 11 | دے | △ | 3 | | 2 3 | 1 | 2 3 | NO | | 9 | | 14 | 2 3 | | 2 3 | | /2 3 | | 72 3 | | | NO No | |
| CIRCLE APPROXIMATE RESPONSE | 14 | 10/17 | 0 1 | 2 | <u> </u> | V /0% | | Ď 1 | YES | | YES | | ⊣ (| 0 | | \bigcirc 1 2 | | 0 6/2 | | 0 (1)2 | 17 | ŭ (| (X) | 1 |
| SOXIN | | | | + | | _ | 72 | | ;e// | _ | ring | , | _ | ου O | _ | | | _ | | | | S P | aring(| |
| APPI | DAY | AM | Nose | Joseph | } | stion | | ing | Ноаг | _ | Throat Gearing | | DAY PM | Runny Nose | ~ | Itchy Nose | _ | Congestion | | zing | | Voice Hoarse | Throat Clearing | |
| CIRCLE APPROXIMATE RESPON | 7 | _ | Runny Nose | 0 to 3 | 0 to 3 | Congestion | 0 to 3 | Sneezing | 0 to 3 Voice Hoarse | Y/N | Throa | X/N | ۵ | Runn | 0 to 3 | Itchy | 0 to 3 | Cong | 0 to 3 | Sneezing |) (c | 0 V V V V V | Thro | Z |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

Z= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

DATE COMPLETED: 10/34/13 SUBJECT NUMBER: AND ODG

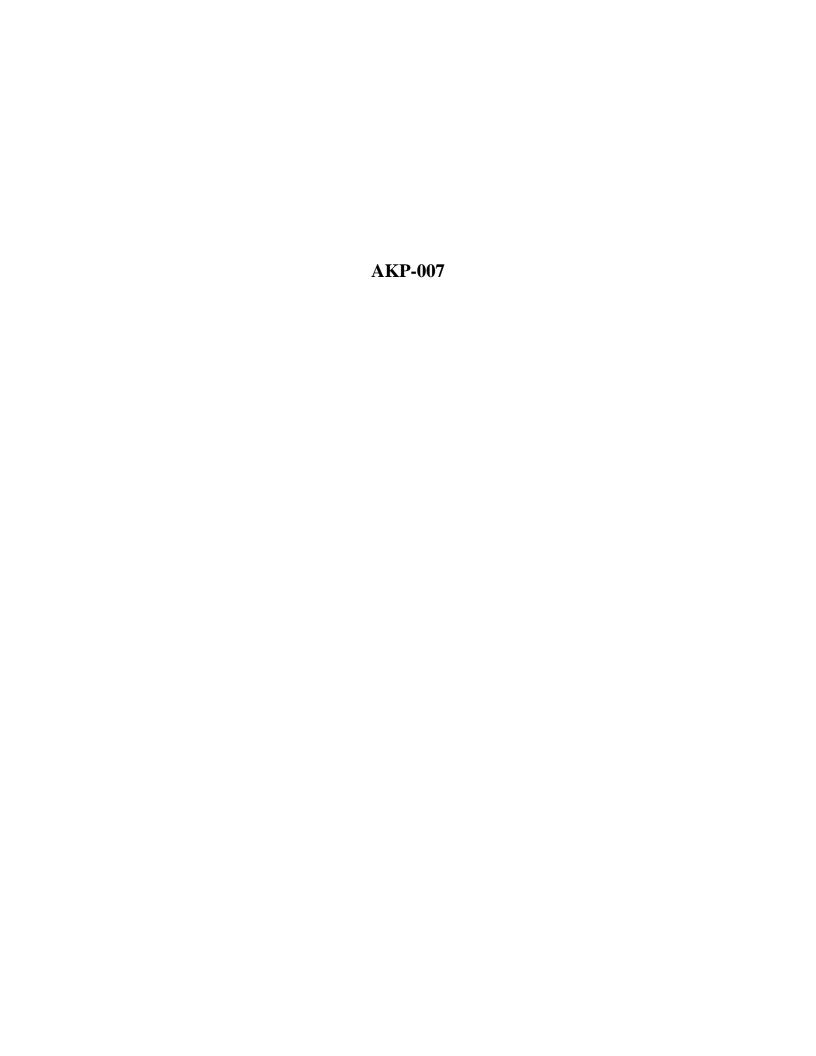
SUBJECT INITIALS AND DATE: 1/1/2 TGC 1941

TGC/2749

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ∠YES □NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| It worked about the same as other |
| nose spray s. |
| Alor would depend upon per price |
| I'm not sure if it the in the weather |
| I'm not see if it has is the weather on the product but I have some an exceptionally dry none now. |
| exceptionally dry nose now. |
| |
| |
| |
| |
| |
| |
| |
| |



2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIENT | <u>DEMOGR</u> | APHICS | | |
|---------------|---------------|---|------------------|---------------------------------|
| Patient De | mographic | ente (Corona de La Corona de Corona | | |
| Date of Bir | th: 13 | 10CT/19 | 66 (dd/mm | m/yyyy) |
| Gender: | □ М | [ale [X]] | Female | |
| If female, b | adicate Chil | dbearing Potentia | 1 | |
| | Ø CI | hildbearing [| Surgically ster | ilized Post-Menopausal |
| Ethnicity: [| Hispanio | Non Hisp | panic | |
| Race: | Asian [| Black 💢 (| Caucasian 🗌 | American Indian |
| | Pacific Islan | nder 🗌 Other | , Specify | |
| | | , | | |
| Smoking E | listory | | | |
| Smoking St | atus: 🔲 N | one (smoked less | than 100 cigare | ettes in lifetime) |
| | ⋈ Fo | ormer <i>(previousl</i> y | smoked more th | nan 100 cigarettes in lifetime) |
| | С | urrent (smokes no | ow) | |
| If subject is | a former or | <i>current</i> smoker, <u>p</u> | olease indicate: | |
| 77 | smoked: | 30 | Ci | garettes per day: 10 pur da |

Version: 02 September 2013



Lovelace Sci **Tc Resources** Clin TrialsLesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

PATIENT NAME JLJ, JLJ

PATIENT ID **AAGF0870**

10/13/1966

REPORT STATUS Final

PAGE

PHYSICIAN

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

Unlisted Physician. REQUISITION NO.

PT. PHONE NO.

09/24/2013 10:30

Resulf

09/24/2013 19:42

09/26/2013 06:06

30920884

PATIENT NO.

| 720881 | U |
|-------------|---|
| ARAPENITO . | |

| _ | - | • | | | _ | - | • | |
|---|---|---|----|---|---|---|---|---|
| | 0 | V | IV | E | N | T | S | ; |

| OMM | IEN | ГS | ; |
|-----|-----|----|---|

| Test | • | In Range | Out of Range Units Reference | | | | Site Code |
|---|----------|---------------|--|------------------|--|--|-----------|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This - NCS Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach Allerg,Derm. pter. | | <0.10 0.30 | 7.20 3.90 0.80 20.50 5.20 5.70 40.40 | H H H H | kU/L kU/L kU/L kU/L kU/L kU/L kU/L kU/L | <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.36 | |
| | Class | ku/L | Interpretation | zes the | TO HOW THIS C | iass cutoris. | |
| | 0 <0. 35 | | Negative for All | ergen | | | |
| | I | 0. 35-0. 69 | Positive for All | ergen | | | |
| | II | 0. 70-3. 49 | Strongly Positive | e | | | |
| | III | 3. 5-17. 49 | Strongly Positiv | e | | | |
| | IV | 17. 5-52. 49 | Strongly Positive | e | | | |
| | v | 52. 5-99. 99 | Strongly Positive | e | | | |
| | VI | >100 | Strongly Positiv | e | | | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-vI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| Allerg,Derm. farinae | | (0.50) | Н | kU/L | <0.35 |
|----------------------|---------|--------|---|------|--------|
| Allerg,Clad, herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg, Firebush | | 3.40 | H | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | <0.10 | | | kU/L | < 0.35 |
| Allerg, Dog Dander | <0.10 | | | kU/L | < 0.35 |
| Allerg, Bluegrass | | 2.50 | Н | kU/L | < 0.35 |
| Allerg, Pigweed | | 6.60 | H | kU/L | < 0.35 |
| Allerg, Mulberry | | 1.20 | H | kU/L | < 0.35 |
| Allerg, Helminth | <0.10 | | | kU/L | < 0.35 |
| hvs. Addr. Phone | UNKNOWN | | | | |

End of Report

Subject shows reactivity to known \$10/18/13

perennial allergans fusion thester

Derm ster and Derm, Jarenas (dust metes)

Meets inclusion criteria - Salger 26 Sept 2013

JLJ, JLJ



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: JLJ,

Gender: Female

Age: 46

Race: Caucasian

Height(in): 63.0 Weight(lb): 154

Any Info:

Id: AKP-007

Date: 10/02/13

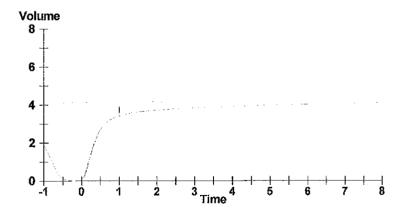
Temp: 22 Physician: PBar: 632

Technician: VL

| יווו אווי | | | | | | | | | | | |
|-----------|-----------------|-------------------|-----------------------------------|--------|------------|-------|-----------------|----|-----------------|---|---------------|
| | | BTPS) | PRI | E-RX | POST-RX | | Flow | | | | |
| Spirant | SHY | Ref | Pre | Pre | Post Post | Post | 16 ₇ | | | | |
| | | | Meas | | Meas % Ref | % Chg | 1 | | | | |
| FVC | Liters | 3.13 | 4.16 | 133 | | | Ţ | | | | |
| FEV1 | Liters | 2.62 | 3.42 | 131 | | | 12 + | | | | |
| FEV1/FV | | 85 | 82 | 97 | | | | | | | |
| FEF25-7 | | 2.97 | 4.01 | 135 | | | † | | | | |
| FEF50% | | 3.59 | ** 5.54 | | | | | | | | |
| FEF75% | L/sec | 1.43 | 1.61 | 112 | | | 8 † | .* | | | |
| IC | Liters | | | | | | 1 | I | | | |
| VC | Liters | 3.13 | | | | | | į | N _X | | |
| PEF | L/sec | 5.95 | 7.79 | 131 | | | 4 🕂 | 1 | · · | | |
| MVV | L/min | 103 | | | | | | 1 | `\ | | |
| PIF | L/sec | | 3.52 | | | | † | j | , ì, | | |
| FEV1/FE | | | 85 | | | | 0 - | | المراجع المراجع | | - |
| | | (Titon 6 to a co | na pinging gring pang pangilan in | estas: | (BTPS) | | ٠ ا | | | | |
| 1 (111) | Volumes | nan iya | मा । हा भूग हुई। | FALSA | V | | + | | - | | |
| ∨tg | Liters | | | | | | | | | | |
| vč | Liters | 3.13 | | | | | -4∤ | | | | |
| TLC | Liters | 4.80 | | | | | Ţ | | | | |
| RV | Liters | 1.64 | | | | | İ | | | | |
| RV/TLC | % | 34 | | | | | -8 + | | | | |
| FRC PL | Liters | 2.58 | | | | | | | | | |
| ERV | Liters | 2.00 | | | | | † | | | | |
| IC | Liters | | | | | | _42 📗 | | | | |
| Takin a | | | | | | | -12 -2 | 0 | 2. 4 | 6 | 8 |
| Diffus | | | | | | | _ | • | Z Volume | | |
| DLCO | mL/mmHg/m | | | | | | | | | | |
| DL Adj | mL/mmHg/m | | | | | | | | | | |
| DLCO/VA | A mL/mHg/min | /L 3.47 | | | | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| | digita | | | | | | | | | | |
| | | | | | | | | | | | |
| Raw Tota | al cmH2O/L/se | | | | | | | | | | |
| Raw Insp | cmH2O/L/se | C | | | | | | | | | |
| Raw Exp | cmH2O/L/se | C | | | | | | | | | |
| Raw | cmH2O/L/se | c 1.49 | | | | | | | | | |
| Gaw | L/sec/cmH20 | | | | | | | | | | |
| sRaw | cmH2O/L/s/L | | | | | | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | | | | | |
| | 1.757QHH (2.07) | . 5.200 | | | | | • | | | | |



Vtg (Raw) Liters





Lovelace Scientific Resources 2441 Ridgecrost Dr SF Albuquerque, NM 87108

Name: JLJ,

Gender: Female

Age: 46

Race: Caucasian

Height(in): 63.0

Weight(lb): 154

Any Info:

Id: AKP-007 Date: 10/09/13

Temp: 20

PBar: 628

Physician:

Technician: VL

| any mio. | | | | | | | COLLINOID | 111. V L | | | | | |
|----------|-------------|-------------|------|----------------------|------------|------------------------|---------------|--------------|----|--|-----|---------------|--|
| Зуноня | (B° | TPS) Ref | Pre | E-RX Pre % Ref | Post | ST-RX Post % Ref | Post % Chg | Flow 16 7 | | | | , | |
| FVC | Liters | 3.13 | 4.31 | 138 | .,,,,,,,,, | , | 75 G.I.g | ļ | | | | | |
| FEV1 | Liters | 2.62 | 3.46 | 132 | | | | | | | | | |
| FEV1/FV | | 85 | 80 | 95 | | | | 12 🛉 | | | | | |
| | 5%L/sec | 2.97 | 3.79 | 127 | | | | 1 | | | | | |
| FEF50% | | 3.59 | 5.34 | 148 | | | | 1 | | | | | |
| FEF75% | | 1.43 | 1.42 | 99 | | | | 8 † | | | | | |
| IC | Liters | | | | | | | | 71 | * | | | |
| VC | Liters | 3.13 | | | | | | I | / | 4 | | | |
| PEF | L/sec | 5.95 | 8.17 | 137 | | | | 4 🖡 | i | \.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\.\. | | | |
| PIF | L/sec | | 4.37 | | | | | | 1 | 1 | | | |
| Plethy | /smograph | (DTDC) | | | | | | 0 | - | i. | 1 1 | ! | |
| Lang | Volumes | (BTPS) | | | | | | • | À, | i i | | | |
| ∨tg | Liters | | | | | | | | | | | | |
| VC | Liters | 3.13 | | | | | | -4 † | | 41 - 1 | | | |
| TLC | Liters . | 4.80 | | | | | | 4 | | | | | |
| RV | Liters | 1.64 | | | | | | | | | | | |
| RV/TLC | % | 34 | | | | | | -8 † | | | | | |
| FRC PL | Liters | 2.58 | | | | | | 1 | | | | | |
| ERV | Liters | | | | | | | | | | | | |
| IC | Liters | | | | | | | -12⊥ -2 | 0 | 2 4 | 6 | 8 | |
| Diffut | | | | | | | | -2 | U | 2 Volume | Ü | 0 | |
| DLCO | mL/mmHg/min | | | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | | |
| DLCOM | | 3.45 | | | | | | | | | | | |
| 1/4 | Litara | | | | | | | | | | | | |

BHT Sec

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 SGaw
 cmH2O/L/s/L

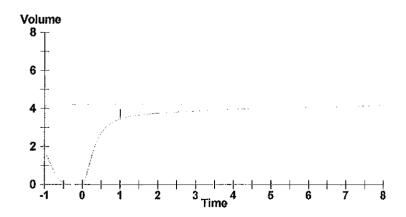
 L/s/cmH2O/L
 3.85

 L/s/cmH2O/L
 0.260

 Vtg (Raw)
 Liters

Liters

Comments:



Introduction for the second



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NW 87108

Name: JLJ,

Gender: Female

Age: 47

Race: Caucasian

Height(in): 63.0

Weight(lb): 159

Id: AKP-007 Date: 10/16/13

Temp: 19

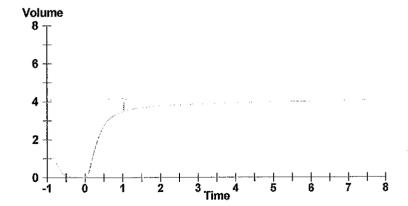
PBar: 631

Physician:

| ny Info: | | | | - | Fechnicia | ın: VL | | | | |
|--|---|--|--|------------------------------|------------------|-----------------|---------|----------|--------|---------------|
| ំពី | , (B | TPS) Ref | PRE-RX Pre Pre Meas % Ref | POST-RX Post Post Meas % Ref | Post % Chg | Flow 16 T | | | | |
| FVC FEV1 FEV1/FVC FEF25-75% FEF50% FEF75% IC VC | 6L/sec L/sec L/sec Liters Liters | 3.12 2.60 84 2.94 3.57 1.41 | 4.15 133 3.50 135 84 100 4.24 144 ** 5.89 ** 165 1.72 122 | lyidas /b i kai | N Only | 12 | X · · · | | | |
| | /olunties/f | 5.93 102 Hedbys | ** 8.78 ** 148 2.34 87 smography | (BTPS) | | 0 | | 1 | ·· · · | |
| Vtg VC TLC RV RV/TLC FRC PL ERV | Liters Liters Liters Liters W Liters Liters Liters | 3.12 4.80 1.64 34 2.54 | | | | -4 -8 | | | | |
| DECO DL Adj DLCO/VA VA BHT | Liters | 22.2 | | | | -12 -2 | 0 | Volume 4 | 6 | 8 |
| Secial. | Self-Electrical Control | | | | | | | | | |
| Raw Total Raw Insp Raw Exp Raw Gaw sRaw sGaw | cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec L/sec/cmH2O cmH2O/L/s/L L/s/cmH2O/L | 3.86 | | | | | | | | |

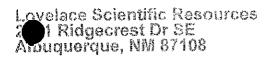


Vtg (Raw) Liters



lepteration straigent







Name: JLJ,

Gender: Female

Age: 47 Race:

Race: Caucasian

Height(in): 63.0 Weight(lb): 156

Any Info:

Id: AKP007 Date: 10/22/13

Temp: 21

PBar: 635

Physician:

Technician: VL

| Any Into: | | | | | | 1 COMMO | III. VL | | | | |
|------------|--------------------|-----------------|-------------|--------------|-------------------------|---------------|-------------|-------|------------|-------------|---|
| | (B1 | PS) | PR | E-RX | POST-RX | | Flow | | | | |
| Spirometr | у , | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | |
| FVC | Liters | 3.12 | 4.01 | 129 | | | † | | | | |
| | Liters | 2.60 | 3.30 | 127 | | | 12 - | | | | |
| FEV1/FVC | % | 84 | 82 | 97 | | | 12 | | | | |
| FEF25-75% | | 2.94 | 3.95 | 134 | | | + | | | | |
| | L/sec | 3.57 | ** 5.52 | ** 154 | | | ایر | | | | |
| | L/sec | 1.41 | 1.52 | 108 | | | 8+ | , f - | | | |
| IC 70% | Liters | | | | | | 1 | | | | |
| VC | Liters | 3.12 | | | | | Ţ | | • | | |
| PEF | L/sec | 5.93 | 8.35 | 141 | | | 4∔ | | | | |
| MVV | L/min | 102 | 0.00 | | | | } | | * | | |
| PIF | L/sec | 102 | 3,18 | | | | † | ; | | | |
| FEV1/FEV | | | 85 | | | | o — | | | | |
| | | محصد بما في ساخ | | wa ka s | (BTPS) | | • • • · · · | , | | | ' |
| Lung v | /olumes/F | 16thysn | nogra | рпу | (/ | | + | | Territory. | | |
| ∨tg | Liters | | | | | | | | ** | | |
| vč | Liters | 3.12 | | | | | -4 † | | | | |
| TLC | Liters | 4.80 | | | | | 1 | | | | |
| RV | Liters | 1.64 | | | | | | | | | |
| RV/TLC | % | 34 | | | | | -8+ | | | | |
| FRC PL | Liters | 2.56 | | | | | ì | | | | |
| ERV | Liters | 2.00 | | | | | † | | | | |
| IC IC | Liters | | | | | | .12 | | | | |
| misst | LILEI S | | | | | | -12 -2 | 0 | 2 4 | 6 | 8 |
| Diffusi | | | | | | | | _ | Volume 4 | | |
| DLCO | mL/mmHg/min | 22.0 | | | | | | | | | |
| DŁ Adj | mL/mmHg/min | 22.0 | | | | | | | | | |
| DLCONA | mL/mHg/min/L | 3.47 | | | | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| Omment | and and along pink | | | | | | | | | | |
| Resist | CHUC | | | | • | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | |
| · Raw Insp | cmH2O/L/sec | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.50 | | | | | | | | | |
| Gaw | L/sec/cmH2O | 0.615 | | | | | | | | | |
| sRaw | cmH2O/L/s/L | 3.86 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | | | | | |
| Vtg (Raw) | | | | | | | | | | | |
| , .g (,,) | | | | | Volume | | | | | | |
| _ | | | | | 8 - | | | | | | |
| Commen | ts: | | | | ١ ١ | | | | | | |
| | | | | | + | | | | | | |
| | | | | | c | | | | | | |

interpretation:

EFFECTS OF AIRPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | 7- | - | ې | | اً ار | 7 | | 6 | | , | | 7 | | | | | |
|------------------------|------------------|----------------|---------|-------|------------|-------|----------|------------|----------|------------|-------------|------------|------------|----------|----------|-----|----------|
| | 9/25/12 19/2/011 | 4 | Mosch | 70 | 9/27/13 | 9 | 7 | 9/20/15 | 7 | 9/20/12 | | 10/01/12 | 112 | 10/07/12 | 21.2 | 0 0 | 575 |
| | 0 CD 2 3 | m | 0 1 (2) | | 1 @ 3 | 1 | (D) | | | 0 1 | | 0 7 | (B) 3. | 0 1 | 1 © | 20 | - Μ |
| | 0 1 (2) 3 | ļ . | 0 1 (2) | 3 0 5 | G 2 3 | 000 | 2 3 | 0 | 2 3 | 0 1 (| (2) 3 | 0 | 2 3 | 01 | 2 3 | 0 1 | 2 3 |
| | 0 1 🕲 3 | - | 0 1 @ | 3 0 (| Ø 2 3 | 0 1 (| 603 | 0 | (2) 3 | 0 1 | (2)3 | 0 1 | (Z) 3 | 0 1 (| (Z) 3 | 0 1 | 2 3 |
| | 0 (1) 2 3 | i | 7 | 3 0 : | 1 2 3 | 0 | 2 3 | 0 | 2 3 | 5 | 2 3 | (S) | 2 3 | D 1 | 2 3 | 0 1 | 2 3 |
| | YES (NO | | YES NO | | ON | YES (| | (FES) | ON ON | YES | 9 | YES | 9 | Q | NO NO | YES | ON N |
| Throat Clearing Y/N | (YES) NO | 0 | (ES) NO | (ES) | ON | | ON ON | (ES) | 8 | (E) | S S | (ES) | ON | | ON ON | YES | SN SN |
| | <i>L</i> - | | 9- | | -5 | 4 | | -3 | | -2 | | 17 | | 0 | | 0 | |
| | 0 10 2 | m | 0 1 3 | 3 | 1 @ 3 | 0 1 (| (Z) 3 | 0 1 | 8 | Q 0 | 2 3 | 0 1 | Ø 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| | 0 (1) 2 3 | | 0 1 @ | 3 0 | (1) 2 3 | 01 | 2 3 | (E) | 2 3 | 000 | 2 3 | 6 0 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| | 0 1 3 | m | 0 @ 2 | 3 0 (| ① 2 3 | 0 1 (| 2 3 | 0 1 | (B) | 0 1 | 6 03 | 0 1 | Ø 3 | 0 7 | 2 3 | 0 1 | 2 3 |
| | 012 | m | 0 ① 2 | (e) | 1 2 3 | 0 | 2 3 | 0 | 2 3 | 6) | 2 3 | 0 | 2 3 | 0 | 2 3 | 0 | 2 3 |
| | YES (N | (g) | YES 🐠 | YES | (2) | YES | 2 | YES | 2 | YES | 9 | YES | 9 | YES | ON N | YES | ON N |
| Throat Clearing Y/N | (ÝES) N | ON | YES (VO | YES | (N) | (E) | ON ON | YES | 2 | YES | 3 | YES | (2) | YES | NO NO | YES | ON ON |
| i | | | | | | | | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: 007 / DATE COMPLETED: 95/3-10/2/13

SUBJECT INITIALS AND DATE: $\sqrt{3}$ 10 2 13

12/1/3



Lovelace Scid c Resources Clin Trials-Leslie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME JLJ, JLJ

PATIENT ID **AAGF0870**

\$EX 10/13/1966

DOB

REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 10/02/2013 13:15 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

10/02/2013 20:37

30920875

0

10/03/2013 06:06

COMMENTS:

007

| | Re | sult | | | i e |
|--------------------------------|--|--|-------------------------------------|---------------------------|------------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Motobalia Danal | | | | | |
| Comp Metabolic Panel Sodium | 136 | | mmol/L | 134-144 | |
| Potassium | 4.3 | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | mmol/L | 98-111 | |
| CO2 | 20 | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | 6-14 | |
| Glucose | | 112 H | mg/dL | 60-100Nd | 5 non |
| | Impaired fasting glucose (1 100-126 mg/dl.(ADA Guidelir | (FG) is defined as | 6: (3160-3167)200 | 3) 056 | 2013 |
| BUN | 11 | | mg/dL | 7-31 | |
| Creatinine | 1.02 | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS 1 | | | | |
| | Please note new reference : | • | • | * La | e ABD. |
| eGFR non-African Am | | 58 L | mL/min/1.73m2 | >60 NC | > 10000 |
| GFR Comment | | | | 3,,,,,,,,,,,,,03 | Cest 2015 |
| | Estimated GFR values are no on IV fluids, obese (BMI>34 | ot accurate in acut 4) or underweight (| e Kidney Tallure BMI<20) people, | >60 NC , inpatients 03 | |
| | the very old or very young, people with acute illnesses | races other than | Caucasian or Afr | ican American, | |
| Calcium | 8.6 | s, or amputations. | mg/dL | 8.4-10.4 | |
| Total Protein | 6.7 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.1 | | gm/dL | 3.4-4.7 | |
| Globulin | 2.6 | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.3 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 74 | | Ŭ/L | 38-150 | |
| AST(SGOT) | 13 | | Ú/L | 6-58 | |
| ALT(SGPT) | 26 | | Ú/L | 14-67 | |
| Fasting | ÑŎ | | 5,2 | 1-1-01 | |
| Phosphorus | 2.7 | | mg/dL | 2,3-5,6 | |
| CBC | | | | | |
| WBC | 4.7 | | x10E3 | 4.0-10.6 | |
| RBC | 4.44 | | x10E6 | 4.00-5.36 | |
| Hgb | 13.2 | | gm/dL | 12.0-16.0 | |
| Hct | 40 | | % | 36-48 | |
| MCV | 90 | | fL | 81-98 | |
| MCHC | 33.1 | | am/dL | 31,2-35.2 | |
| RDW | 13.1 | | % | 11.0-14.5 | - |
| Platelets | 304 | | x10E3 | 150-400 | c also |
| Eos, Respiratory | ••• | Rare * | | NS NO | > INKINION |
| Phys, Addr, Phone | NOT GIVEN | | | 150-400 NS 03 (| Oct rois |
| | | | | | |

End of Report

Manufaire 13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 244 | , | ſ | - | C | | V | | L | | | | 1 | | ٥ | | Ĺ | |
|----------------------|---------------|--------------|----------|------------|----------|------------|----------|----------|------------|------------|------------|---------|----------|---------|----------|-----|----------|
| AM A | 101 | 10/2 | | 10/0 | -باسه | | ر. + | <u> </u> | ده در | <u></u> | r- | <u></u> | ح | <u></u> | <u>6</u> | - | ת |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 1 | ж (| 0 1 | (g) 3 | 0 1 | Ø 3 | 0 | 2 3 | 0 | 2 3 | | 2 3 | (D) | 2 3 | 0 | 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | 3 @ 1 2 | 8 | 0 1 | 2 3 | @ 1 | 2 3 (| 0 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 | 0 | 2 3 | 0 1 | 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1 2 | m | 0 1 (| (2) 3 | ① o | 2 3 | 0 1 | 2 3 | ① o | 2 3 | Ø 1 | 2 3 | 0 | 2 3 | 0 1 | 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0 1 2 | m | 0 | 2 3 | 0 | 2 3 | 0 | 2 3 | 0 | 2 3 | ① 0 | 2 3 | 0 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES NO | (ÝES | ON ON | YES | g | YES | © | YES | £) | YES | (2) | YES | E | YES | Q | YES | S |
| Throat Clearing Y/N | YES NO | (KE) | Q. | YES (| E | (E) | ON O | (E) | ON. | (KE) | QN ON | (ES) | S S | | ON | YES | S S |
| → DAY PM | F | 2 | | æ | | 4 | | Ω | | 9 | | 7 | | 80 | | | 6 |
| Runny Nose 0 to 3 | 0 1 (2) 3 | 0 00 2 | က | | 2 3 | Ð, | 2 3 | ① 0 | 2 3 | 0 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Itchy Nose 0 to 3 | 0 1 3 9 | 6 1 2 | m | 01; | 2 3 | 6)1 | 2 3 | 01 | 2 3 | 0 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 | 0 | 2 3 |
| Congestion 0 to 3 | 0 1 (2) 3 | 0 1 (2) | 3 | ; (f) o | 2 3 | (T) | 2 3 | 0 1 (| (S) 3 | 0 1 | 2 3 | 0^{1} | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Sneezing 0 to 3 | 0 (1) 2 3 (0) | 0 1 2 | m (| 0 1(3 | (2) 3 | (I) | 2 3 | 0 | 2 3 | (I) o | 2 3 | 0 1 (| Ø3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES | (O) | YES | (N) | YES | 9 | YES | (N) | (KES) | ON . | YES | (S) | YES | ON O | YES | NO |
| Throat Clearing Y/N | YES (NO | YES | (S) | YES (| E | YES | ළු | YES | E | YES | (O) | YES | (ON) | YES | NO NO | YES | QN ON |
| CCALEOTO | | | | - | 9 | | 1 | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: ALP-007. DATE COMPLETED: 10/2/13 > 10/4/13

SUBJECT INITIALS AND DATE: (\$\infty\$ (0\q\|\)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scient Resources Clin Trials-Leslie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME JLJ, JLJ

PATIENT ID **AAGF8933**

10/13/1966

REPORT STATUS Final

PAGE

PHYSICIAN

30920927

Test

COMMENTS:

Unlisted Physician.

REQUISITION NO. PT. PHONE NO.

0

COLLECT DATE & TIME 10/09/2013 13:10 RECEIVE DATE & TIME 10/09/2013 21:04 PRINT DATE & TIME 10/10/2013 08:35

PATIENT NO.

AKP007

Result

In Range

Out of Range

Unita

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

Not given

Rare

NS

End of Report

Materia as

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | 7 | | œ | | 6 | 10 | | 17 | | 12 | 13 | | 1, | | _ | 7. |
|---------------------------------------|-----------|---------------|----------|---------|----------|---------|-------------|-------------|---------|-----------|--------|----------------|----------------|------------------|---------------------------------------|--------|
| AM | 10/9/ | - | 01/01 | 100 | | 0 1 | 7 | 10/12/10/18 | | h1/03 | 11/11 | ١ | 13/10 | , _ට ූ | · · · · · · · · · · · · · · · · · · · | 3 |
| Runny Nose 0 to 3 | 0 1 2 | m (D) | 0123 | (S) | 2 3 | 0 (1) 2 | 2 3 | (g 1 2 | m | 0 @ 2 3 | 9 1 2 | က | 0 @ 2 | 2 3 | 0 1 | 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 | © % | 123 | 0 | 2 3 | ه 1 | 2 3 | 0 1 2 | 3 | 0123 | 0 1 2 | m | 0^{1} | 2 3 | 0 1 | 2 3 |
| Congestion 0 to 3 | 0 1 2 | © % |)123 | €) 1 | 2 3 | ව 1 | 2 3 | 0 (1) 2 | 8 | 0 (1) 2 3 | 0 ① 2 | m | 0 0 | 2 3 | 0 1 | 2 3 |
| Sneezing 0 to 3 | 0 1 2 | 3 @ 1 | 123 | 0 | 2 3 | €) H | 2 3 | 012 | 8 | 0123 | Ø1 2 | m | Q ₁ | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES NO | | YES (MO) | (KES) | ON O | | ON. | YES (NO | | YES (NO | YES (N | (S) | YES | B | YES | N 0 |
| Throat Clearing Y/N | YES NO | | MES NO | (E) | ON | (KES) | S S | (YES) NO | | YES (NO) | MES N | Q _N | (KES) | NO NO | YES | 8 |
| DAY PM | 7 | | œ | | 6 | 10 | _ | 11 | | 12 | 13 | | 14 | | | 15 |
| Runny Nose 0 to 3 | Ø 1 2 | е О | 0123 | (e) | 2 3 | 6 | 2 3 | 0 1 2 | 8 | 0 (1) 2 3 | 0 1 2 | т | 0 1 | 2 3 | 0 1 | 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 | <u>ص</u> ۳ | 0123 | (0) | 2 3 | (9) | 2 3 | 0 🛈 2 | 3 | 0 1 (2) 3 | 0 1 2 | т | 0 1 | 2 3 | 0 1 | 2 3 |
| Congestion 0 to 3 | 0 1 2 | 3 0 | ①23 | (g) | 2 3 | 0 | 2 3 | 0 (I) 2 | 3 | 0 1 (2) 3 | 0 1 2 | m | 0 1 | 2 3 | 0 1 | 2 3 |
| Sneezing 0 to 3 | 0 (1) 2 3 | Э Э | 123 | 0 1 | 2 3 | 0 | 2 3 | 0 🗇 2 | 8 | 0 1 (2) 3 | 0 1 2 | က | 0 1 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES (NO |) YES | SS (NO) | YES | E | YES | €)(| YES (NO | | YES (NO | YES N | 9 Q | YES | N N | YES | 8 |
| Throat Clearing Y/N | YES (NO |) YES | SS (NO | YES | 2 | YES | Q | YES (NO | - | YES (NO | YES N | 9 | YES | ON O | YES | 8 |
| SCALE 0 to 3 0= No symptoms detected) | (no sympt | oms de | etected) | | , | | | | O) | Sisspir | | | | | | |
| • | | | | | | | | | | m | | | | | | |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER: ALL-OUT DATE COMPLETED: 19/16/13 NESS SEA SY

water up to the ingles weight grein

REFERENCE LABORATORIES

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scies Resources Clin TrialsLeslie dyatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

PATIENT NAME JLJ, JLJ

PHYSICIAN

Unlisted Physician. REQUISITION NO.

PT. PHONE NO.

PATIENT ID

AAGG2360

10/13/1966

SEX

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

10/16/2013 13:30

RECEIVE DATE & TIME 10/16/2013 20:15 PRINT DATE & TIME

10/17/2013 06:08

30920920 COMMENTS: 0

PATIENT NO.

AKP007

Test

Eos, Respiratory Phys, Addr. Phone

End of Report

Not given

In Range

Result

Out of Range

Rare

Units

Reference Range

Site Code

NS

NCS S 10/18/13

NCS Jealyer PI 18 Oct 2013

JLJ, JLJ

10/17/2013 06:08

FAX24664

Day 14

| | | | Univestigator Initials/Date | | W. St. | | | 172 111 | | | | | * | | • | 3E: of |
|-------------------------|-------------------|-------------------|---|------------|-------------|-----------------------|-----------------|-------------|--|--|--|--------|---|---|---------------------------------|--|
| LSR Study #: | Subject Initials: | | Action Taken | NONE | l | NONE | NON 6 | NONE | | | | 700000 | e as specific as possible* | Date: 26 Feb 2014 | 2/2/14 | PAGE |
| LSR | Sub | g | ** End Date (DD/MIMIN/YYYY) | 23/CT/2013 | 26/201/2013 | 23/0CT/2013 | 16/007/2013 | 22/0ct/2013 | | | | | should be made to be | | Date: 2 | |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Snapita | Buspered | that suspected | sted | | | | | | space provided, but every effort should be made to be as specific as possible** | 1/ Mestrice NO | lu Sreet | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| 0 | | | SEVERITY | mid | kuld. | } | 0 | mild | | | | | | // :(A) | dy): | rc |
| 7710 | 9KP00 | | ** Start Date (DD/MMM/YYYY) | orloctfuls | O4/04/2013 | 1 tent 07/2 ct / 2013 | E7/04/2013 | 15 10ct/203 | | | | | ** If day is unknown, write UNK in | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: _ | Subject Number: | | Adverse Event | Strong WI | Spit plant | dizzness, | Sleep lessnes & | Sught | | The state of the s | | | * | Investigator Sign | SC Sigi | |

. .

| Q LSR#: | Subject Initials: JLJ | CONCOMITANT MEDICATION LOG medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements, | Dose Unit | 500 MG 2 Tabs per Oral UNK/AUG/1999 | oidism 68.5 mg OD Ora | 5 mg PRN ora! | 800/160 my OD Oras 26/Sep/2013, 04 | 500 my T10 ord | | | | * If day or month of medication date s unknown, write UNK in space provided | study): My Land M) Date: 20 Feb 2014 | liele Brown | Lovelace Scientific Resources, inc - ConMeds 04/2013 |
|------------------------|-----------------------|--|---|-------------------------------------|-----------------------|---------------|------------------------------------|------------------|--|--|--|---|---|---------------------------------|--|
| m. 9749 | AKP 1007 | List all <u>prescription</u> medications you | Indication on (What you take it for) | | THE TOTAL | easonal | 3 p ext exica | 3 p crat excused | | | | * If day or mon | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification:_ | Subject Number: | Lis | Name of Medication | EXAVIPLE | Levothyroxim | Benadry | Slukamethoxazulc | Cohalexin | | | | | Investigator Sig | SC SI _E | |

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| | (1) | 3 % | 2 3 | 2 3 | 2 3 | 0 <u>N</u> | NO NO | | 2 3 | 2 3 | 2 3 | 2 3 | <u> </u> | 9 9 |
|--|-----------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|--------|----------------------|----------------------|----------------------|--------------------|---------------------|-----------------|
| | 2 | 7 - | - | ₩ | - | S | S | 6 | | ₩. | , , | Τ, | S | S |
| | ~ | 0 | 0 | 0 | 0 | YES | YES | | 0 | 0 | 0 | 0 | YES | YES |
| ω | 8/1/5 | 1 | m | m | m | NO NO | 9 | | m | m | m | 33 | 9 | 9 |
| 23 | 8/2 | 1 2 | 1 2 | 1 2 | 1 2 | | | œ | 1 2 | 1 2 | 1 2 | 1 2 | | |
| | 6 | 0 | 0 | 0 | 0 | YES | YES | | 0 | 0 | 0 | 0 | YES | YES |
| | 21 |) m | 3 | m | m. | ON | NO | | m | m | m | 3 | NO | ON |
| | Tref | | ① 5 | ① 2 | 1 2 | ŀ | | 7 | 1 2 | 1 2 | 1 2 | 1 2 | | |
| | 9 | 0 | 0 | o | (a) | (ÇE) | | | 0 | 0 | 0 | 0 | YES | YES |
| | 1.0 | (n) | 2 3 | 2 3 | 2 3 | ON ON | 9 | | 2 3 | 2 3 | m | 3 | 9 | S S |
| | 9 | | H | | Η. | _ | | ဖ | 1 | - | 1 2 | (t)2 | | _ |
| | 9 /01 | , O | ව | 9 | <u>ඉ</u> | (ES) | (KE) | | 9 | © | 0 | 0 | | YES |
| | 5/06/09 | m | m | m | m | ON ON | 9 | | m | m | m | m | 9 | S S |
| | 5/20/ | (C) | 1 2 | ① 2 | (J) 2 | | | 2 | 1 2 | 1 2 | 1 2 | (D)2 | ٔ ا | ŀ |
| | | | <u></u> | 0 |) 0 | | ŒS | | © | 6 | 6 | 0 | (KES | |
| | 4,6/,2 | 3 6 | က | 3 | m | 8 | 9 9 | | m | m | 33 | m | (2) | (2) |
| | 4/0/ | | 4 2 | 1 (2) | 1 2 | | 1 | 4 | ⊕ 2 | 1 2 | (I) 2 | 1 2 | | |
| , , , | 101 | 0 | 0(4 | 0 | <u></u> | E | | | 0 | 9 | 0 | 6) | YES | YES |
| | 61/ | Ö | m | т | ო | 9 | 0N. | | m | m | m | က | 9)(2 | § |
| JRS | 3/0//0/ | 1 2 | 1 2 | 1 2 | 1 2 | | _ | ო | (F) | 1 2 | 1 2 | D 2 | | |
| CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS | 9 | (e) | 9 | 0 | 0 | YES | | | 0 | 0 | 0 | 0 | YES | YES |
| X 12 | 19/11/2 | m m | m | m | m | NO NO | <u>8</u> | | m | m | m | 3 | (2) | (2) |
| EVEF | 77 | - | 1 2 | D 2 | (1) 2 | | | 7 | ① 2 | 1 2 | 1 2 | $\frac{1}{3}$ | , i | |
| NSE | | Non-of | 0 | 0 | 0 | (ŝi) | (E) | | o | 0 | (| 0 | YES | YES |
| SPO | 0 | m | m | m | m | 2 | ON O | | m | m | 33 | 3 | Q (| 3 |
| ERE | H 3 | 1 2 | 1 2 | 7 | \forall | | | e-1(| 0 (1)2 | 1 2 | 1 2 | 1 2 | | |
| MAT | 1/0/16/19 | سوا | 6 | 0 | 0 | YES | YES | | ō | 9 | 0 1 | 0)1 | YES | YES |
| SOXI | | | | | | a | Throat Clearing Y/N | | | | | | 9 | Throat Clearing |
| APPI | DAY | Nose | Se | ion | b ₀ 0 | oars | Zlear | M | lose | Se | ion | 50 | oars | Gear |
| CLE, | ک ک | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | oat (| DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | oat (|
| C S | | Runny 0 to 3 | Itch Otc | Conges 0 to 3 | Sne O tc | Voice Y/N | ĮξŠ | _ | Runny 0 to 3 | Itchy N 0 to 3 | Conge: 0 to 3 | Sneezii O to 3 | Voic Y/N | Thro |
| | | | | | | | • | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER:

DATE COMPLETED: 10/16/

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sciic Resources Clin Trials-Lesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME JLJ, JLJ

PATIENT ID AAGF0870 DOB 10/13/1966 SEX REPORT STATUS Final

kU/L

PAGE

PHYSICIAN Unlisted Physician. **COLLECT DATE & TIME** 10/22/2013 13:47

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

0.20

10/22/2013 19:25

10/24/2013 06:05

< 0.35

30920917

Test

Λ

007

COMMENTS:

| Eos, Respiratory Phys, Addr, Phone |
|--|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This |

Allerg, Bermuda Grass Allerg, Alternaria Allerg, Mesquite

Allerg, Cockroach

Allerg Derm. pter.

| F | lesult | | | | | | |
|--------------------|------------|-----|-------|-----------------|-----------|--|--|
| In Range | Out of Ran | ıge | Units | Reference Range | Site Code | | |
| None seen | | | | NS | | | |
| ND PHYSICIAN GIVEN | | | | | | | |
| | 7.10 | н | kU/L | <0.35 | | | |
| | 4.60 | Н | kU/L | <0.35 | | | |
| | 0.80 | Н | kU/L | <0.35 | | | |
| | 21.20 | Н | kU/L | <0.35 | | | |
| | 6.00 | Н | kU/L | <0.35 | | | |
| <0.10 | | | kU/L | <0.35 | | | |
| | 7.40 | H | kU/L | < 0.35 | | | |

0.40 kU/I <0.35 The standard classification system utilizes the following class cutoffs. MAN 24 OUT 2013

Class ku/L Interpretation 0 <0.35 Negative for Allergen I 0. 35-0. 69 Positive for Allergen 0.70-3.49 II Strongly Positive III 3, 5-17, 49 Strongly Positive

ΙV 17. 5-52. 49 Strongly Positive V 52, 5-99, 99 Strongly Positive VΙ >100 Strongly Positive

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| | cinnical allergy. | | | | |
|----------------------|-------------------|------|---|-------|-----------|
| Allerg,Derm. farinae | | 0.50 | Н | kU/L | < 0.35 |
| Allerg,Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg,Firebush | | 3.30 | Н | kU/L | < 0.35 |
| Allerg Cat Dander Ep | <0.10 | | | kU/L | < 0.35 |
| Allerg,Dog Dander | <0.10 | | | kU/L | < 0.35 |
| Allerg, Bluegrass | | 2.80 | Н | kU/L | < 0.35 |
| Allerg, Pigweed | | 7.40 | Н | kU/L | < 0.35 |
| Allerg, Mulberry | | 1.50 | Н | kU/L | < 0.35 |
| Allerg, Helminth | <0.10 | | | kU/L | < 0.35 |
| CBC | | | | | |
| WBC | 5.4 | | | x10E3 | 4.0-10.6 |
| RBC | 4.60 | | | x10E6 | 4.00-5.36 |
| Hgb | 14.0 | | | gm/dL | 12.0-16.0 |
| Hct | 41 | | | % | 36-48 |
| MCV | 90 | | | fL, | 81-98 |

Continued on next page



Lovelace Scfic Resources Clin TrialsLesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquergue, NM 87102 (505) 938-8922

PATIENT NAME JLJ, JLJ

PATIENT ID **AAGF0870** DOR 10/13/1966 SEX

x10E3

REPORT STATUS Final

PAGE 2

Site Code

PHYSICIAN Unlisted Physician, **COLLECT DATE & TIME** 10/22/2013 13:47 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

0.1

10/22/2013 19:25

10/24/2013 06:05

0.0-0.1

30920917

007

COMMENTS:

Test In Range Out of Range Units Reference Range **MCHC** 33.9 gm/dL 31.2-35.2 **RDW** 13.1 % 11.0-14.5 **Platelets** 290 x10E3 150-400 Differential Diff Type **Auto Diff** Neutrophils 48 40-76 Lymphocytes 40 % 16-47 5 % Monocytes 3-13 Eosinophils 6 % 0-5 н Basophils % 0-2 2.5 Abs. Neutrophil x10E3 1.8-7.0 2.1 Abs. Lymphocyte x10E3 1.0-3.4 Abs. Monocyte 0.3 x10E3 0.2-0.8 Abs. Eosinophil 0.3 x10E3 0.0-0.3

Your requisition did not indicate a test for the EDTA tube received. Due to the instability of the specimen, a CBC with differential was performed. If you have any questions, please call Client Services at (505) 938-8922. Federal regulation requires written authorization for any test order modification to be submitted within 30 days. Please fax this report with your authorization signature to (505)938 8034 Tricore Reference Laboratories ATTN: Medical Records Imaging Department.

Monthium 24 Oct 2013

End of Report

Abs. Basophil

Deferred Test

FAX24664

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ☐YES ☒NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| It didn't seem to help much, but allergies can't different symptoms every day for me depending on whether in owtside or dusting the house etc. so it was hard to tell for sure. |
| Cause different symptoms every day for |
| Ne depending en whether in obtside |
| or dusting the house etc. so it was hard |
| to tell browne. |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

AKP-009

4/49 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIEN | T DEMOGRAPHICS |
|---------------------|---|
| Patient] | Demographics |
| | 19100 |
| Date of E | Birth: $/// Feb = (dd/mmm/yyyy)$ Male \Box Female |
| Gender: | Male Female |
| If female, | , Indicate Childbearing Potential W/A |
| | Childbearing Surgically sterilized Post-Menopausal |
| | |
| Ethnicity: | Hispanic Non Hispanic |
| Race: | Asian 🗌 Black 📈 Caucasian 🗌 American Indian |
| | Pacific Islander Other, Specify |
| | |
| Calling populations | |
| Smoking | History and the second |
| G 1' 6 | |
| Smoking S | |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | |
| | Current (smokes now) |
| If subject i | Current (smokes now) is a former or current smoker, please indicate: |

Version: 02 September 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scio ic Resources Clin Trials-Lesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr

24664

PATIENT NAME RA, RA

PATIENT ID **AAGF1615** DOB 02/14/1960

REPORT STATUS SEX Final М

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT, PHONE NO.

09/25/2013 08:57

09/25/2013 19:47

30920897

Result

09/27/2013 06:08

O

PATIENT NO.

CON

AKP009

| MMENTS: | | | |
|---------|--|--|--|
| | | | |

| Test | In Range | | Out of Range Unit | | | Reference Range | Site Code |
|---|----------|---|--|-------------|--|--|-----------|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach Allerg,Derm. pter. | The stan | <0.10 <0.10 <0.10 0.10 <0.10 0.30 dard classifics | 9.50 5.30 29.20 ation system util | H H H | kU/L kU/L kU/L kU/L kU/L kU/L kU/L kU/L | <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 <0.35 | |
| | Class | ku/L | Interpretation | 1200 0110 | . 10110111119 0 | | |
| | ō | <0. 35 | Negative for Al | lergen | | | |
| | ī | 0. 35-0. 69 | Positive for Al | lergen | | | |
| | II | 0. 70-3. 49 | Strongly Positi | ve | - | | |
| | III | 3. 5-17. 49 | Strongly Positi | ve | | | |
| | īv | 17. 5-52. 49 | Strongly Positi | ve | | | |
| | v | 52. 5-99. 99 | Strongly Positi | ve | | | |
| | VI | >100 | Strongly Positi | ve | | | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| The state of the s | Cillical allergi | | | | |
|--|------------------|--------|-------|------|--------|
| (Allerg, Derm. faringe) | - | (0.50) | Н | kU/L | <0.35 |
| Allerg, Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg, Firebush | | 0.80 | Н | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | 0.20 | | | kU/L | < 0.35 |
| Allerg,Dog Dander | 0.10 | | | kU/L | <0.35 |
| Allerg, Bluegrass | | 12.00 | Н | kU/L | < 0.35 |
| Allerg, Pigweed | | 1.80 | H | kU/L | < 0.35 |
| Allerg,Mulberry | 0.20 | | • • • | kU/L | < 0.35 |
| Allerg, Helminth | <0.10 | | | kU/L | < 0.35 |
| Phys, Addr. Phone | Unknown | | | | |
| i ilkal umari i ilona | 4.11.11.4.11.11 | | | | |

Subject shows reactivety to Dust mite (D. farinae)
Serennial allergen confermed by Immunders
testing. Meets inclusion Cretica **End of Report**

09/27/2013 06:08

FAX24664



1 ovelace Scientific Resources 41 Ridgecrest Dr SE Albuquerque, NM 87108

Name: R-A,

Gender: Male

Age: 53 Race:

Race: Hispanic

Height(in): 67.0

Weight(lb): 173

Any Info:

Id: AKP-009 Date: 10/11/13

Temp: 19

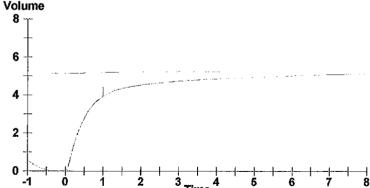
PBar: 630

Physician:

Technician: VL

| • | ary mile. | | | | | ' | | V 🗀 | | | | | |
|------------|-----------|---------------|---------|-------------|--------------|-------------------------|---------------|-----------------|------|---------------------------------------|-------|---|--|
| . . | Spirometr | (E | TPS) | PRI | E-RX | POST-RX | | Flow | | | | | |
| | эриотеи | y | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 _T | | | | | |
| | FVC | Liters | 3.99 | 5.26 | 132 | 111000 70 1101 | , | 1 | | | | | |
| | FEV1 | Liters | 3.24 | 3.94 | 121 | | | | | | | | |
| | FEV1/FVC | | 81 | 75 | 92 | | | 12 🕂 | | | | | |
| | FEF25-759 | | 3.40 | 3.19 | 94 | | | | | | | | |
| | FEF50% | L/sec | 4.15 | 4.27 | 103 | | | | | | | | |
| | FEF75% | L/sec | 1.57 | 1.24 | 79 | | | 8 🕂 | 7.30 | | | | |
| | IC | Liters | ,,,,, | | | | | ŀ | 1 | 4. | | | |
| | VC | Liters | 3.99 | | | | | † | ; | - 1 m | | | |
| | PËF | L/sec | 8.14 | 9.56 | 117 | | | 4. | į | 1.0 | | | |
| | MVV | L/min | 139 | | | | | - | 1 | N | | | |
| | PIF | L/sec | | 1.42 | | | | † | İ | 34 | | | |
| | FEV1/FEV | 6% | | 78 | | | | 0 | | Fig. | h | | |
| | Lima | /olumes/l | Plathys | emoarai | ahv | (BTPS) | | ٠ " | | , , , , , , , , , , , , , , , , , , , | J ' ' | • | |
| | | | Cary | amogra | Jily | , , | | + | | • | | | |
| | Vtg | Liters | | | | | | _ <u></u> | | | | | |
| | VČ | Liters | 3.99 | | | | | -4† | | | | | |
| | TLC | Liters | 6.05 | | | | | + | | | | | |
| | RV | Liters | 2.05 | | | | | | | | | | |
| | RV/TLC | % | 35 | | | | | -8∱ | | | | | |
| | FRC PL | L.iters | 3.29 | | | | | 1 | | | | | |
| | ERV | Liters | | | | | | | | | | | |
| | IC . | L.iters | | | | | | -12 -2 | _ | | | • | |
| | Diffusion | on | | | | | | -2 | 0 | Volume ⁴ | 6 | 8 | |
| | DLÇQ | mL/mmHg/min | 23.6 | | | | | | | 7 0,0,1,10 | | | |
| | DL Adj | mL/mmHg/min | 23.6 | | | | | | | | | | |
| | DLCO/VA | mL/mHg/min/L | . 3.32 | | | | | | | | | | |
| | VA | Liters | | | | | | | | | | | |
| | BHT | Sec | | | | | | | | | | | |
| | Resista | ance | | | | | | | | | | | |
| | Raw Total | cmH2O/L/sec | | | | | | | | | | | |
| | | cmH2O/L/sec | | | | | | | | | | | |
| | | cmH2O/L/sec | | | | | | | | | | | |
| | Raw | cml·l2O/L/sec | 1.40 | | | | | | | | | | |
| | Gaw | L/sec/cmH2O | | | | | | | | | | | |
| | | cmH2O/L/s/L | 4.59 | | | | | | | | | | |
| | | L/s/cmH2O/L | | | | | | | | | | | |
| | Vtg (Raw) | | | | | | | | | | | | |
| | 4 , | | | | | Volume | | | | | | | |
| | | | | | | | | | | | | | |

Comments:



Interpretation:



I ovelace Scientific Resources 41 Ridgecrest Dr SE Albuquerque, NM 87108

Name: R-A, Gender: Male

Age: 53

Race: Hispanic

Height(in): 67.0

Weight(lb): 173

Any Info:

Id: AKP-009 Date: 10/17/13

Temp: 19

PBar: 631

Physician: Technician:

| Spirometry Ref | • | uty iiiio. | | | | | | | | | | | | |
|--|---|------------|--------------|--------------|--------|-----|-----|------|------|-----------------|-------------|-----------|----|---|
| Neas Ref Meas Ref Meas Ref R | | Spiromet | (B 7 | - | | | | | Poet | | | | | |
| FEV1 Liters 3.24 3.92 121 FEV1/FVC % 81 76 93 FEF25-75%L/sec 3.40 3.26 96 FEF50% L/sec 4.15 3.90 94 FEF76% L/sec 1.57 1.51 96 IC Liters 3.99 PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters 3.99 TLC Liters 3.99 TLC Liters 3.99 TLC Liters 3.99 TLC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Li | | • | • | | Meas % | Ref | | | | 16 | | | | |
| FEV1/FVC % 81 76 93 FEF25-75%//sec 3.40 3.26 96 FEF50% L/sec 4.15 3.90 94 FEF75% L/sec 1.57 1.51 96 IC Liters VC Liters 3.99 PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DLCO mL/mmHg/min 23.6 DLCO mL/mmHg/min 23.6 DLCO mL/mmHg/min 23.6 | | FVC | Liters | 3.99 | | | | | | † | | | | |
| FEV1/FVC % 81 | | FEV1 | Liters | 3.24 | 3.92 | 121 | | | | 12 | | | | |
| FEF50% L/sec 4.15 3.90 94 FEF75% L/sec 1.57 1.51 96 IC Liters VC Liters 3.99 PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DLAdj mL/mmHg/min 23.6 DLAdj mL/mmHg/min 23.6 | | FEV1/FVC | : % | 81 | | | | | | '-1 | | | | |
| FEF75% L/sec 1.57 1.51 96 IC Liters VC Liters 3.99 PEF L/sec 8.14 8.89 109 M/V L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | FEF25-759 | %L/sec | 3.40 | 3.26 | | | | | + | | | | |
| C | | FEF50% | L/sec | 4.15 | 3.90 | 94 | | | | ام | | | | |
| VC Liters 3.99 PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DL Adj ml/mmHg/min DL Adj ml/mmHg/min 23.6 DLAdj ml/mmHg/min 23.6 DLAdj ml/mmHg/min 23.6 | | FEF75% | L/sec | 1.57 | 1.51 | 96 | | | | 8† | 1 1 | | | |
| VC Liters 3.99 PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DL Adj ml/mmHg/min DL Adj ml/mmHg/min 23.6 DLAdj ml/mmHg/min 23.6 DLAdj ml/mmHg/min 23.6 | | IC | Liters | | | | | | | 4 | | | | |
| PEF L/sec 8.14 8.89 109 MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | Liters | 3.99 | | | | | | | 1 | ٠ | | |
| MVV L/min 139 PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | L/sec | 8.14 | 8.89 | 109 | | | | 4 | i | 3. | | |
| PIF L/sec 1.16 FEV1/FEV6% 78 Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | MVV | L/min | 139 | | | | | | 1 | į | 4. | | |
| Lung Volumes/Plethysmography Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | L/sec | | 1.16 | | | | | Ť | | ¥., | | |
| Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | FEV1/FEV | 6% | | 78 | | | | | 0 | | 1 1 | -1 | — |
| Vtg Liters VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | Luna \ | √olumes/F | Plethysmo | grapi | hv | (BT | 'PS) | | | | į. | | |
| VC Liters 3.99 TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | 400 | | , | Tast 4 | , | | | | | | | | |
| TLC Liters 6.05 RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | vč | | 3.99 | | | | | | -4 † | | | | |
| RV Liters 2.05 RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | | | | | | | | ļ. | | | | |
| RV/TLC % 35 FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | | 2.05 | | | | | | _ | | | | |
| FRC PL Liters 3.29 ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | | | | | | | | -8 | | | | |
| ERV Liters IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | Liters | 3.29 | | | | | | i | | | | |
| IC Liters Diffusion DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | | | | | | | | T | | | | |
| DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | Liters | | | | | | | -12 <u>+</u> | _ | | _ | _ |
| DLCO mL/mmHg/min 23.6 DL Adj mL/mmHg/min 23.6 | | | | | | | | | | -2 | 0 | Volume 4 | 6 | 8 |
| DL Adj mL/mmHg/min 23.6 | | | | 23.6 | | | | | | | | , vidillo | | |
| | | | | | | | | | | | | | | |
| | | DLCO/VA | | | | | | | | | | | | |

Resistance

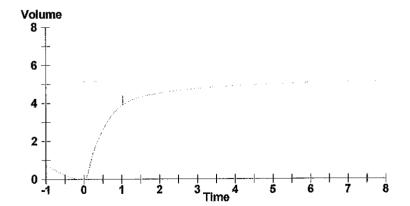
BHT

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec Raw Exp cmH2O/L/sec 1.40 Raw L/sec/cmH2O 0.789 Gaw sRaw cmH2O/L/s/L 4.59 L/s/cmH2O/L 0.218 sGaw Vtg (Raw) Liters

Liters

Sec

Comments:



Interpretation.



Lavelace Scientific Resources 2 - 1 Ridgecrest Dr SE Albuquerque, NW 87108

Name: R-A, Gender: Male

Age: 53

Race: Hispanic

Height(in): 67.0

Weight(lb): 173

Any Info:

Id: AKP-009 Date: 10/24/13

Temp: 20

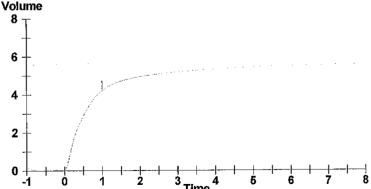
PBar: 634

Physician:

Technician: VL

| | (B | TPS) | PRE | E-RX | POST | r-RX | | Flow | | | | |
|-----------|--------------|----------|-------------|--------------|--------------|------|---------------|-------------|---|---------------|----|---|
| Spirometr | Ϋ́ | Ref | Pre Meas | Pre % Ref | Post Meas | | Post % Chg | 16 | | | | |
| FVC | Liters | 3.99 | 5.64 | 142 | | | | t | | | | |
| FEV1 | Liters | 3.24 | 4.23 | 130 | | | | 12 - | | | | |
| FEV1/FVC | % | 81 | 75 | 92 | | | | '- | | | | |
| FEF25-75% | %L/sec | 3.40 | 3.39 | 100 | | | | ł | | | | |
| FEF50% | L/sec | 4.15 | 4,04 | 98 | | | | 8 | , | | | |
| FEF75% | L/sec | 1.57 | 1.56 | 99 | | | | OΤ | 1 | | | |
| IC | Liters | | | | | | | 4 | - 1 | *. | | |
| VC | Liters | 3.99 | | | | | | | | N., | | |
| PEF | L/sec | 8.14 | 8.71 | 107 | | | | 4+ | i | Ph | | |
| MVV | L/min | 139 | | | | | | 1 | : | ** | | |
| PIF | L/sec | | | | | | | | | W. | | |
| FEV1/FEV | | | 77 | | (m) | -DO) | | 0 | | + + + | 11 | — |
| Lung \ | /olumes/F | Plethysr | nogra | phy | (B) | rps) | | ļ | | | | |
| ∨tg | Liters | | | | | | | -4 | | | | |
| VČ | Liters | 3.99 | | | | | | | | | | |
| TLC | Liters | 6.05 | | | | | | ÷ | | | | |
| RV | Liters | 2.05 | | | | | | | | | | |
| RV/TLC | % | 35 | | | | | | -8 † | | | | |
| FRC PL | Liters | 3.29 | | | | | | 1 | | | | |
| ERV | Liters | | | | | | | | | | | |
| IC | Liters | | | | | | | -12 -2 | ^ | 2 1 | 6 | 8 |
| Diffusi | on | | | | | | | -2 | 0 | 2 Volume 4 | v | U |
| DLCO | mL/mmHg/min | 23.6 | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | |
| DLCO/VA | mL/mHg/min/L | | | | | | | | | | | |
| VA | Liters | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | |
| Resist | | | | | | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | | |
| Raw Insp | | | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.40 | | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.59 | | | | | | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | | | | | | |
| Vtg (Raw) | | • | | | | | | | | | | |
| (1 1-11) | *==:= | | | | Volun | ne | | | | | | |
| | | | | | 9 | | | | | | | |

Commonts:



Interpretation:



Lo ace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: R-A, Gender: Male

Age: 53 Race:

Height(in): 67.0

Weight(lb): 172

Any Info:

ld: AKP-009 Date: 11/01/13

Temp: 19

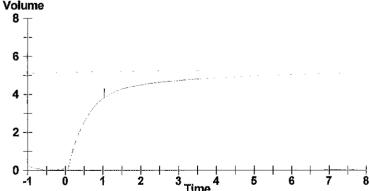
PBar: 633

Physician:

| r nysician. | |
|-------------|-----|
| Technician: | VL. |

| Cuinnanata | (BTPS) | PR | E-RX | POST-RX | | Flow | | | | | |
|----------------|----------------|---------------|--------------|-------------------------|---------------|-------------|-------------|-------------------|-------------|-------------|--|
| Spirometry | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | | |
| FVC Liter | | 5.26 | 132 | | | ŧ | | | | | |
| FEV1 Lite: | rs 3.24 | 3.82 | 118 | | | 12 | | | | | |
| FEV1/FVC % | 81 | 73 | 89 | | | 12.7 | | | | | |
| FEF25~75%L/se | ec 3.40 | 2.87 | 84 | | | + | | | | | |
| FEF50% L/se | ec 4.15 | 3.71 | 89 | | | _ | <i>i</i> - | | | | |
| FEF75% L/se | ec 1.57 | 1.29 | 82 | | | 8⊹ | ; t | | | | |
| IC Lite | rs | | | | | 1 | 1 1 | | | | |
| VC Liter | rs 3.99 | | | | | | 1 | * | | | |
| PEF L/se | ec 8.14 | 9.08 | 112 | | | 4 | | Y. | | | |
| MVV L/m | in 139 | | | | | | | T | | | |
| PIF L/se | ec | | | | | Ť | į | 74 | | | |
| FEV1/FEV6% | | 76 | | | | 0 | | -1 + + | | ⊢ —- | |
| Luna Voli | umes/Pleth | ivsmoora | nhv | (BTPS) | | - | | | | | |
| *** | | , y 01110 910 | bus 1. A | | | † | | | | | |
| Vtg Lite | | | | | | -4 | | | | | |
| VC Liter | | | | | | • | | | | | |
| TLC Liter | | | | | | ŧ | | | | | |
| RV Liter | | | | | | -8 | | | | | |
| RV/TLC % | 35 | | | | | -0 T | | | | | |
| FRC PL Liter | | | | | | + | | | | | |
| ERV Liter | | | | | | 40 | | | | | |
| IC Lite | 18 | | | | • | ·12 -2 | 0 | 2 4 | 6 | 8 | |
| Diffusion | | | | | | -2 | v | Volume 4 | • | • | |
| | mmHg/min 23.6 | | | | | | | | | | |
| | mmHg/min 23.6 | | | | | | | | | | |
| | mHg/min/L 3.33 | | | | | | | | | | |
| VA Liter | | | | | | | | | | | |
| BHT Sec | | | | | | | | | | | |
| Resistanc | 26 | | | | | | | | | | |
| Raw Total cml | 12O/L/sec | | | | | | | | | | |
| Raw Insp cmł | 12O/L/sec | | | | | | | | | | |
| Raw Exp cml | 12O/L/sec | | | | | | | | | | |
| Raw cml- | 12O/L/sec 1,39 | | | | | | | | | | |
| | c/cmH2O 0.791 | | | | | | | | | | |
| | 12O/L/s/L 4.59 | | | | | | | | | | |
| | cmH2O/L 0.218 | | | | | | | | | | |
| Vtg (Raw) Lite | rs | | | | | | | | | | |
| | | | | Volume | | | | | | | |
| Commonte | | | | 8 \pm | | | | | | | |

Comments:



Interpretation.



2441 Ridgecrest Dr SE Albuquerque, NM87108

DOB

Lovelace S itific Resources Clin TrialsLevile Byatt 2441 Ridgecrest Dr SE

Final

REPORT STATUS

Client Nbr 24664

PAGE

1

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT IO RA, X PATIENT IO AAGG02

AAGG0250
COLLECT DATE & TIME

02/14/1966 M RECEIVE DATE & TIME

PRINT DATE & TIME

PHYSICIAN
Unlisted Physician,

PT, PHONE NO.

10/11/2013 13:15

10/11/2013 19:01

SEX

10/14/2013 06:10

REQUISITION NO. 30920911

0

PATIENT NO.

30920911

(

AKP 009

COMMENTS:

Domili

| | , R | esult | | | |
|----------------------|--|--|-----------------|----------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sódium | 137 | | mmol/L | 134-1 44 | |
| Potassium | 4.3 | | mmol/L | 3.5-5.1 | |
| Chloride | 103 | | mmol/L | 98-111 | |
| CO2 | 25 | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | 6-14 | |
| Glucose | 94 | | mg/dL | 60-100 | |
| BUN | 12 | | mg/dL | 7-31 | |
| Creatinine | 0.77 | | mg/dL | 0,62-1.66 | |
| | Creatinine method is IDMS | | | een adjusted | |
| | Please note new reference | range effective 5/23 | • | | |
| eGFR non-African Am | >60 | | mL/min/1.73m2 | >60 | |
| GFR Comment | | | | | |
| | Estimated GFR values are n | ot accurate in acute | Kidney Tallure | inpatients | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | , races other than C s, or amputations. | aucasian or Afr | ican American, | |
| Calcium | 9.7 | • | mg/dL | 8.4-10.4 | |
| Total Protein | 6.9 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.1 | | gm/dL | 3.4-4.7 | |
| Globulin | 2.8 | | gm/dL | 2.4-4.2 | |
| Billrubin, total | 1.0 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 60 | | U/L | 38-150 | |
| AST(SGOT) | 14 | | U/L | 6-58 | |
| ALT(SGPT) | 22 | | U/L | 14-67 | |
| Fasting | NO | | | | |
| Phosphorus | 3.5 | | mg/dL | 2.3-5.6 | |
| CBC | | | | | |
| WBC | 7.0 | | x10E3 | 4.0-10.6 | |
| RBC | 5.20 | | x10E6 | 4.64-6.00 | |
| Hgb | 15.7 | | gm/dL | 14.5-17.7 | |
| Hct | 46 | | ~ % | 42-53 | |
| MCV | 88 | | fL | 81-98 | |
| MCHC | 34.5 | | gm/dL | 31.2-35.2 | |
| RDW | 12.5 | | % | 11.0-14.5 | |
| Platelets | 247 | | x10E3 | 150 -4 00 | |
| Eos, Respiratory | | Few * | | NS | |
| Phys, Addr. Phone | Not given | | | | |

Caliback Accession Comments:

F3200806

AGAP, ALB, ALKP, ALT, AST, BUN, CA, CL, CO2, CREA, EOSR, FAST, GFRCOM, GFRW, GLOB, GLU, HCT, HGB, K, MCHC, MCV, NA, PLT, PO4, RBC, RDW, TBIL, TP, UNKPHY, WBC

10/12/2013 06:28 am FAXED TO 33488546 NC CS111533

End of Report

Mandring no 15 Oct 20:3

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

| | ~ |) | | | | ., | | | | | | | | | _ |
|--|---------------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|--------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|-----------|
| | , , , | 2 3 | 2 3 | 2 3 | 2 3 | NO | NO NO | | 2 3 | 2 3 | 2 3 | 2 3 | NO | NO | |
| | 9 | 0 1 | 0 | 0 | 0 1 | YES | YES | | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES | |
| N | 9 | 2 3 | 2 3 | 2 3 | 2 3 | (N) | ON) | | 2 3 | 2 3 | 2 3 | 2 3 | ON N | ON NO | |
| 112 | 6 | NE) | 0 | 1 | 9 | YES | YES | | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES | |
| | 72/3 | 100 | 2 3 | 2 3 | Ø 3 | O _N | NO | | (Q) 3 | 63 | Ø 3 | Ø 3 | S) | (S) | |
| | 7 | 0 1 / | 0 | ~ (O) | 0 1 (| (VES | XES | 7 | 0 1(| 0 1 | 0 1(| 0 | YES | YES | |
| ⊗ € D | 00% | m (%) | 2 33 | 2 3 | 03 | ON | 8 | | 60 | Ø 3 | е О | 3 | (2) | (N) | 7 |
| 3 | 101 | 13 | 0 1 | 0,1 | 0 1 (| ς <u>ά</u> λ | KES (| -2 | 0 1 (| 0 1 | 0 16 | 0 1 | YES | YES | |
| | 3/2/12 | 9(42) W | 8 | 2 3 | ® | ON | ON ON | | (2,3 | 2,3 | 3 3 | (Z) 3 | (N) | (Š) | |
| | 0 | 0 1 | 0 1 | (0) | 0 1(| KES (| (E) | ကို | 0 1 (| 0 7 | 0 10 | 0 1 (| YES | YES | |
| Mon | 1/04/13 | 2 3 | 2 3 | 2 3 | 2 3 | (8) | (S) | 4 | Ø 3 | Ø3 | 2 3 | Q 3 | (NO) | (2) | |
| ` ₹ | 70/ | | 9 | 9 | 0 1 | YES | YES | 7 | 0 1 | 0 1 | 0 1 | 0 1(| YES | YES | |
| ίΔI | 5//00/ | 8 | (Q) 3 | 2 3 | @ 3 | S S | ON ON | | 8 | 60 3 | 2 3 | 2 3 | 3 | (2) | |
| HOUR | <i>'</i> | 0 1(| 0 1 | (O) | 0 | (ES | (ES | -5 | 0 1 | 0 1 (| 9 | 9 | YES | YES | |
| SRY 12 | 5//3 | Ø 3 | Ø 3 | 2 3 | Ø 3 | ON NO | ON ON | (0) | (2) | 33 | 2 3 | 2 3 | 2 | ٤) | |
| USE EVI | 10/02/1 | 0 | 0 | (G) 1 | 0 1 | (ES | YES | 9 | 0 1 (| 0 7 | (G) (| (G ¹ | YES | YES | |
| ESPO | -1 10/01/3 | 2 3 | G 3 | 2 3 | m (2) | ON | ON NO | 7 | 8 | E (2) | 2 3 | 2 3 | 2) | E) | |
| MATE | 10/01 | 0 1 ② | 0 1 (2) | (S) | 0 1 🔇 3 | (YES | (YES | -7 | 0 10 | 0 1 (2) | (5) | 3 | YES | YES | |
| CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS | DAY AM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | SCALFOTOR |
| 미 | | œ 0 | ± 0 | ŬО | S _I | \ \ \ | | | α o | # O | υo | Sı | > > | ₽ > | v |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: # MOOG DATE COMPLETED: 10/4/13 - 10/11/13

SUBJECT INITIALS AND DATE: RA 10-11-13

4-4

SUBJECT INITIALS AND DATE: FA 10-17-13

9

YES

9

YES

2

YES

<u>g</u>

YES

9

YES

(2)

YES

8

YES

<u>ව</u>)

YES

ම

YES

Voice Hoarse

2

YES

9

YES

9

YES

9

YES

<u></u>

YES

6

YES

E)

YES

€)

YES

 $\mathfrak{E})$

YES

Throat Clearing

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

in Nextvient

Day 1-9.

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | 1 | | | | 1 | | | <u> </u> | | 1 | |
|----------|---------------------|----------------------|----------------------|------------------------------|--------------------|---------------------|------------------------|--------|----------------------|----------------------|----------------------|-------------------|
| | | 2 3 | 2 3 | 2 3 | 2 3 | 8 | 8 | | 2 3 | 2 3 | 2 3 | 2 3 |
| C | > | 5-4 | H | ₩ | ₹-1 | S | S | 0 | | | , · | |
| | | 0 | 0 | 0 | 0 | YES | YES | | 0 | 0 | 0 | 0 |
| | | m | က | m | m | 9 | QN ON | | 3 | m | m | m |
| c | یل ر | 2 | 7 | 7 | 7 | Z | 2 | | 7 | 2 | 7 | 7 |
| | ا ا ا | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES | | 0 1 | 0 1 | 0 1 | 0 1 |
| F | | | m | 3 | 33 | 2 | | | m | m | m | m |
| - | T. | 7 |) 2 | 7 | 2 | الغ | 3 | 4 | 2 | 7 | 7 | 7 |
| ' | + 101 | | 9 | 7 7 | 9 | YES | YES | ' | 1 | 17 | 7 | 4 |
| _ | | 6 | 0 | Ø | 0 | <u>}</u> | | ļ | 0 | 0 | 0 | 0 |
| | <u>9</u> | 2 3 | 2 3 | 2 3 | 2 3 | 8 | B | | 2 3 | 2 3 | 2 3 | 2 3 |
| ? | و | 1 2 | | - | \vdash | S | S | -2 | Н | ~ | Н | |
| L | ***** | 6 | ⊘ | (9) | ® | YES | YES | | 0 | B | <i>(9)</i> | Ø 1 |
| | 10 | m | m | m | 3 | 8) | £ | | 3 | m | m Δ | w. |
| ကု | <u>~</u> | 1 2 | 6 | 1 2 | Ø 2 | | | ကှ | 1 | \mathbb{G}_2 | $\frac{1}{6}$ | $^{1}\mathcal{C}$ |
| 10/15 | 6 | 20 | 0 | 0 | YES | YES | | 0 | 0 | 0 | 0 | |
| | | m | m | m | m | §) | 8 | | m | m | m | m |
| 4 | 7 | 2 | la _ | 2 | | | 4 | 0 | 2 | 10 | 02 | |
| | 101 | 0 | 0 | 0 | 0 | YES | YES | | 0 1 | 0 | 0 7 | 0 |
| | | m | m . | m | 2 | 9 | g) | | n | m | m | 23 |
| ιŅ | $\overline{\omega}$ | 7 | 0 | 2 | 2 | | | r. | 2 | 5 2 | 2 | 0 |
| | 10 13 | () | 0 1 | 0 | 0 | YES | YES | | 0 | (a) | © | 0 |
| | | m | m | e | m | <u> </u> | Ì | | 3 | m | m | 3 |
| φ | <u>2</u> | 7 | 7 | 2 | 7 | €) | | ٻو | $\frac{1}{2}$ | \mathcal{O} | 2 | $^{1}\mathcal{O}$ |
| 1, | 0 | \vdash | 5 1 | 1 | 1 | YES | YES | | | 1 | 0 | 1 |
| | | 2 3 🚳 | © ~ | <i>®</i> | 0 | | | | 0 | 0 | 0 | 0 |
| ~ | | 2 | 2 3 | 0 1 2 3 0 1 2 3 VES NO | | 9 | YES NO | | 0 1 Ø 3 | 0 1 Ø 3 | @ 1 2 3 | 0 1 2 3 |
| -را | 10/11 | $\overline{}$ | 0 | ₩- | \vdash | YES | SS | -7 | 7 (| - | | Θ |
| | بوسر. | 0 | 0 | 0 | 0 | - | | | 0 | 0 | © | 0 |
| | | d) | | ĺ | | မ | Throat Clearing Y/N | _ | a) | | | |
| DAY | AM | Nose | ose | tion | <u>5</u> 0 | loan | Clea | PP | Nose | ose | tion | වි |
| ò | 4 | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | oat | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing |
| | | Runny 0 to 3 | Itchy N 0 to 3 | Conge 0 to 3 | Sneezil 0 to 3 | Voic Y/N | Thro Y/N | | Runny 0 to 3 | Itchy N O to 3 | Conge 0 to 3 | Sneezi |
| | | | L | | J | | | V | | | | L |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

DATE COMPLETED: 10/11 //3 - 10/1/13 SUBJECT NUMBER: #K-2009



Lovelace Scle c Resources Clin TrialeLeshe Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME R-A, R-A

PHYSICIAN Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

30920899 COMMENTS:

0

PATIENT ID **AAGG2990** DOB 02/14/1960 SEX М

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

10/17/2013 14:00

RECEIVE DATE & TIME 10/17/2013 19:46 PRINT DATE & TIME 10/18/2013 06:07

PATIENT NO.

ACP009

NC3 Salyer 18 Oct 2013

Result

In Range

Out of Range

Rare

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr. Phone

Test

Not given

NS

End of Report

FAX24664

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| SCALE 0 to 3 | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | 0 to 3 | | Throat Clearing | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 12 | DAY AM | CIRCLE APPROXIVIA LE RESPONSE EVERY 12 HOURS |
|--------------|------------------------|---------------------|--------------------|----------------------|----------------------|----------------|-----|-----------------|---------------------|--------------------|----------------------|-------------------|------------------|-------------|--|
| | YES | YES | Ø 1 2 |) (a) 1 | @1 2 | ⊕ ₁ | 7 | YES | ΥES | 0 | | 2 | 90 | 11101 | WAIL |
| | (3) | (No | 2 3 | 2 3 | သ | u | | de de | | ر کاسی س | 2 3 | 2 3 | 1 2 3 | 7 | (ESPO |
| | ΥES | YES | @ 1 | 6 | @12 | ⊕ 1 2 | | YES | YES | 0 | <u>(</u> 0 1 | 0 🗘 2 | @ 1 | 10/18 | NSE EV |
| | (8) | (N) | <u>0</u> 123 | 2 3 | ω | ۷ 3 | | (3) | 6 | 0 0 2 3 0 1 2 3 | 2 3 | 2 3 | @123 | 97 | EKY 12 |
| | YES | YES | Ø 1 | @ 1 | () 1 | T @ | | YES | YES | (<u>a</u> | @ 1 | @ 1 | @123 | 10/19 | HOUK |
| | (3 | (ह ै) | Ø 1 2 3 | 2 3 | 2 3 | 1 2 3 |) | | 6 | 2 3 | 2 3 | 2 3 | 2 3 | 18 | 10 |
| | YES | YES | Ø 1 2 3 | © 1 | @12 | G | . 1 | YES | YES | @123 | © 1 | @ 1 | @123 | / D/ | |
| | 8 | 6 | 2 3 | 2 3 | 2 3 | 1 2 3 | . | (No | | 2 3 | 2 3 | 2 3 | 2 3 | 120 | |
| | YES | YES | Ø 1 | @ 1 | () 1 2 | (0) | | YES | YES | © 123 | @1 | @1 | @ 1 2 | 10/21 | |
| | ® | 8 | 123 | 2 3 | 2 3 | 1 2 3 | 11 | 8 | (No | 2 3 | 2 3 | 2 3 | 2 3 | 21 | |
| | YES | YES | D.0 | () 1 | 0 1 2 | (C) | 1 | YES | YES | 0 Œ | Q 1 | 0 (1) 2 | @1 2 | 10, | |
| | (ह) | (3) | 0 (1) 2 3 | 2 3 | ω | 1 2 3 | | 8 | (B) | ,2 3 | 123 | ,2 3 | ω | 12 10/22 | |
| | (3) | (B) | 61 | 6 1 | A 1 | 0 1 | | ŒS N | N SED | 0 12 3 10 1 2 | Ú 1 2 | @12 | 010 | 10/23 | |
| | ON | NO N | 2 3 | 2 3 | 2 3 | 163 | | NO | ON | 2 3 | 2 3 | 2 3 | (2 3 |) (S | |
| Ì | YES | YES | 0 1 | 0 1 | 0 1 | | | (Tes | (A) | @ 1 | @ 1 | G_{-1} | 0 1 | 107 | |
| | NO | N O | 2 3 | 2 3 | 2 3 | ک د | 1 | NO | NO | 2 3 | 2 3 | 2 3 | (2 3 | 24 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | C | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | ј ша | |
| | NO NO | NO | 2 3 | 2 3 | 2 3 | N | ì | NO | N O | 2 3 | 2 3 | 2 3 | 2 3 | 15 | |

SCALE U TO 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

DATE COMPLETED: 10/24/13

SUBJECT NUMBER: # 009

We A

SUBJECT INITIALS AND DATE: 24 16/24/13



1001 Woodward Pi. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scie Resources Leslie Byatt, Clm Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME RA, RA

PATIENT ID **AAGF1615**

DOB 02/14/1960 SEX REPORT STATUS M Final

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

10/24/2013 13:36

10/24/2013 18:13

10/25/2013 06:09

30920969

0

PATIENT NO.

Test

COMMENTS:

AKP009

Result

Out of Range

Rare

Mysell Subil

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

Not given

In Range

NS

End of Report

FAX24664

| | | | | <u>></u> | 7 | <u>~</u> | · >- | 2 | • | _> | - | | , | | - , |
|-----------------------|---|-------------------|---|-------------|---------------------|---------------|-----------|-----------|---------------|-------------|----------|------|---|--|---|
| | A | | Investigator Initials/Date | Mak 25 Edi. | | | | | | Me stoly | | | | * | |
| LSR Study #: | Subject Initials: \mathcal{R} - \mathcal{R} | | Action Taken | s non | Ç | non | 2000 | 100 | | DYZUS NON E | | | | e as specific as possible | Date: 27 Fd 2014 |
| LSR | Sub | 90 | ** End Date (DD/MMM/YYYY) | 2/0ct/20/8 | St/Nov/zor3 | exhov/2013 | CHNOWZORS | OTHONEOLS | , | MoVals | | | | should be made to be | Date: |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Surveiled | Surported | Sugarted | Susperted | Susperted | | Surgerted | | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | Max ais no |
| | | | SEVERITY | midd | Buld | 3 mild | Mild | m, 1 | | mi Id | | | | ite UNK in spac | X |
| 576 | AKPOOG | | ** Start Date (DD/MIMM/YYYY) | 18 | 1 | (3) Car (3013 | \geq | | 0se . | 1/00/2013 | | | | If day is <u>unknown,</u> wr | Investigator Signature (at end of study): |
| Study Identification: | Subject Number: | · | Adverse Event | Sore throat | Note no contraction | Bunning at | - 1 | Pre- | at to Otheron | application | 0 51 F.C | | | * | Investigator Sign |

Date: 4 Date:

10 Dydle
Lovelace Scientific Resources, Inc - AdverseEvents 04/2013

SC Signature (at end of study): UDM



Lovelace Scic c Resources Leslie Byatt, Cim Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME R-A, R-A

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID **AAGG2990** DOB 02/14/1960 REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician, **COLLECT DATE & TIME**

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

11/01/2013 09:50

11/01/2013 19:02

SEX

М

11/04/2013 06:13

30920886

0

PATIENT NO.

ACP009

COMMENTS:

| | Re | esult | | | |
|----------------------|--|--|-----------------------------------|---------------------------|-----------|
| Test | in Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Södium | 138 | | mmol/L | 134-144 | |
| Potassium | 4.1 | Nes gs 11/8/ | Mmol/L | 3.5-5.1 | |
| Chloride | 105 | Nes & III8 | 3 mmol/L | 98-111 | |
| CO2 | 26 | 744 | mmol/L | 20-30 | |
| Anion Gap | 7 | - Company | | 6-14 | |
| Glucose | | (104) H | mg/dL | 60-100 | |
| DUN | Impaired fasting glucose (100-126 mg/dl (ADA Guideli | nes Diabetes Care 26: | (3160-3167)200 | 13) | |
| BUN | 12 | | mg/dL mg/dL | 7-31 | |
| Creatinine | 0.78 Creatinine method is IDMS | traceshle EstGED Cal | | 0.62-1.66 een adjusted | |
| | Please note new reference | | | dell dajastaa | |
| CIMIN ALL A | | Tange errective 3/23/ | | . 00 | |
| eGFR non-African Am | >60 | | mL/min/1.73m2 | >60 | |
| GFR Comment | Estimated GER values are n | ot accurate in acute | kidnev failure | . inpatients | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | or underweight (BM), races other than Ca | MI<20) people, aucasian or Afr | rican American, | |
| Calcium | people with acute illnesse 9.2 | s, or amputations. | mg/dL | 8.4-10.4 | |
| Total Protein | 7.0 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.3 | Nes gs 11/8 | 7//3 gm/dL | 3.4-4.7 | |
| Globulin | 2.7 | | am/dL | 2.4-4.2 | |
| Bilirubin, total | | (1.3) H | mg/dL | 0.3-1.2 | |
| Alk Phos | 59 | | Ŭ/L | 38-150 | |
| AST(SGOT) | 12 | | Ü/L | 6-58 | |
| ALT(\$GPT) | 23 | | Ü/L | 14-67 | |
| Fasting | NO | | | | |
| CBC | | | | | |
| ЙВС | 6,2 | • | x10E3 | 4.0-10.6 | |
| RBC | 5.50 | | x10E6 | 4.64-6.00 | |
| Hgb | 16.0 | | gm/dL | 14.5-17.7 | |
| H čt | 48 | | % | 42-53 | |
| MCV | 87 | | fL. | 81-98 | |
| MCHC | 33.6 | | gm/dL | 31.2-35.2 | |
| RDW | 12.2 | | % | 11.0-14.5 | |
| Platelets | 248 | | x10E3 | 150-400 | |
| Eos, Respiratory | | (Few) * | | NS | |
| Phys, Addr, Phone | | NCS SS III | R/13 | | |
| | NO PHYSICIAN GIVEN | //w yk ''' | WfT | | |

End of Report

Jelalyer-PI NCS 8 Nov 2013

| LSR#; | Subject Initials: \mathcal{K} – \mathcal{M} | nd supplements. | 1, 15 % (25%) | (esn Julio Too) | | | | | | | | | 4102- | <i>- - - - - - - - - -</i> | PAGE: |
|-----------------------|---|---|--------------------------------------|-----------------|--------------|--------------|---|--|--|--|--|--|---|---------------------------------|---|
| | | OG medications, vitamins | * Start Date (Day/Month/Year) | UNICAUG/1999 | S65//- | 1993 | | | | | | * If day or month of medication date is unknown, write UNK in space provided | Date: 27 Fu | Date: 2/31/ | |
| | | CONCOMITANT MEDICATION LOG | Frequency Route | 2 Tabs per Oral | QD Oral | 0. PD. | | | | | | nknown, write UN | J 100 | | nc - ConMeds 04/2013 |
| | 1 | NCOMITANT N | Unit Freq | MG | MB G | 8 F | • | | | | | dication date is <u>u</u> | Mulai | Byde | Lovelace Scient& Resources, Inc - ConMeds 04/2013 |
| | | COI | Dose | 200 | 1 / | (D) | | | | | | nonth of me | | Lale | Lovela |
| 2749 | 600 22 | CONCOMITANT MEDICATION LOG List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. | Indication (What you take it for) | Diabetes | Dietary | Spudachs | | | | | | * If day or m | e (at end of study): | SC Signature (at end of study): | |
| Study Identification: | Subject Number: | List all | 76 127 | EXAMPLE | nultivitamin | 15.4 15.4 | | | | | | | Investigator Signature (at end of study): | SC Signatuı | |

i

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| , [| <(| ~ ~ | o s | 0 0 | 0 = | 0 37 | | ~ | ~ <i><</i> | 0 0 | 0 0 | 0 = | 0 70 | | |
|------|-----------------|---------------------|--------------------|-------------------|----------------------|----------------------|--------|---------------------|---------------------|--------------------|-------------------|----------------------|-------------------------|----------------------------|-----|
| 2001 | Throat Clearing | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | D/ | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | | _ |
| | t Cle | Ноа | ing | estio | Nose | / No: | DAY PM | t Cle | Hoa | ing | estio | Nose | / No: | M | DAY |
| , | arin | rse | | n | | se | Z | arin | rse | | ח | ,,, | se | | - |
| - | | | (2 | Ø | <u>(</u> | 8 | | | | 0 | 0 | 0 | | _ | |
| | YES | YES | Q 1 | 1 | 3 1 | @12 | 14 | YES | YES | 1 | | | | 10/24/13 10/25/13 10/26/13 | 1 |
| | 8 | B | 2 | 2 | 2 | 2 | 4 | 130 | - N | 2 | 2 | 2 | 123 | 7 | 14 |
| F | | | 3 | 3 (| 3 | 3 3 | | | | 3 @ | 3 | 3 | 3 | W | |
| | YES | YES |) 1 | Ø 1 | (S2 1 | 9 1 | | YES | YES |) 1 | 1 | 1 | 1 | 0 | 1 |
| | Ø | SÉ | 2 | 2 | 2 | 1 2 | 15 | 8 | (3) | 2 | 2 | 2 | 1 2 | 152 | 15 |
| - | | | w | 3 | ω | ω | | | | 3 (| ω | 3 (| <u> </u> | ũ | |
| | YES | E | 0 C | 0 \$ | 0 # | 0 | ۱۱ | YES | YES | Ø 1 | Ø | Ø 1 | 0 6 2 3 | 201 | |
| | B | ON | Ø 2 | 2 | 2 | Ø 2 | 16 | (3) | 8 | 2 | 2 | 2 |) 2 | 10% | 16 |
| - | | | 3 | 3 | ω | ω | | | | ω | 3 | 3 | 3 (| W | |
| İ | ΥES | YES | 0 & | 0 () | 0 | 0 @ | | YES | YES | 0 | Ø 1 | Ø 0 | 6 1 2 3 | 10/27/13/10/28/13 | |
| | | (B) | W 2 |) 2 | 2 | 2 | 17 | | æ | 2 | 2 | 2 | 2 | 72/ | 17 |
| L | § | | 3 | w | 3 | 3 | | 6 | <u>(5</u> | ω | ω | 3 | 3 (| w | |
| | YES | YES |) 1 | Ø 1 | 6 | <i>Q</i> 1 | | YES | YES | O 1 | 9 1 | <i>(</i>) 1 | <u>6</u> 1 | 0 | |
| | | ٩ | 1 2 | 1 2 | 1 2 | 12 | 18 | ł | | _ 2 | . 2 | 2 | 123 | 182 | 18 |
| | ₹ | B | ω | 3 | 3 | 3 | | ₩ | 8 | 3 | ω | 3 | ω | 13 | |
| | ΥES | YES | 0 | Ø | 0 2 | 0 | | YES | YES | Ô: | (h) 1 | D 1 | <i>Q</i> , , | 19/29/13 | |
| | | | € 2 | 1 2 |) (1) 2 | 1 2 | 19 | | | 1 2 | 1 2 | 1 2 | 1 2 | 729 | 19 |
| | <i>§</i> | Ğ, |) ω | 3 | 3 | ω | | 8 | OKA) | ໍ່ນ | ω | ω | ω | //3 | |
| | ΥES | YES -ر | 6 | Ô | Ó | Ø | | YES | YES | 0 (| Ø | 0 (| B | ~ | |
| | | Ò | 1 2 | 1 2 | 1 2 | 1 2 | 20 | | \sim | @ 2 | 1 2 | Ø 2 | 1 2 | 3 | 20 |
| | <i>₹</i> | ि | З | သ | 3 | ω | | (g) | B | 3 | သ | ω | ω | /3 | |
| | ΥES | ΥES | 0 /1 | B | 0 | 9 | | ΥES | YES | 19 | B | 9 | Ø | 79 | |
| | | | 1 2 | 1 2 | 1 2 | 1 2 | 21 | I | | 1 2 | 1 2 | 1 2 | 1 2 | '31, | 21 |
| | 8 | Ö | ω | ω | 3 | ω | | 8 | B | ω | ω | ω | ω | /13 | |
| | YES | ΥES | 0 | 0 | 0 | 0 | | YES | ΥES | 0 | 0 | 0 | 0 1 2 3 0 1 2 3 0 1 2 3 | 11/ | |
| | | | 1 2 | 1 2 | 1 2 | 1 2 | 22 | | | 10 | 1 2 | 10 | 1 2 | 01/ | 22 |
| | O | N O | ω | ω | ω | ω | | 6 | € | w | ω | ω | ω | (J ₂) | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living

Y=Yes N= No

SUBJECT NUMBER: AKPO 09

DATE COMPLETED:

SUBJECT INITIALS AND DATE: FA 11-1+13

Em 11/01/13

R-A /AKPOO9 11/01/13

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE: Would you use / purchase this nasal wash product in the future?" ☐YES ☐NO You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: Sinus irritation after using spray

AKP-010

2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| | Initials: CHA Site #: Subject #: OI |
|---------------|---|
| PATIENT | <u>DEMOGRAPHICS</u> |
| Patient D | omographics - |
| | |
| Date of Bi | th: $O(1) J(1) / 1950$ (dd/mmm/yyyy) Male \Box Female |
| Gender: | Male |
| If female, l | ndicate Childbearing Potential VIA |
| | Childbearing Surgically sterilized Post-Menopausal |
| Ethnicity | Hispanic Non Hispanic |
| | • |
| Race: | Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| | |
| Smoking l | <u> Listory</u> |
| Smoking S | atus: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| If subject is | a former or current smoker, please indicate: |
| Year | smoked: 10 Cigarettes per day: 1pk per c |

Version: 02 September 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scie c Resources Clin TrialsLesive Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

PATIENT NAME CHA, X

PATIENT ID **AAGF1636**

07/06/1956

SEX REPORT STATUS Final

PAGE 1

PHYSICIAN

Unlisted Physician. REQUISITION NO.

COLLECT DATE & TIME

RECEIVE DATE & TIME 09/25/2013 20:13 PRINT DATE & TIME

PT. PHONE NO.

09/25/2013 11:40 PATIENT NO.

09/27/2013 06:08

30920891

0

COMMENTS:

AKP010

| COMMENTS: | | | | |
|-----------|--------|------|--|--|
| | MANACO | ENTS | | |

| Test |
|-----------------------------------|
| Allerg,Panel 18 Allerg,Juniper |
| Allerg, Juniper |
| Allerg, Cottonwood |
| Allerg, West. Ragweed |
| Allerg, Russian This |
| Allerg, Bermuda Grass |
| (Allerg,Alternaria) |
| Allerg, Mesquite |

Allerg, Cockroach Allerg, Derm. pter.

| | Result | | | | |
|----------|------------|----|-------|-----------------|-----------|
| In Range | Out of Ran | ge | Units | Reference Range | Site Code |
| | 5.80 | Н | kU/L | <0.35 | |
| 0.30 | 0.00 | ,, | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| | 1.00 | Н | kU/L | <0.35 | |
| | 5.60 | Ĥ | kÚ/L | <0.35 | |
| | (1.40) | Ĥ | kU/L | <0.35 | |
| 0.30 | | | kU/L | < 0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |

The standard classification system utilizes the following class cutoffs. class ku/t. Interpretation

| Class | KU/ L | Tires bi eracion |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| V | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| · · · · · · · · · · · · · · · · · · · | rimical aftergy. | | | | |
|---------------------------------------|------------------|-------------|---|------|--------|
| Allerg, Derm. farinae | 0.10 | | | kU/L | <0.35 |
| Allerg, Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allera Firebush | | <u>0.70</u> | H | kU/L | <0.35 |
| Allerg, Cat Dander Ep | | (0.60) | Н | kU/L | < 0.35 |
| Allerg, Dog Dander | | (17.80) | Н | kU/L | <0.35 |
| Allerg, Bluegrass | | 2.00 | Н | kU/L | < 0.35 |
| Allerg, Pigweed | 0.10 | | | kU/L | < 0.35 |
| Allerg, Mulberry | <0.10 | | | kU/L | < 0.35 |
| Allerg, Helminth | <0.10 | | | kU/L | < 0.35 |
| Phys, Addr. Phone | Not given | | | | |

Inmuno CAP testing confirms reactivity to berennial

aero aller gens, mold (all ternaria), Cat dander 4-epi thelium

and dog dander. Mee to laboratory inclusion criteria

CHA, X

09/27/2013 06:08

Salyer

27 Sept 2013

CHA, X



Loyelsce Scientific Mosources 2461 Midgerrest Dr SE Altaquerges, NM 17108

Name: CHA, Gender: Male

Age: 57 Ra Height(in): 72.0

Race: Caucasian

Any Info:

Weight(lb): 246

Id: AKP-010 Date: 10/31/13

Temp: 21

PBar: 631

Physician:

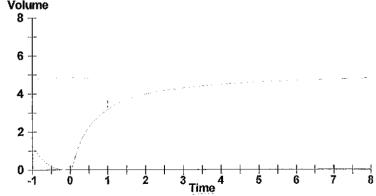
Technician: VL

| any inio: | | | | | | | I GOLLILOIG | III. V L | | | | | |
|--------------|---------------|---------|-------------|--------------|--------------|---------------|---------------|------------------|-----|-------------|-------------------|---|--|
| | (B | TPS) | PRI | E-RX | POS | T-RX | | Flow | | | | | |
| Sparate in | i v | Ref | Pre Meas | Pre % Ref | Post Meas | Post % Ref | Post % Chg | 16 | | | | | |
| FVC | Liters | 4.96 | 4.85 | 98 | | | _ | ţ | | | | | |
| FEV1 | Liters | 3.99 | 3.21 | 81 | | | | 40 | | | | | |
| FEV1/FVC | | 80 | 66 | 83 | | | | 12 | | | | | |
| FEF25-759 | | 4.01 | 1.98 | 49 | | | | 1 | | | | | |
| FEF50% | L/sec | 4.89 | 2.42 | 50 | | | | | | | | | |
| FEF75% | L/sec | 1.88 | 0.83 | 44 | | | | 8⊹ | | | | | |
| IC | Liters | 1.00 | 0.00 | 7-7 | | | | | | | | | |
| | Liters | 4.96 | | | | | | † | 1 " | | | | |
| VC | | | 7.87 | 86 | | | | 4 | ! | 1. | | | |
| PEF | L/sec | 9.20 | 1.01 | 00 | | | | 7 | 1 | 14 | | | |
| MVV | L/min | 151 | 0.62 | | | | | + | i | In . | | | |
| PIF | L/sec | | 69 | | | | | _ | } | 100 | | | |
| FEV1/FEV | | | | | (13 | TPS) | | 0. | j | | | — | |
| | eolinnes/E | Helitys | rright: | My | (5 | irə) | | + | | | | | |
| Vtg | Liters | | | | | | | -4 | | | | | |
| VC | Liters | 4.96 | | | | | | | | | | | |
| TLC | Liters | 7.18 | | | | | | ļ. | | | | | |
| RV | Liters | 2.46 | | | | | | _ | | | | | |
| RV/TLC | % | 36 | | | | | | -8 + | | | | | |
| FRC PL | Liters | 3.55 | | | | | | | | | | | |
| ERV | Liters | | | | | | | T | | | | | |
| IC | Liters | | | | | | | -12 [⊥] | | | | _ | |
| Ölffusi | | | | | | | | -12 -2 | 0 | 2 Volume | 6 | 8 | |
| DIAC | | 00.0 | | | | | | | | volume | | | |
| DLCO | mL/mmHg/min | | | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | | |
| | mL/mHg/min/L | 3.24 | | | | | | | | | | | |
| VA_ | Litera | | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | | |
| Maniet | | | | | | | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | | | |
| Raw | cml-l2O/L/sec | 1.27 | | | | | | | | | | | |
| Gaw | L/sec/cmH2O | 0.852 | | | | | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.49 | | | | | | | | | | | |
| sGaw | | 0.223 | | | | | | | | | | | |
| Vtg (Raw) | | | | | | | | | | | | | |
| | | | | | Volu | ne | | | | | | | |
| ********* | | | | | 8 - | - | | | | | | | |
| - John Holes | 2.50 | | | | | | | | | | | | |

Norm Set: Knudson (1983)



la de communicación



Name: CHA, Gender: Male

Age: 57 Race: Caucasian Height(in): 72.0 Weight(lb): 246

Any Info:

Id: AKP-010 Date: 11/07/13

Temp: 19

PBar: 639

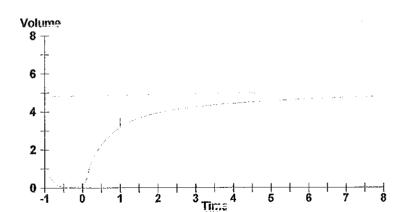
Physician:

| • | ,,, | OIOIOII. | |
|---|-----|----------|----|
| T | eo | hnician: | ٧L |

| \ny into: | | | | | | i echnicia | ın: VL | | | | | |
|---------------------------------------|---------------------------------------|---------------------|--------------------|-----------|-------------------|---------------|-----------------|-----|---------|-----|-------------|--|
| 1 1 1 1 1 1 1 1 1 1 | (B | TPS) Ref | PRE Pre Moen | Pro | Post-RX Post Post | Post % Chg | Flow 16 T | | | | | |
| FVC FEV1 | Liters | 4.96 0.69 | 4.99 3.21 | 100 80 | | _ | 12 | | | | | |
| FEVOR: | <u>,C %</u> | 30 | 04 | 81 | | | 12 T | | | | | |
| FEF25-7 | E0/1 /000 | 4.01 | 1,7€ | 44 | | | + | | | | | |
| FET50% | L/sec | 4.89 | 2.28 | 47 | | | | | | | | |
| FEF /5% | | 1.88 | 0.63 | 33 | | | 8 † | 73 | | | | |
| IC | Liters | | | | | | 1 | ; ; | · . | | | |
| VC | Liters | 4.96 | | | | | i | ; | 1 | | | |
| PEF | L/sec | 9.20 | 8.69 | 94 | | | 4 🕂 | - 1 | N | | | |
| MV∨ | L/min | 151 | | | | | | į. | N | | | |
| PIF | L/sec | | 1.57 | | | | Ť | i | , | | | |
| FEV1/FE | TV/Q0/. | | 69 | | | | 0 | 1 / | · | n-p | ⊢ —! | |
| 13-15 | Maria sanga | ar in the | नंतरभूत्र व | 1 (1) | (BTPS) | | + | | 4.1 | .f | | |
| Vtg | Litors | | | | | | | | | | | |
| VČ | Liters | 4.96 | | | | | -4 † | | | | | |
| TLC | Liters | 7.18 | | | | | Ţ | | | | | |
| RV | Liters | 2.46 | | | | | | | | | | |
| RV/TLC | % | 36 | | | | | -8 🕴 | | | | | |
| FRC PL | Liters | 3.55 | | | | | 1 | | | | | |
| ERV | Liters | | | | | | Ţ | | | | | |
| IC | Liters | | | | | | -12± -2 | _ | | _ | _ | |
| (Million) | Spring v | | | | | | -2 | 0 | Volume⁴ | 6 | 8 | |
| DLCO | mUmalighain | 20.3 | | | | | | | veiums | | | |
| DL Adj | ml/mmHa/min | 20.3 | | | | | | | | | | |
| | mL/mmHg/min | 22.0 | | | | | | | | | | |
| ÷Α | Liters | 20 | | | | | | | | | | |
| ВНТ | 8 | | | | | | | | | | | |
| Qasi. | - | | | | | | | | | | | |
| | • • | | | | | | | | | | | |
| Paur Tok | | | | | | | | | | | | |
| | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | | | | | | | | | | | |
| , | | . ~7 | | | | | | | | | | |



Gaw sPow



Integrated air air



Lauripos Sciencias Acerson read this received the St. Abovernoons was bress

Name: CHA, Gender: Male

Race: Caucasian Age: 57 Height(in): 72.0

Weight(lb): 246

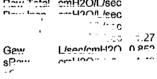
Id: AKP-010 Date: 11/14/13

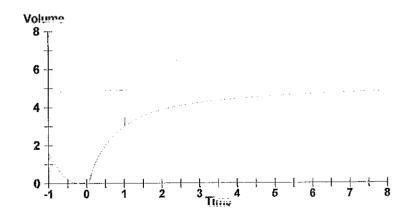
Temp: 20

PBar: 632

Physician: Technician:

| Any Info: | | | | | | i echnicia | ın: | | | | , | |
|------------------------|--------------------------|--------------|--------------------|---------------------|------------------------------|---------------|---------------------|-------|----------|---|----|--|
| proved | (B. | Ref | ppg Pre Mons | FRX Pre % Ref | POST-RX Post Post Meas % Ref | Post % Chg | Flow 16 † | , | | | | |
| FVC FEV | Liters | 4.9ú | 4.51 | 99 70 | | v | 12 | | | | | |
| | | 3 0 | 32 | 77 | | | | | | | | |
| FEF25-75 | | 4 01 | 1.70 | 42 | | | † | | | | | |
| FEF50% FEF75% IC | L/sec L/sec Liters | 4.89 1.88 | ** 2.10 0.69 | ** 43 37 | | | 3 | /\ | | | | |
| VC PEF | Liters L/sec | 4.96 9.20 | 7.94 | 86 | | | 4 | | | | | |
| MVV PIF | L/min L/sec | 151 | 1.58 65 | | | | | | | | | |
| FEV1/FEV | 6% Yasamaka, A | de thy r | | | (BTPS) | | 0 ' | [- 1 | 100 7 | | —' | |
| Vtg VC | Liters Liters | 4.96 | | | | | -4 | | | | | |
| TLC | Liters | 7.18 | | | | | ţ | | | | | |
| RV | Liters | 2.46 | | | | | -8∤ | | | | | |
| RV/TLC | % | 36 | | | | | -6 | | | | | |
| FRC PL | Liters | 3.55 | | | | | † | | | | | |
| ERV | Liters | | | | | | .12 | | | | | |
| IC Uliantes | Liters | | | | | | -12 -2 | 0 | Volume 4 | 6 | 8 | |
| DLCO | mL/mml/g/min | 29.3 | | | | | | | | | | |
| DL Adj | mL/mmHg/min | 29.3 | | | | | | | | | | |
| | -m! /m! lg/min/l | 0.25 | | | | | | | | | | |
| VA BHT | Liters Scr | | | | | | | | | | | |
| हेंचे स्टब्स र | (2) (\$1.5) (C | | | | | | | | | | | |
| Pau Total | cmH2O/L/sec | | | | | | | | | | | |





Interpretation





Name: CHA,

Gender: Male Age: 57

Race: Caucasian

Height(in): 72.0

Weight(lb): 246

Any Info:

Id: AKP-010 Date: 11/21/13

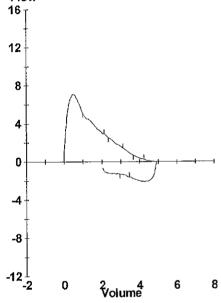
Temp: 21

PBar: 630

Physician:

Technician: VL

| • | | | | | | | |
|---|----------------|-------------|-------------|------------|-------|--------------------|----------|
| | | (BTPS) | PRE-RX | POST-RX | | Flow | |
| | Spirometry | Ref | Pre Pre | Post Post | Post | 16 T | |
| | | | Meas % Ref | Meas % Ref | % Chg | | |
| | FVC Liters | 4.96 | 4.96 100 | | | 1 | |
| | FEV1 Liters | 3.99 | 3.16 79 | | | 12 | |
| | FEV1/FVC % | 80 | 64 80 | | | 14 | |
| | FEF25-75%L/sec | 4.01 | 1.84 46 | | | + | |
| | FEF50% L/sec | 4.89 | 2.45 50 | | | | |
| | FEF75% L/sec | 1.88 | 0.67 36 | | | 8 🛉 | |
| | IC Liters | | | | | 1 | \wedge |
| | VC Liters | 4.96 | | | | | |
| | PEF L/sec | 9.20 | 8.73 95 | | | 4 ∤ | |
| | MVV L/min | 151 | | | | j | 1 |
| | PIF L/sec | | 2.07 | | | † | |
| | FEV1/FEV6% | | 68 | | | 0 | |
| | Lung Volum | ee/Plethye | mography | (BTPS) | | • | <u></u> |
| | _ | icon icuryo | iilograpiiy | | | † | |
| | Vtg Liters | | | | | -4 ¹ | |
| | VC Liters | 4.96 | | | | | |
| | TLC Liters | 7.18 | | | | + | |
| | RV Liters | 2.46 | | | | | |
| | RV/TLC % | 36 | | | | -8 | |
| | FRC PL Liters | 3.55 | | | | 1 | |
| | ERV Liters | | | | | Ī | |
| | IC Liters | | | | | -12 [⊥] _ | _ |
| | | | | | | | ^ ^ |



Resistance

Diffusion DLCO mL

DL Adi

VA

BHT

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 sRaw
 cmH2O/L/s/L

 sGaw
 L/s/cmH2O/L

 L/s/cmH2O/L
 0.223

DLCO/VA mL/mHg/min/L 3.24

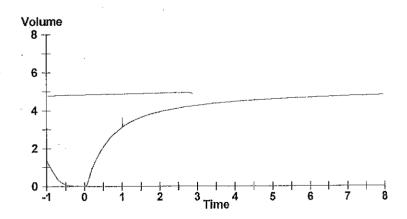
Liters

Sec

mL/mmHg/min 29.3 mL/mmHg/min 29.3

Vtg (Raw) Liters

Comments:



Interpretation:



Lovelace S itific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME CHA, CHA

PATIENT ID **AAGH0028**

COLLECT DATE & TIME

07/06/1956

REPORT STATUS Final

PAGE 1

PHYSICIAN

Unlisted Physician. REQUISITION NO. PT. PHONE NO. 10/31/2013 14:38

RECEIVE DATE & TIME 10/31/2013 20:48 PRINT DATE & TIME 11/01/2013 06:06

30920901

PATIENT NO.

AKP010

| COMMENTS: | CON | MME | NTS | ; |
|-----------|-----|-----|-----|---|
|-----------|-----|-----|-----|---|

| ラ | U | ANPU' |
|-----------|---|-------|
| MANAGNITO | | |

| | · F | lesult | | | |
|----------------------|---|--|-----------------------------------|----------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 140 | 4.0 | mmol/L | 13 4 -144 | |
| Potassium | 3.8 | NCS. | mmol/L | 3.5-5.1 | |
| Chloride | 105 | 06 11/1/2 | mmol/L | 98-111 | |
| CO2 | 25 | בנונוי נוצ | mmol/L | 20-30 | |
| Anion Gap | 10 | 477 | | 6-14 | |
| Glucose | | 107 (H) | mg/dL | <u> 6</u> 0-100 | |
| DUN | Impaired fasting glucose (100-126 mg/dl (ADA Guidel | (1FG) is defined as a ines Diabetes Care 26: | (3160-3167)200 | 3) | |
| BUN | 14 | | mg/dL | 7-31 | |
| Creatinine | 1.10 Creatinine method is IDMS | troscoble Estero es | mg/dL IsuTandan bas b | 0.62-1.66 | |
| | | | | een aujusteu. | |
| | Please note new reference | range effective 5/23, | | | |
| eGFR non-African Am | >60 | | mL/min/1.73m2 | >60 | |
| GFR Comment | Fetimeted CFD values and a | and necessary in neutra | kd dnov dod Tuno | donationto | |
| | Estimated GFR values are non IV fluids, obese (BMI>: the very old or very young people with acute illness | 34) or underweight (BI 3, races other than Ca | MI<20) people, aucasian or Afr | ican American, | |
| Calcium | people with acute illnesse 9.2 | es, or amputations. | ma(dl | 5 4 40 4 | |
| Total Protein | 6.9 | | mg/dL gm/dL | 8.4-10.4 6.1-8.2 | |
| Albumin | 3.9 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.0 | | gm/dL | 2,4-4.2 | |
| Bilirubin, total | 0.4 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 67 | | U/L | 38-150 | |
| AST(SGOT) | 18 | | Ŭ/L | 6-58 | |
| ALT(SGPT) | 34 | | Ú/Ľ | 14-67 | |
| Fasting | NOT GIVEN | | | 1.4.01 | |
| CBC | | | | | |
| УУВС | 9.0 | | x10E3 | 4.0-10.6 | |
| RBC | 5,36 | | x10E6 | 4.64-6.00 | |
| Hgb | 15.8 | | gm/dL | 14.5-17.7 | |
| Hčt | 48 | | % | 42-53 | |
| MCV | 89 | | fL. | 81-98 | |
| MCHC | 33.0 | · | gm/dL | 31.2-35.2 | |
| RDW | 13.0 | | % | 11.0-14.5 | |
| Platelets | 236 | | x10E3 | 150-400 | |
| Eos, Respiratory | None seen | | | NS | |
| Phys. Addr. Phone | NOT GIVEN | | | | |

End of Report

Salyer-PI 1 Nov 2013

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| Š | ₹ # | Y/N V \oig | οñ | ο Ŭ | 0 7 | 0 20 | | くせ | V/N Voic | o ñ | 0 Ŭ | ㅇ ㅠ | 0 2 | | |
|--------------|------------------------|---------------------|--------------------|----------------------|----------------------|----------------------|--------|-----------------|---------------------|--------------------|-------------------|----------------------|----------------------|-------------------|-----|
| SCALE 0 to 3 | Throat C Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 ta 3 | DAY PM | Throat C | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | AM | 7,7 |
| 0 to 3 | Throat Clearing Y/N | barse | 04 | ion | še. | lose | PM | Throat Clearing | oarse | , oq | ion | se | lose | S | < |
| | YES | YES | 0 | 1 | 0 | 0 | | () |) E | (E) |), 0 | 9 | 0 | 10/ | _ |
| | UN NO | (S | 1 2 3 | 1 0 3 | 2 3 | 0 1 🙋 3 | -7 |) NO | No | 1 2 3 | 1 (2)/3 | Ø1 2 3 | 1 2 (3) | 1/2/01 | 7 |
| | ES |) YES | °(1) | 0 | ļ. <u></u> | | | YES | YES | <u> </u> | 0 | 0 | | _ <u>_</u> | |
| | S NO | S | $\binom{1}{2}^2$ 3 | 12(| 0 2 3 601 | 01280123 | -б | S MO) |) (NO) | 0(1)2 | 12(| D2 3 | 0 1 (2)3 | 10/25/13 (42/13 | v |
| | | ~ | , ss , ss | 0 | 3 (6) | 30 | | | | 3 | (3) | 3 (A) | 3 0 | G. | _ |
| | YES 1 | YES 春 | (A) 12 | 1 (25) | \(\frac{1}{2} \) | 1 2 | փ | (ÝES) | YES (| ①2 | | ¥ 2 | 0 1(2)3 | 92% | п |
| | NO | | 2 3 | ω | ω | | | NO O | É | 3 | (B) | 3 | | d(3 | |
| | YES | YES | (b) 1 | 0 1 | 6 | 0 1 (2) | -4 | |) YES | (O) | 28)016 | (D) | 0 1 | 10/2 | |
| | ON |) (F | (b) 1 2 3 | 2(3) | 2 3 | | | NO | (o) | 2 3 | 2)3 | 2 3 | 0 1233 | 2//13 | - |
| | YES | YES | | 0 1 | 0 | \bigcirc 1 | | YES | YES | 0 | 0 | ٥ | 0 1 | 10/2 | |
| | 8 |) (3 |) 2 3 | © 3 | 2 3 | 1 2 3 | ψ | O | |) 3 | 0 1 2((3) | ις ω (| 0 1 2(3) | 10/27/13 10/28/13 | ן נ |
| | YES | YES | <u>O</u> 1 2 | 0 1 | <u>Ф</u> 1 | 0 1 | | (ES | YES | 0(1) | 0 | (b) | 0 | ~0 | |
| | (S) | (E |) ² ω | 28 | 2 3 | 1 2(3) | -2 | NO | (No | 2 3 | 2(3) | 2 3 | €)3 | 129/13 | נ |
| | YES | YES | 6 | 0 | (b) | 0 | | (YES | YES | 0 | 0 | (a) | 0 1 | 10% | i |
| | (Z) |) (E |) ~ ს | (N) 3 | 2 3 | 2 3 | 1 | NO | (F) |)23 | 2 (3) | 2 3 (5) | 2(3) | 30/13 | , |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES |) K | (I) | 0 | (S) | 0 1 | ō | |
| | NO | N O | 2 3 | 2 3 | 2 3 | 2 3 | | NO | (Z) | 2 3 | [] 3 | 2 3 | (2) | 3//2 | 1 |
| | ΥES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 | 0 1 | 0 1 | × | |
| | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 0 | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 5 / 12 | 1 |

CALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No AK

SUBJECT NUMBER: 0

DATE COMPLETED: 10/31/13

SUBJECT INITIALS AND DATE:

19/2/18

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 7 7 7 | - | ۲ | 7 | • | ш | 9 | 1 | c | |
|------------------------|-----------|-----------|-----------|------------|----------------|----------------|----------|-----------|---------|
| | 16/2: /- | | 7.17 | 707/21 | 11/2/11 | 11/2/1. | , , ; ; | | 178/11 |
| AM | 12/13 | /10/1 | 21/20/, 8 | 3 11/69/13 | 1/204(15 | 1,00113 | 7,007 | (1/07) | c/ko/, |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 🗇 2 3 | 0 1 3 | 0 1 2 3 | 0 (1) 2 3 | ó 📞 3 | O(1) 2 3 | 0 (1) 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0 2 3 | 0123 | 0123 | 0123 | 1 2 3 4 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 位 2 3 | 0 1 2 (8 | 0 1(2) 3 | 0 1(2) 3 | 0 1 2 3 | 0 [1] 2 3 | 0 1(2) 3 | 0 1 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1/2 3 | Q 2 3 | . 6)1 2 3 | 0123 | 6 1 2 3 | Ø 1 2 3 | 0(1) 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (0) | YES (MO | YES (NO | YES (NO | YES NO | YES (NO | VES (NO | YES NO |
| Throat Clearing Y/N | YES NO | YES NO | YES NO | NO (| YES NO | YES (NO | YES (NO) | YES NO | YES NO |
| DAY PM | 1 | 7 | w. | 4 | ro, | 6 | 7 | ∞ | 6 |
| Runny Nose 0 to 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0(1) 2 3 | 0 (1) 2 3 | 0 1 2) 3 | 0(1)23 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose (0 to 3 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 | 01 2 3 | Ø 1 2 3 | 0 1 3 | 0123 | 0 1 2/3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 (2)3 | 0 1 (2) 3 | 0 1 2(3 | 0 1 2 3 | 0 1 2 3 | o Y 🖭 3 | 0 11 2 3 | 0 1/2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 6)123 | 0 1 2 3 | (0)1 2 3 | 0123 | Ø1 2 3 | 0123 | 01 2 3 | 0 1/2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | VES (MO | YES (NO | YES (NO | YES (NO | YES NO | YES NO | YE\$ NO | YES NO |
| Throat Clearing Y/N | NO (SJ) | ON, SEV | NES NO | (KES) NO | YES (NO | (YES) NO | YES (NO | v£s no | YES NO |
| | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) $Y=Yes\ N=No$

SUBJECT NUMBER: ALL

DATE COMPLETED:

SUBJECT INITIALS AND DATE: 🛚



Lovelace Scie © Resources Leslie Byatt, Cmr Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID **AAGH3323**

DOB 07/06/1956 SEX REPORT STATUS Final

PAGE 1

Site Code

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 11/07/2013 14:30

RECEIVE DATE & TIME 11/07/2013 20:29 PRINT DATE & TIME 11/08/2013 06:06

REQUISITION NO.

PATIENT NAME

X, CHA

PT. PHONE NO.

PATIENT NO.

30920956

O

AKP010

COMMENTS:

Glucose

Creatinine

BUN

Result Test Out of Range Units In Range Reference Range Comp Metabolic Panel Sodium 139 mmol/L 134-144 Potassium 4.0 mmol/L 3.5-5.1 Chloride 107 mmol/L 98-111 CO2 21 mmol/L 20-30 Anion Gap 11

> 13 mg/dL 7-31 mg/dL 1.02 0.62-1.66 Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

Please note new reference range effective 5/23/2013.

eGFR non-African Am **GFR Comment**

84

mL/min/1.73m2

x10E3

mg/dL

>60

11.0-14.5

150-400

NS

6-14

60-100

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium 8.5 mg/dL 8.4-10.4 **Total Protein** am/dL 6.8 6.1-8.2 Albumin 3.9 gm/dL 3.4-4.7 Globulin 2.9 gm/dL 2.4-4.2 Billrubin, total 0.4 mg/dL 0.3-1.2 Alk Phos 69 Ū/L 38-150 AST(SGOT) 19 U/L 6-58 ALT(SGPT) 30 U/L 14-67 NO Fasting Phosphorus 2.8 mg/dL 2.3-5,6 CBC ЖВС 7.7 x10E3 4.0-10.6 RBC 5.16 x10E6 4.64-6.00 Hgb 15.7 am/dL 14.5-17.7 Hct 46 % 42-53 NCS St 11/8/13 MCV 90 fL 81-98 **MCHC** 31.2-35.2 33.9 gm/dL **RDW** 13.1 %

Eos, Respiratory **FAX RESULTS 348** Phys. Addr. Phone 8546

219

End of Report

Platelets

Salyer-PI NAS 8 Nov 2013

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAV 7 | 7 | ٥ | σ | 10 | 11 | 12 | 13 | 17 | 10 |
|----------------------|--------------------|----------------|--------------------|-----------|-------------|--------------|-----------|--------------|---------|
| AM | 7 | = | 19 | 11.10 | 11/11 | 1117 | 17/13 | <i>51[11</i> | 11/15 |
| Runny Nose 0 to 3 | 0 1 2 3 | 0923 | 0 0 2 3 | 0 🕭 2 3 | O123 | 0 1(2) 3 | 0 1023 | 0 0 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 /8 | b 1 2 3 | 0123 | 0 1 (2) 3 | 0123 | 0123 | 0123 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1 2 | 0 1 2 3 | 0 1 🕲 3 | 0 1 2 3 | 0 1 🕃 3 | 0 1 2 (3) | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | $0 \frac{1}{2} $ 3 | 0123 | 0 1 (2)3 | 01 2 3 | 0 (1) 2 3 | 1 2 3 | 0 (1)2 3 | Ø1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO | YES ((O | YES KNO | YES ÅØ | YES (NO | Kes NO | YES (TO) | YES NO |
| Throat Clearing Y/N | YES NO | YES (NO) | YES NO | YES (NO) | YES 🔞 | YES) NO | YES) NO | (FES) NO | YES NO |
| DAY PM | 7 | 8 | 6 | 10 | 11 | ,12 | 13 | 14 | 15 |
| Runny Nose 0 to 3 | 0 (1) 2 3 | 0 1 2 3 | 0123 | 0123 | 0 1 2 3 | 0 🖄 2 3 | © 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| | 6) 1 2 3 | 0 1 2 3 | (b) ₁₂₃ | 0123 | 40) 1 2 3 (| Ø 1 2 3 | Ø1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 (2) 3 | 0 123 | 0 (1)2 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 1 🕲 3 | 0 1 2 🗑 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0123 | (0)123 | 6)123 | (b) 1 2 3 | 0123 | (O) 1 2 3 | (D)1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (10) | YES NO | YES (NG | YES NO | YES (NO) | VES (NQ | YES (NO) | YES NO | YES NO |
| Throat Clearing Y/N | VES (NO) | YES NO | YES (NO) | YES NO | VES (NO) | ON) SEA | on € | YES NO | YES NO |
| | | = | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: # 10 0

DATE COMPLETED:

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc sific Resources Leslie Byatt, oin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME X, CHA

PATIENT ID

07/06/1956

SEX REPORT STATUS Final М

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO.

AAGH3323 COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

30920938

Test

0

11/14/2013 09:50

11/14/2013 19:24

11/15/2013 06:10

Out of Range

Rare

PATIENT NO.

COMMENTS:

AKP010

Result

In Range

Units

Reference Range NS

Site Code

Eos, Respiratory Phys, Addr. Phone

End of Report

NOT GIVEN

MM Nov 2013



Lovelace Se ific Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME CHA, CHA

PATIENT ID AAGH0028

оов **07/06/1956** REPORT STATUS

PAGE 1

PHYSICIAN
Unlisted Physician,

COLLECT DATE & TIME 11/21/2013 10:52

Result

RECEIVE DATE & TIME

SEX

M

PRINT DATE & TIME

REQUISITION NO.

PT, PHONE NO.

PATIENT NO.

11/21/2013 19:02

11/22/2013 06:08

30920937

0

PATIENT NO

COMMENTS:

AKP010

| CHAIMIMIMIATO | | | |
|---------------|--|--|--|
| | | | |
| | | | |

| | | Result | | | |
|------------------------------------|--|-----------------------|---|----------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | • |
| Sodium | 140 | | mmol/L | 13 4 -144 | |
| Potassium | 4.0 | | mmol/L | 3.5-5.1 | |
| Chloride | 105 | | mmoi/L | 98-111 | |
| CO2 | 27 | | mmol/L | 20-30 | |
| Anion Gap | 8 | | | 6-14 | |
| Glucose | 87 | | mg/dL | 60-100 | |
| BUN | 13 | | mg/dL | 7-31 | |
| Creatinine | 0.91 | | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDMS | traceable. EstGFR Ca | Iculation has b | | |
| | Please note new reference | range effective 5/23 | /2013. | _ | |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | |
| Of it commone | Estimated GFR values are on IV fluids, obese (BMI> the very old or very youn | not accurate in acute | kidney failure | , inpatients | |
| | on IV fluids, obese (BMI> | 34) or underweight (E | MI<20) people, | • • • | |
| | the very old or very youn | g, races other than (| aucasian or Afr | ıcan American, | |
| Calalium | people with acute illness | es, or amputations. | mg/dL | | |
| Calcium | 8.9 | | ~ | 8.4-10.4 | |
| Total Protein | 7.0 | | gm/dL | 6.1-8.2 | |
| Albumin | 3.8 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.4 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 66 | | U/L | 38-150 | |
| AST(SGOT) | 15 | | U/L | 6-58 | |
| ALT(SGPT) | 28 | | U/L | 14-67 | |
| Fasting | NO | | | | |
| CBC | | | | | |
| WBC | 7.5 | | x10E3 | 4.0-10.6 | |
| RBC | 5.38 | | x10E6 | 4.64-6.00 | |
| Hgb | 16.3 | | gm/dL | 14.5-17.7 | |
| Hct | 48 | | % | 42-53 | |
| MCV | 89 | | fL. | 81-98 | |
| | - | | gm/dL | | |
| MCHC | 33.9 | | | 31.2-35.2 | |
| RDW | 13.1 | | % | 11.0-14.5 | |
| Platelets | 209 | | x10E3 | 150-400 | |
| Differential | Auto Diff | | | | |
| Diff Type | | | 0/ | 40.70 | |
| Neutrophils | 54 | | % | 40-76 | |
| Lymphocytes | 32 | | % | 16-47 | |
| Monocytes | 10 | | % | 3-13 | |
| Eosinophils | 3 | | % | 0-5 | |
| Basophils | 1 | | % | 0-2 | |
| Abs, Neutrophil | 4.1 | | x10E3 | 1.8-7.0 | |
| Abs, Lymphocyte | 2.4 | | x10E3 | 1.0-3.4 | |
| Abs. Monocyte | 0.7 | | x10E3 | 0.2-0.8 | |
| Abs. Eosinophil | 0.2 | | x10E3 | 0.0-0.3 | |
| Abs. Basophil | 0.1 | | x10E3 | 0.0-0.1 | |
| Eos, Respiratory | V. 1 | Many * | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | NS | |
| Dhyo Addr Dhono | | ******** | | 110 | |
| Phys. Addr. Phone | NO PHYSICIAN GIVEN | | | | |

NO PHYSICIAN GIVEN

Deferred Test

Your requisition did not indicate a test for the EDTA tube received. Due to the instability of the specimen, a CBC with differential was performed. If you have any questions, please call Client Services at (505) 938-8922.

Continued on next page

CHA, CHA

questions, please call Client Services at (505) 938-8922.



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc tific Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME CHA, CHA

PATIENT ID **AAGH0028** DOB 07/06/1956 SEX М

REPORT STATUS Final

PAGE 2

PHYSICIAN

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

11/21/2013 10:52

11/21/2013 19:02

11/22/2013 06:08

30920937

PATIENT NO.

AKP010

COMMENTS:

Test

Result

In Range

Out of Range

Units

Reference Range

Site Code

Federal regulation requires written authorization for any test order modification to be submitted within 30 days. Please fax this report with your authorization signature to (505)938 8034 TriCore Reference attories ATTN: Medical Records Imaging Department.

27 Nov-2013 infero

SIGNATURE

DATE

End of Report

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAV 14 | 14 | 15 | 16 | 17 | 80 | 19 | . 20 | 21 | 22 | |
|-----------------|-----------------|----------------|------------------|-------------|------------------|--------------|-------------------|------------|--------|--------------|
| AM | ゴミ | | | | ا <u>ئے</u> = | ا الح | 12 12 | 17/11 | 72 11 | · |
| Runny Nose | 0 1 2 3 | 00 2 3 | 0 1 2 3 | 0 1 2 3 | 0(I) 2 3 | 0 1 2 3 | 6 1 2 3 | 0 (1) 2 3 | 0 1 2 | Ж |
| 0 to 3 | / |) |) | |) | | |) | | \neg |
| Itchy Nose | b 1 2/3 | 0 1 2 3 | (A) 123 | (6)123 | 0 1 2 3 | Ø 123 | $(6)_{123}$ | (0)123 | 0 1 2 | ന |
| 0 to 3 | / |) |) |) |) | |) | (| | Т |
| Congestion | 0\1/2 3 | 0 1 2 8 | 0 1 2 3 | 0 1 2 (8) | 06723 | 0 1 (2)3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | | (|) |) | 2 |) | > | | | \neg |
| Sneezing | 0 1/2 3 | 1 2 3 (A) | 0123 | (b)1 2 3 | 0 1 2 3 | (0) 1 2 3 | 0123 | (0)123 | 0 1 2 | ω |
| 0 to 3 | < | (|) | (| (| , | • |) | | |
| Voice Hoarse | YES NO | YES 'NO | YES NO | YES (NO | YES (NO) | YES (NO) | YES ((G) | YES | YES NO | 0 |
| N/N | _ | <i>)</i> (| , (|) (| |)(| | (| | |
| Throat Clearing | YES NO | (YES) NO | YES NO | VES NO | (NO) SEX | ON S∃A | YES NO | (YES) NO | YES NO | 0 |
| N/Y | |) | |) |) | | |) | | T |
| DAY PM | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 71 | 22 | |
| Nose | 50 1 2 3 | 0123 | 0 1 🔾 3 | 2 3 | 0 (1) 2 3 | 0(1) 2 3 | 0123 | 0 1 2 3 | 0 1 2 | د |
| 0 to 3 | | | 4 |) | > | | | | | T |
| lose | 60 1 2 3 | O 1 2 3 | (4) 1 2 3 | 2 3 | 0 1 2 3 | (0) 1 2 3 | (0 ₁₂₃ | 0 1 2 3 | 0 1 2 | 8 |
| Congestion | 0 1(2)3 | 0 1 2 3 | 0 1 2(3) | 0 (4)2 3 | 0 (1)2 3 | 0 1 (2) 3 | 0(4)2 3 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | | 2 | | | , | | | , | , | |
| Sneezing | 6 2 2 3 | 0(1) 2 3 | 0(1) 2 3 | (0)123 | 0/123 | 0 1 2 3 | (0)123 | 0 1 2 3 | 0 1 2 | m |
| 0 to 3 | (|) | |) | (| (|) | | | |
| Voice Hoarse | YES 40 | YES (186 | YES (NO) | YES (NO) | YES (NO | YES (80) | YES (O) | YES NO | YES | 9 |
| N/N | | | |) (| | | T | | | Т |
| Throat Clearing | YES | YES NO | YES NO | YES (NO | VES (B) | YES (80 | YES NO | YES NO | YES | 0 2 |
| Y/N | |) |) | > | | | | | | 7 |
| SCALE 0 to 3 | | | | | | | | | | • |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: #KP010

ו אין וין וו DATE COMPLETED:

SUBJECT INITIALS AND DATE:_

CAL 1010 11/21/13

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" ☐YES ☐NO |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| It HELPEY CLEAR MY HEAD FOR 1/2 HOURS AFTER TAKING It. WAS GOOD tO USE JUST BEFORE |
| AFTER TAKING It. WAS GOOD tO USE JUST BEFORE GOING TO BED. |
| At TIMES I FECT A CITICE BURNING WHEN |
| TAKENO THE SDRAW |
| |
| |
| |
| |
| |
| |
| |
| |
| Subject completed this questionnant, but inactuer tently did not initial, and date the bottom. En late entry |
| Subject initials and Date Study Staff Initials and Date |

| | | ·1 | | Ī/v | | , | | | | | · | | 7 | | |
|-----------------------|-----------------------|-------------------|---|--------------|---|---|-----|--|------|------|---|---|---|---------------------------------|--|
| | # | | Investigator Initials/Date | MM 21 March | | | では、 | | | | | * | M | | PAGE: of |
| LSR Study #: 0749 | Subject Initials: f | | Action Taken | Secon | | | | | | | | as specific as possible | 21/180-201 | 81/18/11 | |
| LSR | [qnS | <u>ā</u> | ** End Date (DD/MMM/YYYY) | 29/NOV/2013 | | | | | | | | should be made to be | 112 Date: 211 | Date: [1 | |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | 5 us peted | / | | | | | | | ** If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible ** | M Mu quing an | cha mas | Lovelace Scientific Resources, Inc AdverseEvents 04/2013 |
| | | | SEVERITY | mild | | | | | | | | te UNK in spac | :() | Vi: She | <u> </u> |
| 5749 | AKP 010 | | ** Start Date (DD/MMM/YYYY) | "31/OCT/2012 |) | | | | | | | * If day is <u>unknown,</u> wri | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: | Subject Number: | | Adverse Event | iming. | | | | | | | | * | Investigator Si | SCS | |

| Study Identification: | 5749 | | 1 | | | | LSR #: | |
|-----------------------|---|----------------------|------------------------|--|--------------------|--|-------------------|------------------------------------|
| Subject Number: | AKPOOG EM | 9126/13 | \(\frac{1}{2}\) | | | | Subject Initials: | CHA |
| List all | CONCOMITANT MEDICATION LOG | CONC ou are takir | OMITA | CONCOMITANT MEDICATION LOG | ATION L | OG medications, vitamin | s and supplemer | ıts. |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS (for Clinic use) |
| EXAMPLE | Diabetes | 500 | MG | 2 Tabs per | Öral | UNK/AUG/1999 | | |
| Flonase | Spussings | / | houds | のゆう | ZN# | -712009 | 29/20/12/12 | |
| Multivitanin | Dietary | | 172 | 00 | erai | 866//- | | × |
| 615/1 | Die Fary | 006 | me | 90 | eral | 1108//- | | X |
| | | • | <u> </u> | | | | | |
| • | | | | | | | | |
| St. Table | | | | | | | | |
| | | | ; | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or month | | lication da | ate is <u>unkno</u> | <u>wn,</u> write U | of medication date is unknown, write UNK in space provided | | |
| Investigator Signati | Investigator Signature (at end of study): | | Mark | twie W | 0 | Date: 21/0 | 160-2013 | |
| SC Signat | $\mathcal{S}_{\mathcal{S}}$ (Signature (at end of study): | Secre | 2 | made | S S S | Date: 11/21/13 | 71 (1.3) | • |
| 1 | | Lovelac | e Scientific Re | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | nMeds 04/2013 | | | PAGE: l of |

AKP-011

2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| <u>P</u> | PATIENT DEMOGRAPHICS |
|--------------|---|
| | Patient Demographics |
|] | Date of Birth: 09 / Apr/ 1940 (dd/mmm/yyyy) |
| (| Date of Birth: $09/Apr/1940$ (dd/mmm/yyyy) Gender: \square Male \square Female |
|) | If female, Indicate Childbearing Potential |
| | Childbearing Surgically sterilized Post-Menopausal |
|] | Ethnicity: Hispanic Non Hispanic |
| | Race: Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| | Smoking History |
| S | Smoking Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| Ι | f subject is a <i>former</i> or <i>current</i> smoker, please indicate: |
| | Years smoked: 13 Cigarettes per day: 40 |

Version: 02 September 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scient Resources Clin Trials-Leslie pyatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME RCD, RCD

PATIENT ID **AAGF6660** DOB 04/09/1940 SEX REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO. COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

PATIENT NO.

10/04/2013 11:33

10/04/2013 19:52

10/08/2013 06:06

30920921

COMMENTS:

AKP011

| Test |
|---|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite |
| Allerg,Cockroach |
| Allerg,Derm. pter. |

| | | Result | | | | |
|---|----------|---|-----|-------|-----------------|-----------|
| , | in Range | Out of Rai | nge | Units | Reference Range | Site Code |
| | | 6.60 | Н | kU/L | <0.35 | |
| | 0.20 | * | •• | kU/L | < 0.35 | |
| | <0.10 | | | kU/L | <0.35 | |
| | 0.20 | | | kŪ/L | <0.35 | |
| | 0.10 | | | kU/L | < 0.35 | |
| | | 2.70 | Н | kU/L | <0.35 | |
| | | 0.50 | H | kU/L | < 0.35 | |
| | <0.10 | | | kU/L | <0.35 | |
| | <0.10 | | | kU/L | <0.35 | |

The standard classification system utilizes the following class cutoffs. class Interpretation

| Class | KU/ L | Title(b) ecacion |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| TIT | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| v | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| | Cilliteal arrergy. | | | | |
|----------------------|--------------------|------|---|------|--------|
| Allerg,Derm. farinae | <0.10 | | | kU/L | < 0.35 |
| Allerg Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg,Firebush | <0.10 | | | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | 0.30 | | | kU/L | < 0.35 |
| Allerg,Dog Dander | <0.10 | | | kU/L | < 0.35 |
| Allerg,Bluegrass | 0.20 | | | kU/L | < 0.35 |
| Allerg, Pigweed | | 0.50 | Н | kU/L | < 0.35 |
| Allerg, Mulberry | <0.10 | | | kU/L | < 0.35 |
| Allerg,Helminth | 0.20 | | | kU/L | < 0.35 |
| Phys, Addr, Phone | NOT GIVEN | | | | |
| * * | | | | | |

End of Report

Positive esult.

The Sub-I 08 Oct 2013



Name: RCD,

Gender: Male

Age: 73

Race: Caucasian

Height(in): 75.0

Weight(lb): 221

Any Info:

ld: AKP-011 Date: 10/16/13

Temp: 19

PBar: 631

Physician:

Technician:

| Ariy iriio. | | | | | | , 0011111010 | | | | | | |
|-------------|---------------|----------|-------------|--------------|-------------------|--------------|-------------|----------|-------------|--------------|---|--|
| Spirometr | v (81 | PS) | | E-RX | POST-RX Post Post | Post | Flow | | | | | |
| | , | Ref | Pre Meas | Pre % Ref | Meas % Ref | % Chg | 16 T | | | | | |
| FVC | Liters | 5.16 | 3.80 | 74 | | | † | | | | | |
| FEV1 | Liters | 4.06 | 2.90 | 72 | | | 12 | | | | | |
| FEV1/FVC | % | 77 | 76 | 99 | | | ·~ | | | | | |
| FEF25-759 | | 3.89 | 2.42 | 62 | | | + | | | | | |
| FEF50% | L/sec | 4.85 | 4.95 | 102 | | | | | | | | |
| FEF75% | L/sec | 1.76 | 1.18 | 67 | | | 8 | | | | | |
| IC | Liters | | | | | | 1 | \wedge | | | | |
| VC | Liters | 5.16 | | | | | _ | / \ | | | | |
| PEF | L/sec | 9.35 | 11.71 | 125 | | | 4† | | V / | | | |
| MVV | L/min | 141 | | | | | 1 | | 1 | | | |
| PIF | L/sec | | | | | | Į. | ł | why . | | | |
| FEV1/FEV | | | 77 | | (DITION) | | 0 ++ | | | | | |
| Lung \ | /olumes/F | Plethysr | nogra | phy | (BTPS) | | 1 | | | | | |
| Vtg | Liters | | | | | | -4 | | | | | |
| vč | Liters | 5.16 | | | | | | | | | | |
| TLC | Liters | 7.66 | | | | | + | | | | | |
| RV | Liters | 2.94 | | | | | ایا | | | | | |
| RV/TLC | % | 42 | | | | | -8+ | | | | | |
| FRC PL | L.iters | 4.23 | | | | | 1 | | | | | |
| ERV | Liters | | | | | | | | | | | |
| IC | Liters | | | | | | -12⊥ -2 | | 0 4 | 6 | 8 | |
| Diffusi | on | | | | | | -2 | 0 | 2 Volume | O | ь | |
| DLCO | mL/mml-lg/min | | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | |
| DLCO/VA | mL/mHg/min/L | 2.92 | | | | | | | | | | |
| | 1 11 | | | | | | | | | | | |

Resistance

VA

BHT

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 sRaw
 cmH2O/L/s/L

 4.31

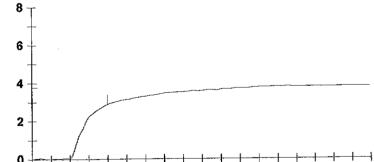
 sGaw
 L/s/cmH2O/L

 Vtg (Raw)
 Liters

Liters

Sec

Comments:



Version: IVS-0101-20-5B

Interpretation:

Volume



Name: RCD,

Gender: Male Age: 73

Race: Caucasian

Height(in): 75.0

Weight(lb): 221

Any Info:

Id: AKP-011 Date: 10/23/13

Temp: 20

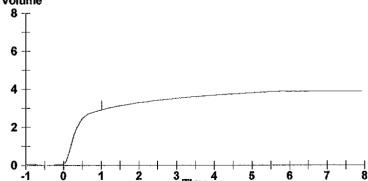
PBar: 634

Physician:

Technician: VL

| (B1 | rps) | PRI | E-RX | POST-RX | | Flow |
|-----------------------|----------|-------|------------------|------------|-------|---|
| Spirometry | Ref | Pre | Pre | Post Post | Post | 16 T |
| | | | % Ref | Meas % Ref | % Chg | 10 |
| VC Liters | 5.16 | 3.89 | 75 | | | † |
| EV1 Liters | 4.06 | 2.93 | 72 | | | 12 - |
| EV1/FVC % | 77 | 75 | 98 | | | 12 |
| EF25-75%L/sec | 3.89 | 2.32 | 60 | | | + |
| EF50% L/sec | 4.85 | 5.43 | 112 | | | |
| EF75% L/sec | 1.76 | 0.57 | 32 | | | 8† |
| C Liters | | | | | | 1, |
| 'C Liters | 5.16 | | | | | |
| EF L/sec | 9.35 | 9.84 | 105 | | | 4+ / \ |
| fVV L/min | 141 | | | | | |
| IF L/sec | | | | | | |
| EV1/FEV6% | | 75 | | | | 0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 |
| ung Volumes/F | Plethysm | ograi | phv | (BTPS) | | |
| - | , | - 3 | J= 1.1. J | | | 7 |
| | E 40 | | | | | -4 [∤] |
| C Liters | 5.16 | | | | | |
| LC Liters | 7.66 | | | | | † |
| RV Liters | 2.94 | | | | | -8+ |
| V/TLC % | 42 | | | | | -0 |
| RC PL Liters | 4.23 | | | | | + |
| RV Liters | | | | | | 40 |
| Liters | | | | | | -12 1 -2 0 2/olume 4 6 8 |
| iffusion | | | | | | -2 0 2 4 6 8 |
| LCO mL/mmHg/min | | | | | | |
| L Adj mL/mmHg/min | 25.0 | | | | | |
| LCO/VA mL/mHg/min/L | 2.93 | | | | | |
| /A Liters | | | | | | |
| SHT Sec | | | | | | |
| Resistance | | | | | | |
| law Total cmH2O/L/sec | | | | | | |
| aw Insp cml+2O/L/sec | | | | | | |
| Raw Exp cmH2O/L/sec | | | | | | |
| Raw cmH2O/L/sec | 1.02 | | | | | |
| Baw L/sec/cmH2O | | | | | | |
| Raw cmH2O/L/s/L | 4.31 | | | | | |
| Gaw L/s/cmH2O/L | | | | | | |
| (ig (Raw) Liters | V,EVE | | | | | |
| 127 (1 12-57) MINOUN | | | | | | |
| | | | | Volume | | |

Comments:



Version: IVS-0101-20-5B

Interpretation:



Name: RCD,

Gender: Male Age: 73

Race: Caucasian

Height(in): 75.0

Weight(lb): 221

ld: AKP-011 Date: 10/29/13

Temp: 20

PBar: 630

Physician:

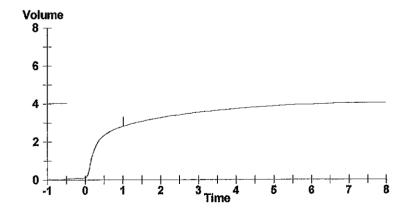
| Any Info: | | | | | | 7 | Fechnicia | ın: VL | | | | |
|---|--|---|--|---|--------|-----------------------|------------------|---|-----------|-------------|-----|----------|
| Spiromet | ry (B | TPS) Ref | Pre | E-RX Pre % Ref | Post | T-RX Post % Ref | Post % Cha | Flow 16 T | | | | |
| FVC FEV1 FEV1/FVC FEF25-75' FEF50% FEF75% IC VC PEF MVV PIF | | 5.16 4.06 77 3.89 4.85 1.76 5.16 9.35 141 | Meas 4.02 2.83 70 1.65 3.88 0.43 | % Ref 78 70 92 42 80 24 | Meas ' | % Ref | % Chg | 12 - 8 - 4 - | \bigcap | | | |
| FEV1/FEV | | Plethys | 72 mogra: | phv | (B | TPS) | | 0 | | 1 | + + | - |
| Vtg VC TLC RV RV/TLC FRC PL ERV IC Diffus DLCO DL Adj DLCO/VA VA BHT | Liters Liters Liters % Liters Liters Liters Liters Liters On mL/mmHg/min mL/mHg/min/L Liters Sec | 5.16 7.66 2.94 42 4.23 | | | | | | -4 -8 -12 -12 | 0 | 2 Volume | 6 | 8 |
| Resist | | | | | | | | | | | | |
| Raw Total Raw Insp Raw Exp Raw | cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec | 1.02 | | | | | | | | | | |

Comments:

Vtg (Raw) Liters

Gaw

sRaw sGaw



Version: IVS-0101-20-5B

Interpretation:

L/sec/cmH2O 1.015

cmH2O/L/s/L 4.31 L/s/cmH2O/L 0.232



Name: RCD,

Gender: Male

Age: 73

Race: Caucasian

Height(in): 75.0

Weight(lb): 221

Any Info:

ld: AKP-011 Date: 11/08/13

Temp: 19

PBar: 634

Physician:

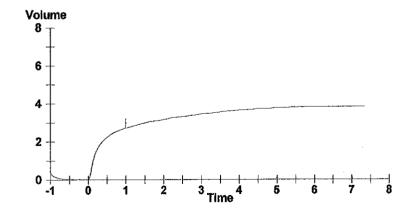
Technician: VL

| Tany milo. | | | | | | | | | | | | | |
|------------|---------------|---------|-------------|--------------|---|---|---------------|--------------------|-------|-------------|----------------|---|--|
| Cuitanana | , (E | TPS) | PR | E-RX | | ST-RX | | Flow | | | | | |
| Spirome | มy | Ref | Pre Meas | Pre % Ref | Post Meas | Post % Ref | Post % Chg | 16 _T | | | | | |
| FVC | Liters | 5.16 | 3.82 | 74 | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | + | | | | | |
| FEV1 | Liters . | 4.06 | 2.73 | 67 | | | | 12 🖁 | ٨ | | | | |
| FEV1/FV0 | | 77 | 71 | 93 | | | | 12 † | /\ | | | | |
| FEF25-75 | | 3.89 | 1.69 | 43 | | | | + | 11 | | | | |
| FEF50% | L/sec | 4.85 | 2.95 | 61 | | | | | - / / | | | | |
| FEF75% | L/sec | 1.76 | 0.58 | 33 | | | | 8† | 1 \ | | | | |
| IC | Liters | | | | | | | | ' | \ | | | |
| VC | Liters | 5.16 | | | | | | | - 1 | 1 | | | |
| PEF | L/sec | 9.35 | 12.53 | 134 | | | | 4 † | ł | | | | |
| MVV | L/min | 141 | | | | | | | | ١. | | | |
| PIF | L/sec | | | | | | | Ţ | í | | | | |
| FEV1/FE\ | | | 71 | | | | | 0 | | | | | |
| Lung ' | Volumes/I | Plethys | mogra | phy | (E | BTPS) | | 1 | | | | | |
| Vtg | Liters | | | | | | | _ | | | | | |
| vč | Liters | 5.16 | | | | | | -4- | | | | | |
| TLC | Liters | 7.66 | | | | | | 1 | | | | | |
| RV | Liters | 2.94 | | | | | | _ | | | | | |
| RV/TLC | % | 42 | | | | | | -8+ | | | | | |
| FRC PL | L.iters | 4.23 | | | | | | 1 | | | | | |
| ERV | Liters | | | | | | | | | | | | |
| IC | Liters | | | | | | | -12 <u> </u> -2 | _ | | _ | _ | |
| Diffus | | | | | | | | -2 | 0 | 2 Volume | 6 | 8 | |
| DLCO | mL/mmHg/mir | | | | | | | | | | | | |
| DL Adj | mL/mmHg/mir | | | | | | | | | | | | |
| | 、mL/mHg/min/l | _ 2.93 | | | | | | | | | | | |
| VA | Liters | | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | | |

Resistance

Raw Total cmH2O/L/sec
Raw Insp cmH2O/L/sec
Raw Exp cmH2O/L/sec
Raw cmH2O/L/sec 1.02
Gaw L/sec/cmH2O 1.015
sRaw cmH2O/L/s/L 4.31
sGaw L/s/cmH2O/L 0.232
Vtg (Raw) Liters

Comments:



Interpretation:

Norm Set: Knudson (1983)

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | 1-1 | φ | rţ. | 4. | £ <u>1</u> | -2 | 1-1 | 0 | 0 | |
|----------------------|--------------|----------------|----------------|--------------|--------------|----------|---------|---------|-------|----------|
| AM | 0 0 10 | 101 | 10/12 | 10 13 | <u>主</u> 0 | 51701 | 201 | 1017 | | |
| Runny Nose 0 to 3 |)) | 0 🗇 2 3 | 0 Q 2 3 | 0 (10 2 3 | 0 (1) 2 3 | 0 (0)2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Itchy Nose 0 to 3 | ; | 0123 | Ø123 | © 123 | Ø123 | 0 1 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | | 0 1 🕲 3 | 0(1) 2 3 | 0(T)2 3 | 0 (1) 2 3 | 0(1)2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | | 3 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0123 | (O)1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | 33 |
| Voice Hoarse Y/N | 教 | YES (NO) | YES (NO) | YES (MO) | YES (NO) | YES (NO | YES NO | YES NO | YES | ON ON |
| Throat Clearing Y/N | | (YES) NO | YES NO | YES) NO | YES NO | YES NO | YES NO | YES NO | YES | ON NO |
| DAY PM | -7 | ې | ī, | 4 | .8 | -2 | 17 | 0 | 0 | |
| Runny Nose 0 to 3 | 0 1 🖒 3 | 0 🛈 2 3 | (d) 1 2 3 | 0123 | 0(1)2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | 3 |
| Itchy Nose 0 to 3 | Ø 1 2 3 | Ø 1 2 3 | O 1 2 3 | 0123 | 0123 | 0(1)2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | 3 |
| Congestion 0 to 3 | 0 1 🗇 3 | 0 3 2 3 | 0 ①2 3 | 0(D2 3 | 0 ① 2 3 | 0 1 2 3 | 0 1 2.3 | 0 1 2 3 | 0 1 2 | 23 |
| Sneezing O to 3 | 0 (02 3 | 0(1) 2 3 | © 123 | O 123 | O 123 | 0.123 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (NO) | VES (NO) | YES (NO | YES (NO) | YES (NO) | YES NO | YES NO | YES NO | YES | ON |
| Throat Clearing Y/N | (YEG) NO | (YES) NO | (YES) NO | YES NO | YES) NO | YES NO | YES NO | YES NO | YES | N N |
| | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

=Yes N= No

SUBJECT NUMBER: ALP DIV

DATE COMPLETED: $I0/10/15-i9/\alpha/13$

SUBJECT INITIALS AND DATE: (18/13

Stat Ru nere ot



Lovelace S tific Resources Clin TrialsLestie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME RCD, RCD

PATIENT ID **AAGF6660** DOB 04/09/1940 SEX REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

10/16/2013 14:30

10/16/2013 20:20

10/17/2013 06:08

30920913

PATIENT NO.

0

AKP011

| COM | η⊨N | 13 | ; | |
|-----|-----|----|---|--|
| | | | | |

| | Re | sult | | | |
|------------------------------------|---|---|---|------------------------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 139 | | mmol/L | 134-144 | |
| Potassium | 4.3 | | mmol/L | 3.5-5.1 | |
| Chloride | 103 | | mmol/L | 98-111 | |
| CO2 | 26 | | mmol/L | 20-30 | |
| Anion Gap | 10 | | | 6-14 | |
| Glucose | 96 | | mg/dL | 60-100 | |
| BUN | 20 | | mg/dL | 7-31 | |
| Creatinine | 1.27 | | mä/dL | 0.62-1.66 | |
| | Creatinine method is IDMS 1 | raceable. EstGFR Ca | lculation has b | een adjusted | |
| | Please note new reference a | ange effective 5/23 | /2013. | | . 1 |
| eGFR non-African Am GFR Comment | | 56 L | mL/min/1.73m2 | >60 NC | 3 91 |
| GFK Comment | Estimated GFR values are no on IV fluids, obese (BMI>34 the Property old or very young, | ot accurate in acute) or underweight (B races other than C | kidney failure MI<20) people, aucasian or Afr | a, inpatients 🖊 rican American, | 0/18/13 |
| Calcium | people with acute illnesses | s, or amputations. | roon fall | 0.4.6.4 | |
| Total Protein | 7.0 | | mg/dL | 8.4-10.4 | |
| Albumin | 4.4 | | gm/dL gm/dL | 6.1-8.2 | |
| Globulin | 2.6 | | gm/dL | 3.4-4.7 2.4-4.2 | |
| Bilirubin, total | 0.8 | | mg/dL | 2.4-4.2 0.3-1.2 | |
| Alk Phos | 111 | | Ü/L | | |
| AST(SGOT) | 20 | | U/L | 38-150 6-58 | |
| ALT(SGPT) | 36 | | U/L | 14-67 | |
| Fasting | NO | | O/L | 14-07 | |
| Phosphorus | 3.6 | | mg/dL | 2.3-5.6 | |
| CBC | | | mgran | 2.3-0.0 | |
| WBC | 10.0 | | x10E3 | 40400 | |
| RBC | 5.35 | | x10E3 | 4.0-10.6 | |
| Hgb | 17.2 | | gm/dL | 4.64-6.00 | |
| Hct | 49 | | 9/1/GL % | 14.5-17.7 | |
| MCV | 91 | | 70 fL | 42-53 | |
| MCHC | 35.2 | | gm/dL | 81-98 | |
| RDW | 12.9 | | gn/dL % | 31.2-35.2 | |
| Platelets | 228 | | 70 х10ЕЗ | 11.0-14.5 | |
| Eos, Respiratory | None seen | | XIVES | 150-400 | |
| Phys, Addr, Phone | Not given | | | NS. | |

End of Report

NCS Salyer PI 180ct 2013

RCD, RCD 10/17/2013 06:08

Randomization

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 747 | , | | c | • | L | 9 | r | o | c |
|----------------------|----------------|----------------|----------------|----------------|----------------|--------------------|------------------|----------------|---------|
| <u> </u> | ٦, | <u></u> | ď, | t | n | ٥. | | o | ת |
| AM | 01/10 | 1011 | 10/18 | 10/19 | 10/20 | 12/01 | 10/22 | 10/23 | |
| Runny Nose | 0 1 2 3 | 0 (1)2 3 | 0(1)2 3 | 0 (1)2 3 | 0 (1) 2 3 4 | (<u>0</u>) 1 2 3 | 6 0123 | (0.11 2 3 | 0.123 |
| Itchy Nose | 0 1 2 3 | (0 123 | Ø 1 2 3 | 0123 | (0) 1 2 3 | ©1 2 3< | 0123 | O 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0(1) 2 3 | 0 Ø 2 3 | 0 🗓 2 3 | 0(1/2 3 | 0(1)2 3 | O 1 2 3 | ©123 | 0 1 2 3 |
| Sneezing | 0 1 2 3 | @ 1 2 3 | 0 123 | 0123 | 0 (1) 2 3 | 1 2 3 | Ø123(| 0123 | 0 1 2 3 |
| Voice Hoarse | YES NO | YES (NO) | YES (NO) | YES (NG) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES NO |
| Throat Clearing Y/N | YES NO (| YES NO | (YES) NO | (YES) NO | (YES) NO (| YES NO | YES (NO) | YES (NO) | YES NO |
| DAY PM | 1 | 2 | 8 | 4 | ī | 9 | 7 | ∞ | 6 |
| Runny Nose 0 to 3 | 0 (1) 2 3 | 0①23 | (0123(| 3 1 2 3 | 1 2 3 (| Ø 1 2 3 | () 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| ose | 1 2 3 | © 1 2 3 | 1 2 3 | 0 (1)2 3(| 0)123 | (2) 2 3 (| 0123 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1(2) 3 | 0 2 3 | 0(1)2 3 | 0 2 3 | 0123 | 0 (1)2 3(| 0123 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | © 1 2 3 | 0 D 2 3 | 0(1)23 | © 123 | Ø 1 2 3(| Ø12.3 | (d) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO) | YES (NO) | YES NO | YES (NO) | YES (NO) | YES (NO) | YES NO | YES NO |
| Throat Clearing Y/N | (YES/ NO (| YES NO (| YES) NO | YES NO | (YES) NO | (YES) NO (| ON) SALV | YES NO | YES NO |
| SCALE 0 to 3 | | | | 1 | | | 4 | | |

0= No symptoms (no symptoms detected)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SCALE 0 to 3

DATE COMPLETED: 101 SUBJECT NUMBER: PW 311

SUBJECT INITIALS AND DATE: R CL 10/23/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci fic Resources Leslie Byatt, Cun Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME RCD, RCD

PATIENT ID DOB **AAGF6660** 04/09/1940

SEX М

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT, PHONE NO.

COLLECT DATE & TIME 10/23/2013 14:36

RECEIVE DATE & TIME

PRINT DATE & TIME

30920900

PATIENT NO.

10/24/2013 17:52

10/25/2013 06:09

COMMENTS:

Test

0

AKP011

Out of Range

Man Jubit
29 out 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone None seen Not given

In Range

NS

End of Report

| DAILY SYMPTOMS SCOI | S S | RE SHEET (RHINITIS DIARY) ONSE EVERY 12 HOURS 8 9 9 | IINITIS DIAF HOURS 9 | ۲۷) با مار | 17 | 12 | | Next 52 | 27.9.27 |
|-------------------------|-----------|---|----------------------------|---------------|-------------------|-------------------|------------------|---------|-------------|
| 01 72/01 54/01 | 01 12/01 | 13 | 32/ | 20/26 | 12/01 | 30/01 | 57/07 | 08/01 | 10/3 |
| 0 1 2 3 0 🚭 2 3 0 🤄 | 2 3 | | 2 3 | 0 📆 2 3 | 0(1)2 3 | (0) 1 2 3 | 6 0123 | 0 1 2 3 | 0 1 2 |
| 0 1 2 3 0 1 2 3 0 1 | 123 | 44 | 2 3 | (O) 1 2 3 (| (0 1 2 3 | 1 2 3 0 | (0)1 2 3 | 0 1 2 3 | 0 1 2 |
| 0123/0123(0) |)123(0) | | 123 | <u> </u> | 0(1)2 3 | 6123 | 0)123 | 0 1 2 3 | 012 |
| 0 1 3/3 (0)1 2 3(0)1 | 123 | (e) | 123 | 0 @ 2 3 \$ | (<u>0</u>)1 2 3 | 0123 | O 123 | 0 1 2 3 | 0 1 2 |
| YES/ NO YES (NO) YES | ON | } YES | | YES (NO | YES (NO) | YES (NO | YES (NO | YES NO | YES NO |
| YÉS NO YES (NO) YES | (NO) |) YES | (NG) | YES (NO.) | YES NO | YES (NO | YES (NO) | YES NO | YES NO |
| 7 8 | 8 | a p | 6 | 10 | 11 | 12 | 13 | 14 | 15 |
| (9) 2 3 (9) 1 2 3 (9) 1 | 123(0) | / | 1 2 3(| 9123(| (0)1 2 3 | (c) 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 |
| 0)123(0)123(0)1 | 1 2 3 (0) | | 2 3 (| (0) 1 2 3 (| 0123 | (0)1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 |
| 0(1)2 3 (1) 1 2 3 (9): | 123(0) | $\overline{}$ | 123 | Ø123(| (0 123 | (O)1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 |
| 16012300123(0) | 123(9) | | . 2 3 |) E Z I(Q) | <u> </u> | (<u>0</u>)1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 |
| YES (NO) YES (NO) YES | (ON) | YES | (NO) | YES (NO) | YES (NO | YES (NO) | YES NO | YES NO | YES NO |
| YES) NO YES (NO) YES | (NO) | YES | (S) | YES (NG) | YES (NO | YES (NO) | YES NO | YES NO | YES NO |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: HY

DATE COMPLETED:

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sa lific Resources Leslie Byatt, win Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME X, RCD **PHYSICIAN**

PATIENT ID **AAGG8637**

09/04/1940

SEX M

REPORT STATUS Final

PAGE

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 10/29/2013 14:30 RECEIVE DATE & TIME

PRINT DATE & TIME

30920918

Test

0

PATIENT NO.

10/29/2013 19:11

10/30/2013 06:09

AKP011

COMMENTS:

In Range

2000 2013

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone None seen Unknown

NS

Callback Accession Comments:

T3427433

EOSR, UNKPHY

10/29/2013 09:29 pm FAXED TO

3488546 NCCS1685

End of Report

FAX24664 10/30/2013 06:09

| LSR Study #: 2749 | Subject Initials: RW | | Action Taken Initials/Date | | | | | | | | | | e as specific as possible** | 13 Now 2013 | : 11/12/13 | PAGE: 1 of |
|--------------------------------|----------------------|-------------------|---|--|---|---|---------------|---|--|---|--|--|--|---|-----------------------------------|--|
| IST | Sul | | ** End Date (DD/MMM/YYYY) | Table Transfer Annual Control of the | | | To the second | } | | - | | | ould be made to b | Date: / | Date: | |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | | | / | | | | | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | marie un | Un braid | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| | | | SEVERITY | | / | / | | | | | | | te UNK in space |): 108 | V): MS | à |
| ArPhamic | ALPOIL | | ** Start Date (DD/MMM/YYYY) | | | | | | | | | | f day is <u>unknown,</u> wri | investigator Signature (at end of study): _ | SC Signature (at end of study): _ | |
| Study Identification: AKPhammc | Subject Number: | · | Adverse Event | | | | | | | | | | ** | Investigator Sign | SC Sign | |

, }

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | | | i | | | | | | | C ~+ 0 3 14 73 |
|----------|----------|----------------|------------------|--------------|------------------|-----------------|---------------------|----------------|------------------|-----------|----------------------|
| | 南 | YES (NO) | YES (NÖ) | (YES) NO | YES (NO | YES (NO) | YES NO | YES (NO.) | YES (NO) | (YES) NO | Throat Clearing Y/N |
| | ر مر | YES (NO) | YES (NO) | YES (NO | YES (NO) | YES (NO) YES | YES (NO) | YES (NO | YES (NO) | YES (NO) | Voice Hoarse Y/N |
| | . C | © 1 2 3 | © 123, | O 1 2 3 | 2 0 1 2 3 | | O1 23 W 123 | <u>(0)</u> 123 | <u> </u> | (6) 1 2 3 | Sneezing 0 to 3 |
| | - | 0 1 2 3 | 0 1 2 3 | Ø 1 2 3 | © 123 | | ó ⊕ 2 3 | <u>©</u> 1 2 3 | O 1 2 3 | 0 🗘 2 3 | Congestion 0 to 3 |
| | · 0 | © 123 | ①123 | @123 | (0)1 2 3 | ©1 2 3 (| | 3(1) 23 (1) 23 | © 1 2 | Ø 1 2 3 | Itchy Nose 0 to 3 |
| | | 0 1 2 3 | $\bigcirc 1 2 3$ | 0 123 | 0 1 2 3 | 0 2 3 | ©123 | 01230123 | (0)1 2 3(| 0√⅓ 2 3 | Runny Nose 0 to 3 |
| } | 24 | 22 | 21 | 20 | 19 | 18 | 17 | 16 | 15 | 14 | DAY PM |
| | 南 | YES NO | YES (NO | YES (NO) | YES (NO) | YES (NO) | (YES) NO | N O | (YES) NO (YES) | YES NO | Throat Clearing Y/N |
| がいる | ての | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) YES | YES (NO) YES | YES (NO. | YES (NO) YES | ¥ES NO | Voice Hoarse Y/N |
| , Q | O | <u>0</u> 1 2 3 | 3(0)123 | (D)1 2 30 | <u>0</u> 1 2 3 | 2 3 | W1 2 3 (D) 1 | ©123 | ©1 2 3 © 1 | 0/123 | Sneezing 0 to 3 |
| gercq | 0 | (D)1 2 3 | ①1 2 3 · | (O)1 2 3, | ①1 2 3 | | 0 2 3 0 2 3 6 1 2 3 | | 0(1)2 3 | 0 1/2 3 | Congestion 0 to 3 |
| 0 | O | (D)1 2 3 | ①123 | 0)1 2 3 | ① 1 2 3 | O 1 2 3 | <u>©</u> 123 | | <u>(</u> 0)1 2 3 | 0 1 7 3 | Itchy Nose 0 to 3 |
| 0 | ****** | 0 1 2 3 | 0 (1) 2 3 (| 0123 | 2 3 | (<u>0</u> 123(| <u>(0)</u> 1 2 3 | ① 1 2 3 | 0 3 | 0 1 2/3 | Runny Nose 0 to 3 |
| 11/8 | | 11/12 | 11/5 | 71/14 | 11/13 | 11/2 | 11 1 | /D/B/ | 10/30 10B | 1000 | AM |
| | | 22 | 21 | 00 | 10 | 1,8 | 17 | 1.6 | <u>ј</u> | 1// | DAV |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ### 011 DATE COMPLETED: 11/8/13

SUBJECT INITIALS AND DATE: RC8 11/8/2013



2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Lovelace Sc. Ific Resources Leslie Byatt, Clin Trials

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME RCD, RCD

PATIENT ID AAGH3924 DOB 04/09/1949 SEX М

REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician,

COLLECT DATE & TIME 11/08/2013 11:11 PT. PHONE NO.

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PATIENT NO.

11/08/2013 18:52

11/11/2013 06:08

30920951

COMMENTS:

AKP011

| 0020001 | V | 4 |
|---------|---|---|
| OMMENTS | | |

| | Re | esult | | | |
|---------------------------------------|--|--|---|------------------------------------|-----------|
| Test | in Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 138 | | mmol/L | 134-144 | |
| Potassium | 4.0 | | mmol/L | 3.5-5.1 | |
| Chloride | 103 | | mmol/L | 98-111 | |
| CO2 | 23 | | mmol/L | 20-30 | |
| Anion Gap | 12 | 400 | . 0 | 6-14 | e Man |
| Glucose | Impaired fasting glucose (100-126 mg/dl (ADA Guideli | 1 06 H IFG) is defined as a nes Diabetes Care 26: | mg/dL fasting glucos (3160-3167)200 | 60-100 //2 e level of //2 3) | Nov 13 |
| BUN | 14 | | mg/dL | 7-31 | |
| Creatinin e | 1.20 | | mg/dL | 0,62-1.66 | |
| | Creatinine method is IDMS | | | een adjusted. | |
| | Please note new reference | range effective 5/23, | /2013. | | |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | |
| GFR COMMENT | Estimated GFR values are non IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | 4) or underweight (RM | /T<20) neonle. | • | |
| Calcium | people with acute illnesse | s, or amputations. | | | |
| Total Protein | 5.3 6.9 | | mg/dL gm/dL | 8.4-10.4 | |
| Albumin | 4.4 | | gm/dL gm/dL | 6.1-8.2 3.4-4.7 | |
| Globulin | 2.5 | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.9 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 110 | | Ü/L | 38-150 | |
| AST(SGOT) | 21 | | Ú/L | 6-58 | |
| ALT(SGPT) | 38 | | U/L | 14-67 | |
| Fasting | Not given | | | ,,,_, | |
| CBC | _ | | | | |
| WBC | 8.2 | | x10E3 | 4.0-10.6 | |
| RBC | 5.35 | | x10E6 | 4.64-6.00 | |
| Hgb | 17.3 | | gm/dL | 14.5-17.7 | |
| Hct | 49 | | % | 42-53 | |
| MCV | 92 | | fL | 81-98 | |
| MCHC | 35.2 | | gm/dL | 31.2-35.2 | |
| RDW | 13.2 | | % | 11.0-14.5 | |
| Platelets | 197 | | x10E3 | 150 -4 00 | |
| Eos, Respiratory Phys, Addr, Phone | None seen Unknown | | | NS | |
| r riye, Addir, i Holid | VIIIII VIII | | | | |

End of Report

Montaine Sub-I

TGC/OOD

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" YES W |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| BURNING SENSATION, BAO TASTE |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

AKP-014

/ 2/49 AKPharma PERENNIAL ALLEKGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| | En ils |
|--------|--|
| PATI | ENT DEMOGRAPHICS |
| Patie | ent Demographics |
| Date | of Birth: 09 / Apr/ 1955 (dd/mmm/yyyy) |
| Gend | er: Male Female |
| If fen | nale, Indicate Childbearing Potential |
| | Childbearing Surgically sterilized Post-Menopausal |
| Ethni | city: Hispanic Non Hispanic |
| Race: | : Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| Smol | the control of the co |
| Smok | ting Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| If sub | ject is a former or current smoker, please indicate: |
| | Years smoked: 30 Cigarettes per day: 15 |

Version: 02 September 2013

Page 3 of 5



Lovelace So ific Resources Clin TrialsLeslie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

PATIENT NAME DNG, DNG

PATIENT ID **AAGF4531** DOB 04/09/1955 SEX REPORT STATUS Final

PAGE

Site Code

PHYSICIAN

Unlisted Physician.

COLLECT DATE & TIME

Result

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT, PHONE NO.

10/01/2013 13:40

10/01/2013 20:30

10/03/2013 06:06

PATIENT NO.

30920877

COMMENTS:

AKP-014

| Test |
|---|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite |
| Allerg,Cockroach |

Allerg, Derm. pter.

In Range Out of Range Units Reference Range 45.40 kU/L Н < 0.35 <0.10 kU/L < 0.35 <0.10 kU/L < 0.35 <0.10 kU/L <0.35 0.20 kU/L < 0.35 <0.10 kU/L < 0.35 < 0.10 kU/L < 0.35 <0.10 kU/L <0.35 <0.10 kU/L <Q.35

The standard classification system utilizes the following class cutoffs. class ku/L Interpretation

| 0 | <0. 35 | Negative for Allergen |
|-----|--------------|-----------------------|
| I | 0. 35-0. 69 | Positive for Allergen |
| 11 | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| V | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-vI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| ciinical allergy. | | | | |
|---------------------------------------|---|--|---|--------|
| <0.10 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | 12.50 | Н | kU/L | < 0.35 |
| | 0.60 | Ĥ | kU/L | < 0.35 |
| · · · · · · · · · · · · · · · · · · · | 24.50 | H | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | | | | |
| | <0.10 <0.10 <0.10 <0.10 <0.10 | <0.10 <0.10 <0.10 12.50 0.60 24.50 <0.10 | <0.10 <0.10 <0.10 12.50 H 0.60 H 24.50 H <0.10 <0.10 | <0.10 |

NO PHYSICIAN GIVEN

Important info

CLARIFICATION OF PATIENTS NAME PER CLIENT THEY ONLY USE LETTER

End of Report

Meets inclusion criteria.

Mentaniero

03 Oct 2013

DNG, DNG

10/03/2013 06:06

FAX24664



Name: NGB,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 63.0

Weight(lb): 126

Any Info:

ld: AKP-014 Date: 10/14/13

Temp: 18

PBar: 627

1_{Volume}2

Version: IVS-0101-20-5B

Physician: Technician:

Post

% Chg

Flow

6

2

0

| 0-1 | | (BTPS) | PR | E-RX | POST-RX | | |
|-----------|----------|------------|-------|-------|---------|-------|--|
| Spirometr | у | Ref | Pre | Pre | Post | Post | |
| | | | Meas | % Ref | Meas | % Ref | |
| FVC | Liters | 2.93 | 3.41 | 116 | | | |
| FEV1 | Liters | 2,39 | 2.34 | 98 | | | |
| FEV1/FVC | % | 83 | 69 | 83 | | | |
| FEF25-75% | L/sec | 2.60 | 1.35 | 52 | | | |
| FEF50% | L/sec | 3.31 | 1.98 | 60 | | | |
| FEF75% | L/sec | 1.13 | 0.40 | 35 | | | |
| IC | Liters | | | | | | |
| VC | Liters | 2.93 | | | | | |
| PEF | L/sec | 5.65 | 6.85 | 121 | | | |
| MVV | ∐min | 93 | | | | | |
| PIF | L/sec | | 2.23 | | | | |
| FEV1/FEV6 | % | | 73 | | | | |
| Lung V | olum/ | es/Plethys | mogra | phy | (E | BTPS) | |

| Vtg | Liters | |
|--------|--------|------|
| VČ | Liters | 2.93 |
| TLC | Liters | 4.71 |
| RV | Liters | 1.74 |
| RV/TLC | % | 37 |
| FRC PL | Liters | 2.79 |
| ERV | Liters | |
| IC | Liters | |

Diffusion

DLCO mL/mmHg/min 18.3 DL Adj mL/mmHg/min 18.3 DLCO/VA mL/mHg/min/L 3.20

VA Liters BHT Sec

Resistance

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

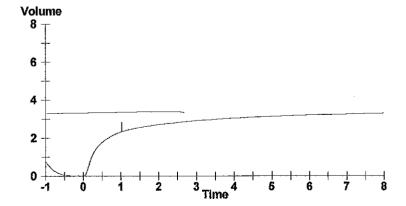
 Gaw
 L/sec/cmH2O

 sRaw
 cmH2O/L/s/L

 sGaw
 L/s/cmH2O/L

 Vtg (Raw)
 Liters

Comments:







Name: NGB,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 64.0

Weight(lb): 126

Any Info

ld: AKP-014

Date: 10/21/13

Temp: 22

PBar: 633

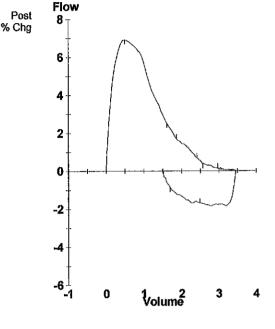
Physician:

Technician: VL

| ату што. | • | | | | | |
|----------|----------|------------|-------|-------|------------|---|
| | | (BTPS) | PR | E-RX | POST-RX | • |
| Spirom | etry | Ref | Pre | Pre | Post Post | |
| | | | Meas | % Ref | Meas % Ref | |
| FVC | Liters | 3.06 | 3.46 | 113 | | |
| FEV1 | Liters | 2.49 | 2.44 | 98 | | |
| FEV1/FV | /C % | 83 | 71 | 85 | | |
| FEF25-7 | 75%L/sec | 2.69 | 1.49 | 55 | | |
| FEF50% | L/sec | 3.40 | 2.28 | 67 | | |
| FEF75% | L/sec | 1.18 | 0.38 | 32 | | |
| IC | Liters | | | | | |
| VC | Liters | 3.06 | | | | |
| PEF | L/sec | 5.78 | 6.92 | 120 | | |
| MVV | L/min | 93 | | | | |
| PIF | L/sec | | 1.84 | | | |
| FEV1/FI | | | 75 | | | |
| Lung | Volum | es/Plethys | mogra | phy | (BTPS) | |
| Vtg | Liters | | | | | |
| VČ | Liters | 3.06 | | | | |
| TLC | Liters | 4.91 | | | | |

1.83

37 2.93



ERV Liters Liters Diffusion

RV

RV/TLC

FRC PL

mL/mmHg/min 18.7 mL/mmHg/min 18.7 DLCO DL Adj DLCO/VA mL/mHg/min/L 3.23 VΑ

Liters

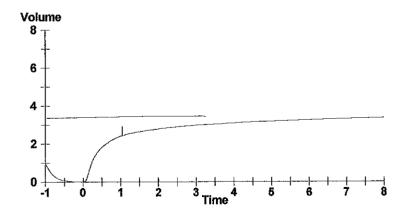
Liters

Liters **BHT** Sec

Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec Raw cmH2O/L/sec L/sec/cmH2O 0.703 Gaw cmH2O/L/s/L 3.80 sRaw sGaw L/s/cmH2O/L 0.263 Vtg (Raw) Liters

Comments:



Version: IVS-0101-20-5B



POST-RX

Post Post

Meas % Ref

(BTPS)

Name: NGB,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 64.0

Weight(lb): 124

Any Info:

ld: AKP-014 Date: 10/28/13

Temp: 19

Physician:

PBar: 628

1 Volume

Version: IVS-0101-20-5B

Technician: VL

Post

% Chg

Flow

8

6

2

0

-2

| | | | | | _ |
|----------|--------|-------------|-------|-------|---|
| | | (BTPS) | PRI | E-RX | |
| Spiromet | ıry | Ref | Pre | Рге | |
| | | | Meas | % Ref | |
| FVC | Liters | 3.06 | 3.35 | 109 | |
| FEV1 | Liters | 2,49 | 2.28 | 92 | |
| FEV1/FVC | % | 83 | 68 | 82 | |
| FEF25-75 | %L/sec | 2,69 | 1.18 | 44 | |
| FEF50% | L/sec | 3.40 | 1.84 | 54 | |
| FEF75% | L/sec | 1.18 | 0.32 | 27 | |
| Ю | Liters | | | | |
| VC | Liters | 3.06 | | | |
| PEF | L/sec | 5.78 | 6.95 | 120 | |
| MVV | l./min | 93 | | | |
| PIF | L/sec | | 1.32 | | |
| FEV1/FEV | /6% | | 72 | | |
| Luna \ | Valum | as/Plathysi | modra | nhv | |

Lung Volumes/Plethysmography

Vtg VC Liters Liters 3.06 TLC 4.91 Liters RV Liters 1.83 **RV/TLC** 37 Liters 2.95 FRC PL **ERV** Liters Liters

Diffusion

DLCO mL/mmHg/min 18.5 DL Adj mL/mmHg/min 18.5 DLCO/VA mL/mHg/min/L 3.21

VA Liters BHT Sec

Resistance

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

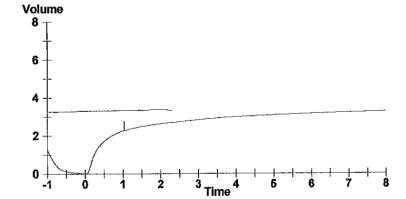
 sRaw
 cmH2O/L/sec

 sRaw
 L/s/cmH2O/L

 sGaw
 L/s/cmH2O/L

Vtg (Raw) Liters







Name: NGB,

Gender: Female

Age: 58 Ra Height(in): 63.8

Race: Caucasian

Weight(lb): 124

Any Info:

ld: AKP-014

Date: 11/04/13

Temp: 20 Physician:

PBar: 628

Physician: Technician: VL

| | | | | DV. | POS | TDV | | | | | | |
|-----------|--------------|------------|--------|-----|--------------|---------------|---------------|-----------------|--|--|-----|--------|
| Spirometr | , (вт | 'PS) | PRE | | | | Doot | Flow | | | | |
| Opironica | y | Ref | Pre | Pre | Post Meas | POSI V Dof | Post % Chg | 8 T | | | | |
| | | 0.00 | Meas 9 | | weas | 70 IXEI | 70 Ong | 1 | /' \ | | | |
| FVC | Liters | 3.02 | 3.56 | 118 | | | | | / \ | | | |
| FEV1 | Liters | 2.46 | 2.45 | 100 | | | | 6 | / \ | | | |
| FEV1/FVC | | 83 | 69 | 83 | | | | 1 | 1 | | | |
| FEF25-75% | | 2.66 | 1.35 | 51 | | | | † | 1 | | | |
| FEF50% | L/sec | 3.37 | 2.36 | 70 | | | | 4 + | 1 | | | |
| FEF75% | L/sec | 1.16 | 0.39 | 33 | | | | 7 | 1 | \ | | |
| IC | Liters | | | | | | | + | 1 | | | |
| VC | Liters | 3.02 | | | | | | | l | 7 | | |
| PEF | L/sec | 5.75 | 7.64 | 133 | | | | 2 † | | V. | | |
| MVV | L/min | 93 | | | | | | | | . \. | | |
| PIF | L/sec | | 1.40 | | | | | ļ | 1 1 | John John | اما | |
| FEV1/FEV6 | 3% | | 74 | | | | | 0 + | 1- | | - 4 | \neg |
| Luna V | /olumes/P | Plethysma | ograp | hv | (B | TPS) | | | , | Den' | | |
| _ | | 1001190111 | 9. or | | | | | Ī | | 7 | ~/ | |
| Vtg | Liters | | | | | | | -2 | | | | |
| VC | Liters | 3.02 | | | | | | _ | | | | |
| TLC | Liters | 4.87 | | | | | | † | | | | |
| RV | Liters | 1.81 | | | | | | -4 | | | | |
| RV/TLC | % | 37 | | | | | | T | | | | |
| FRC PL | Liters | 2.92 | | | | | | 4 | | | | |
| ERV | Liters | | | | | | | | | | | |
| IC | Liters | | | | | | | -6 ¹ | 0 1. | • | 3 | 4 |
| Diffusi | on | | | | | | | -1 | ∪ to | lume 2 | • | _ |
| DLCO | mL/mmHg/min | 18.4 | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | |
| | mL/mHg/min/L | | | | | | | | | | | |
| | | | | | | | | | | | | |

Resistance

BHT

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec
 1.30

 Gaw
 L/sec/cmH2O
 0.700

 sRaw
 cmH2O/L/s/L
 3.80

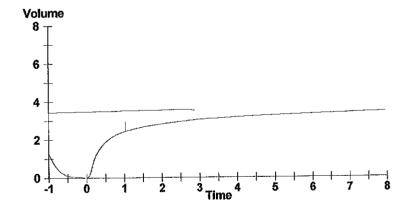
 sGaw
 L/s/cmH2O/L
 0.263

 Vtg (Raw)
 Liters

Liters

Sec

Comments:



Version: IVS-0101-20-5B

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | M | | | | | | | | | | | | | |
|----------|---|----------------------|----------------------|--------------------|---------------------|------------------------|--------|--|----------------------|----------------------|--------------------|---------------------|------------------------|-----------|
| | 0 1 2 3 | 2 3 | 2 3 | 2 3 | ON | ON ON | 0 | 2 3 | 2 3 | 2 3 | 2 3 | NO | ON ON | |
| , | 10/ | 0 7 | 0 1 | 0 1 | YES | YES | | 0 | 0 1 | 0 1 | 0 1 | YES | YES | |
| 0 | 32 | 2 3 | (2)3 | 2 3 | ON | ON N | 0 | 2 3 | 2 3 | 2 3 | 2 3 | NO | ON | |
| 10%. | | 0 | 0 | 0 | (ES) | (KES) | | 0 | 0 1 | 0 1 | 0 | YES | YES | |
| 1.00 | 7 2 2 3 4 7 8 7 8 | 2 3 | 2 | 2 3 | (2) | (S) | F | $\begin{array}{c} \\ \\ \\ \\ \end{array}$ | 2 3 | (Z) ₃ | © 3 | | 2 | |
| 10/.2/ | 0 1 | 01 | 0 1 | 0 | YES | YES | ļ , | 0 1 | 0 | 0 1 | 0 1 | YES | YES | |
| 4,1 | 1003 | 2 3 | 1(2) 3 |)23 | ON - | | -2 | 23 | 2 3 | (2)3 | 5 | NO | | |
| 2 | 0 | 0 | 0 1 | 0 | (ES) | YES | | 0 1 | 0 | 0 | 0 1 | (KES) | YES | |
| -3 | (2) 3 | 2 3 | (2) 3 | 2 3 | | 2 | ကု | $\bigcirc 3$ | 2 3 | 23 | (2) 3 | NO NO | (2) | |
| ē, | 0 1 | 01 | 0 | 0 | YES | YES | ' | 0 | 0 | 0 1 | 0 1 | (ES) | YES | |
| 107. | 103 | 2 3 | 1(2) 3 | 1(2) 3 | | (S) | 4 | (2) 3 | 2 3 | (2) 3 | 2 3 | ON (| | |
| | | 0 | 0 | 0 1 | YES | YES | | 0 | 0 | 0 1 | 0 1 | (ES) | YES | |
| 10/09/12 | 200 | 2 3 | 2 | (2) | ON (| ON (| -5- | 2 3 | 2 3 | (3) | (3) | ON N | NO | |
| | | $\bigcirc 1$ | 0 1 | 0 1 | | (ge) | | | 0 | 0 | 0 1 | (YES) | SES) | ļ |
| -6 | | 2 3 | 2 3 | 2 3 | ON C | | 9- | 2 3 | 2 3 | 2(3) | $\frac{1}{2}$ | ON (| 2 | |
| 0 | 0 | 0 | 0 1 | 0 | (SES) | YES | | 0 (| 0 | 0 | 0 | (SES) | YES | |
| 7- /0/01 | 2 3 | 2 3 | 2 3 | 0 (1) 2 3 | (<u>P</u>) | | -7 | 2 3 | 2 3 | (7) | 2 3 | S (| <u>ON</u>) | |
| 0/0 | 0 1 2 | 0 1 2 | 0(1) 2 | (F) o | YES | YES | | 6 | <u>6</u> | 0 1 | 0 1 2 | (NES) | YES (| |
| | | 9.0 | no | | arse | earing | Mc | ose | ė, | uo. | | arse | Throat Clearing Y/N | () |
| DAY | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | iroat Cl N | COACEDANO |
| | <u> </u> | ≝ o | 0 5 | ν. O | Voic Y/N | | | ğ 0 | 1 5 C | ٥ <u>-</u> | ız o | Void Y/N | Thro Y/N | Ü |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ALPOIH DATE COMPLETED: 10/7/13 - 10/14/13

SUBJECT INITIALS AND DATE MY 10/14/13

,

NGB



Lovelace Sc lific Resources Clin Trials-Leslie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME ATNGB, ATNGB PATIENT ID **AAGG1070** DOB. 04/09/1955 SEX REPORT STATUS F Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

PT. PHONE NO.

10/14/2013 10:30 PATIENT NO.

10/14/2013 19:41

10/15/2013 13:31

30920912

0

AKP014

COMMENTS:

| | Pa | sult | | | |
|------------------------------------|--|----------------------|----------------|---------------------------|--------------------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 141 | | mmol/L | 134-144 | |
| Potassium | 4.2 | | mmol/L | 3.5-5.1 | |
| Chloride | 103 | | mmol/L | 98-111 | |
| CO2 | 30 | | mmol/L | 20-30 | |
| Anion Gap | 8 | | | 6-14 | |
| Glucose | | 104 H | mg/dL | 60-100 NC | s mark |
| | Impaired fasting glucose (I 100-126 mg/dl.(ADA Guidelin | (FG) is defined as a | fasting alucos | e level of // 3) | s MAM. Oct 2013 |
| BUN | 18 | | mg/dL | 7-31 | |
| Creatinine | 0.86 Creatinine method is IDMS t | raceable. EstGFR Cal | mg/dL | 0.50-1.40 een adjusted | |
| | Please note new reference r | | | y | |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | |
| | Estimated GFR values are no on IV fluids, obese (BMI>34 |) or underweight (BM | lI<20) people. | - | |
| | the very old or very young, people with acute illnesses | races other than Ca | ucasian or Afr | ican American, | |
| Calcium | 9.2 | • | mg/dL | 8.4-10.4 | |
| Total Protein | 7.1 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.0 | | gm/dL | 3447 | |

gm/aL Globulin 3.1 gm/dL 2.4-4.2 Bilirubin, total 0.6 mg/dL 0.3-1.2 Alk Phos 55 Ũ/L 38-150 AST(SGOT) 26 U/L 6-58 ALT(SGPT) 29 U/L 14-67 Fasting NO **Phosphorus** 4.0 mg/dL 2.3-5,6 CBC WBC 7.5 x10E3 4.0-10.6 **RBC** 4.38 x10E6 4.00-5.36 Hgb 14.2 gm/dL 12.0-16.0 Hct 42 % 36-48 MCV 96 fL. 81-98 **MCHC** 33.6 gm/dL 31,2-35,2 **RDW** 13.2 % 11.0-14.5 **Platelets** 350 x10E3 150-400 Eos, Respiratory None seen NS Phys, Addr. Phone

NO PHYSICIAN GIVEN

Important Info

CLARIFICATON OF NAME PER CLIENT THEY USE LETTERS AS THE NAME

End of Report

16 Oct 2013

SUBJECT INITIALS AND DATE: ## 10/21/13

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | ₩. | 7 | m` | ರ- | ഗ~ | 9- | 7, | | ത |
|----------------------|----------------|------------------|---|------------------------------|--------------------|-----------|-------------------|-------------|---------|
| AM | 19/14 | 1/0// | 2/1/11 | 10/17 | 10/18 | 10/19 | 10/20 | 10/21 | 10/22 |
| Runny Nose 0 to 3 | 0123 | 0 (1) 2 | $\begin{vmatrix} 3 & 0 & \overline{1}(2) \end{vmatrix}$ | $ \stackrel{0}{}_{1}(2)_{3}$ | (<u>0</u>) i 2 3 | 0 1 (2) 3 | 0 1(2) 3 | $0 \ 1(2)3$ | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | (0)1 2 | 3 (0) 1 2 3 | (0) 1 2 3 | 0 1 2 3 | 0123 | 0 2 3 | 0)123 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 (1) 2 | 3 0 (1) 2 3 | 0 1(2)3 | 0(1)2 3 | 0(1)2 3 | 0(1)23 | 0 1(2)3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | (<u>0</u>) 2 | 3 (0) 1 2 3 | 0(1) 2 3 | 0(1) 2 3 | 0 1(2) 3 | 0 1(2)3 | 0(1)2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO) | y YES (NO | YES (NO) | YES (NO) | YES (NO | NO Jajo | (YES) NO | YES NO |
| Throat Clearing Y/N | YES NO | VES (NO | (KES) NO | VES (NO) | VES (NQ) | YES (NO) | VES (NO) | (VES) | YES NO |
| > DAY PM | 1 | 7 | 8 | 4 | 2 | 9 | 7 | 8 | 6 |
| Runny Nose 0 to 3 | (0/123 | 0) 1 2 | 3 0(1) 2 3 | 0 1(2)3 | 0 (1) 2 3 | 0 1 (2) 3 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | (6)123 | (0) 1 2 | 3 (0) 1 2 3 | (0) 1 2 3 | (0) 1 2 3 | 0123 | (<u>0</u>)1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | <u>(0)</u> 123 | 0(1)2 | $3\left \widetilde{0(1)}\right ^2$ | 0 1(2)3 | 0(1)2 3 | 0 1 2(3) | 0(1)23 | 0 1 2 3 | 0 1 2 3 |
| Sneezing (| 9123 | $\bigcirc 1 \ 2$ | 3(0)1 2 3 | 0.1(2)3 | (<u>0</u>)1 2 3 | 0 1 2)3 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO | VES) NO | (YES) NO | (YES) NO | YES (NO) | (FS) NO | YES NO | YES NO |
| Throat Clearing Y/N | YES (NO) | YES (NO | (YES) NO | YES (NO) | YES (NQ) | YES (NO) | (VES) (NG) | YES NO | YES NO |
| 0.000 | | | | | | , 4 | | | |

SCALE 0 to 3

SCALE 0 to 3

YTRA
0= No symptoms (no symptoms detected)
1= Mild symptoms (symptoms present but easily tolerated)
2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER AKPOIG

Y=Yes N= No

DATE COMPLETED:_



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Clin Trials-Lestie Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME NGB, NGB

PHYSICIAN

30920915

COMMENTS:

Test

Unlisted Physician. REQUISITION NO.

PT. PHONE NO.

0

PATIENT ID **AAGG4464** DOB 04/09/1955 SEX

REPORT STATUS Final

PAGE

COLLECT DATE & TIME 10/21/2013 10:45

RECEIVE DATE & TIME 10/21/2013 18:29 PRINT DATE & TIME

10/22/2013 06:06

PATIENT NO.

AKP014

In Range

Result

Out of Range

Montaine NO 22 Oct 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Not given

NS

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| CHOCK AFFROMINIA IL NEUT ONUL LUENT AZ 1100NU | 7 77 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 | 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | 200 | | | | | | |
|---|--|---------------------------------------|-----------------|----------------|----------------|------------------|-----------|-----------|---------|
| DAY | 7 | ∞ ् | ດ ຸ | 10 | 11 | 12 | 13 | 14 | 12 |
| AM | 121/13 | 10/22/13 | 13 9/23/13 | 10/2413 | 1925(13 | 21/02/13 | 10/27/13 | 10/28/13 | 1922/13 |
| Nose | 10 123 | 0003 | 0.123 | 0(D)2 3 | 0 1 2(3) | $0 \bigcirc 2$ 3 | 0 1 🕲 3 | 0 (T) 2 3 | 0 1 2 3 |
| 0.10.3 | , | 2 2 C | | (| • | • | | , , | , |
| Itchy Nose | 0 1 2 3 | 01 2 3 | $\binom{0}{2}$ | <u>C</u> 1 2 3 | Q 1 2 3 | 6 1 2 3 | 0123 | O_{123} | 0 1 2 3 |
| Congotion | , | 100 | 100 | 0.60 | 100 | 0 1 1 3 3 | 2 6 6 6 6 | - | , |
| 0 to 3 | ۷ ہــــــــــــــــــــــــــــــــــــ | $\vec{\mathcal{C}}$ | 0 165 | c 7 → 0 | 2 T O | | 0 (2 5 | 2 7 0 | 0 I 2 3 |
| Sneezing | 0 1 2 3 | 0123 | 0 T) 2 3 | 0123 | 0 1(2)3 | 0123 | 0123 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 | - | | |)) | | (| |) | |
| Voice Hoarse | YES NO | (YES) NO | (YES) NO | YES (NO | (YES) NO | YES (NO) | (YES) NO | YES (NO) | YES NO |
| N/Y | | b |) (| (|) |) (|) |) (| |
| Throat Clearing | YES NO | YES (NO | (ES) NO | YES (VO) | YES (NO) | YES (NO) | YES (NO) | YES (NO | YES NO |
| DAY PM | 7 | 8 | 6 | 10 | 11 | 12 | 13 | 14 | 15 |
| Runny Nose | 0 1 2 3 | 0 1 (2) 3 | 0(1)2 3 | 0 1(2)3 | 0 🛈 2 3 | 0 🛈 2 3 | 0 1 🕲 3 | 0 1 2 3 | 0 1 2 3 |
| | 0173 | 0)123 | 01 2 3 | 01 2 3 | 0173 | 0000 3 | 0173 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 | } | } |) I |) | l I | P | i (| 1 | 1 |
| Congestion | 0 1 2 | 0 1(2)3 | 0 (02 3 | 0.1(2)3 | 0 1 3 | 0(1)2 3 | 0 1(2) 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing | 0 1 2 | 0 (1) 2 3 | 0123 | $0(1)^{2}$ 3 | 0(1)2 3 | 0)123 | 0.1(2)3 | 0 1 2 3 | 0 1 2 3 |
| 0 to 3 | | (| (| |)(| | | | |
| Voice Hoarse | (ES) NO | YES NO | YES (NO) | (YES) NO | VES) NO | YES (NO) | NO (SE) | YES NO | YES NO |
| Throat Clearing | (YES) NO | YES (NO | YES (NO) | YES (NO | (M) SIA | (YES) NO | (YES) NO | YES NO | YES NO |
| Y/N | | , | | |) |) |) | | |
| CCALEDAGO | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

DATE COMPLETED:_

18% 18% 18%

SUBJECT NUMBER: ALC P.

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

ntific Resources Lovelace € Leslie Byat., Jin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME NGB, NGB

PATIENT ID

AAGG4464

DOB 04/09/1955 SEX

REPORT STATUS

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME

RECEIVE DATE & TIME

Final

PRINT DATE & TIME

0

10/28/2013 10:40

10/28/2013 19:01

10/29/2013 06:03

30920968

Test

COMMENTS:

PATIENT NO. AKP014

Result

Out of Range

MP211 Sub-I 28 29 Oct 2013 29 Oct 13

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr. Phone None seen Not given

In Range

NS

End of Report

Subject Initials: $\overline{\mathcal{OG}}$ ** If day is <u>unknown</u>, write UNK in space provided, but every effort should be made to be as specific as possible** Date: 27 Feb 2014 Action Taken 1 Spect Jons Now E THE DY/NOV/DOLS HONE = 04/05/NOV/3013 NOVE LSR Study #:_ (рр/ммм/үүүү) ** End Date ADVERSE EVENT LOG (Suspected/Not Suspected) Relationship to Study Drug SWACIUM 03/NOV/2013 mild Finger 03/NOVIOUS Mild 14/OCT/2013 MULA SEVERITY 610 ユダケ Investigator Signature (at end of study): 27/0cr/2013 (DD/MMM/YYYY) Study Identification: 2749 ** Start Date Strigen age 12 Subject Number: Adverse Event SWOTTEN SWell 80 d

Date: 2/01/1

Lovelace Scientific Resources, Inc - AdverseEvents 04/2013

SC Signature (at end of study): __

LSR #: Study Identification; Al Pharma Allegy さってと Subject Number:

2749

Subject Initials: NGB

CONCOMITANT MEDICATION LOG

List all <u>prescription</u> medications you are taking. Also include <u>over the counter</u> medications, vitamins and supplements.

| Ongoing at EOS: (for, Clinicuse) | | X | × | X | X | | X | | X_{i} | | | |
|--------------------------------------|-------------------|---------------|------------|------------|---------|--------------|-------------|------------|------------------|---|--|--|
| Stop Date | | | | | | | | | | | | |
| * Start Date (Day/Month/Year) | UNIC/AUG/1999 | 2013 | 2013 | 2010 | ।ववत | (102 | 2013 | 2011 | 2000 | | | * If day or month of medication date is <u>unknown</u> , write UNK in space provided |
| Route | Oral | 0 <i>d</i> | rP () | ار () | Pt | Po | PD | 00 | Po | | | <u>m</u> , write UI |
| Frequency | 2 Tabs per day | So | Q.O | 000 | QO | QO | Q0 | (QD | ٥ ٢ | • | | te is <u>unknow</u> |
| Unit | MG | کر کے | ر ک | 29 | 2 | 效 | C 3 4 | ms | my | 7 | | ication da |
| Dose | -200 | (LOD) | 12.00 | ے | 5,0 | 0000 0000 | 006 | 750 | 12.5 | | | ith of med |
| Indication (What you take it for) | Diabetes | svpplemend | Supplement | SVPPlement | 上光 | S8 70 | J 40 | SUPPlement | worker retention | | | * If day or mon |
| Name of Medication | EXAMPLE | Cal clum + Dz | Fish ou | MVT | Demarin | alucisamine | chondro the | MSM | た元 | | | |

Investigator Signature (at end of study): .

SC Signature (at end of study):_

Date:

Date: 2

Lovelace Scientific Resources, Inc - ConMeds 04/2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| [" | 2 | m | m | 2 | | | | 8 | m | m | m | | 1 |
|---------------|-----------------------------|----------------------|------------------------------|--------------------|---------------------|--|--------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|
| 0 | 2 | 2 | 7 | 2 | S S | 8 | 0 | 7 | 2 | 2 | 7 | NO NO | 8 |
| | 0 | 0 1 | 0 1 | 0 1 | YES | YES | | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES |
| 1/12 | 2) 3 | 2 3 | $\bigcirc 3^3$ | (Z) 3 | NO | ON | | 2 3 | 2 3 | 2 3 | 2 3 | ON N | ON |
| | 0 1(| 01 | 0 1(| 0 1(| (YES) | (FES) | 0 | 0 1 | 0 1 | 0 1 | 0 | YES | YES |
| 12/2 | 2 3 | 2 3 | 2 3 | 2 3 | (S) | | _(| 23 | 2 3 | (2) | 2 3 | (2) | (S) |
| -1 | | | 0 | 0 (1) | YES | YES | | 0 | | 0 1 | | YES | YES |
| -2- | 20 3 | 2 3 | $\left(\frac{2}{3}\right)^3$ | 23 | | NO | 2 | 2 3 | 2 3 | 2 3 | 2 3 | 9 | S S |
| 111 | 0 1 | $\bigcirc 1$ | 0 1(| 0 1 | YES | YES) |) ' | 0(1 | (O) | \bigcirc | 0 | | (SE) |
| -3 | | 2 3 | © 3 | O 3 | 8 | NO | 5- | 2 3 | 2 3 | 2 3 | 12 3 | NO | NO NO |
| : | | 0 | 0 1 | 0 1(| (ES) | | | 0 | 0 | | (1) | (ES) | (VES) |
| 24/12 | 54/15)2 ^{6/13} | 2 3 | $\bigcirc 3$ | 12 3 | ON | | - | 2 3 | 2 3 | 2 3 | 2 3 | (2) | |
| . (0) | | 0 | 0 1 | | (SES) | YES | 4 | \bigcirc | 0 | <u>O</u> | <u>6</u> | YES | YES |
| 5/12 | (C) (C) | 2 3 | 23 | 2 3 | NO | ON N | ν. | (2) 3 | 2 3 | 2 | 2 3 | ON | |
| 14301 | 0 1 | \bigcirc | 0 1(| 0 | (ES) | | | 0 1 | 0 | 0 1 | <u>@</u> (| (KES) | YES |
| -e /29// 2 | 2 3 | 2 3 | 2 3 | 2 3 | P | ON | 9 | 2 33 | 2 3 | O | 2 3 | (2) | |
| (a) | 0 | 0 | 0 | 0 | YES (| SE SE SE SE SE SE SE SE SE SE SE SE SE S | 1 | 0 1 | \bigcirc_1 | स्म | 0 | YES | YES (|
| 7-10/06/01 | 2 % | 2 3 | 2 3 | 2 3 | 9 | ON | 7 | 2 3 | 2 3 | 2 3 | 2 3 | ON (| |
| 7- | | 1 | 0 | 0 1 | YES | YES | 7- | 0 (1) 2 | 0 1 2 3 | 0(1)2 | 0(1) | (YES | YES |
| | Se | a) | c | | ırse | saring | Σ | Se | nı. | c | | ırse | earing |
| DAY | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N |
| | Runny 0 to 3 | Itchy N | Conge 0 to 3 | Sneezi 0 to 3 | Voic Y/N | Thro Y/N | | Rur O to | Itchy I 0 to 3 | Conge 0 to 3 | Sneezi 0 to 3 | Voio/ | Thro |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: ALPOIN DATE COMPLETED: 11/04/13

SUBJECT INITIALS AND DATE: HELD 11/04/13



Albuquerque, NM87108-5129

Lovelace Sci. fic Resources Leslie Byatt, C... Trials 2441 Ridgecrest Dr SE

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME NOB, NOB

PATIENT ID AAGH1349

DOB 04/09/1955

REPORT STATUS Final SEX F

PAGE

Unlisted Physician,

COLLECT DATE & TIME 11/04/2013 10:32 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

11/04/2013 20:19

11/05/2013 06:10

30920950

PHYSICIAN

| AKP014 | |
|--------|--|
|--------|--|

| COMMENTS | : |
|----------|---|
|----------|---|

| | F | lesuit | | | | |
|---------------------------------------|---|--|------------------------------------|--|--------------------------------|-----------|
| Test | In Range | Out of Rang | je – | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 137 | | | mmol/L | 134-144 | |
| Potassium | 4.0 | | | mmol/L | 3.5-5.1 | |
| Chloride | 103 | | | mmol/L | 98-111 | |
| CO2 | 28 | | | mmol/L | 20-30 | |
| Anion Gap | 6 | | | | 6-14 | |
| Glucose | 100 | | | mg/dL | 60-100 | |
| 5111 1 | Impaired fasting glucose (100-126 mg/dl (ADA Guidel | (IFG) is define ines Diabetes (| ed as a f Care 26: (| | | |
| BUN | 16 | | | mg/dL | 7-31 | |
| Creatinine | 0.82 | tracachia Fac | aces cala | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS Please note new reference | | | | een adjusted. | |
| 000 461 4 | | range errectiv | • | | | |
| eGFR non-African Am GFR Comment | >60 | | ı | mL/min/1.73m2 | >60 | |
| Of it Comment | Estimated GFR values are rong in it fluids, obese (BMIS) the very old or very young people with acute illness | not accurate in 34) or underwei 3, races other | n acute k ight (BM) than Cal | kidney failure, (<20) people, ucasian or Afr | , inpatients ican American, | |
| Calcium | 8.9 | ioi oi ampacaci | 01101 | mg/dl_ | 8.4-10.4 | |
| Total Protein | 7.1 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.9 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.5 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 55 | | | Ŭ/L | 38-150 | |
| AST(SGOT) | 25 | | | U/L | 6-58 | |
| ALT(SGPT) | 28 | | | U/L | 14-67 | |
| Fasting | NOT GIVEN | | | | | |
| CBC | | | | | , | |
| WBC | 7.7 | | | x10E3 | 4.0-10.6 | |
| RBC | 4.12 | | | x10E6 | 4.00-5.36 | |
| Hgb | 13.1 | | | gm/dL | 12.0-16.0 | _ |
| Hat | 41 | | | % | 36-48 | a win |
| MCV | 00.4 | 99 | Н | fL | 81-98 // | 7 1/20-17 |
| MCHC | 32.1 | | | gm/dL ** | 31.2-35.2 | 7 Nov 13 |
| RDW Blotolete | 13.2 | | | % 4053 | 11.0-14.0 | |
| Platelets For Proping to 1 | 278 | | | x10E3 | 150-400 | |
| Eos, Respiratory Phys, Addr, Phone | None seen PHYS UNKN | | | | NS | |

End of Report

TGC/OOD

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" YES W |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| BURNING SENSATION, BAO TASTE |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

AKP-015

2/49 AKPharma PERENNIAL ALLEA JIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIENT D | EMOGRAPHICS | 5 | | | |
|----------------|---|--|--------------------------------------|------------|-------------|
| | | | | | |
| Patient Dem | ographics | | | | |
| Date of Birth: | 08/Ju | N 1955 (dd/r | nmm/yyyy) | | |
| Gender: | ☐ Male | Female | , | | |
| TCC 1 T 1 | ' Class | | | | |
| if female, Ind | icate Childbearing I | | | | |
| | Childbearin | g 🔀 Surgically s | sterilized | Post-Menop | ausal |
| | <u></u> | | | | |
| Ethnicity: | Hispanic N | Ion Hispanic | | | |
| | Hispanic N | | . | | |
| Race: A | sian 🗌 Black | Caucasian [| | | |
| Race: A | sian 🗌 Black | | | | |
| Race: A | sian 🗌 Black | Caucasian [| | | |
| Race: A | sian 🗌 Black | Caucasian [| | | |
| Race: A | sian | Caucasian [| | | |
| Race: A | sian Black cific Islander tory | Caucasian C | | | |
| Race: A | sian Black cific Islander tory | Caucasian [| | | |
| Race: A | sian Black cific Islander tory s: None (smok | Caucasian C | arettes in lifeti | me) | |
| Race: A | sian Black cific Islander tory s: None (smok | Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Ca | arettes in lifeti | me) | |
| Race: A | tory s: None (smok | Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Cother, Specify Caucasian Ca | arettes in lifeti e than 100 cigo | me) | |

Version: 02 September 2013



Lovelace Sci Ic Resources Clin TrialsLesne Byatt 2441 Ridgecrest Dr SE Albuquerque, NM87108

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME BJK, BJK

PHYSICIAN Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

PATIENT ID **AAGF5252**

06/08/1955

SEX

REPORT STATUS Final

PAGE

COLLECT DATE & TIME 10/02/2013 10:38 RECEIVE DATE & TIME 10/02/2013 20:39 PRINT DATE & TIME

10/03/2013 06:06

30920894 COMMENTS: O

PATIENT NO.

AKP015

| Test |
|---|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West,Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach Allerg,Derm. pter. |

| | Result | | | | |
|----------|------------|-----|-------|-----------------|-----------|
| In Range | Out of Ran | ıge | Units | Reference Range | Site Code |
| 0.20 | | | kU/L | <0.35 | |
| | 1.40 | Н | kU/L | <0.35 | |
| | 2.20 | Ĥ | kU/L | <0.35 | |
| , | 27.60 | H | kU/L | <0.35 | |
| | 35.80 | H | kU/L | <0.35 | |
| 0.30 | | • • | kU/L | <0.35 | |
| 2000 | 4.50 | Н | kU/L | <0.35 | |
| _ | 0.40 | H | kU/L | <0.35 | |
| 0.28 | | • • | kU/L | <0.35 | |

The standard classification system utilizes the following class cutoffs. Class ku/L Interpretation

| 0 | <0. 35 | Negative for Allergen |
|-----|--------------|-----------------------|
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| v | 52, 5-99, 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Н

Н

Н

0.40

3.80

15.50

5.10

0.80

| Allerg,Derm. farinae | |
|----------------------|-------------|
| Allerg Clad. herb. | <0.10 |
| Allerg, Firebush | |
| Allerg,Cat Dander Ep | <0.10 |
| Allerg, Dog Dander | <0.10 |
| Allerg, Bluegrass | , - |
| Allerg, Pigweed | |
| Allerg, Mulberry | |
| Allerg, Helminth | <0.10 |
| Phys, Addr. Phone | NOT GIVEN |
| FAX RESULTS | |
| FAX PHONE NUMBER | 348 8546 |
| LANCE LIGHT HOUNDER | V-IV VUTO |

End of Report

meets inclusion criteria

Mometanine M

03 Dit 2017

< 0.35

<0.35

< 0.35

< 0.35

<0.35

<0.35

< 0.35

<0.35

kU/L

kU/L

kU/L

kU/L

kU/L

kU/L

kU/L

kU/L

kU/L



Name: BJK,

Gender: Female

Age: 58

Race: Caucasian Height(in): 62.0

Weight(lb): 100

Any Info:

Id: AKP-015

Date: 10/16/13

Flow

16

12

8

4

0

-8

-12⊥ -2

0

₹olume

Version: IVS-0101-20-5B

8

Temp: 19

PBar: 631

Physician: Technician:

Post

% Chg

| | | | |
|----------------|-------------|------------------|------------|
| Outron to | (BTPS) | PRE-RX | POST-RX |
| Spirometry | Ref | Pre Pre | Post Post |
| | | Meas % Ref | Meas % Ref |
| FVC Liters | 2.80 | 3.35 120 | |
| FEV1 Liters | 2.29 | 2.66 116 | |
| FEV1/FVC % | 84 | 80 95 | |
| FEF25-75%L/sec | 2.51 | 2.70 108 | |
| FEF50% L/sec | 3.21 | 4.48 140 | |
| FEF75% L/sec | 1.08 | 0.88 82 | |
| IC Liters | | | |
| VC Liters | 2.80 | | |
| PEF L/sec | 5.53 | ** 8.75 ** 158 | |
| MVV L/min | 93 | | |
| PIF L/sec | | | |
| FEV1/FEV6% | | 82 | |
| Lana Volur | nes/Plethys | smography | (BTPS) |
| Lung Volui | TIOUR TOURS | JUNEST CAPILY | |

| Vtg | Liters | |
|--------|--------|------|
| VČ | Liters | 2.80 |
| TLC | Liters | 4.51 |
| RV | Liters | 1.66 |
| RV/TLC | % | 37 |
| FRC PL | Liters | 2.86 |
| ERV | Liters | |
| IC | Liters | |
| T | • | |

Diffusion

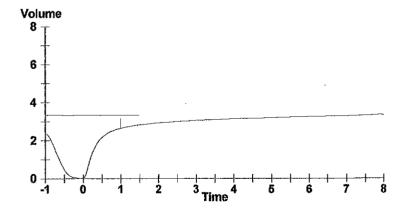
DLCO mL/mmHg/min 15.7 DL Adj mL/mmHg/min 15.7 DLCO/VA mL/mHg/min/L 3.22 VA Liters

BHT Sec

Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec Raw Exp Raw L/sec/cmH2O 0.686 Gaw cmH2O/L/s/L 3.81 sRaw L/s/cmH2O/L 0.262 sGaw Vtg (Raw) Liters

Comments:





Name: BJK,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 62.0

Weight(lb): 100

Any Info:

ld: AKP--015 Date: 10/24/13

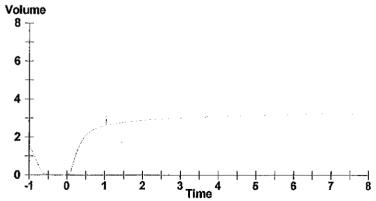
Temp: 20

PBar: 634

| Physician: |
|-------------|
| Technician: |
| |

| Contract contract to the contract of the contr | (BTPS) | PRE-RX | POST-RX | Flow | |
|--|---------------|-----------------------|-------------------------|-----------------------|--|
| Spirometry | Ref | Pre Pre Meas % Ref | Post Post Meas % Ref | Post 8 | |
| FVC Liters | 2.80 | 3.23 116 | Meas 70 Mei | % Grig | $f = \int_{\mathbb{R}^{N}} ds$ |
| FEV1 Liters | 2.29 | 2.66 116 | | | |
| FEV1/FVC % | 84 | 82 98 | | 6+ | |
| FEF25-75%L/sec | 2.51 | 2.95 118 | | 1 | |
| FEF50% L/sec | 3.21 | 4.34 135 | | _ [| To. |
| FEF75% L/sec | 1.08 | 0.96 89 | | 4 + | · · |
| IC Liters | | | | 1 | N. Carlotte |
| VC Liters | 2.80 | | | | \ |
| PEF L/sec | 5.53 | 7.88 143 | | 2+ | N. |
| MVV L/min | 93 | | | 1 | \ \ \ \ |
| PIF L/sec | | | | T . | A Marine Marine Commencer of the Commenc |
| FEV1/FEV6% | SINK L . S | 83 | (DTDO) | 0 | |
| | nes/Plethys | mography | (BTPS) | - | result of the second |
| Vtg Liters VC Liters | | | | -2 | |
| VC Liters | 2.80 | | | -2 † | |
| TLC Liters | 4.51 | | | 4 | |
| RV Liters | 1.66 | | | ام | |
| RV/TLC % | 37 | | | -4 † | |
| FRC PL Liters | 2.86 | | | 1 | |
| ERV Liters | | | | _ | |
| IC Liters | | | | -6 [⊥] -1 | 0 1 2 3 4 |
| Diffusion | | | | -1 | 0 1 _{Volume} 2 3 4 |
| | nHg/min 15.7 | | | | |
| | nHg/min 15.7 | | | | |
| DLCO/VA mL/ml- | lg/min/L 3.24 | | | | |
| VA Liters | | | | | |
| BHT Sec | | | | | |
| Resistance | | | | | |
| Raw Total cmH20 | | | | | |
| Raw Insp cmH20 | | | | | |
| Raw Exp cmH20 | | | | | |
| | D/L/sec 1.33 | | | | |
| | mH2O 0.686 | | | | |
| sRaw cmH20 | | | | | |
| | H2O/L 0.262 | | | | |
| Vtg (Raw) Liters | | | | | |

Comments:



Version: IVS-0101-20-5B



Lov Joe Scientific Resources A Ridgecrest Dr SE Almiguorque, NM 87108

Name: BJK,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 62.0

Weight(lb): 101

Any Info:

ld: AKP-115 Date: 10/30/13

Temp: 21

PBar: 629

Physician: Technician: VL

| Carleynon | | (BTPS) | PR | E-RX | POST-RX | | - Flann | | | | |
|-----------|-----------|----------|-------------|--------------|-------------------------|---------------|-------------------------|---------------|-----------------------|------------------|---|
| Spirane | чиу | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | Flow 16 _T | | | | |
| FVC | Liters | 2.80 | 3.32 | 119 | | 70 U.S | 1 | | | | |
| FEV1 | Liters | 2.29 | 2.74 | 120 | | | | | | | |
| FEV1/FV | C % | 84 | 82 | 99 | | | 12∳ | | | | |
| FEF25-78 | 5%L/sec | 2.51 | 2.90 | 116 | | | | | | | |
| FEF50% | L/sec | 3.21 | 4,42 | 138 | | | T | | | | |
| FEF75% | L/sec | 1.08 | 0.95 | 88 | | | 8∤ | 25 | | | |
| IC | Liters | | | | | | ŀ | / / | | | |
| VC | Liters | 2.80 | | | | | t | ŕ | · . | | |
| PEF | L/sec | 5.53 | 8.08 | 1 46 | | | 4 | - 1 | ¥ | | |
| MVV | L/min | 93 | 0.00 | 0 | | | ** | ! | 1 | | |
| PIF | L/sec | | | | | | + | 1 | , Y | | |
| FEV1/FE | V6% | | 85 | | | | | į | À. | | |
| Lung | Volumes | /Plethys | | phy | (BTPS) | | 0 1 | | `\ * - | - - | — |
| Vtg | Liters | | | | | | T | | | | |
| VČ | Liters | 2.80 | | | | | -4 ∮ | | | | |
| TLC | Liters | 4.51 | | | | | | | | | |
| RV | Liters | 1.66 | | | | | † | | | | |
| RV/TLC | % | 37 | | | | | -8 + | | | | |
| FRC PL | Liters | 2.85 | | | | | -0 | | | | |
| ERV | Liters | | | | | | + | | | | |
| ic | Liters | | | | | | امه | | | | |
| Diffus | ion | | | | | | -12⊥ -2 | 0 | 2 4 | 6 | 8 |
| DLCO | ml/mmHa/m | in 15.8 | | | | | _ | • | Volume | _ | • |

Resistance

DLCO

BHT

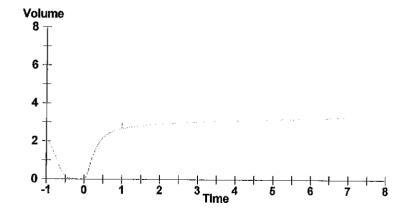
Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec cmH2O/L/sec Raw 1.34 Gaw L/sec/cmH2O 0.684 cmH2O/L/s/L sRaw 3.81 L/s/cmH2O/L 0.262 sGaw Vtg (Raw) Liters

DLCO mL/mmHg/min 15.8
DLCO/VA mL/mHg/min/L 3.21

Liters

Sec

Comments:





Name: BJK,

Gender: Female

Age: 58

Race: Caucasian

Height(in): 62.0

Weight(lb): 104

Any Info:

Id: AKP-015 Date: 11/06/13

Temp: 19

PBar: 637

Physician:

Technician: VL

| Any inio. | | | | | | I CONTINUE | Alli VI | | | | |
|---|---|--|--|--------------------------------------|--------|------------|------------------------|---|-------------|---|---|
| Spiromet | ry (B1 | Γ PS) Ref | PR Pre Meas | E-RX Pre % Ref | POST-R | st Post | Flow 8 _T | | | | |
| FVC FEV1/FVC FEF25-75' FEF50% FEF75% IC VC PEF MVV PIF FEV1/FEV | %L/sec L/sec L/sec Liters Liters L/sec L/min L/sec 6% | 2.80 2.29 84 2.51 3.21 1.08 2.80 5.53 93 | 3.31 2.68 81 2.89 5.01 0.81 7.51 | 118 117 97 115 156 75 | | | 4- | | | | |
| Lung \ | /olumes/F | Plethysr | nogra | phy | (BTPS |) | | | | | |
| Vtg VC TLC RV RV/TLC FRC PL | Liters Liters Liters Liters % Liters | 2.80 4.51 1.66 37 2.83 | | | | | -2 -4 | | | | |
| ERV IC Diffusi DLCO DL Adj | mL/mmHg/min mL/mmHg/min | 16.1 | | | | | -6 ¹ | 0 | 1 Volume | 3 | 4 |
| DLCONA | mL/mHg/min/L | 3.26 | | | | | | | | | |

Resistance

VA BHT

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 sGaw
 L/s/cmH2O/L/s/L

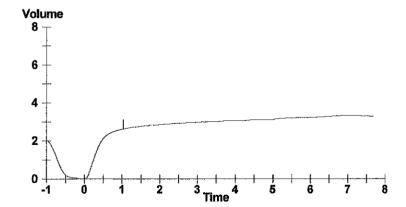
 3.81

 sGaw
 L/s/cmH2O/L

 Vtg (Raw)
 Liters

Liters Sec

Comments:



Version: IVS-0101-20-5B

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | -7 | 9- | -5 | | £, | -2 | -1 | 0 | C | |
|------------------------------------|----------------------------|--------------|-----------------------|-----------|-------------------|----------|-----------|---|-----------|-------------|
| AM | 10/09/13 | 10/10/13 | 10/11/13 | | 10/12/13 10/13/13 | 10/14/13 | 10115/13 | 19/10/13 | 1/4 1/61 | |
| Runny Nose 0 to 3 | 0 1 2(3) | 0 1.2(3) | 0 1 2 | 0.1(2)3 | 0 1 2 (3 | D 1 2(3) | 0 1 2(3) | 0 1 2 3 | 0 1 2 3 | |
| Itchy Nose 0 to 3 | 0 1(2)3 | 0 1 | 0 1 2(3) | 0 1(2)3 | 0 1. | 0 1 | 0(D)2 3 | 0 1(2)3 | 0 1 3 | |
| Congestion 0 to 3 | 0 1(2)3 | 0 1(2)3 | 0(1)2 3 | 0 1 2 | 0 (1)2 3 | 0(1) 3 | 0(1)2 3 | o(T) 2 3 | 9 3 | |
| Sneezing 0 to 3 | 0 1 2 (3) | 0 1(2)3 | 0 1 (2)3 | 0 1(8)3 | 0 1(2)3 | 0 1/23 | 0 1(2)3 | 0 1 2 3 | 0 103 | |
| Voice Hoarse Y/N | (YES) NO | (YES) NO | (YES) NO | on (E) | WES NO | (YES) NO | KES NO | YES NO | YES NO | |
| Throat Clearing Y/N | YES (NO) | YES (NG) | YES (NO | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO | |
| DAY PM | · '- | | τ̈́ | 4 | ကု | -2 | با | 0 | 0 | |
| Runny Nose 0 to 3 | 0 1 2(3) | 0 1(2)3 | 0 1 2(3) | 0 1 23 | 0 1 2(3) | 0 1 2 | 0 1 2 | 0.0 | 0 1(2) 3 | |
| Itchy Nose 0 to 3 | 0 1 (2)3 | 0 1 | 0(1)2 3 | 0(1)2 3 | 0 1(2)3 | 0 1 2 3 | 0(T)2 3 | 0 1/2 3 | 0 1 (2) 3 | |
| Congestion 0 to 3 | 0 1 2 3 | 0 1(2)3 | 0 1 (2)3 | 0 1 (2 3 | 0 1(2)3 | 0 1(2)3 | 0 1033 | 0 1(2)3 | 0 1(2)3 | |
| Sneezing 0 to 3 | 0 1 2 (3) | 0 1(2)3 | 0 1(2)3 | 0 1 (2)B | 0 1(2)3 | 0 1 3 | 0(1)/3 3 | 0 1(2)3 | 0 1(2)3 | |
| Voice Hoarse Y/N | (YES) NO | YES) NO | (YES) NO | YES) NO | (ES) NO | (YES) NO | MES) NO (| YES NO | (YES) NO | |
| Throat Clearing Y/N | YES (NO) | YES (NO) | YES (MO) | (YES) NO | YES (NO) | YES (NO) | YES (MO) | YES (NO) | YES NO | |
| O= No symptoms | (no eymptom | loctootob so | | | | | | Se la la la la la la la la la la la la la | 30 | 10 1-1-1 |
| 1= Mild symptoms (symptoms present | tion symptoms is (symptoms | | but easily tolerated) |) | 1 | | | 1919 | | |

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

DATE COMPLETED: 10/9/13 ~ 10/16/ (3

SUBJECT INITIALS AND DATE: 10:16:13 B

AKPOIS SUBJECT NUMBER: BJK

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scie c Resources Clin Trials-Lesue Byatt 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Client Nbr 24664

PATIENT NAME BJK, BJK

PATIENT ID AAGF5252 DOB 06/08/1955 REPORT STATUS Final

PAGE 1

PHYSICIAN Unlisted Physician,

REQUISITION NO.

COLLECT DATE & TIME 10/16/2013 11:00 RECEIVE DATE & TIME 10/16/2013 20:17 PRINT DATE & TIME

30920898

PT. PHONE NO.

PATIENT NO.

10/17/2013 06:08

0

AKP015

| COMMENTS | : |
|---|---|
| CA AND IN THE STREET A SECTION AS A SECTION | , |

| Result |
|--------|

| Test | In Range | Out of Rar | ige | Units | Reference Range | Site Code |
|------------------------------------|--|--|--------------------------------|---------------------------------|-----------------|-----------------------|
| Comp Metabolic Panel | | | | | | |
| Sodium | 138 | | | mmol/L | 134-144 | 00 -10/17 |
| Potassium | | 3.4 | L | mmol/L | 3.5-5.1 NC | s 98 10/18/13 |
| Chloride | 101 | | | mmol/L | 98-111 | |
| CO2 | 28 | | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | | 6-14 | |
| Glucose | 68 | | | mg/dL | 60-100 | |
| BUN | 8 | | | mg/dL | 7-31 | |
| Creatinine | 0.84 | | _ | _ mg/dL | 0,50-1.40 | |
| | Creatinine method is IDMS | | | | een adjusted. | |
| | Please note new reference | range effecti | ve 5/23/ | 2013. | • | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| O. I. Common. | Estimated GFR values are i | not accurate i | n acute | kidnev failure. | inpatients | , |
| | Estimated GFR values are rong IV fluids, obese (BMI>: the very old or very young people with acute illness | 34) or underwe g, races other es. or amputat | eight (BM than Ca tions. | I<20) people, ucasian or Afr | ican American, | · |
| Calcium | 8.7 | , | | mg/dL | 8.4-10.4 | |
| Total Protein | 6.9 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.6 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.3 | | | gm/dL | 2.4-4.2 | |
| Bllirubin, total | 0.3 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 113 | | | Ŭ/L | 38-150 | |
| AST(SGOT) | 25 | | | U/L | 6-58 | • |
| ALT(SGPT) | 25 | | | U/L | 14-67 | |
| Fasting | NO | | | | , , | |
| Phosphorus | 2.8 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | - | | |
| WBC | | 2.4 | L | x10E3 | 4.0-10.6 /VC | 5 10/18/13 |
| RBC | | 3.90 | L | x10E6 | 4.00-5.36 NC | 5/0//8//3 |
| Hgb | 14.8 | | | gm/dL | 12.0-16.0 | ₹. - ∤ |
| Hct | 42 | | | - % | ባል ላይ | |
| MCV | | 109 | Н | fL | 81-98 /VCS | 10/18/13 |
| MCHC | 34,9 | | | gm/dL | 31.2-35.2 | |
| RDW | 12,6 | | | % | 11.0-14.5 | |
| Platelets | 273 | | | x10E3 | 150-400 | |
| Eos, Respiratory | | Few | * | | NS | |
| Phys, Addr, Phone | Not given | | | | - • • | |

End of Report

Nes Jelayer PI 180et 2013

BJK, BJK

10/17/2013 06:08

FAX24664

Randomization

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | | r | | | | Ψ | r | | | | r | | |
|-----|------------------|---------------------|--------------------|----------------------|----------------------|----------------------|--------|------------------------|---------------------|--------------------|----------------------|----------------------|-----------------------------------|---|
| Y/N | Throat Clearing/ | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | AM |
| | YES) NO | YES (NO) | 0 1(2)8 | 0 3 | 0 1 2(3) | 0 1 2(3) | 113 | (YES) NO | (YES) NO | 0 1 (2)3 | 0 🗓 2 3 | 0 1/2(3) | 0 1/2 (3) | 1016 |
| | YES NO | YES NO | 0 1(2)3 | 0 1 2 3 | 0 1 2(3) | 0 1 2(3) | 2 | YES) NO | YES (NO) | 0 1(2)3 | 0 1(2)3 | 0 1 2(3) | 0 1 2 3 | 1017 1016 |
| | MES NO | YES NO | 0 1(2)3 | ①1 2 3 | 0 3 | 0 1 2(3) | ω | YES NO | YES) NO | 0(1)2 3 | 0 ①2 3 | 0 1 2 3 | | 10/13 |
| | γes \ NO | YES NO | 0 1(2)3 | 0 7 3 | 0 1 2(3) | 0 1 2(3) | 4 | (YES) NO | (YES) NO | 0 1/2/3 | 0 🛈 2 3 | 0 1 2(3) | 0 1 2 (3) | 10 <u>10</u> <u>10</u> <u>10</u> <u>10</u> <u>10</u> <u>10</u> <u>10</u> <u>1</u> |
| | MES NO | YES NO | 0 1(2)3 | 0 (1)2 3 | 0 1(2)3 | 0 1 2(3) | ப | (YES) NO | YES (NO) | 0 1(2)3 | 0(Ī)2 3 | 0 1 2(3) 0 | 0 1 2 (3) | 10/20 |
| | YES NO | YES (NO | 0(1)2 3 | 0 (1) 3 | 0 1 2/3 | 0 1 2/3 | 6 | (YES) NO (| YES (NO) | 0 2 3 | 0(1)2 3 | 0 1 2(3) | 0 1 2 3 | 10/21 |
| | YES NO | YES (NO) | 0 1(2)3 | 0 (1)2 3 (| 0 1 2 3 | 0 1 2(3) | 7 | YES) NO | YES (NO) | 0 (1)2 3 | Q(T) 2 3 | 0 1 | 0 1 2 3 | 10/22 |
| | YES NO | YES (NO) | 0 1(2)3 | 3 (0)1 2 3 | $0 \ 1(2)3$ | 0 1 2(3) | 8 | (YES) NO | YES (NO) | 0 1(2)3 | $\bigcirc 1 2 3$ | 2(3) 0 1(2)3 | $\frac{3}{2}$ 0 1 2 $\frac{3}{3}$ | 10/23 |
| | YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 9 | YES NO | YES (NO) | 0 1(2)3 | $\bigcirc 1 \ 2 \ 3$ | 0 1(2)3 | 0 1 2(3) | 10.24 601 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ALP DOIS DATE COMPLETED: 142413

SUBJECT INITIALS AND



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci fic Resources Leslie Byatt, Can Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

BJK, BJK

PHYSICIAN

Unlisted Physician, REQUISITION NO.

30920971

PT. PHONE NO. 0

AAGF5252

PATIENT ID

DOB 06/08/1955 SEX

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

10/24/2013 13:14

RECEIVE DATE & TIME 10/24/2013 17:54 PRINT DATE & TIME

10/25/2013 06:09

PATIENT NO.

AKP015

COMMENTS:

Test

Result

In Range

Out of Range

Mornismot 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Not given

NS

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 0 1 2 3 0 | DAY 7 8 9 10 AM 1924/13 1925/13 1924/13 197 27/ |
|---|--|
| 0 1 2 3 0 1 2 | 13 19/25/13 19/26/13 19/ |
| 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 2 3 0 1 2 | 13 19/25/13 19/26/13 19/ |
| 9 0 1 2 3 0 1 | 13 19/25/13 19/26/13 19/ |
| 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 2 3 0 1 2 3 0 1 2 2 3 0 1 2 3 0 1 2 3 0 1 2 2 3 0 1 2 | 19/24/3 19/ |
| 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 2 2 3 0 4 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 2 3 0 1 2 3 0 1 2 2 3 0 1 2 3 0 1 2 3 0 1 2 2 3 0 1 | 19/24/3 19/ |
| 0 1 2 3 0 1 2 | 2 |
| 0 1 2 3 0 1 2 3 0 1 2 0 1 2 3 0 1 2 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 0 1 2 3 0 1 2 3 0 1 2 2 0 1 2 3 0 | 2 |
| 0 1 2 3 0 1 2 3 0 1 2 0 1 2 3 0 1 2 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 0 1 2 3 0 1 2 0 1 2 3 0 1 2 | 2 |
| 2 3 0 1 2 3 0 1 2 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 2 3 0 1 2 | <i>l</i> 3 |
| 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 1 2 3 0 1 2 3 | 7/13 |
| 3 0 1 2 3 0 1 | |
| | 19/28/13 |
| | 2/2/2 |
| | 12 129/13 |
| YES YES ON ON ON ON ON ON ON ON ON ON ON ON ON | 19, |
| NO NO 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 | 39/13 |
| 2 3 0 1 2 2 3 0 1 2 2 3 0 1 2 2 3 0 1 2 2 3 0 1 2 NO YES N NO YES N NO YES N | 13 39/3 19/31/18 11/01 |
| 0 1 2 3 0 1 2 3 0 1 2 3 0 1 2 3 7 YES NO 7 YES NO 7 YES NO 7 YES NO | 14 <u>/</u> 12 |
| 0 1 2 0 1 2 0 1 2 0 1 2 0 1 2 VES NO YES NO YES NO YES NO YES NO | ∞ |
| NO NO NO NO NO NO NO NO NO NO NO NO NO N | 15 |
| | <u> </u> |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

AKPO15
SUBJECT NUMBER: 130 K DATE COMPLETED: 10/30/13

SUBJECT INITIALS AND DATE: BJ



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace S tific Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME **BJK, BJK**

PATIENT ID

DOB **AAGF5252** 06/08/1955 SEX

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 10/30/2013 11:10

RECEIVE DATE & TIME

PRINT DATE & TIME

O

10/30/2013 20:05

10/31/2013 06:06

30920965 COMMENTS:

AKP015

PATIENT NO.

Result

Test

In Range

Out of Range

Jelyer PI 1 Movember 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Not given

NS

End of Report

| | | | | > | | | | | | | | |
|------------------------------|-----------------------------------|-------------------|---|---------------------------|--|--|--|--|--|---|---|---|
| | | | Investigator Initials/Date | WW END | | | | | | ** | | PAGE: C of |
| LSR Study #: | Subject Initials: \mathcal{BTK} | | Action Taken | NONE | | | | | | e as specific as possible | Date: 27 Ful 2014 | 4/1x/x |
| LSF | Suk | (5) | ** End Date (DD/MIMM/YYYY) | 9NOV/2013 | | | | | | ould be made to be | | Date: |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Surperted | | | | | | ** If day is <u>unknown,</u> write UNK in space provided, but every effort should be made to be as specific as possible** | May huyaine wh | MW BYM Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| | | | SEVERITY | 3 med | | | | | | rite UNK in spac | dy): | 3 |
| Study Identification: 2749 | Subject Number: MKP 015 | | Adverse Event 1 (b)/MMM/YYYY) | at apolitication/oct/2013 | | | | | | ** If day is <u>unknown</u> , w | Investigator Signature (at end of study): | SC Signature (at end of study): |

| Study Identification: | 8040 | | · I | | | | LSR#: | |
|-------------------------|--|---------|---------------------------|--|-------------------|---|-------------------|------------------------------------|
| Subject Number: \iint | AKPO15 | | { | | | | Subject Initials: | BTK |
| List all | List all <u>prescription</u> medications you | CON | COMITA | CONCOMITANT MEDICATION LOG | ATION I | CONCOMITANT MEDICATION LOG are taking. Also include over-the-counter medications, vitamins and supplements. | s and suppleme | nts. |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at FOS (for Clinic use) |
| EXAMPLE | Diabetes | 500 | * MG | ZaTabs per | Oral | UNK/AUG/1999 | | |
| Floriase | Seasongs | 2-3 | Sharde | Court | ANH | /f200Z | 0//580/2012 | |
| PHeara | Spasonal es | 60 | ma | 8 | oral | ١,, | 2/1005/10 | |
| 0 | | | 9 | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or month | | ication da | te is <u>unknow</u> | <u>n,</u> write U | of medication date is <u>unknown</u> , write UNK in space provided | | |
| Investigator Signatu | Investigator Signature (at end of study): | | Jun ? | an m | | Date: 27 Fd | horp | |
| SC Signat | SC Signature (at end of study): | Chalu | 20 | ald | | Date: 2/5/ | 14 | , , |
| | | Lovelac | s Scientific uR es | Lovelace ScientificAResources, Inc - ConMeds 04/2013 | Meds 04/2013 | | PA | PAGE: 6 of |

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | 14 | | 16 | 17 | 1,8 | , 19 | . 20 | 21 | 22 | |
|----------------------|-----------------|-----------|-------------|----------|------------------|-----------------|-------------|--------------|------------|-----|
| AM | 10/30/13 | 5) /3/((3 | 11/01/13 | 11/03/13 | _ | 51/50/, 51/50/. | 5/40/11 | 11/02/13 | 3 11/00/13 | 120 |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 1 (2) 3 | 0(1)2 3 | 0(1)2 3 | 0 1(2)3 | 0 1(2)8 | 0 1 2(3) | 0 1 2(3) | 0 1 2(| (m) |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0(1)2 3 | 0 1 2 3 | 0123 | O1 2 3 | O 1 2 3 | 0 1 (2) 3 | 01 2 3 | 01 2 | m |
| Congestion 0 to 3 | 0 1 2 3 | Ø1 2 3 | 0123 | 0 1 2 3 | ()1 2 3(| 0123 | 0 1 2 3 | 1 2 3 | Ø 1 2 | m |
| Sneezing 0 to 3 | 0 1/2 3 | 0 1(2)3 | O1 2 3 (| 0)1 2 3 | 0123 | 0 1(2)3 | 0 2 3 | 0 2 3 | 01 2 | m |
| Voice Hoarse Y/N | YES NO | YES (NO | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO | 6 |
| Throat Clearing Y/N | YES NO | YES NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | YES (NO) | (YES) NO | (YES) NO | |
| DAY PM | 14 | 15 | 16 | 17_ | 18 | 19 | 20 | 21 | 22 | |
| Runny Nose 0 to 3 | 0 1(2)3 | 0 1(2)3 | 0(1)2 3 | 0 1(2)3 | 0 1(2)3 | 0 1(2)8 | O 2 3 | 0 1(2)3 | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1(2)3 | 0 1 2 3 | 0)123(| 0 1 2 3(| 0123 | 0 1 2 3 | 0 1 2 3 | 0,1.23 | 0 1 2 | m |
| Congestion (| <u>0</u> 1 2 3(| (0) 2 3 | (O)1 2 3(| 0 1 2 3(| 0 2 3(| 0)1 2 3(| 0)123 | 0 123 | 0 1 2 | n |
| Sneezing (| 0)123 | (O)1 2 3 |) E ([) o | 0 2 3 (| 0,123(| 0)123 | $0(1)^2$ 3(| 0)123 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (NO | (YES) NO | YES (NO) | YES (NÔ) | YES (NO | YES (NO) | YES (NO) | YES (NO | YES NO | |
| Throat Clearing Y/N | (YES) NO | (YES) NO | (YES) NO (| YES NO | YES NO (| YES) NO | YES NO | VES) NO | YES NO | |
| CCALEDTO | | | | | | | | | | ٦ |

u {

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER:

DATE COMPLETED: 11/00/13

SUBJECT INITIALS AND DATE:

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: X,BJK Medical Record: AAGH2720 DOB: 06/08/1955

Age:58Y Sex:F Account Number: 30920958

Attending MD: Unlisted Physician

Patient ID:AKP015 Patient Phone:0

W3391759 COLL: 11/06/2013 11:00 REC: 11/06/2013 22:03 PHYS: Unlisted Physician Reg#: 30920958

| Comp Metabolic Panel | | | | |
|----------------------|-----|---------------|--------------|-----------------------------------|
| Sodium | | 139 | [134-144] | mmol/L |
| Potassium | | 3.6 | [3.5-5.1] | mmol/L |
| Chloride | | 104 | [98-111] | mmol/L |
| CO2 | | 28 | [20-30] | mmol/L |
| Anion Gap | | 7 | [6-14] | |
| Glucose | | 72 | [60-100] | mg/dL |
| BUN | | 14 | [7-31] | mg/dL |
| Creatinine | | 0.74 | [0.50-1.40] | |
| | | Creatinine me | ethod is IDM | S traceable. EstGFR Calculation |
| | | | | e range effective 5/23/2013. |
| eGFR non-African Am | | >60 | [>60] | mL/min/1.73m2 |
| GFR Comment | | | | not accurate in acute kidney |
| Gra Comment | | failure, i | inpatients o | n IV fluids, obese (BMI>34) or |
| | | | nt (BMI<20) | |
| | | | | ng, races other than Caucasian or |
| | | | | ple with acute illnesses, or |
| | | amputation | | |
| Calcium | | 8.5 | [8.4-10.4] | mg/dL |
| Total Protein | | 7.0 | [6.1 - 8.2] | gm/dL |
| Albumin | | 4.1 | [3.4-4.7] | gm/dL |
| Globulin | | 2.9 | [2.4-4.2] | gm/dL |
| Bilirubin, total | | 0.4 | [0.3-1.2] | mg/dL |
| Alk Phos | | 118 | [38-150] | U/L |
| AST (SGOT) | | 24 | [6-58] | U/L |
| ALT (SGPT) | | 21 | [14-67] | U/L |
| Fasting | | NOT GIVEN | | |
| CBC | | | | |
| WBC | | 7.2 | [4.0-10.6] | x10E3 |
| | L | 3.57 | [4.00-5.36] | |
| | ш | 13.3 | [12.0-16.0] | am/dL |
| Hgb Hct | | 41 | [36-48] | ુ માત્ર વર્ષો ક |
| | Н | 113 | [81-98] | fL |
| | 7.1 | | - | |
| MCHC | | 32.8 | [31.2-35.2] | |
| RDW | | 12.5 | [11.0-14.5] | |
| Platelets | | 246 | [150-400] | x10E3 |
| | | | | |

CONTINUED

None seen

Printed: 02/27/2014 07:58

INTERIM REPORT

Eos, Respiratory

Patient Name: X,BJK

Medical Record #: AAGH2720

Location: CORE

Page: 1

passentine no 27 Feb 2014

[NS]

BJK AKP 015 Effects of AkPharma's Calcium Glycerophosphate 11/6/13 Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" YES NO |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: Kinda Bums when putting it in the Daily Diary: |
| it in vose |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

Subject initials and Date

Study Staff Initials and Date M 11/6/12

AKP-021

2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PA | ATIENT DEMOGRAPHICS |
|----|---|
| þ | atient Demographics |
| D | eate of Birth: 11 / fly / 1945' (dd/mmm/yyyy) |
| G | ender: Male Female |
| If | female, Indicate Childbearing Potential |
| | ☐ Childbearing ☐ Surgically sterilized ☐ Post-Menopausal |
| E | thnicity: Hispanic Non Hispanic |
| R | ace: Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| Ś | moking History |
| Sr | moking Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| If | subject is a former or current smoker, please indicate: |
| | Years smoked: 24 Cigarettes per day: 20 |

Version: 02 September 2013

Page 3 of 5



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Se tific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME X. UFV

PATIENT ID **AAGH4686**

08/11/1945

SEX М

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

PT. PHONE NO.

11/11/2013 13:05

11/11/2013 19:57

11/13/2013 06:09

30920936

0

PATIENT NO.

AKP021

COMMENTS:

Test Allerg,Panel 18 Allerg,Juniper Allerg, Cottonwood Allerg, West, Ragweed Allerg, Russian This Allerg, Bermuda Grass Allerg, Alternaria Allerg, Mesquite Allerg, Cockroach Allerg, Derm. pter.

| | Result | | | | |
|----------|------------|-----|--------|-----------------|-----------|
| In Range | Out of Rai | nge | Units | Reference Range | Site Code |
| | 5.60 | Н | kU/L | <0,35 | |
| | 1.00 | Ĥ | kU/L | <0.35 | |
| 0.10 | | | kU/L | <0.35 | |
| | 7.00 | Н | kU/L | < 0.35 | |
| | 2.20 | Н | kU/L | <0.35 | |
| 0.10 | | | kU/L | <0.35 | |
| | 1.10 | Н | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kl I/I | ∠በ ዓፍ | |

The standard classification system utilizes the following class cutoffs. Interpretation

| Class | KU/ L | Interpretation |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| v | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| Allerg,Derm. farinae | 0.10 | | | kU/L | < 0.35 |
|----------------------|-----------|---------------|---|------|--------|
| Allerg,Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg, Firebush | | 1.70 | Н | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | | 5.70 | Н | kU/L | < 0.35 |
| Allerg, Dog Dander | | 0.40 * | Ĥ | kU/L | < 0.35 |
| Allerg,Bluegrass | | 2.00 | H | kU/L | < 0.35 |
| Allerg,Pigweed | | 1.40 | H | kU/L | < 0.35 |
| Allerg, Mulberry | 0.20 | | | kU/L | < 0.35 |
| Allerg,Helminth | <0.10 | | | kU/L | < 0.35 |
| hvs Addr Phone | NOT GIVEN | | | | |

End of Report

13 Now 2013



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: UFV,

Gender: Male

Age: 68

Race: Hispanic

Height(in): 67.0

Weight(lb): 180

Any Info:

ld: AKP-021

Date: 11/27/13

Temp: 19

PBar: 637

Physician:

Technician: VL

| Spirometry | (B | TPS) | PR | E-RX | POS | T-RX | | |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------------------|--------------|------|---------------|--------------------|
| FVC Lite FEV1 Lite FEV1/FVC % | rs rs | Ref 3.54 2.80 79 | Pre Meas 2.95 2.17 74 | Pre % Ref 83 78 93 | Post Meas | Post | Post % Chg | Flow 8 |
| FEF25-75%L/se FEF50% L/se FEF75% L/se C Liter | 9C 9C 18 | 2.86 3.60 1.22 | 1.58 2.44 0.48 | 55 68 39 | | | | 4 |
| VC Liter PEF L/se MVV L/mi PIF L/se FEV1/FEV6% | ic in | 3.54 7.62 120 | 7.62 5.09 | 100 | | | | 2 |
| Lung Volu | ımes/F | Plethy | 76 Smoarar | hv | (B | TPS) | | 0 |
| Vtg Liter VC Liter FLC Liter RV Liter RV/TLC % FRC PL Liter ERV Liter C Liter | S S S S | 3.54 5.82 2.30 40 3.23 | - . | y | | ŕ | | -2 |
|)LAdj mL/m | nmHg/min 1Hg/min/L | 20.6 20.6 3.05 | | | | | | -6-1 0 1volume 3 4 |

Resistance

 Raw Total Raw Insp Raw Exp
 cmH2O/L/sec cmH2O/L/sec
 1.43

 Raw Exp Raw
 cmH2O/L/sec
 1.43

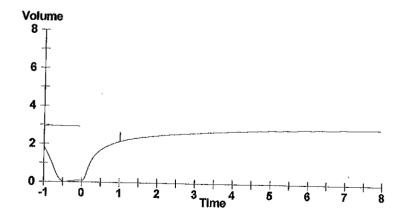
 Gaw
 L/sec/cmH2O
 0.775

 sRaw
 cmH2O/L/s/L
 4.61

 L/s/cmH2O/L
 0.217

 Vtg (Raw)
 L/ser

Comments:



Version: IVS-0101-20-5B



Lovelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP,

Gender: Male

Age: 68 Race:

Height(in): 67.0

Weight(lb): 179

Any Info:

ld: 021

Date: 12/04/13

Temp: 19

PBar: 622

Physician:

Technician: CRD

| Any into. | | | | | | Technicia. | n: CRD | |
|--|--|--|--|---|-------------------|------------|--------------------------------|---|
| Spirome | etry (E | Ref | PR Pre | E-RX Pre | POST-RX Post Post | Post | Flow | |
| FVC FEV1 FEV1/FV FEF25-7! FEF50% FEF75% IC VC | Liters Liters C % 5%L/sec L/sec L/sec Liters Liters | 3.54 2.80 79 2.86 3.60 1.22 | Meas 2.96 2.17 73 1.51 3.03 0.41 | % Ref 84 77 92 53 84 33 | Meas % Ref | % Chg | 6 4 | |
| PEF MVV PIF FEV1/FEV | L/sec L/min L/sec | 3.54 7.62 120 | 6.71 5.37 78 | 88 | | er. | 2 | |
| Lung ' | Volumes/F | Plethysm | oarai | phv | (BTPS) | | 0 | # |
| Vtg VC TLC RV RV/TLC FRC PL ERV IC Diffusi | Liters Liters Liters Liters % Liters Liters Liters | 3.54 5.82 2.30 40 3.24 | -9 | <i></i> | | | -2 -4 -6 ₋₁ (| |
| DLCO DL Adj DLCO/VA VA BHT | mL/mmHg/min mL/mmHg/min mL/mHg/min/L Liters Sec | 20.5 | | | · · | | ~-1 (| ⁰ 1 _{Volume} 2 3 4 |
| Resist | ance | | | | | | | |
| Raw Total | cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec | | | | | Ĭ. | | |



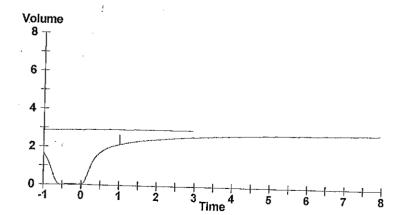
Vtg (Raw) Liters

Raw

Gaw

sRaw

sGaw



Interpretation:

cmH2O/L/sec

cmH2O/L/s/L

L/sec/cmH2O 0.777

L/s/cmH2O/L 0.217

4.61



Lovelace Scientific Resources 11 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKPO21,

Gender: Male

Age: 68

Race:

Height(in): 67.0

Weight(lb): 179

Any Info:

ld: AKP021 Date: 12/12/13

Temp: 19

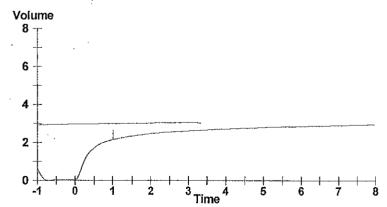
PBar: 638

Physician:

Technician: CRD

| Any Info: | | | 1 | ecnnicia | n. CRD | <u> </u> |
|---|---|--|-------------------|----------|----------------------|-----------------------------|
| Spirometry | (BTPS) Ref | PRE-RX Pre Pre | POST-RX Post Post | Post | Flow 8 T | |
| FVC Liters FEV1 Liters FEV1/FVC % FEF25-75%L/sec FEF75% L/sec IC Liters VC Liters PEF L/sec MVV L/min PIF L/sec FEV1/FEV6% Lung Volun | 3.54 2.80 79 2.86 3.60 1.22 3.54 7.62 120 | Meas % Ref 3.05 86 2.17 77 71 90 1.32 46 2.77 77 0.34 27 7.66 100 4.79 76 | Meas % Ref (BTPS) | % Chg | 6 - 4 - 2 | |
| Vtg Liters VC Liters TLC Liters RV Liters RV/TLC % FRC PL Liters ERV Liters IC Liters Diffusion | 3.54 5.82 2.30 40 3.24 | mography | | | -2 -4 -6 -1 | 0 1 _{Volume} 2 3 4 |
| DL Adj mL/mm | aHg/min 20.5 aHg/min 20.5 g/min/L 3.06 | | , \ | | | |
| Resistance | | | • | | | |
| Raw Total cmH2C Raw Insp cmH2C Raw Exp cmH2C Raw cmH2C Gaw L/sec/c sRaw cmH2C | 0/L/sec 0/L/sec 0/L/sec 1.42 mH2O 0.777 | , | | | | |







Levelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: Ufv,

Gender: Male

Race: Hispanic Age: 68

Height(in): 67.0

Weight(lb): 181

ld: akp021

Date: 12/18/13

Temp: 20

PBar: 634

Physician:

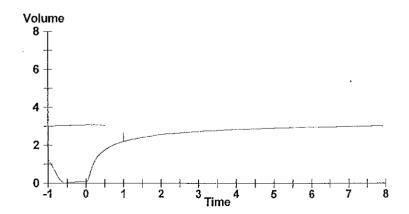
Technician: DG

| Any Info: | | | | | | Technicia | n: DG | |
|-----------|--------------|---------------------|-------------|----------------------|------------------------------|---------------|-------------|---------------------|
| Spiromet | ry (B | TP S) Ref | Pre Meas | E-RX Pre % Ref | POST-RX Post Post Meas % Ref | Post % Chg | Flow 16 | |
| FVC | Liters | 3.54 | 3.07 | 87 | | | + | |
| FEV1 | Liters | 2.80 | 2.22 | 79 | | | 12 | |
| FEV1/FVC | | 79 | 72 | 91 | | | '~ | |
| FEF25-759 | %L/sec | 2.86 | 1.47 | 51 | | | + | |
| FEF50% | L/sec | 3.60 | 2.17 | 60 | | | | |
| FEF75% | L/sec | 1.22 | 0.43 | 35 | | | 8 - | Λ |
| IC | Liters | | | | | | <u></u> | / \ |
| VC | Liters | 3.54 | | | | | | |
| PEF | L/sec | 7.62 | 8.15 | 107 | | | 4 🕆 | |
| MVV | L/min | 120 | | | | | | |
| PIF | L/sec | | 6.26 | | | | Ť | |
| FEV1/FEV | 6% | | 75 | | | | 0 | |
| Lung \ | /olumes/I | Plethysn | nogra | phy | (BTPS) | | _ | |
| Vtg | Liters | • | _ | • | | | | 1 |
| VČ | Liters | 3.54 | | | | | -4 † | / |
| TLC | Liters | 5.82 | | | | | | У |
| RV | Liters | 2.30 | | | | | Ť | |
| RV/TLC | % | 40 | | | | | -8- | |
| FRC PL | Liters | 3.22 | | | | | <u> </u> | |
| | Liters | 3.22 | | | | | + | |
| ERV IC | | | | | | | 40 | |
| 10 | Liters | | | | | | -12 -2 | 0 2 4 6 8 |
| Diffusi | on | | | | | | _ | 0 2 4 6 8 Volume |
| DLCO | mL/mmHg/min | 20.6 | | | | | | |
| DL Adj | mL/mmHg/min | 20.6 | | | | | | |
| DLCONA | mL/mHg/min/L | | | | | | | |
| VA | Liters | | • | | | | | |
| BHT | Sec | | | | | | | |
| Resist | ance | | | | • | | | |

Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec cmH2O/L/sec Raw L/sec/cmH2O 0.773 Gaw cmH2O/L/s/L 4.62 sRaw L/s/cmH2O/L 0.217 sGaw Vtg (Raw) Liters

Comments:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | 7.1.1.1 | <u> </u> | | | | | | 1 | | ľ | | | | Ĺ | | | |
|----------------------|-------------|----------|---------|------------|-----|------------|----------|----------|------------|------------|----------|------------|----------|------------|------------|-----|-------------|
| DAY | /- / | | φ. | • | -ڻ- | 7- | - · | ν'n | | 7- | | l . | | ə / | _ | | ر ا ا |
| AM | 11/20 | | 11/21 | 11 | 2 | 117 | 3 | 2/11 | £ | 11 | 55 | 111 | 3 | 2/11 | ۲, | 111 | 7 |
| Runny Nose | 0 1 2 | 33 | 0123 | 6 | 2 3 | 01 | 2 3 | 0 | 2 3 | o D | 2 3 | ⊕ | 2 3 | 0 🕝 2 | 2 3 | 0 1 | 2 3 |
| 0.03 | | | | | | - 1 | | | | | 1 | | | ١. | | | |
| Itchy Nose 0 to 3 | 0 1 2 | 3 | 0123 | Q 1 | 2 3 | © 1 | 2 3 | (d) | 2 3 | 6 | 2 3 | 6 | 2 3 | 6 | 2 3 | 0 | 2 3 |
| Congestion 0 to 3 | 0 1 2 | 3 | Ø 123 | 0 1 | 2 3 | <u>@</u> | 2 3 | () () | 2 3 | 0 | 2 3 | θ | 2 3 | <i>Ø</i> | 2 3 | 0 1 | 2 3 |
| Sneezing | 0 1 2 | ς. | Ø123 | <u>ත</u> | 2 3 | 0 | 2 3 | Ø1. | 2 3 | 01 | 2 3 | 7 B | 2 3 | 9 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse | YES | 8 | YES 🐠 | YES | 9 | YES | P | YES | 9 | YES | (N) | YES | 9 | YES | ©) | YES | 9 |
| Throat Clearing Y/N | YES | S S | YES 🐠 | YES | (2) | YES | 8 | Œ | 9 | (ES) | Q. | | <u>8</u> | YES | (2) | YES | NO NO |
| DAY PM | -7 | | ٩ | • | rλ | ľ | 4 | ကု | | -2 | | -1 | |) | 0 | | 0 |
| Runny Nose 0 to 3 | 012 | m | 0123 | 01 | 2 3 | <u>(a)</u> | 2 3 | (D) | 2 3 | 00 | 2 3 | 0 Ø | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Itchy Nose 0 to 3 | Ø 1 2 | m | Ø 1 2 3 | 0 | 2 3 | 01 | 2 3 | () () | 2 3 | H | 2 3 | © 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Congestion 0 to 3 | 0 12 | m | Ø123 | <u>@</u> | 2 3 | 01 | 2 3 | Ø 1 | 2 3 (| Ø 1 | 2 3 | Ø 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Sneezing 0 to 3 | Ø 1 2 | 3 | Ø123 | 0 1 | 2 3 | 01 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 | 0^{1} | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES (A) | (g) (| YES (NO | YES | 9 | YES | | YES | (G) | YES | B | YES | -g) | YES | <u>N</u> | YES | 8 |
| Throat Clearing Y/N | YES | (ON) | YES (NÔ | (ES | NO | | ON | YES | (2) | | S S | | 9 | YES | 8 | YES | 8 |
| SCAIF 0 to 3 | | | | | | <u> </u> | | | | | | | | | | | |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ALP 021 DATE COMPLETED:

Y=Yes N=No

SUBJECT INITIALS AND DATE: LE 12 1 1/27/13



Lovelace Sci ic Resources Leslie Byatt, Cun Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME UFV, UFV PHYSICIAN

PATIENT ID **AAGH3348**

08/11/1945

REPORT STATUS Final

PAGE 1

Unlisted Physician,

COLLECT DATE & TIME 11/27/2013 12:50

М RECEIVE DATE & TIME

SEX

PRINT DATE & TIME

REQUISITION NO.

PT, PHONE NO.

PATIENT NO.

None seen

NOT INDICATED

11/27/2013 18:36

11/28/2013 06:11

NS

30920930

0

COMMENTS:

AKP021

| | R | esult | | | | |
|------------------------------------|--|---|---------------------|-----------------------------------|---------------------------|-----------|
| Test | In Range | Out of Rang | je | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 140 | | | mmol/L | 134-1 44 | |
| Potassium | 4.1 | | | mmol/L | 3.5-5.1 | |
| Chloride | 105 | | | mmol/L | 98-111 | |
| CO2 | 28 | | | mmol/L | 20-30 | |
| Anion Gap | 7 | | | .6.00 | 6-14 | |
| Glucose | 74 | | | mg/dL | 60-100 | |
| BUN Creatinine | 16 1,36 | | | mg/dL | 7-31 | |
| Creamme | Creatinine method is IDMS | traceable. Est | rcer cal | mg/dL Iculation has be | 0.62-1.66 hetzuiha nea | |
| | Please note new reference | | | | - | ~ |
| eGFR non-African Am GFR Comment | Trade fier ference | 52 | L | mL/min/1.73m2 | >60 /// | es worm |
| GFK Comment | Estimated GER values are n | ot accurate i | n acute | kidnev failure | innatients | |
| | Estimated GFR values are r on IV fluids, obese (BMI>: the very old or very young people with acute illnesse | 34) or underwe , races other es. or amoutat | ight (BN than Ca | MI<20) people, aucasian or Afr | ican American, | |
| Calcium | 9.3 | | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.1 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.9 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 1.1 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | .97 | | | U/L | 38-150 | |
| AST(SGOT) | 20 | | | U/L | 6-58 | |
| ALT(SGPT) | 36 | | | U/L | 14-67 | |
| Fasting | NO | | | | 0050 | |
| Phosphorus | 3.3 | | | mg/dL | 2.3-5.6 | |
| CBC WBC | 6.3 | | | x10E3 | 40400 | . |
| RBC | 0.5 | 6.05 | ш | x10E3 | 4.0-10.6 | es mon |
| Hgb | | 18.5 | H | am/dL | 4.04-0.00 // 0 | 10 more |
| Hct | | 56 | H | % | 42.53 1/ | of Mann |
| MCV | 93 | ~~ | - 11 | fĽ | 81-98 | 72 16de 1 |
| MCHC | 33.0 | | | gm/dL | 31.2-35.2 | |
| RDW | 13.4 | | | % | 11.0-14.5 | |
| Platelets | 192 | | | x10E3 | 150-400 | |
| | Maria a a a a | | | | L Les | |

End of Report

Eos, Respiratory

Phys, Addr, Phone

MMusuie no 03 Dec 2013

SUBJECT INITIALS AND DATE:_

©

MES

(NO)/YES

YES

(2)

YES

9

©

YES

(2)

YES

9

YES

©

YES

Throat Clearing

©)

Š

XES

2

YES

©

YES

(S)

YES

(

YES

\$

YES

9

YES

9

YES

Voice Hoarse

ന

~

ŝ

7

ന

ന

~

2 3

0

ന

~

0 1

ന

7

↤

6

ന

2

(

Sneezing

0 to 3

0 to 3

0 to 3

QX 2/3 0 ന m 9 ന ന **(2)** EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) **O** D 2 **(1)** 2 7 N 6 \leftarrow **0** 1 1 YES 0 9 E) m ന ന ന ന **€** 0 1/2 **8** 2 1/ 6 **0** 0/1YES/ **(**) <u>(0)</u> ന ന ന <u>m</u> 0123 **§** 9 0)12 (A) 12 $\bigcirc 1$ 2 0)12 N ~ ON PATIENT-PERCEIVED BREATHING COMFORT \bigcirc_1 ш YES YES **6** 11/27/13 11/28(13 11/28/13 11/39/13 12/11/13 12/13 10 1 2 3 0 0 2 3 0 0 2 3 0 0 0 2 3 0 1 0 3 0 1 2 3 **E** 0123 ന ന ന **S** 0123 0123 0123 ന ~ 2 7 ~ o 9 (E) \leftarrow \vdash YES YES 6 6 m **©** ന ന ന ന 9 ~ 0 Ø N 2 Ŋ 9 (d) **@** 1 **((E)** Н Н YES 0 0 0 ന **©** ന ന ന ന **(2)** 012 0 (D) 2 N ~ N 4 (f) 1 Θ --YES YES 0 0 DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) **©**123 **@** 0123 **(2)** ന ന ന ന N 7 N ~ ന CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS ල ම Θ $\overline{}$ $\overline{}$ YES YES 0 9 0 m m m 8 m ന ന **E**) 7 N 0 0 2 ~ N 2 (1 (<u>0</u> 2 **©**1 **Q** ~ \vdash YES YES <u>6</u> 0 **رب** ന ന ന ന ന Š **©** 2 7 ~ 2 N \bigcirc 91 \vdash YES YES 0 б 0 0 Throat Clearing Voice Hoarse Runny Nose DAY PM Runny Nose Congestion Congestion Itchy Nose Itchy Nose Σ Sneezing 0 to 3

0 to 3

0 to 3

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER:

DATE COMPLETED: 12/4/13

Returned 12/12/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace S wiffic Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129 Client Nbr 24664

PATIENT NAME UFV, UFV

31033173

Test

COMMENTS:

PATIENT ID AAGI5590

DOB **08/11/1945** SEX REPORT STATUS

M Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO. PT. PHONE NO.

0

COLLECT DATE & TIME 12/04/2013 14:10

945 M F RECEIVE DATE & TIME 12/04/2013 20:06

PRINT DATE & TIME 12/05/2013 06:16

PATIENT NO.

CALIBALIA

AKP021

Result

Out of Range

Rare

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

NOT GIVEN

In Range

NS

End of Report

10 Dec 2013

51/21/21

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| L | 15/2/2 | <u>3</u> | (S) | | 2 | | 2 3 | | 2 3 | (| 2 | | ON N | 15 | 2 | 1 | 2/3 | 2 3 | | /2 3 | ON | | |
|-----------------------------|------------|------------|------------|--------|--------------|--------|------------|------------|--------------|--------|--------------|-----|---------------------|--------|------------|----------|------------|------------|-----|----------------|--------------|-----|---|
| | 7 | 2 | 0 1 | | (A) | | (g) | Į. | 0 | | YES | (| (ES) | -1 | 0 1 | | 0 1 | 0 1 | | 0 1 | YE\$ | | |
| | + | 1/13 | 2 3 | 1 | 2 3 | | 2 3 | | 2 3 | 1 | © | į | Ş | 4 | 2 3 | | 2 3 | 2 3 | | 2 3 | E | \(| |
| ŀ | 14 | 1 | 0 @ 2 | - 1 | ⊕ | | (C) | - 1 | (a) | | YES | | YES | 14 | O 0 | | (C) | 0 1 | , | 0 1 | YES | | |
| | ~ | 0/13 | 1 🛇 3 | | 2 3 | | 2 3 | - 1 | 2 3 | | E) | | ON N | 3 | 2 3 | | 2 3 | 2 3 | | 2 3 | E) | , \ | |
| , | 12 13 | /2 | 0 1 (| | (D) |) | @ 1 |) | (C) | | γES | | (ES) | 13 | D 0 | | 9 | Ø 1 |) | 9 | YES | | |
| | | 5 | 2 3 | 1 | 2 3 | | 2 3 | | 2 3 | (| 9 | | (S) | | 2 3 | | 2 3 | 2 3 | | 2 3 | Q | (| 1 |
| ; | 17 | 15/0 | 0 🛈 2 | | 9 | , | 91 |) } | <u>@</u> | | YES | | YES | 12 | 0 | \ | 0 | 0 1 | , (| 1 | YES | i | |
| - | | 2 | 2 3 | | 2 3 | | 2 3 | | 2 3 | | <u>(§</u>) |) | © | | 2 3 | | 2 3 | 2 3 | | 2 3 | 9 | (| |
| | 10 11 | 20/08 | 0 Ø 2 3 | | С | | 0 1 | , | 91 | , | YES | | YES | 11 | 0 | | 0 | 0) 1 |) (| \bigcirc_{1} | YES | | |
| | - ' | /(33 - | ന | | 2 3 | | 2 3 | | 2 3 | | 9 | | ON | | 2 3 | | 2 3 | 2 3 | , | 2 3 | (P) |)) | (|
| | 7,13 | 0/2 | 0 1 0 | ļ | 1 (a) | | 0 | , | Q | ļ | YES | | | 10 | 9 | | © | 0 1 |) | 0 | YES | | |
| <u> </u> | | 13 | 2 3 | | 2 3 | | 2 3 | | 2 3 | | © |) | 9 | | 2 3 | | 2 3 | 2 3 | | 2 3 | 9 | | |
| EVERT 12 HOURS | 15/2/2/ | 30% | 0 @ 2 | , | ء ھ | | 0 1 |) { | $\bigcirc 1$ | | YES | | YES | 6 | 0 | | 0 | 6 | 2 | 1 | YES | | |
| 77 17 | | _ | ₾23 | | 2 3 | | 2 3 | | 2 3 | | (E) | , (| SS) | | 2 3 | | 2 3 | 2 3 | | 2 3 | 9 | (| |
| SE EVE | ∞ , | 12/0 | 0 | ļ | (Q) |) | 0 1 | . | 0 1 | , | YES | | YES | ∞ | 0 | | © 1 | @ 1 |) | 0 1 | YES | | l |
| EST C | - | 4/13 | 3/ | 7 | 2/3 | _ | £ 3 | | 2 3 | | 9 | | 9 | | 2 3 | | 2 3 | 2 3 | | 2 3 | 6 | (| |
| MAIER | ^ , | 12/04/13 | 0 1 2 | | 0 1 | | 0 | | 0 1/ | _ | YEŞ | _ | ÆS/ | | 0 @ 2 | | @ 1 | 0 1 |) | Ø 1 | YES | | |
| CIRCLE APPROXIMALE RESPONSE | DAY | AM | Runny Nose | 0 to 3 | Itchy Nose | 0 to 3 | Congestion | 0 to 3 | Sneezing | 0 to 3 | Voice Hoarse | N/A | Throat Clearing Y/N | DAY PM | Runny Nose | 0 to 3 | Itchy Nose | stion | | Bu | Voice Hoarse | N/A | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: AKPOZI

DATE COMPLETED: 12/12/13

SUBJECT INITIALS AND DATE: CATULITY



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

AAGI9605

Lovelace S: tific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME UFV, UFV

PATIENT ID

COLLECT DATE & TIME

12/12/2013 14:00

DOR 08/21/1945

REPORT STATUS SEX Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

RECEIVE DATE & TIME 12/12/2013 20:32 PRINT DATE & TIME

12/13/2013 08:14

31033182

Test

0

AKP021

COMMENTS:

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

PHYS UNKN

In Range

Many

NS

End of Report

NES AME SUNT

| Study Identification: | | | LSF | LSR Study #: | |
|---|---------------|---|---------------------------|----------------------------|--|
| Subject Number: AKP 03 / | | | lu2 | Subject Initials: | 7 |
| | | ADVERSE EVENT LOG | (5) | | |
| Adverse Event (DD/MMM/YYYY) | SEVERITY | Relationship to Study Drug (Suspected/Not Suspected) | ** End Date (DD/MMM/YYYY) | Action Taken | Investigator Initials/Date |
| | | | | | |
| | 2 | | | | |
| | 5/ | | | | |
| | | 1 | | | |
| | | 2 | | | |
| | | xe' | | | |
| | | | | | |
| | | | 4 | | |
| | | | 77 | | |
| | | | | | |
| | | | | | |
| | | | | b / | |
| ** If day is <u>unknown,</u> write UNK in | · UNK in spac | space provided, but every effort should be made to be as specific as possible** | sould be made to bo | e as specific as possible* | * A The state of t |
| Investigator Signature (at end of study): | | Mpm Saine NO | Date: | Date: 27 Fd 2014 | |
| SC Signature (at end of study): | B | In Broth | Date: 2 | 2/24/14 | |
| | | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 | | <u> </u> | PAGE: of |

·)

of

PAGE:

Ongoing at £0\$ (for Clinic use) Ø × Subject Initials: \mathscr{UF} Ì Ó N 2749 List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. 8//nc/6 Stop Date 10/9/13 LSR #: * If day or month of medication date is unknown, write UNK in space provided (Day/Month/Year) UNK/AUG/1999 8/2013 9/21/13 6100 * Start Date 4012 2012 2003 7007 2000 1108 CONCOMITANT MEDICATION LOG J. Š Route Ó Orali in h. Ç 0 2 Tabs per day Frequency の天 8 OFFS 8 る氏 5 B 2/2 2 MS Unit ΩŒ Mes MS 3 E 200 \$ 3008 325 1000 Dose 200 80 B 7, AK Pharne SUPPLEMENT (What you take it for) OAD phylasos Indication allugus Diabetes allugies delinger allera 1. 1.pido BPH るで Study Identification: Name of Medication watadme 2/18/10 EXAMPLE Oratadens [Juticas in Subject Number: Vita 03 LUINDANK

Date: 18 Dec 2017

Date 12-18-13

PAGE: __

SC Signature (at end of study)

Investigator Signature (at end of study): __

Lovelace Scientific Resources, Inc - ConMeds 04/2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | 1 | | | | | | | | - 1 | . | . 1 | | 1 |
|-----|----------|----------------------|----------------------|----------------------|--------------------|------------------|------------------------|--------|----------------------|--------|----------------------|--------------------|---------------------|---------------------|
| _ | | 2 3 | 2 3 | 2 3 | 2 3 | NO | NO | 2 | 2 3 | 2 3 | 2 3 | 2 3 | NO | NO |
| 22 | | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES | 22 | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES |
| - | 13 | <u>ີ</u> ຕ | 3 | 3 | m | NO | ON | | 3 | 3 | 3 | 3 | ON | ON |
| 17 | 5//6 | 1 2 | 1 2 | 1 2 | 1 2 | | | 21 | 1 2 | 1 2 | 1 2 | 1 2 | | |
| | 12/ | 0 | 0 | 0 | 0 | YES | YES | _ | 0 | 0 | 0 | 0 | YES | YES |
| | 21/81/ | 2,3 | 2 3 | 2 3 | 2 3 | © | @ | _ | z 3/ | 2/3 | þ 3 | 2 3 | <u> </u> | 2 |
| 20 | 12/1 | o (🕏 2 | 0 1 | 0 1 | \bigcirc 1 | YES | YES | 20 | 1 | 0 1 | 0 |) o | YE\$ | /ES |
| Γ. | 17/13 | 3 | 3 | 3 | 3 | | (C) | | 5 3 | 2 3 | 2 3 | 2 3 | g) | (2) |
| 19 | 12/11 | o (🗘 2 | 0 1 2 | 0 1 2 | © 1 2 | YES | YES | 19 | 0 ① 2 | 0 1 2 | 0 1 2 | 01 | YES | YES |
| | | 3 | m | 3 | 3 | (2) | © | | 3 | 3 | 3 | 3 | © (| (Q) |
| 18 | 12/10/13 | o (D 2 |) 1 2 |) 1 2 | 1 2 | YES | YES | 18 | (E) 2 |) 1 2 |) 1 2 |) 1 2 | YES | YES |
| | 3 | 3 0 | <u>ල</u> ා ස | 3 G | 3 (a) | | | | 3 0 | © ° | Э Э г | 3 0 8 | | |
| 17 | 15/ | 2 | 7 | 7 | 7 | 9 | Q | 17 | 7 | . 2 | . 2 | 7 | 9 | |
| ,,, | 12/15/13 | (T) | 6 | 0 1 | B | YES | YES | | €0 | 0 1 | 0 | 0_{1} | YES | YES |
| , | 14/13 | 2 3 | 2 3 | 2 3 | 2 3 | @ (| 9 | | 2 3 | 2 3 | 2 3 | 2 3 | 9 | (O |
| 16 | 12/14 | 0 0 | 0 1 | 61 | 01 | YES | YES | 16 | 0 (1) | 9 | 0 | 0 1 | YES | YES |
| | 13 | 3 | m. | 3 | က | 9 | (2) | | ო | 8 | 8 | | <u>Q</u> | (S) |
| 15 | 13/ | © 2 | 1 2 | 1 2 | 1 2 | | | 12 | 1 2 | 1 2 | 1 2 | 1 2 | | |
| | [2] | 0 / | 0 | © | 6 | YES | YES | | 0 | 0 | 6 | 0 | YES | YES |
| 1 | 112/13 | 2 3/ | 2/3 | 4 3 | (2 3 | 2 | 2 | 4 | 2 3 | 2 3 | 2 3 | 2 3 | (2) (| (S) |
| 14 | 15/11 | 1 | 0 | 0 | 0 1 | YE9 | YES | 14 | 0 D 2 | 0 | 60 | 0 | YES | YES |
| DAY | AM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | ose | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)
2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: \mathcal{UFV}

AKP OA) DATE COMPLETED: 12/18/13

SUBJECT INITIALS AND DATE: WHY 12/18/13



Lovelace Scie Resources Leslie Byatt, Cha frials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME UFV, UFV

PATIENT ID **AAGH3348** DOB 08/11/1945 SEX REPORT STATUS Final М

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 12/18/2013 13:55

Result

RECEIVE DATE & TIME 12/18/2013 18:43 PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

12/19/2013 06:09

31033197

0

COMMENTS:

AKP021

| | | esult | | | | |
|----------------------|--|----------------------------------|----------|-----------------------------------|-----------------|-----------|
| Test | In Range | Out of Ran | ge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | • | | | | |
| Sodium | 143 | | | mmol/L | 134-144 | |
| Potassium | 4.4 | | | mmol/L | 3.5-5.1 | |
| Chloride | 106 | | | mmol/L | 98-111 | |
| CO2 | 26 | | | mmol/L | 20-30 | |
| Anion Gap | | | | THINQUE | 6-14 AA | ` |
| Glucose | •• | 158 | н | mg/dL | 60-100 | MINCS |
| BUN | 19 | 100 | П | mg/dL | 7-31 | |
| Creatinine | 1.40 | | | mg/dL | 0.62-1.66 | |
| 010daniii10 | Creatinine method is IDMS | traceable. Es | tGFR Ca | lculation has be | en adiusted. | |
| | Please note new reference | | | | | |
| eGFR non-African Am | Trease note new reterence | • | | | No. | D 1105 |
| GFR Comment | | 50 | L | mL/min/1.73m2 | >60 <i>[M/]</i> | mocs |
| Grk Comment | Estimated CED values and m | A TONING T | h nell+a | kidney fedlums | | |
| | on IV fluids, obese (BMT>3 | 10t accurate 14) or underwe | iaht (BI | Kiuney iaiture, MI<20) people. | mpacrents | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 the Very old or very young people with acute illnesse | , races other | than C | aucasian or Afr | ican American, | |
| Calcium | 9.7 | b, or amparae | , | mg/dL | 8.4-10.4 | |
| Total Protein | 7.1 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.6 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.5 | | | gm/dL | 2.4-4.2 | |
| Billrubin, total | 0.9 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 94 | | | Ü/L | 38-150 | |
| AST(SGOT) | 16 | | | U/L | 6-58 | |
| ALT(SGPT) | 28 | | | U/L | 14-67 | |
| Fasting | ÑÔ | | | V/L | 14-01 | |
| Phosphorus | 3.6 | | | mg/dL | 2.3-5.6 | |
| • | V. • | | | HIGIOL | 2.0-0.0 | |
| CBC WBC | 5.7 | | | x10E3 | 40400 | |
| RBC | 5.7 5.67 | | | x10E3 | 4.0-10.6 | |
| | 17.6 | | | | 4.64-6.00 | |
| Hgb Hct | 17.6 52 | | | gm/dL | 14.5-17.7 | |
| MCV | | | | % | 42-53 | |
| * | 92 | • | | fL | 81-98 | |
| MCHC | 33.8 | | | gm/dL | 31.2-35.2 | |
| RDW | 13.2 | | | % | 11.0-14.5 | |
| Platelets | 205 | | | x10E3 | 150-400 | man Ilac |
| Eos, Respiratory | | Rare | * | | NS /// | Mr UCS |
| Phys, Addr, Phone | Unknown | | | | / | |
| 3 | | | | | | |

End of Report

Montaine no 19 Dec 2013

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ☐¥ES ☐NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| I NOTICED RELIEF AFTER 15 -20 MINUTES |
| BY THE TIME IT WAS TIME FOR MORE |
| BY THE TIME IT WAS TIME FOR MORE SPRAY MY NOSE WHAT WHAT WHAT. |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

[Type text] Subject initials and Date 2nV

Study Staff Initials and Date Em 12/18/13

AKP-032

4749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| | RAPHICS |
|----------------------------------|--|
| Patient Demographi | |
| Date of Birth: 24 | 101 Jan 1 1945 (dd/mmm/yyyy) |
| | Male Female |
| If female, Indicate Chil | Idbearing Potential |
| . 🗀 d | Childbearing Surgically sterilized Post-Menopausal |
| Ethnicity: Hispani | c Non Hispanic |
| Race: Asian [| Black Caucasian |
| Pacific Isla | ander Other, Specify |
| | |
| Smoking History | |
| Smoking Status: N | None (smoked less than 100 cigarettes in lifetime) |
| . 0 | ormer (previously smoked more than 100 cigarettes in lifetime) |
| | Furrent (smokes now) |
| If subject is a <i>former</i> or | current smoker, please indicate: 1962 - 2002 |
| | |

Version: 02 September 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Leslie Byatt, Jun Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME **ESN, ESN**

PATIENT ID **AAGH1347**

DOB 01/26/1945 SEX REPORT STATUS F Final

kU/L

PAGE

Site Code

PHYSICIAN

Unlisted Physician. 11/04/2013 15:07

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

<0.35

PT. PHONE NO.

11/05/2013 06:10

30920876

Λ

PATIENT NO.

11/04/2013 20:18

Test

<0.10

COMMENTS:

Allerg,Panel 18 Allerg,Juniper

Allerg, Cottonwood Allerg, West. Ragweed Allerg, Russian This Allerg, Bermuda Grass Allerg.Alternaria Allerg, Mesquite

Allerg, Cockroach

Allerg Derm. pter.

REQUISITION NO.

032

| | Result | | | |
|----------|------------|-----|-------|-----------------|
| In Range | Out of Ran | iße | Units | Reference Range |
| | 6.00 | Н | kU/L | <0.35 |
| 0.30 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | 19.10 | Н | kU/L | < 0.35 |
| | 6.50 | Н | kU/L | < 0.35 |
| | 7.90 | Н | kU/L | < 0.35 |
| | 1.50 | H | kU/L | < 0.35 |

0.30 kU/L The standard classification system utilizes the following class cutoffs. Interpretation

| Class | KU/L | Interpretation |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| ıı | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| īv | 17. 5-52. 49 | Strongly Positive |
| V | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| | citilical attergy, | | | | |
|-----------------------|--------------------|------|---|------|--------|
| Allerg, Derm. farinae | 0.10 | | | kU/L | <0.35 |
| Allerg,Clad. herb. | 0.20 | | | kU/L | <0.35 |
| Allerg, Firebush | | 3.10 | H | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | 0.20 | | | kU/L | <0.35 |
| Allerg, Dog Dander | | 1.00 | Н | kU/L | < 0.35 |
| Allerg, Bluegrass | | 3.30 | Н | kU/L | < 0.35 |
| Allerg, Pigweed | | 8.90 | Н | kU/L | < 0.35 |
| Allerg, Mulberry | | 8.00 | Н | kU/L | < 0.35 |
| Allerg, Helminth | | 0.50 | H | kU/L | < 0.35 |
| Phys, Addr, Phone | PHYS UNKN | | | | |
| | | | | | |

End of Report

pph 2013



Lovelace Scientific Resources Ridgecrest Dr SE Auguerque, NM 87108



Name: ESN,

Gender: Female

Age: 68

Race:

Height(in): 65.0

Weight(lb): 145

Any Info: 2749

ld: 032

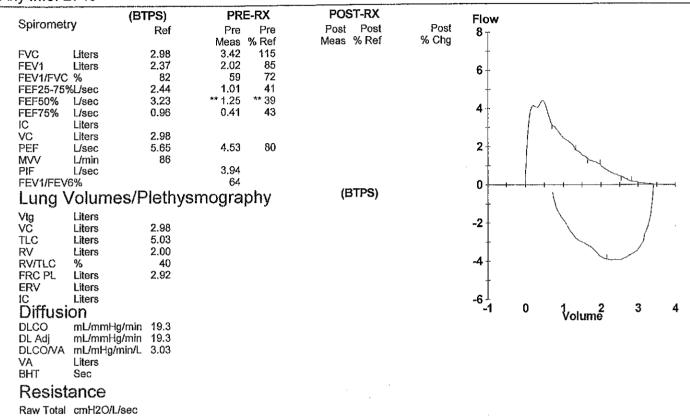
Date: 11/25/13

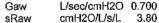
Temp: 19

PBar: 632

Physician:

Technician: CRD26





Vtg (Raw) Liters

cmH2O/L/sec cmH2O/L/sec

cmH2O/L/sec

L/s/cmH2O/L 0.263

1,30

3.80

Raw Insp

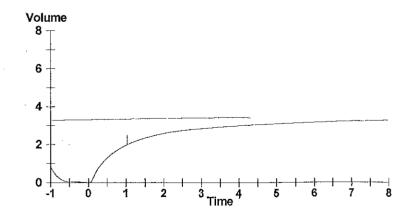
Raw Exp

Raw

sGaw

Comments:

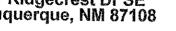
Interpretation:



Version: IVS-0101-20-5B



Lovelace Scientific Resources 11 Ridgecrest Dr SE Albuquerque, NM 87108



Name: ESN,

Gender: Female

Age: 68

Race: Caucasian

Height(in): 65.0

Weight(lb): 145

Any Info:

ld: AKP-032 Date: 12/02/13

Temp: 20

PBar: 632

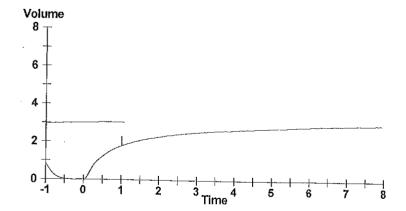
Physician:

Technician: VL

| | /E | BTPS) | ממ | r nv | B007 P | | | |
|-----------|-----------------|--------------|---------|----------|-----------|----------|----------------------------|-------|
| Spirome | try (" | • | | E-RX | POST-R) | | Flow | |
| · | • | Ref | Pre | Pre | Post Pos | | 8 т | |
| FVC | Liters | 0.00 | | % Ref | Meas % Re | ef % Chg | - 1 | |
| FEV1 | Liters | 2.98 | 3.04 | 102 | | | † | |
| FEV1/FV0 | Litters | 2.37 | 1.81 | 76 76 | | | 6 + | |
| FEF25-75 | 270 9/1 Jano | 82 | 59 | 73 | | | 0 | |
| FEF50% | L/sec | 2.44 | 0.87 | 36 | | | + | |
| FEF75% | L/sec | 3.23 | ** 1.19 | ** 37 | | | | |
| IC IC | Liters | 0.96 | 0.34 | 36 | | | 4+ | |
| VC | Liters | 2.00 | | | | | 1 / \ | |
| PEF | L/sec | 2.98 5.65 | 4.04 | | | | - | |
| MVV | L/min | 86 | 4.24 | 75 | | | 2+ | |
| PIF | L/sec | 00 | 4.37 | | | | 1 | _ |
| FEV1/FEV | | | 64 | | | • | 1 | |
| | | Dia the care | | | (BTPS) | | 0 + | 1 |
| | /olumes/l | remysn | iogra | ony | (011-3) | | \ | ~ |
| Vtg VC | Liters | | | | | | Ţ \ | 1 |
| VČ | Liters | 2.98 | | | | | -2 + | 1 |
| TLC | Liters | 5.03 | | | | | | / |
| RV | Liters | 2.00 | | | | | † |) |
| RV/TLC | % | 40 | | | | | -4 | |
| FRC PL | Liters | 2.92 | | | | | • | |
| ERV | Liters | | | | | | + | |
| IC | Liters | | | | | | اء | |
| Diffusi | on | | | | | | -6 [⊥] -1 0 1, | 2 3 4 |
| DLCO | mL/mmHg/min | 19.3 | | | | | -1 0 1 Volu | me T |
| DL Adj | mL/mmHg/min | 19.3 | | | | | | |
| DLCO/VA | mL/mHg/min/L | | | | | | | |
| VA | Liters | 0.00 | | | | | | |
| 8HT | Sec | | | | | | | |
| | | | | | | | | |
| Resist | ance | | | | | | | |

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec cmH2O/L/sec 1.30 L/sec/cmH2O 0.700 Raw Gaw sRaw cmH2O/L/s/L 3.80 L/s/cmH2O/L 0,263 sGaw Vtg (Raw) Liters

Comments:





Lovelace Scientific Resources Aidgecrest Dr SE Albuquerque, NM 87108



Name: ESN,

Gender: Female

Age: 68

Race: Caucasian

Height(in): 65.0

Weight(lb): 145

Any info:

ld: AKP-032 Date: 12/09/13

Temp: 19

PBar: 630

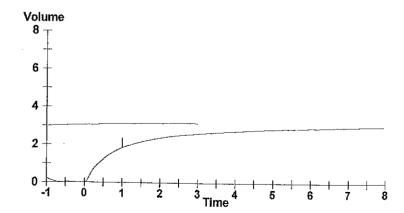
Physician:

Technician: VL

| Any Info: | | | | | | Technicia | in: VL | | | | |
|-----------|--------------|---------|-------------|--------------|-------------------------|---------------|-----------------|-------|-------------|-----|---|
| Spirome | hry (I | BTPS) | PR | E-RX | POST-RX | | Flow | | | | |
| ophomo | u y | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 8 _T | | | | |
| FVC | Liters | 2.98 | 3.18 | 107 | 111000 70 1001 | 70 Ong | ‡ | | | | |
| FEV1 | Liters | 2.37 | 1.86 | 79 | | | _ | | | | |
| FEV1/FV0 | | 82 | 58 | 72 | | | 6+ | | | | |
| FEF25-75 | %L/sec | 2,44 | 0.89 | 36 | | | 1 | | | | |
| FEF50% | L/sec | 3.23 | ** 1.26 | ** 39 | | | | | | | |
| FEF75% | L/sec | 0.96 | 0.34 | 36 | | | 4 - | | | | |
| IC | Liters | | | | | | | - / \ | | | |
| VC | Liters | 2.98 | | | | | 7 | - 1 ' | V | | |
| PEF | L/sec | 5.65 | 4.42 | 78 | | | 2∮ | | \sim | | |
| MVV | L/min | 86 | | | | | | - 1 | \ | | |
| PIF | L/sec | | 4.56 | | | | Ţ | | 1 | | |
| FEV1/FEV | | | 64 | | | | 0 | | | 1 | |
| Lung \ | √olumes/ | Plethys | smogra | phy | (BTPS) | | | . (| . , , | , i | • |
| Vtg | Liters | | | - | | | T | / | | | |
| VC | Liters | 2.98 | | | | | -2+ | , | \ | 1 | |
| TLC | Liters | 5.03 | | | | | | | | | |
| RV | Liters | 2.00 | | | | | 7 | | | | |
| RV/TLC | % | 40 | | | | | -4 | | | | |
| FRC PL | Liters | 2.92 | | | | | - 1 | | | 1 | |
| ERV | Liters | | | | | | † | | | | |
| IC . | Liters | | | | | | -6 [†] | | | | |
| Diffusi | on | | | | | | -6⊥ -1 | 0 | 1 2 | 3 | 4 |
| DLCO | mL/mmHg/mir | n 19.3 | | | | | | | 1 Volume | | |
| DL Adj | mL/mmHg/mi | | | | | | | | | | |
| DLCO/VA | mL/mHg/min/l | | | | * | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| Resist | ance | | | | | | | | | | |
| | cmH2O/L/sec | | | | • | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1,30 | | | | | | | | | |
| Gaw | L/sec/cmH2O | | | | | 4 - 4 | | | | | |
| sRaw | cmH2O/L/s/L | 3.80 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | | | | | |
| Via (Dau) | | 0.200 | | | | | | | | | |



Vtg (Raw) Liters





Levelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP-032,

Gender: Female

Age: 68

Race:

Height(in): 65.0

Weight(lb): 146

Any Info:

ld: AKP-032 Date: 12/16/13

Temp: 19

PBar: 637

Physician:

Technician: CRD

| 7 day ii ii O. | | | | rechnicia | III. UKD |
|---|---|--|----------------------|-----------|--------------------------------|
| Spirometry | (BTPS) Ref | PRE-RX Pre Pre | POST-RX Post Post | Post | Flow 8 T |
| FVC Liters FEV1/FVC % FEF25-75%L/sec FEF50% L/sec FEF75% L/sec IC Liters VC Liters PEF L/sec MVV L/min PIF L/sec FEV1/FEV6% | 2.37 82 2.44 3.23 0.96 | Meas % Ref 3.29 110 1.90 80 58 71 0.88 36 ** 1.18 ** 37 · 0.34 35 4.57 81 4.29 63 | Meas % Ref | % Chg | 4 |
| | mes/Plethys | | (BTPS) | | 0 |
| Vtg Liters VC Liters VC Liters RV Liters RV/TLC % FRC PL Liters ERV Liters IC Liters Diffusion DLCO mL/mi DLCO/VA mL/mi VA Liters BHT Sec | 2.98 5.03 2.00 40 2.91 mHg/min 19.4 nHg/min 19.4 Hg/min/L 3.05 | g, | | | -2 -4 -6-1 0 1volume 3 4 |
| Resistance |) | | | | |
| Raw Total cmH26 | O/L/sec | | | | |

Comments:

Vtg (Raw) Liters

Raw Exp

Raw

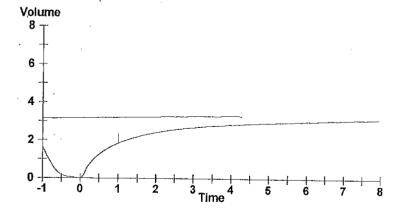
Gaw sRaw sGaw

Raw Insp cmH2O/L/sec

cmH2O/L/sec cmH2O/L/sec

L/sec/cmH2O 0.698 cmH2O/L/s/L 3.80

L/s/cmH2O/L 0.263



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | j | | | | | | | | 400 | 1/1/2/13 | State | 1 | |
|----------------------------|---------------------|---------------------|-------------------|------------------------|----------------------|---------------|---------------------|---------------------|--------------------|--------------------------------|--------------------------|-----------------|---------------------------------|-------------|
| Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | (3) Itchy Nose 0 to 3 | Runny Nose | 1 | DAV |
| YES (NO | YES NÒ | 0 1 (2) 3 | 0 10 3 | 0 ① 2 3 | 0 1 Ø 3 | -7 | YES (NO.) | YES (NO) | 0 1(2)3 | 0 1 (2)3 | 0 1(2)3 | 0 1 2 3 | 11/18/13 | _7 , |
| YES (NO) YES (NO) YES (NO) | YES (NO) | 0 1 🔘 3 | 0 1 6 3 0 1 6 3 | 0 (1) 2 3 0 (1) 2 3 | 0 1(2)3 | 6 | YES (NO) | YES (10) YES (10) | 0 1(2) 3 | 0 1 2 3 0 1 2 8 0 1 2 3 0 1 23 | 0 1(2) 3 | 0 1 (2) 3 | 1 | ٠ ه- |
| YES (SO) | YES 🔞 YES | 0 1 🔘 3 | 0 1 ② 3 | ©1 2 3 (Ø1 2 3 (Ø1 2 3 | 0 1 🖉 3 | ե | YES NO | NO (SES) | 0 1 2 3 0 1 2 3 | 0 1 2 | 0123 | 0 1 2 3 0 1 2 3 | 11/19/18 11/20/13 11/21/13 | , , |
| | | 0 (1) 2 3 0 (1) 2 3 | 0 1 🖄 0 🗇 2 3 | 0)123 | 0 1 2 3 0 1 2 3 | 4 | YES (NO) | YES (ÑO) | 0 1@3 | 0 1 2 ③ | 1 (2)3 (1) 2 3 | 0 (1) 2 3 | 11/21/13 | |
| YES (NO) | YES NO | | 0 🛈 2 3 | 0123 | | ψ | YES NO | YES NO | 0 1 2 3 0 1 | 0 123 | ① 1 2 3 | 0'1(2)3 | 11/12/18 | <u>ل</u> ا |
| YES (NO) | YES (NO) | 0 1 2 3 | 0 1 ②3 | 0 1 2 3 | 0 1 🙉 3 | -2 | YES (NO) | YES (NÓ) | (2) ₃ | 0 1 ②3 | (6) 1 2 3 | 0 1 (2) 3 | u Prylis | <u>-</u> 5 |
| YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | -1 | YES (NO) YES | YES NO | 0(1)2 3 | 0 (1) 2 3 | 2 3 1 2 3 | 0 🛈 2 3 | 11/25/18 | . |
| YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 | NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 4/13 111/27/13 6/12/13 11/27/13 | > |
| YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 | YES NO | YES NO | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | य 2711 | > |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ACCOUNTED DATE COMPLETED: 11/25/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc fic Resources Leslie Byatt, Cun Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME ESN, ESN

PATIENT ID

AAGH1347

DOB 01/26/1945 SEX F REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 11/25/2013 11:22 RECEIVE DATE & TIME 11/25/2013 20:32

PRINT DATE & TIME 11/26/2013 06:04

30920940

Test

0

PATIENT NO.

032

COMMENTS:

Result

in Range

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone

NOT GIVEN

Approx 27 Novron3

Many

NS

End of Report

FAX24664

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| SCALE 0 +5 3 | Throat Clearing | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | AM | DAY |
|--------------|-----------------|---------------------|--------------------|-------------------|-----------------------------|----------------------|--------|---------------------|---------------------|--------------------|-------------------|----------------------|----------------------|---|--------|
| <u>.</u> | earing | arse | | ň | ē |)Se | š | earing | arse | | on | Ö. | | | |
| | YES | (YES) | 0 1(| 0 (1)2 |) (<u>0</u>) | 0 1(| | YES | YES | . O | 0 | 1 | 0 1 | 11/2 | |
| (| Ô | NO | 1(2)3 | 2 3 | 2 3 (| 1(2)3 | | ON N | NO NO | 2 3 | 2 3 | 2 3 | 2 3 | 5/13 | - |
| | ΥES | YES | © 12 | (a) | (a) 1 | 0 (1) | | YES | YES | @12 | 1 | <u>@</u> | 01 | 11/2 | |
| | (8) | | 2 3 | 1 2 3 | 0)123(0)123 | 0 (1) 2 3 | 2 | (N) | (3) | 2 3 | © 1 2 3 | 123 | 2 3 | 1913 | 2 |
| | ΥES | YES | <u>(6)</u> 1 2 | . @1 | 0 (±) | 0 (1 | | YES | YES | <u>(6)</u> | (b)1 | ① 1 2 | (0) 1 | 11/2 | ٤, |
| | (§ | (No) | 2 3 | 2 3 | 0 🛈 2 3 | 0 ①2 3 | 3 | (NO) |) (S) | ©1 2 3 | (b)1 2 3 | 2 3 | 2 3 | 11/25/13 11/26/13 11/27/13 11/28/13 11/29/13 11/39/13 | ω |
| | YES | YES | \bigcirc 1 | (0)1 2 | 0 (Î) | <u> </u> | | YES | YES | 0)1 | 601 | <u></u> | \bigcirc 1 | (1/2 | |
| | (3) | (N) | 2 3 | 2 3 | 2 3 | 2 3 | 4 | (ON) | NO | (0)1 2 3 | (6)1 2 3 | 2 3 | 2 3 | 8/13 | |
| | ΥES | YES | <u>@</u> 1 2 3 | 6) 1 | <u></u> | © 1 2 3 | | YES | YES | © 1 | Ø 1 2 3 | 9 | $\bigcirc 1$ | 11/2 | , |
| | (ð | (3) | | 2 3 | 0 (1) 2 3 (0) 1 2 3 (6) 1 2 | | 5 | (g) | (R) | 2 3 | | 2 3 | 2 3 | 9/13 | , |
| | YES | YES | ()1 2 | | 6 1 | 0 12 | _ | YES | YES | @ | (6) 1 2 | 0 | $\bigcirc 1$ | 11/2 | |
| | 6 | 3 | 2 3 | 2 3 | 2 3 | 2 3 | 6 | (3) | | © 1 2 3 | 2 3 | 2 3 | 2 3 | 12/13 | , |
| | YES | YES | Ø 1 | 6 00 1 | © 1 | © 1 | | YES | YES | © 1 | 0 D | (b) 1 | © 1 | 12/1 | , |
| | (3) | (3) | 2 3 | 2 3 | 2 3 | 2 3 | 7 | 8 | No | 2 3 | 2 3 | 2 3 | 2 3 | 113 | 7 |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | \bigcirc 1 | (O) 1 | 6 | © 1 | 121 | |
| | NO NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 00 | (NO |) (T | 2 3 | 1 2 3 | 2 3 | 2 3 | 413 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 113 14413 143 15 | |
| | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 9 | NO | ON | 2 3 | 2 3 | 2 3 | 2 3 | 3/53 | , B |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: #KP032

DATE COMPLETED: 12/02/13

SUBJECT INITIALS AND DATE: LAM 12.2-13

REFERENCE LABORATORIES

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc lific Resources Leslie Byatt, Ulin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME X, ESN

PATIENT ID **AAGI4135**

01/26/1945

REPORT STATUS SEX Final

PAGE

PHYSICIAN Unlisted Physician,

PT. PHONE NO.

COLLECT DATE & TIME 12/02/2013 13:32

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PATIENT NO.

12/02/2013 18:26

12/03/2013 06:14

30920893

0

COMMENTS:

AKP032

| Result | |
|--------|--|

| | • | WAR II | | | | |
|------------------------------------|---|----------------------------------|---------------------|-----------------------------------|-----------------|-----------|
| Test | In Range | Out of Ran | ge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | - | | | |
| Sodium | 140 | | | mmol/L | 134-144 | |
| Potassium | 3.9 | | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | | mmol/L | 98-111 | |
| CO2 | 26 | | | mmol/L | 20-30 | |
| Anion Gap | 7 | | | | 6-14 | |
| Glucose | 86 | | | mg/dL | 60-100 | |
| BUN | 23 | | | mg/dL | 7-31 | |
| Creatinine | 0.72 | | _ | mg/dL | 0,50-1.40 | |
| | Creatinine method is IDMS | | | | een adjusted. | |
| | Please note new reference | range effecti | ve 5/23/ | /2013. | | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| | Estimated GFR values are a | not accurate i | n acute | kidney failure | inpatients | |
| | Estimated GFR values are on IV fluids, obese (BMI>) the Very old or very youn people with acute illness | 34) or underwe g, races other | ight (BN than Ca | MI<20) people, aucasian or Afr | ican American, | |
| Calcium | 9.1 | es, or amputat | I OHS. | mg/dL | 8.4-10.4 | |
| Total Protein | 6.7 | | | gm/dL | 6.1-8.2 | |
| Albumin | 4,3 | | | gm/dL | 3.4-4.7 | |
| Giobulin | 2,4 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.5 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 55 | | | Ú/L | 38-150 | |
| AST(SGOT) | 17 | | | U/L | 6-58 | |
| ALT(SGPT) | 24 | | | U/L | 14-67 | |
| Fasting | NOT GIVEN | | | | ,,,,, | |
| Phosphorus | 3.4 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | • | | |
| WBC | 6.0° | | | x10E3 | 4.0-10.6 | |
| RBC | | 3.80 | L | x10E6 | 4.00-5.36 | |
| Hgb | • | 11.8 | L | gm/dL | 12.0-16.0 | |
| Hct | 36 | | | % | 36-48 | |
| MCV | 96 | | | fL | 81-98 | |
| MCHC | 32,4 | | | gm/dL | 31.2-35.2 | |
| RDW | 12.6 | | | ~ % | 11.0-14.5 | |
| Platelets | 268 | | | x10E3 | 150-400 | |
| Eos, Respiratory | | Moderate | * | | NS | |
| Phys, Addr, Phone | NOT GIVEN | | | | * * ** | |

End of Report

Suls I Maren 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | | _ | | | ` | | • | | 7 | , | 7 | | 13 | | 7.5 | _ | 7 | |
|----------------------|--------------|-----------|----------|------------|--------------|------------|----------|----------|----------|-----------|----------|-------------|----------|----------|----------|--------|--------|----------|
| DAY | _ | ****** | 00 | | ת | | _ | 2 | -1 | , T | ┥. | 77 | -i | _ | 4 (| 2 | ì | |
| AM | <u>_</u> | 77 | 7 | 40 | 7 | + | 1 | M | 7 | 9 | ス | <u>(,</u> | | 7 | ∴ પ | 1 | | |
| Runny Nose | 0 1 | 2/3 | 0 | 2 3 | \bigcirc 1 | 2 3 | 9 | 2 3 | (O) | 2 3 | €) | 2 3 | 0 | 2 3 | <u></u> | 2 3 | 0 | 3 |
| | | Mark Sand | K | | | | < | | - 1 | | | | | | ļ | - 1 | Ì | |
| Itchy Nose | 0 1 | 2 3 | © | 2 3 | $\bigcirc 1$ | 2 3 | 7 | 2 3 | <u>9</u> | 2 3 | 9 | 2 | 9 | 2 | 9 | 2 3 | 0 1 | 5 3 |
| ş | - 1 | _ | 1 | ŀ | سرا | | | 1 | 1 | | 1 | 1 | +_ | | (F) 1 | | 1 | 6 |
| Congestion | 0 1 | ~√~ W | <u>0</u> | 2 3 | 9 | 2 3 | <u>)</u> | 2 3 | <u>ව</u> | 2.3 | <u>_</u> | 5 3 | ∂ | 2 | - 3 | ر 2 | T 0 | |
| | | |)_ | | | | | | Ç | - 1 | ١. | - 1 | | | | | | |
| Sneezing | 01 | 2 3 | 0 | 2 3 | 0 | 2 3 | (O) | 2 3 | 0 1 | 2 3 | 9 | 2 3 | 0 | 2 3 | <u>.</u> | 2 3 | 0 | 2 3 |
| | *** | , |) | (| Į, | (|) | | | | | | | | | (| | 1 |
| Voice Hoarse | YES | N N | YES | 8 | YES | <u>ş</u>) | YES | <u></u> | YES | <u>\$</u> | YES | 2 | YES | 3 | YES | §) | YES | 2 |
| • | _ | | | (| | (| | 1 | | | | | | | | | | |
| Throat Clearing |) YES | ON ON | YES | (2) | YES | <u>Q</u> | YES | <u>Q</u> | YES | 2 | YES | | YES | (g) | YES | 2 | YES | 9 |
| DAY PM | | | | ∞ | | 6 | | 10 | 1 | 11 | 1 | 12 | Τ, | 13 | 14 | 5 | 15 | |
| | 01 | 2 3 | (Q) | 2 3 | 0 | 2 3 | © | 2 3 | 01 | 2 3 | 0 1 | 2 3 | 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| | i | | _ | | | | | | | | ۔ا | 1 | L | Т | 1 | | Т | 1 |
| Itchy Nose 0 to 3 | © 1 2 | 2 3 | 0 1 | 2 3 | 6 | 2 3 | 9 1 | 2 3 | (C) | 2 3 | 9 | 2 3 | 6 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| ion | 0)12 | 2 3 | 0 | 2 3 | 0 1 | 2 3 | © | 2 3 | 0 1 | 2 3 | <u>و</u> | 2 3 | <u>1</u> | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| 0 to 3 | <u>)</u> | | • | | | | (| ļ |) | | | | | | | | | |
| Sneezing | (O) 1 2 | 2 3 | 0 1 | 2 3 | (0) | 2 3 | <u></u> | 2 3 | 0 | 2 3 | (S) | 2 3 | <u>6</u> | 2 3 | 0 | 2 3 | 0 | 2 3 |
| |) | |) | (|) | ļ | | (|) | { |) | (| | (| | ! | | |
| Voice Hoarse | YES | E | YES | E | YES | E | YES | S | YES | <u>(</u> | YES | ©). | YES | S | YES | 9 | YES | <u> </u> |
| Throat Clearing | YES | 9 | YES | P | YES | Q | YES | 2 | YES | 2 | YES | E | YES | § | YES | ON | YES | S S |
| | |) | | , | |) | | | | | |) | | l | |] | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: KKP032 DATE COMPLETED: 13/09/

SUBJECT INITIALS AND DATE

TriCore

Fax Number

TUE DEC 10 09:37:44 2013 Page 1 01 1

TRICORE REFERENCE LABORATORIES

Lovelace St. ...tiffic Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID

DOB

REPORT STATUS

PAGE

ESN, ESN PHYSICIAN

AAGH1347

01/26/1945

Final

PRINT DATE & TIME

Test

COLLECT DATE & TIME 12/09/2013 14:10 RECEIVE DATE & TIME

REQUISITION NO.

PT. PHONE NO.

12/09/2013 19:12

SEX

12/10/2013 09:15

PATIENT NO.

31033177

Ð

032

COMMENTS:

Result

In Range

Out of Range

11 Dac 2013

Units

Reference Range

Site Code

Eos, Respiratory

Moderate

NS

End of Report

VS 115/13

LSR Study #: 2 2749 Study Identification:

Subject Number: AKP 032

Subject Initials: ESN

ADVERSE EVENT LOG

| Investigator Initials/notes | Sept. Commence of the commence | | 10000000000000000000000000000000000000 | | | | |
|---|--|-----------------|--|--|--|--|--|
| Action Taken | Non | your | | | | | |
| ** End Date (DD/MMM/YYYY) | 21/5an/2011,110rd | 21/5an/2014/10M | | | | | |
| Relationship to Study Drug (Suspected/Not Suspected) | Susperty | moretul | | | | | |
| SEVERITY | mich | mùd | | | | | |
| ** Start Date (DD/MMM/YYYY) | 14000/2013 | 1/0e/2013 | | | | | |
| Adverse Event | sinus congestion 14 Deg 2013 mild | Browth | | | | | |

if day is <u>unknown,</u> write UNK in space provided, but every effort should be made to be as specific as possible**

Investigator Signature (at end of study):

SC Signature (at end of study): Exic (Ca) The deference Bate: 1/17

Main as Love Ly. 117114

PAGE:

اً م

Lovelace Scientific Resources, Inc.- AdverseEvents 04/2013

Ongoingateos (for Clinic use) List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. Subject Initials:C Date: 19/DOC/2013 Stop Date Date: 191706 2013 LSR#: 900 999 1000 N N UNK/AUG/1999 1000 * If day or month of medication date is <u>unknown</u>, write UNK in space provided -- 12012 (Day/Month/Year) * Start Date CONCOMITANT MEDICATION LOG Oral Route Prai 10,a1 <u>8</u>5 gai Sold ! 010 2 Tabs per day Frequency PRN \subseteq , MG. 2 Unit 200 Dose 000 SC Signature (at end of study) B HUPERTHINGIGISM (What you take it for) Indication Depressior Investigator Signature (at end of study); TUSUT Tabetes Study Identification: 2749-evothyroxul Mosamuse Madu ESI ami Name of Medication itaprolam razadîn Subject Number: EXAMPLE Sodium

Loveface Scientific Resources, Inc - ConMeds 04/2013

| Study Identification: 2749 | | | | | LSF | LSR #: | I |
|--|--|------------------------|---|----------------------------|--|-----------------------------------|-------------------|
| Subject Number: 033 | | | | | Sub | Subject Initials: \mathcal{ESM} | . 1 |
| List all | CO prescription me | NCOMIT dications, o | TANT MED | CONCOMITANT MEDICATION LOG | CONCOMITANT MEDICATION LOG List all prescription medications, over-the-counter medications, and supplements. | | |
| Medication | Dose | ğ | Frequency | Route | * Start Date | * Stop Date (CRC Initials/Date) | SO3 te BuioBuo |
| Onega 3 Suetal Gran | 1000 H | bu | 90 | Q | 8661//- | | Ę |
| Blooms Symphy | 66 46 | bul | Ø | A | 1061/ | | Þ |
| photogo unissuo | ment 1 | SKI | 90 | 00 | 81//- | 200 | Ø |
| MONORON KIGHTHE | Olt of | bu | B | Q | 100/160 | 7 | <u>A</u> |
| intollin Herma | R | J-M/ | PRU | HMZ | 161/ | | A |
| Tenduchat Osto | 0/ | SZ. | WKly | 00 | 86/f-1/- | | Ø |
| | | <u> </u> | | li | | | \$ |
| | | | | | | | |
| | : | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| | | | | | | | |
| * Use DD/MMM/YY | //Y format for da | ates. If day | or month of | f date in unk | * Use DD/MIMIM/YYYY format for dates. If day or month of date in unknown, write UNK in space provided. | ice provided. | |
| The Manual Manua | The state of the s | Loveface Scie | Lovelace Scientific Resources, Inc. ConMeds 10/2013 | Inc - ConMeds 10 | /2013 | PAGE: B | of Of |

ì.

* Mother 19 Da 2013 Sieva malbrach 12/18/13

| DAILY SYMPTOMS | LOMS SCOP | SE SHEI | 호 남 | SCORE SHEET (RHINITIS DIARY) | DIAF | ₹ | | | | | | | | 7 | | 4 |
|--------------------|--|----------------|---------------|------------------------------|------|-------|-------|-------|------|------------|-------|---|--------------|------------|---|--------|
| CIRCLE APPROXIMATE | IIMATE RESPU | ONSE EV | ERY 12 | HOURS | | | | | | | | | • • | 力を上 | | 1 |
| DAY | , 14 | 7 | Z. | 16 | , | 1 | 7 | *** | 00 | 15 | | 20 | | 21 | , | 2 |
| AM | 12/09/13 (2/10/13 12/11/13 12/13/13 12/13/13 12/14/13 12/15/13 12/16/13/13/13/13/13/13/13/13/13/13/13/13/13/ | 1/2/1 | 0/(3 | 12/11/ | (3 | 12/ | 12/13 | 1/2/ | 3/13 | 12/ | 14/13 | 12/15 | (3 | 12/16 | <u> </u> | 12/2 |
| Runny Nose | 0 1 2 3 | (F) 0 | 2 3 | (I) 0 | 2 3 | 0 | 2 3 | (T) 0 | 2 3 | @ 1 | 2 3 | 0 (1) | m | 0 10 | m | - |
| 0 to 3 | | | |) | |) | |) | |) (| ! |) |) |)) |) | 1 |
| Itchy Nose | 0/123 | 0 1 | 2 3 | 0 | 2 3 | (d) 1 | 2 3 | 0)1 | 2 3 | 601 | 2 3 | 23 (01 23 (01 23 (01 23 (0) 1 2 | m | 6) 1 2 | m | 1 |
| 0 to 3 | |) | | | |) | |)_ | |) } | 1 |)) | · <u>·</u> |) | } | 1 |
| Congestion | 0 1 2 3 | (O) 1 | 2 3 | 0) | 2 3 | 0 1 | 2 3 | 0)1 | 2 3 | 01 | 2 3 | 23 10 1 2 3 1 | ~ | 0 (1) | ď | 7 |
| 0 to 3 | |) | | | | 2 | |) | | |) | |) | , |) | 1 |
| Sneezing | 0 1 12 3 | 0 | 2 3 | 0 17 | 2) 3 | 0 | 2 3 | 01 | 2 3 | 6)1 | 2 3 | 2304)2301/2301230123/0123 (0123 (0123 (01) 23 (01) 23 (01) 23 (01) | ~ | 011 | ~ | - |
| 0 to 3 | |) | ï | <i>J</i> | ` | | |) | 1 |) |) | | <u></u>) | ;) ! |) | i > |
| Voice Hoarse | YES NO | YES | (O) | YES / | 9 | YES | 6 | YES | 6 | YES | 6 | NO YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES | 0 | YES (| 6 | YES |
| N/X | | • |) | _ |) | |) | |) | |) |) | 1 | | <u> </u> | ! |
| | | | | | | j | (| | 1 | | | | 1 | | | |

ന

~

ന

7

2

7

| | 9 9 | 2 | 2 3 | 2 3 | 2 3 | 2 3 | NO | 9 |
|---|--|--------|---|---|--|--|--|---|
| | YES | 2 | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES NO |
| | 8 | | 2 3 | 8 | m 2 | m 2 | ON ON | ON |
| | YES | 21 | 0 1 3 | 0 1 | 1 | 0 1 | YES | YES |
| - | (<u>Q</u>) | | 2 3. | 8 2 | 6 | 8 | (2) | |
| | Yes (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES NO | 20 | 0 \$\Phi 2 3 0 1 \$\Delta 3 0 \$\Delta 2 3 \Delta 1 2 3 \Delta 1 2 3 0 \$\Delta 2 3 0 1 2 3 | 0 1 2 3 0 6 2 3 6 1 2 3 6 1 2 3 6 1 2 3 6 1 2 3 6 1 2 3 0 1 2 3 | (9 1 2 3 (0) 1 2 3 (0) 1 2 3 (0) 1 2 3 (0) 1 2 3 (0) 1 2 3 (0) 1 2 3 | 0(1) 2 3 0 1 2 (3) 0 (4) 2 3 (0) 1 2 3 (0) 1 2 3 0 (4) 2 3 0 1 2 3 0 1 2 3 | YES (NO YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES NO YES NO | YES (NO) YES (NO) YES (NO) YES (NO) YES (NO) YES NO |
| | E | 5 | 2 3 | 2 3 | 2 3 | 2 3 | (NO) | (ON) |
| | YES | H | 61 | 0 1 | 0 1 | 0 1 | YES | YES |
| \ | <u>§</u> | 00 | 2 3 | 2 3 | 2 3 | 2 3 | 9 | (F) |
| | YES | F | \bigcirc | 0 1 | 0 | Ď1 | YES | YES |
| (| E | | 2 3 | 2 3 | 2 3 | 2 3 | S | <u>Ş</u>) |
| İ | YES | 1. | (<u>(</u>) | 01 | Q | 0 | YES | YES |
| | <u> </u> | i,C | Ø 3 | 2 3 | 2 3 | 2(3) | (<u>§</u>) | 8 |
| | YES | Ţ | 0 1 | () | 0 | 0 1 | YES (| YES |
| (| <u>N</u> | 5 | 2 3 | 2 3 | 2 3 | 2 3 | (NO | NO NO |
| | YES | 1 | D 0 | 0 | Ø 1 | 9 | YES | YES |
| 7 | ON | 14 | | 2 3 | 2 3 | 2 3 | NO | (NO) |
| | YES | ÷. | 0 ① 2 3 | 01 | 0 1 | 9 | YES | YES |
| | Throat Clearing YES Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: E5N

DATE COMPLETED: 13/16/13

SUBJECT INITIALS AND DATE:



Lovelace S tific Resources Leslie Byatı, Jin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME ESN, ESN

PATIENT ID **AAGJ0931**

DOB 01/26/1945

REPORT STATUS SEX Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

12/16/2013 14:30

12/16/2013 19:07

12/17/2013 06:14

31033174

n

PATIENT NO.

AKP032

| 1000177 | · · | AIXE O |
|----------|-----|--------|
| OMMENTS: | | |

| | R | esult | | | | |
|------------------------------------|--|--|---|--------------------------------|----------------------------------|----------------|
| Test | In Range | Out of Range | Uı | nits | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 140 | | mn | nol/L | 134-144 | |
| Potassium | 4.3 | | | nol/L | 3.5-5.1 | |
| Chloride | 106 | | mn | nol/L | 98-111 | |
| CO2 | 27 | | mn | nol/L | 20-30 | |
| Anion Gap | 7 | | | | 6-14 | |
| Glucose | 89 | | m | g/dL | 60-100 | |
| BUN | 25 | | m | g/dL | 7-31 | |
| Creatinine | 0.80 | | m | g/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | | | on has b | oeen adjusted. | |
| | Please note new reference | range effective | 5/23/2013. | | | |
| eGFR non-African Am GFR Comment | >60 | | mL/mir | /1.73m2 | >60 | |
| or it comment | Estimated GFR values are ron IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | ot accurate in a 34) or underweigh , races other the | acute kidney nt (BMI<20) nan Caucasia | failure people, n or Afr | e, inpatients rican American, | |
| Calcium | 9.3 | .s, or empacación | m | g/dL | 8.4-10.4 | |
| Total Protein | 6.9 | | | n/dL | 6.1-8.2 | |
| Albumin | 4.2 | | | n/dL | 3.4-4.7 | |
| Globulin | 2.7 | | | n/dL | 2.4-4.2 | |
| Bilirubin, total | 0.5 | | m | g/dL | 0.3-1.2 | |
| Alk Phos | . 55 | | | Ĵ/L | 38-150 | |
| AST(SGOT) | 18 | | į | J/L | 6-58 | |
| ALT(SGPT) | 25 | | Į | J/L | 1 4 -67 | |
| Fasting | NO | | | | | |
| Phosphorus | 4.1 | | m | g/dL | 2.3-5.6 | |
| CBC | | | | | | |
| WBC | 6.7 | | x1 | 0E3 | 4.0-10.6 | ma and |
| RBC | | 3.91 | L x1 | 0E6 | 4.00-5.36 | m NCS |
| Hgb | 12.4 | | gn | n/dL | 12.0-16.0 | • |
| Hct | 37 | | | % | 36-48 | |
| MCV | 95 | | | fl_ | 81-98 | |
| MCHC | 33.4 | | дл | n/dL | 31.2-35.2 | |
| RDW | 12.6 | | | % | 11.0-14.5 | Da LIAC |
| Platelets | 263 | | | 0E3 | 150-400 | m NCS |
| Eos, Respiratory | | Rare | * | | NS " | ▼ = = • |
| Phys, Addr, Phone | Not given | | | | | |

End of Report

Marsub I 17 Dec 2013

| | <u> </u> | | Orgolingat | R | Þ | K | <u>N</u> | A | A | Ø | | | | | | g of | |
|-----------------------|-------------------|--|------------------------------------|----------|----------------|----------|----------|---------|-----------|--------|--|--|---|---|--|---|-----|
| | Subject Initials: | | * Stop Date (CRC Initials/Date) | | | 8 | 7 | _ | | | | | | | provided. | PAGE: | |
| LSR#: | Subjec | CONCOMITANT MEDICATION LOG List all prescription medications, over-the-counter medications, and supplements. | *Start Date | 8661/1 | 86611 | 861//- | 100/16 | 1661/ | X6/f/- | | | | | | * Use DD/MIMIM/YYYY format for dates. If day or month of date in unknown, write UNK in space provided. | 8// | - 1 |
| ı | | CONCOMITANT MEDICATION LOG | oy Route | PO | - Of | 00 | 00 | HIE! | 1 00 1 | A | | | | | າ of date in unknow | Lovelace Scientific Resources, Inc - ConMeds 10/2013 19 Dac 2013 12 S | |
| | | NCOMITANT M | Unit | Mg OD | mg 00 | THO 00 | mg (Q) | Mes PRI | ma Wally | ` ` | | | | | tes. If day or month | Lovelace Scientific Resour |) |
| | | CO all prescription mec | Dose | 17 (000) | art do | loment 1 | 720 pt | 2 | 10 | | | | | | YYYY format for da | Main no | |
| 2749 | 933 | List | uogeapor | Supplien | Cirtary Sandan | Dietary | Right | Hofmaa | 08/60 | | | | 1 | : | * Use DD/MMM/ | Money | |
| Study Identification: | Subject Number: | | Wedication | Mega 3 | B (Mynghex | otassium | YNOKON | nolin | endronati | | | | | | | * " | |

AKP-035

2749 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| Initials: ADS Site #: Subject #: ANPOBS |
|--|
| PATIENT DEMOGRAPHICS |
| Patient Demographics |
| Date of Birth: 27 / May 1981 (dd/mmm/yyyy) |
| Gender: |
| If female, Indicate Childbearing Potential |
| Childbearing Surgically sterilized Post-Menopausal |
| Ethnicity: Hispanic Non Hispanic |
| Race: Asian Black Caucasian American Indian |
| Pacific Islander Other, Specify |
| |
| Smoking History |
| Smoking Status: None (smoked less than 100 cigarettes in lifetime) |
| Former (previously smoked more than 100 cigarettes in lifetime) |
| Current (smokes now) |
| If subject is a former or current smoker, please indicate: |
| Years smoked: Cigarettes per day: |
| - 10/11/2 A 24 A 10/1/2 AB |

Version: 02 September 2013



Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Lovelace Se

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME X, ADS

PATIENT ID AAGH4692 DOB. 05/27/1981 SEX

REPORT STATUS Final

tific Resources

PAGE

Site Code

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO. **COLLECT DATE & TIME** 11/11/2013 10:38 RECEIVE DATE & TIME

PRINT DATE & TIME

PATIENT NO.

11/11/2013 20:02

11/13/2013 06:09

30920947

Λ

AKP035

COMMENTS:

Test Allerg,Panel 18 Allerg,Juniper Allerg, Cottonwood Allerg, West. Ragweed Allerg, Russian This Allerg, Bermuda Grass Allerg, Alternaria Allerg, Mesquite Allerg Cockroach

Allerg, Derm. pter.

| | Result | | | |
|----------------|------------|------|-------|-----------------|
| In Range | Out of Rar | រដិច | Units | Reference Range |
| | 25.30 | Н | kU/L | <0.35 |
| 0.20 | | | kU/L | <0.35 |
| 0.20 | | | kU/L | < 0.35 |
| | 24.70 | Н | kU/L | <0.35 |
| | 0.90 | H | kÜ/L | < 0.35 |
| <0.10 | | • • | kU/L | < 0.35 |
| - - | 1.70 | Н | kU/L | <0.35 |
| | 1.60 | Й | kU/L | <0.35 |

kU/L The standard classification system utilizes the following class cutoffs. Class ku/L Interpretation

| 0 | <0. 35 | Negative for Allergen |
|-----|--------------|-----------------------|
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| V | 52. 5-99. 99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal, Class 2 and higher should be considered positive Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| Allerg Derm. farinae | 0.20 | | | kU/L | <0.35 |
|----------------------|-----------|-------|-------|------|--------|
| Allerg, Clad. herb. | <0.10 | | | kU/L | < 0.35 |
| Allerg,Firebush | | 1.50 | Н | kU/L | < 0.35 |
| Allerg,Cat Dander Ep | | 13.50 | H | kU/L | < 0.35 |
| Allerg,Dog Dander | | 0.50 | H | kU/L | < 0.35 |
| Allerg,Bluegrass | | 0.90 | Ĥ | kU/L | < 0.35 |
| Allerg, Pigweed | | 25.70 | Ĥ | kU/L | <0.35 |
| Allerg, Mulberry | | 0.60 | Ĥ | kU/L | < 0.35 |
| Allerg, Helminth | <0.10 | | • • • | kU/L | < 0.35 |
| Phys. Addr. Phone | NOT GIVEN | | | | 2,24 |

End of Report

13 Nov 2013



Albuquerque, NM 87108



Name: ADS,

Gender: Female

Age: 32

Race: Hispanic

Height(in): 61.0

Weight(lb): 199

Any Info:

Id: AKP-035 Date: 11/27/13

Temp: 19

PBar: 637

Physician: Technician:

| Spirome | stru (| BTPS) | PR | E-RX | POS | ST-RX | | P41 |
|-------------|------------------|------------|------------|--------------|-----|---------------|---------------|----------------------------------|
| | | Ref | | Pre % Ref | | Post % Ref | Post % Chg | Flow 16 _[|
| FVC FEV1 | Liters Liters | 3.15 | 4.77 | 152 | | | | + |
| FEV1/FV | Liters C % | 2.72 87 | 4.04 85 | 149 98 | | | | 12 |
| FEF25-75 | 5%l /sec | 3.26 | 4.63 | 96 142 | | | | '- |
| FEF50% | L/sec | 3.77 | 5.57 | 148 | | | | † |
| FEF75% | L/sec | 1.70 | 2.89 | 170 | | | | 8 + |
| IC | Liters | ***** | 4.00 | | | | | |
| VC | Liters | 3.15 | | | | | | † (' |
| PEF | L/sec | 6.05 | 6.93 | 115 | | | | 4 |
| MVV | ∐min | 113 | | | | | | |
| PIF | L/sec | | 5.11 | | | | | |
| FEV1/FEV | | | 86 | | | | | 0 |
| Lung | Volumes/ | 'Plethys | mogra: | phv | (B | TPS) | | |
| Vtg | Liters | ** | • | J . | | | | † \ \ |
| vč | Liters | 3.15 | | | | | | -4 |
| TLC | Liters | 4.52 | | | | | | |
| RV | Liters | 1.35 | | | | | | Ť |
| RV/TLC | % | 30 | | | | | | -8+ |
| FRC PL | Liters | 1.96 | | | | | | |
| ERV | Liters | | | | | | | † |
| IC | Liters | | | | | | | -12 [⊥] -2 0 2 4 6 8 |
| Diffus | | | | | | | | -2 0 2 4 6 8 Volume |
| DLCO | mL/mmHg/mi | | | | | | | volume |
| DL Adj | mL/mmHg/mi | | | | | | | |
| DLCO/VA | | L 3.79 | | | , | | | |
| VA | Liters | | | | | | | |
| BHT | Sec | | | | | | | |

Resistance

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

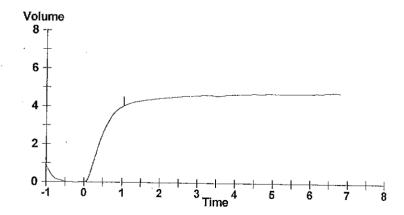
 Gaw
 L/sec/cmH2O
 0.471

 sRaw
 cmH2O/L/s/L
 4.00

 sGaw
 L/s/cmH2O/L
 0.250

 Vtg (Raw)
 Liters

Comments:





Lovelace Scientific Resources 2 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP,

Gender: Female

Age: 32

Race:

Height(in): 61.0

Weight(lb): 199

Any Info:

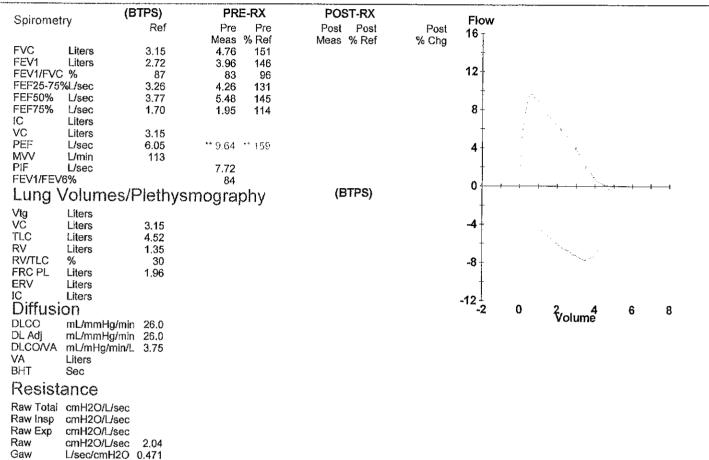
Id: AKP035 Date: 12/06/13

Temp: 19

PBar: 631

Physician:

Technician: CRD

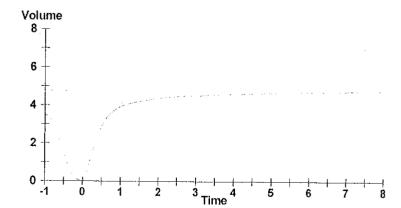




Vtg (Raw) Liters

sRaw

sGaw



Interpretation:

cmH2O/L/s/L

L/s/cmH2O/L 0.250

4.00



Lovelace Scientific Resources 2 / 1 Ridgecrest Dr SE Albuquerque, NM 87108

Name: ADS,

Gender: Female

Age: 32

Race: Hispanic

Height(in): 61.0

Weight(lb): 199

Any Info:

Id: AKP-035 Date: 12/13/13

Temp: 22

PBar: 630

Physician:

| mnysician. | |
|-------------|----|
| Technician: | VL |

| Spirome | tru (B | TPS) | PRI | E-RX | POS | ST-RX | | |
|-----------|--------------|-----------|-------|-------|------|---------|---------|---|
| Ophome | su y | Ref | Pre | Pre | Post | Post | Post | Flow |
| | | | | % Ref | | % Ref | % Chg | 16 _T |
| FVC | Liters | 3.15 | 4.59 | 146 | | 70 1101 | 70 Orig | |
| FEV1 | Liters | 2.72 | 3.87 | 143 | | | | |
| FEV1/FV | | 87 | 84 | 97 | | | | 12 + |
| FEF25-75 | %L/sec | 3.26 | 4.54 | 140 | | | | |
| FEF50% | L/sec | 3.77 | 5.58 | 148 | | | | † |
| FEF75% | ∐sec | 1.70 | 2.07 | 121 | | | | 8 |
| IC | Liters | | _,_, | | | | | |
| VÇ | Liters | 3.15 | | | | | | † / \ |
| PEF | L/sec | 6.05 | 8.65 | 143 | | | | 4 |
| MVV | L/min | 113 | | | | | | *1 |
| PIF | L/sec | | 5.25 | | | | | + / |
| FEV1/FE\ | /6% | | 86 | | | | | · · · · · · · · · · · · · · · · · · · |
| Luna ' | Volumes/F | Plathyema | arar | ahı. | (B | TPS) | | 0 |
| | | Garysine | ygraf | Jily | ν | , | | |
| Vtg VC | Liters | | | | | | | |
| VC | Liters | 3.15 | | | | | | -4 † |
| TLC | Liters | 4.52 | | | | | | |
| RV | Liters | 1.35 | | | | | | 1 |
| RV/TLC | % | 30 | | | | | | -8+ |
| FRC PL | Liters | 1.96 | | | | | | |
| ERV | Liters | | | | | | | † |
| <u>IC</u> | Liters | | | | | | | _12 |
| Diffusi | on | | | | | | | -12 \frac{1}{2} 0 \frac{7}{2} \frac{1}{2} |
| DLCO | mL/mmHg/min | 26.0 | | | | | | -2 0 2 4 6 8 Volume |
| DL Adj | mL/mmHg/min | 26.0 | | | | | | |
| | mL/mHg/min/L | 3.74 | | | | | | |
| V/A | Litora | * | | | | | | |

Resistance

VA

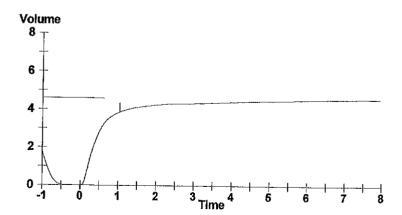
BHT

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec Raw cmH2O/L/sec 2.04 L/sec/cmH2O 0.471 cmH2O/L/s/L 4.00 Gaw sRaw sGaw L/s/cmH2O/L 0.250 Vtg (Raw) Liters

Liters

Sec

Comments:





Lovelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: ADS,

Gender: Female

Age: 32 Race: Hispanic

Height(in): 61.0

Weight(lb): 199

Any Info:

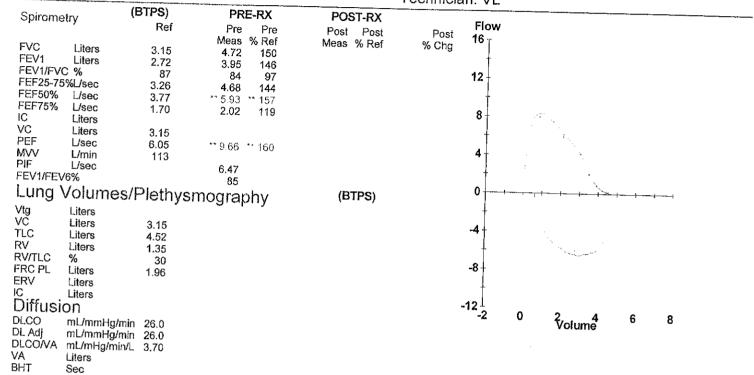
Id: AKP-035 Date: 12/20/13

Temp: 19

PBar: 624

Physician:

Technician: VL



Resistance

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

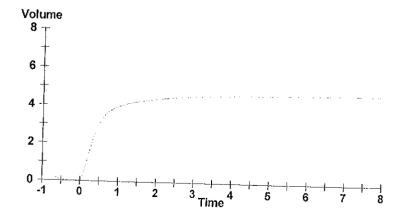
 Gaw
 L/sec/cmH2O
 0.471

 sRaw
 cmH2O/L/s/L
 4.00

 sGaw
 L/s/cmH2O/L
 0.250

 Vtg (Raw)
 Liters

Comments:



DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | -7 | -9- | | ਐ | 7 | _ | ۲, | | | | 7 | | | | | _ |
|------------------------|----------------|----------|-------------|--------------|----------|------------|---------------|----------|----------------|------------|------------|------------|--------|---------------|----------|--------|
| | 11/20/13 | - | Ž. | 122/3 | 7 | 23/13 | | 1/24/13 | 72 | | 11/26/1 | 5 | | 11/27/12 | 11/28/13 | 8/13 |
| Runny Nose | 0 1 2 3 | 0 0 2 | 3,20 | 6 2 3 | 0 1 | (2) 3 | 0 1 | (P) 3 | 0 1, | 1 23 | 0 1 | 2(3) | 0 1 | 2 | | 2 3 |
| | | | | (| (| | ر ا | <u> </u> | | | |) (| | , (| | |
| | 0 1 🕅 3 | 0 🗘 2 | 3 | 1 (2) 3 | (D) o | 2 3 | (B) 0 | 2 3 | 0 1 | 2(3) | 0 1 | 2 (3) | ۳ 0 | 2 (3) | 0 1 | 2 3 |
| | Ø 1 2 3 | 0 1 2 |) (B) | (E) 2 3 | 0 1 | 2.3 | 0 0 | 2 3 | D ₀ | 2 3 | 0 1 | 283 | 0 1 | <u>(2</u>) 3 | 0 1 | 2 3 |
| | 0 1 (2) 3 | 0 1 (2) | 3 | 1 2 3 | 0 | 2 | 6)1 | 2 3 | 0 1 | 2 (3) | 0 1 | 2 (3) | 0 1 | 2 (3) | 0 | 2 3 |
| | (| > 4 | 1 | |) | |) | | | > (| (| > | | } | | |
| Voice Hoarse Y/N | YES (NO) | (ES) N | NO YES | ON /S | YES | Ę) | YES | <u>Q</u> | YES |) () | 12) | N N | YES (| OZ) | YES | 8 |
| Throat Clearing Y/N | WES NO | (YES) NO | O KES | ON | YES | (S) | YES | © | YES | Ş | (ES) | ON N | (KES) | S S | YES | 2 |
| DAY PM | 7-~ | 9 | | | 4- | | ကု | | -2 | | 1.0 | | 0 | | 0 | |
| | 0 (2 3 (| O r 2 | 3 0 | 1 2 3 | 0 1 (| 3 | 0 10.2 | m Z | 0 | 2(3) | B 0 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| | o 🖄 2 3 | 0 (1) 2 | 0 (| 1 2 3 | 0 | 2 3 | 0 ① 2 | rs - 2 | 0 1 | 2 @ | 0 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Congestion 0 to 3 | © 1 2 3 | 0 1 2 | 9) m | 1 2 3 | 0 (1) | 2 3 | Ø1 2 | 6 3 | 0 1 | (2) 3 | 0 1 (| £ 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| | 1 2 3 (| (S) | 3 0 (| (1) 2 3 | 0) 1 | 2 3 | 0. 🕲 2 | 8 | 0 1 | 2 (3) | 0)1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| Voice Hoarse Y/N | YES MO | YES (MO) | y YES | S (RO) | YES < | (ON) | YES | (A) | YES (| E) | YES | (F) | YES | 9 | YES | N S |
| Throat Clearing Y/N | YES (NO) YES | YES (MO | <u>) ((</u> | ON/ S | YES | (2) | YES | © | SE P | 9 Q | YES | (2) | YES | ON O | YES | 8 |
| • | | | - | | | | | | | | | 1 | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER:

ALPO35 ADS DATE COMPLETED: 11 Day

SUBJECT INITIALS AND DAFE



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc fic Resources Leslie Byatt, un Triais 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PAGE

PATIENT NAME X, ADS

PATIENT ID **AAGH4692** DÓB 05/27/1981

REPORT STATUS SEX F Final

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 11/27/2013 13:57

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

11/27/2013 18:50

11/28/2013 06:11

30920929

0

AKP035

COMMENTS:

| | R | esult | | | |
|----------------------|--|--------------------------|--------------|-----------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 138 | | mmol/L | 134-144 | |
| Potassium | 4.0 | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | mmol/L | 98-111 | |
| CO2 | 25 | | mmol/L | 20-30 | |
| Anion Gap | 6 | | THIT OF L | 6-14 | |
| Glucose | 80 | | mg/dL | 60-100 | |
| BUN | 14 | | mg/dL | 7-31 | |
| Creatinine | 0.61 | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | traceable. EstGFR Calcu | lation has b | een adjusted. | |
| | Please note new reference | | | | |
| eGFR non-African Am | >60 | ml | _/min/1.73m2 | >60 | |
| GFR Comment | | | | | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 | ot accurate in acute kin | dhey failure | e, inpatients | |
| | the very old or very young people with acute illnesse | . races other than Cauca | asian or Afr | rican American, | |
| Calcium | 8.8 | ,, | mg/dL | 8.4-10.4 | |
| Total Protein | 7.2 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.1 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.1 | | gm/dL | 2.4-4.2 | |
| Blilrubin, total | 0.4 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 71 | | Ú/L | 38-150 | |
| AST(SGOT) | 17 | | U/L | 6-58 | |
| ALT(SGPT) | 29 | | U/L | 14-67 | |
| Fasting | NO | | | | |
| Phosphorus | 3.9 | | mg/dL | 2.3-5.6 | |
| CBC | | | | | |
| WBC | 5.8 | | x10E3 | 4.0-10.6 | |
| RBC | 5.01 | | x10E6 | 4.00-5.36 | |
| Hgb | 14.0 | | gm/dL | 12.0-16.0 | |
| Hct | 44 | | % | 36-48 | |
| MCV | 87 | | fL. | 81-98 | |
| MCHC | 32.0 | | gm/dL | 31.2-35.2 | |
| RDW Blacks at a | 12.6 | | % | 11.0-14.5 | |
| Platelets | 354 Name and a | | x10E3 | 150-400 | |
| Eos, Respiratory | None seen | | | NS | |
| Phys, Addr, Phone | Not given | | | | |

End of Report

18 Dec 2013

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | 0 1(2) 3 | 0 1(2) | 0 1(Z) 0 1(Z) 0 1(Z) | 0 1(2) 0 1(2) 0 1(2) | 0 1(0 1(0 1(VES | 0 1(0 1(VES | 0 1(0 1(0 1(VES | 0 1 (0 1 (VES) | 0 1 (0 1 (YES) 0 1 (O 1 () 0 () 0 () | 0 1(0 1(0 1(VES (YES 0 1 (| 0 1 (0 1 (YES) 0 1 (O 1 (YES) 0 1 (O 1 (YES) 0 1 (O 1 (YES) (YES) 0 1 (O 1 (YES) (YE | 0 1 (0 1 (VES) |
|----------|-----------|-----------|----------------------------|----------------------------|-------------------------------|--------------------------------|--|--|---|---|--|---|
| | 0(1) 2 3 | | 0 1 2 0 1 2 | 0 1 2 0 1 2 0 1 2 0 1 2 | 0 (1) 0 1 0 1 XFS | 0 1 0 1 VES | 0 1 0 1 0 1 VES VES | 0 1 0 1 | 0 1 0 1 | VES (YES) 0 1 0 1 0 0 1 0 0 1 0 0 1 0 0 0 0 0 0 | VES YES 0 1 0 0 0 1 0 0 0 0 1 0 0 0 0 1 0 0 0 0 1 0 0 0 0 1 0 0 0 0 1 0 | (YES) |
| | 0(1/2 3 | | | | | | | | | | | |
| 0 1000 | > | 0 | 0 0 | 0 0 0 | Y CE O O | V KE VE | A KE | | | | 0 0 0 0 0 0 | |
| Ç | (U) 1 2 3 | 7 (C) | y @ 77 | | | | ້ ັ ທ ຸ | · · \ | | | | 25 |
| 10 3 0 1 | 2 | | | | | | | | | | | |
| 0 1 5 3 | | 0 1(2) 3 | 0 1(2) | 0 1(2) | 0 1 (2) 0 1 (3) VES (NO | 0 1 (2) 0 1 (3) VES (NI) | 0 1 (2) 0 1 (3) 0 1 (3) VES (NU | 0 1(2) 0 1(3) VES (NO VES (NO 3) | 0 1(2) 0 1(3) 0 1(3) VES (N(3) 0(3) 2 | 0 1(2) 0 1(3) 0 1(3) VES (NK VES NC 0 1 2 | 0 1(2) 0 1(3) VES (NO 0 1 2 0 1 (2) | 0 1(2) 0 1(3) 0 1(3) VES (NI) 3 0 (1) 2 0 1 (2) VES (NI) |
| 0 1 3 3 | < | 0 1 (2) 3 | 1 10 | H H | 1 (1 (ES) | 1 (1 (ES | 1 (1 (1 (ES) | 1 (1 (1 (1 (1 (1 (1 (1 (1 (1 (1 (1 (1 (1 | 0 1 (0 1 (YES YES O 1 (0 1 (| 0 1 0 1 VES YES YES 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 1 0 | 0 1 0 1 YES YES YES 0 1 0 0 0 1 0 0 0 0 1 0 | 0 1 (0 1 (VES YES VES O 1 (VES VES VES VES VES VES VES VES VES VES |
| 123 | | 0 1 2 3 | 7 7 7 | 7 7 7 | 2 2 2 | N N N Z Z | 2 2 2 I | 2 2 2 2 | | NO. NO. 2 3 3 2 3 2 3 2 3 3 2 3 3 2 3 3 2 3 | No. No. 2 3 3 3 3 3 2 2 3 3 2 3 3 3 3 3 3 3 3 | NO. NO. S 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 3 |
| 9- | | | | | | | | | e arse earing | Itchy Nose O to 3 Congestion O to 3 Sneezing O to 3 Voice Hoarse Y/N DAY PM Runny Nose O to 3 Itchy Nose O to 3 Congestion O to 3 | earing earing see | earing earing on on on on on on on on on on on on on |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER:

DATE COMPLETED: 12/00/13

SUBJECT INITIALS AND DATE:_



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc. ific Resources Leslie Byatt, win Trials 2441 Ridgecrest Dr SE

Client Nbr 24664

Albuquerque, NM87108-5129

PATIENT NAME ADS, ADS

COLLECT DATE & TIME

PATIENT ID **AAGI6767** DOB 05/27/1981 SEX

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

RECEIVE DATE & TIME

PRINT DATE & TIME

31033176

PT. PHONE NO. 0

12/06/2013 09:17 PATIENT NO.

12/06/2013 18:04

12/09/2013 09:36

AKP035

COMMENTS:

Test

Result

Out of Range

Units

Reference Range

In Range

Site Code

Eos, Respiratory Phys, Addr. Phone

NOT GIVEN

Rare

10 Dec 2013

NS

End of Report

FAX24664

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| , | 3 | | | | | | | | | | | | | | | | | | | | | | , |
|-----|------------|--------------|------------------|----------------------|--------------|--------|-----------|------------|--------------|-----|---------------------|--------|---------------|----------|------------|--------------|----------|--------------|--------|--------------|-----|-----------------|--------|
| ľ | 114 | 2 3 | 2 3 | 1 | 2 3 | | 2 3 | T | 2 | | Q | 5 | 2 3 | 1 | 7 2 | 2 3 | ı | 2 3 | | 2 | | <u> </u> | |
| Ħ | 3 12 | 0 1 | 0 | | 0 1 | | 0 1 | | YES | | YES | 15 | 0 1 | 1 | | 0 1 | | 0 1 | | YES | | YES | |
| - · | 13/1 | E 3 | 23 |)) | (2) 3 | | 203 | | <u>Q</u> | | 9 | 4 | 2 3 | | 2 3 | 2 3 | | 2 3 | | 9 | | 8 | |
| 1, | 13 | ME. | 0 1. | | 0 1 | - 1 | Ť 0 | | YES | (| (ES) | 14 | 0 1 | | - - | 0 1 | į | 0 | | YES | | YES | |
| • | 2/13 | 2(3) | 2 (3) |) | 2 3 | (| 2(3) | | 2 | | ON O | 3 | 2 3 | 1 | ار ک | 2.3 | | 2 3 | | 9 | | 2 | |
| 13 | 14/15 | 0 1 | 0 1 | | 0 (1)2 | | 0 | | ΥES | (| (ES | 13 | 0 | |) 1 | (E) 0 | | £) | | YES | k | | |
| | [11/13 | 2(3) | 5 3 | | 2 3 | (| 2 | | <u>Q</u> | , | 9 | 2 | 2 3 | | 2 3 | 2 3 | | 2 3 | (| 6 Z | >{ | 2 | |
| 1 | 12/1 | 0 1 | 7 | | 0) 1 | , | 0 | - 1 | YES | | (FS) | 12 | 0 | | | ©o | >k | 0 | | YES | Ė | YES | |
| | W | 3 | 3 | | 2 3 | | <u>2</u> | (| E) | , (| <u>S</u> | _ | 2 3 | | 2 3 | 2 3 | | 2 3 | () | 8 |)(| <u></u> |] |
| - | 12/s/ | 0 1 (| 7 | 1 | P | | 0 1 | | YES | | YES | 11 | 0 | | (E) 0 | (<u>1</u>) | | 0 | | YES | | YES | |
| _ | 3 | 2 3 | 2 3 | | 2 3 | | 2 3 | , | <u></u> | 7(| (NO) | 0 | <i>(Q</i>) 3 | | 2 3 | 23 | <u> </u> | В | < | 2 | > | 2 | |
| | 12/00/13 | (1) | 0 |) | ((0) |) ا | 0 (10) 2 |) | YES | | YES | 10 | 0 1 | 7 | 0 | 0 | | 0 1(| | YES | | , ∤ES | |
| | 2/8/ | 2 3-3 | Ç | | 12 3 | (| 6 | | (N) |)(| QN) | | 2 3 | | 6/ E | 2 3 | | (g) 3 | | <u>S</u> |)(| <u>g</u>) | |
| ٥ | 7/80/21 | 0 1 | 7 | + | 0 (1)2 |) | 0 1 | | YES | | YES | 6 | 0 | 1 | 0 10 | 0 | | 0 1 | | YES | | YES | |
| | 67/13 | (B) 3 | رم | | 2 3 | | 2 (3) | (| 9) | (| 9 | | 2 3 | 1 | 2 3 | 2 3 | _ | 2 3 | | 6 | X | 6N) | |
| × | (2/0) | 0 1 | 6 | - - | (B) 0 | | 0 1 | | YES | | YES | 00 | 0 | | <u> </u> | 0 | , | (<u>-</u>) | | YES | , | YES | |
| | 613 | Ø 3 | 0 | ر ار د | | | | , | E) | (| Š S | | 0 1 2 3 | | 2 3 | 0 1 2 3 | | 0 1 2 3 | | 02 | > (| 60 | |
| 7 | 121/0/0/23 | 0 1 Ø 3 | 0 1 6 3 | - - | 0 (1) 2 3 | , | 0 1 2 (3) | | YES | | YES | 1 | 0 | · · | 0 (1) 2 3 | 0 | | 0 | | YES | ļ | YES | |
| | - | | | 13 | | | | | rse | | Throat Clearing Y/N | Σ | Se | | d) | C. | | | | ırse | | earing | |
| 2 | A A | Runny Nose | C CO O | O to 3 | Congestion | 53 | Sneezing | 03 | Voice Hoarse | 7 | roat Cle | DAY PM | Runny Nose | 0 to 3 | Itchy Nose | Congestion | 0 to 3 | Sneezing | 93 | Voice Hoarse | 7 | Throat Clearing | 2 |
| | | Rur | 5 1 | 7 - | Ö | 0 to 3 | Sne | 0.7 | Vol | Ϋ́ | F X | _ | Ru | <u> </u> | itcl t | S | 0 | Š | 0 t | \$ | Y/N | Th. | Z > |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N=No

SUBJECT NUMBER:

DATE COMPLETED: 19(13/13

SUBJECT INITIALS AND DATE:___

PDS 12/13/13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID

AAGI6767

Lovelace S. tlfic Resources Leslie Byatt, Jin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME

ADS, ADS **PHYSICIAN**

Unlisted Physician,

REQUISITION NO. 31033183 COMMENTS:

0

PT. PHONE NO.

05/27/1981

SEX F

REPORT STATUS Final

PAGE

1

COLLECT DATE & TIME 12/13/2013 09:10 RECEIVE DATE & TIME

PRINT DATE & TIME

12/13/2013 19:07

12/16/2013 06:13

PATIENT NO.

AKP035

Test

In Range

Not given

Result

Out of Range

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone

End of Report

NS

pcs Man Sub-

| | · | | | × | l | <u>M</u> | , | | | | | | | |
|-----------------------|------------------------|-------------------|---|-------------------|--------------------|------------------|--|------|--|--|--|---|--|--|
| | | Ellre/li | Investigator | Mar Colonia | | Me 2012 213 | のでは、 | | | | | | | ie; of of |
| LSR Study #: | Subject Initials: ATDS | 61)to/11 | Action Taken | 2020 | | Non | | | | | | as specific as possible** | 12/30/13 | |
| LSR | Sub | DG & C.W.S. | ** End Date (DD/MMM/YYYY) | 04/0e/2018 | | 20c/2013 | _ | | | | | hould be made to be | Date: 20 D | Events 04/2013 |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Susperted | | Surperted | | | | | | ** If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible ** | Mostains and | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| 57 [| AKPO35 | HC S SH | ** Start Date SEVERITY (DD/MMM/YYYY) | Nov/2013 mod | 5 | 05/Dec/2013 mild | | | | | | unknown, write UNK in spac | or Signature (at end of study): | Lov |
| Study Identification: | Subject Number: A K | | Adverse Event (DD) | of application 27 | Uncersonity to Att | Stroking 05 | 7 | | | | | ** If day is | Investigator Signature (at end of study); SC Signature (at end of study); | |

| LSR#: 2749. | Subject Initials: ADS | and supplements, | Stop Date (for Clinic use) | | 11/u/B | 10/23/18 | | | | | | | 5/027 | Date: 1 (271 (3 | 220 |
|-----------------------|-----------------------|---|--------------------------------------|---------------------------|---------|--|----------|---|--|--|--|--|---|--|----------|
| | | OG medications, vitamins | * Start Date (Day/Month/Year) | UNIK/AUG/1999 | 4/6/13 | 1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1- | 10/19/15 | | | | | * If day or month of medication date is <u>unknown</u> , write UNK in space provided | Date: 20 Dec 2013 | Date: 11/2711 3 | |
| | | ATION L | Route | Oral | 60 | 61 | 00 | | | | | <u>n</u> , write UN | | Megs 04/2013 | |
| | | CONCOMITANT MEDICATION LOG | Frequency | /2 Tabs per ≟ ** day € | ard | pm. | prn | , | | | | e is <u>unknow</u> | nie un | Lovelace Scientific Resperces, 109, Continues of |) |
| | ı | OMITAI | Unit | MG | 2 st | the | É | | | | | ication daf | my | Scientific Reg | ? |
| | | CONC ou are takir | Dose | 500 | 22 | | Son | | | | | th of medi | | Lovether Scien | |
| Ateporne | ALP USS | CONCOMITANT MEDICATION LOG List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. | Indication (What you take it for) | Diabetes | allegio | alle que. | Kne par | | | | | * If day or mon | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: | Subject Number: | List all] | Name of Medication | EXAMPLE | Bunder | Waldinata | proposer | 0 | | | | | Investigator Signatu | SC Signatu | |

. 1

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 7.7 | 7.7 | | 76 1 17 | 76 | | 1, | | 100 | | 1 | | 6 | | 6 | - | [| , ה ה |
|-----------------|----------------------|-------------|----------|---------|---------|----------|------|----------------------------|---|----------------|--------|--------|------------|-----|----------|--------|---------------------|
| ΔM | 12/13/13 | 7 | 7/15 | 12/15 | 15/12 | 12/11/21 | | 12/12/12/18/12/12/14/19/12 | 7/12 | 12 | 1/8 | 12/16 | 3/12 | | 1 | 17/12. | ا د ر |
| Runny Mose | 101 | Ĉ | , (C | , d | 10 | | | 0(1) | 2 0 | 7 7 | 100 | , , |) [| | | ; c | 1, |
| 0 to 3 | | | | 4 | າ (ໄ | | |)) | | |)) | | رر | 4 | ٥ ا | | 7 |
| Itchy Nose | 0 1 2 | 3 0 1 | (Z) 3 | 0 1 | (S) | 0 1(2) | 2) 3 | 0 1% | ო გე | 0 1- 3 | 243 | 0 1 | 2 3 | 0 1 | 2 (3) | 0 1 | 2 3 |
| 0 to 3 | | | | | | | | | <u> </u> | | , , | | | - 1 | | | |
| Congestion | 0 Z | 3 0 B | 2 3 | 0 | 6. | 0 [2] | | 0 1 | 3 | 0 13 | (L), J | 0 | (5) (5) | 0 | 2 | 0 1 | 2 3 |
| 0 to 3 | ******* | | | | , | | | | | | | | (| | (| | |
| Sneezing | 0 1 2 | 3 0 1 | 1(2) 3 | ₩ H | 1 2 3 | 0 1.2 | 2 | 0 1 % | ന | 0 1 | 24-3 | 0 1 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| 0 to 3 | | |) | |) (| |) (| | اجا | |) | |) | |) | | |
| Voice Hoarse | YES \ NO |) YES | (Q) | YES | N Q | YES | ON | YES | <u>S</u> | YES | 2 | YES | <u>Q</u> | YES | ŊQ. | YES | 2 |
| N/Y | all and the section. | |) (| - 10.00 | Y | (|) | (|)) | (| | (|) | (|) | | |
| Throat Clearing | YES NO | YES | (OR) | YES | Õ | (YES) | 9 | ۸ES | 2 | (VES) | οN | KES, | 9 | YES | <u>8</u> | YES | 8 |
| N/N | are yan | |) | | 3 |) | | |) |) | |) | |) | | | |
| DAY PM | 14 | 15 | [5 | 16 | | 17 | : | 18 | _ | 19 | | 20 | | 21 | π. | 7 | 22 |
| Runny Nose | : z(Ū) o | ₹/0/ş | 2.3 | 0(1) | 2_3 | 0 (T) 2 | 2 3 | 0 (1) | 2 3 | 0(<u>1)</u> 2 | 2 3 | 0 1 | 6/3 | 0 1 | 2 3 | 0 1 | 2 3 |
| 0 to 3 | > |) (| | ۷ | |) | | | |) | | |) | | - | | |
| Itchy Nose | 0 🗓 2 | 3 0 1 | 2 3 | | 2 3 | 0 ① 2 | 2 3 | 0 (0) | 2 3 | 0 🕦 2 | 2 3 | 0 1 | £(3) | 0 1 | 2 3 | 0 1 | 2 3 |
| Congestion | 0 2 2 | 3 0 7 | 2 3 | 0 | 2 3 | 0 (I) 2 | 2 3 | 0 2 | 2 3 | 0 172 | 2 3 | 0 (1)2 | 2 3 | 0 | 2 3 | 0 | 2 3 |
| 0 to 3 | > | <u></u> , (| | | |) | | | |) | | > | | | | | |
| Sneezing | 8 Z (I) O | 3 0 1 | 2 3 | : € 0 | 2 3 | 0 A 2 | 8 | 0 (1) 2 | 2 3 | 0 (T) 2 | 2 3 | 0 1(2 | 2 3 | 0 1 | 2 3 | 0 1 | 2 3 |
| 0 to 3 | (| | | > | |) | | C | | フ | | 9 | 3 | | | | |
| Voice Hoarse | YES. (NO | YES | ON | YES | ON | YES (| (QU) | YES | ON ON ON ON ON ON ON ON ON ON ON ON ON O | YES 🔞 | (ON) | YES | (O) | YES | ON | YES | NO NO |
| Y/N |) | 7 | | | | = |)(| |) | - |) | |) (| | | | |
| Throat Clearing | YES NO | YES | (Ö | YES | 9 | YES | (Q) | YES (| | YES 🔨 | 0 | YES | ÓN. | YES | NO | YES | 8 |
| N/N | / | <u> </u> | <u> </u> | | | |) | | —) | |)) | |) | | | | |
| SCALE 0 to 3 | | | | | | | | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: ACPOS DATE COMPLETED: 120 (13

SUBJECT INITIALS AND DATE: 495. 1820 3



Lovelace Sc ific Resources Leslie Byatt, o.in Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME X, ADS

PATIENT ID AAGJ3400 DOB 05/27/1981

REPORT STATUS **Final**

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO.

COLLECT DATE & TIME RECEIVE DATE & TIME 12/20/2013 09:10 12/20/2013 20:03

PRINT DATE & TIME 12/23/2013 06:08

31033186

n

PATIENT NO.

AXP035 COMMENTS: -

| | Re | esult | | | |
|------------------------------------|--|--|--|--------------------|-----------|
| Test | in Range | Out of Range | Units | Reference Range | Site Code |
| | . • | | | | |
| Comp Metabolic Panel Sodium | 139 | | mmol/l | 404 444 | |
| Potassium | 4.2 | | mmol/L mmol/L | 134-144 | |
| Chloride | 103 | | mmol/L | 3.5-5.1 | |
| CO2 | 26 | | ****** | 98-111 | |
| Anion Gap | 10 | | mmol/L | 20-30 | |
| Glucose | 10 | 115 ⊢ | J_11 | 6-14 60-100 N/C | c Mann |
| Oldcose | Impaired fasting glucose (100-126 mg/dl.(ADA Guideli | TEG) is defined as | mg/dL a fasting glucos 6: (3160-3167)200 | e level of | |
| BUN | 11 | | mg/dL | 7-31 | |
| Creatinine | 0.62 | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | traceable. EstGFR C | alculation has b | een adjusted. | |
| | Please note new reference | | | • | |
| eGFR non-African Am GFR Comment | >60 | - | mL/min/1.73m2 | >60 | |
| Of It Sometone | Estimated GFR values are n | ot accurate in acut | e kidney failure | , inpatients | |
| | Estimated GFR values are non IV fluids, obese (BMI>3- the very old or very young, people with acute illnesse. | 4) or underweight () , races other than (s. or amoutations. | BMI<20) people, Caucasian or Afr | ican American, | |
| Calcium | 9.1 | -7 | mg/dL | 8,4-10,4 | |
| Total Protein | 7.2 | | am/dL | 6.1-8.2 | |
| Albumin | 4.1 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.1 | | gm/dL | 2,4-4,2 | |
| Bilirubin, total | 0.5 | | mg/dL | 0.3-1.2 | - |
| Alk Phos | 70 | | Ŭ/L | 38-150 | |
| AST(SGOT) | 14 | | U/L | 6-58 | |
| ALT(SGPT) | 28 | | U/L | 14-67 | |
| Fasting | YES | | | 4. | |
| Phosphorus | 3.2 | | mg/dL | 2.3-5.6 | |
| CBC WBC | E E | | -4050 | 4 = 4 = = | |
| RBC | 5.5 | | x10E3 | 4.0-10.6 | |
| | 5.04 | | x10E6 | 4.00-5.36 | |
| Hgb | 14.2 | | gm/dL | 12.0-16.0 | |
| Hct | 44 | | % | 36-48 | |
| MCV | 87 | | fL | 81-98 | |
| MCHC | 32.3 | | gm/dL | 31.2-35.2 | |
| RDW | 12.3 | | % | 11.0-14.5 | |
| Platelets | 340 | | x10E3 | 150-400 1 1/1 | 1 MM |
| Eos, Respiratory | | Many * | | 150-400 NS NO | - WKYUL |
| Phys, Addr, Phone | NO PHYSICIAN LISTED | | | | 1 1 |

End of Report

Mantinens mb I 12/26/13

ADS AKPO35

12/20/13

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| this product worked great for ston Relief from Runny house, but didn't Real help with any thing else, It also had a slight Burn when used that writed last a few min. |
| |
| |
| |

| Subject initials and Date Y 17120 Study Staff Initials and Date W | [Type text] Subject initials and Date_ | ADS. 12/20/ | ろ Study Staff Initials and Date | Em | 12/20/1 | 2 |
|---|--|-------------|------------------------------------|----|---------|---|
|---|--|-------------|------------------------------------|----|---------|---|

AKP-037

2,49 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| <u>P</u> | PATIENT DEMOGRAPHICS |
|----------|---|
| | Patient Demographics |
| | Date of Birth: 02 / Sep / 1952 (dd/mmm/yyyy) |
| | Gender: Male Female |
| | If female, Indicate Childbearing Potential |
| | Childbearing Surgically sterilized Post-Menopausal |
| • | Ethnicity: Hispanic Non Hispanic |
| J | Race: Asian Black Caucasian American Indian |
| | Pacific Islander Other, Specify |
| | |
| 1 | Smoking History |
| | Smoking Status: None (smoked less than 100 cigarettes in lifetime) |
| | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
|] | If subject is a former or current smoker, please indicate: 21 pack |
| i | Years smoked: 42 Cigarettes per day: 10 |

Version: 02 September 2013

Page 3 of 5



Lovelace Scie-₃ Resources Leslie Byatt, Chu Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

AAG10973

09/02/1952

REPORT STATUS Final

PAGE 1

B, HE **PHYSICIAN**

COLLECT DATE & TIME Unlisted Physician, 11/22/2013 11:00 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

11/25/2013 06:12

Result

11/22/2013 17:31

30920960

0

PATIENT NO.

AKP037

COMMENTS:

| | | | 103411 | | | | |
|--|----------|----------------|-------------------|---------------|----------------------|-------------------------|-----------|
| Test | • | In Range | Out of Rang | je | Units | Reference Range | Site Code |
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed | | 0.30 0.10 | 8.60 | Н | kU/L kU/L kU/L | <0.35 <0.35 <0.35 | |
| Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria | | <0.10 | 11.60 2.50 | H H | kU/L kU/L kU/L | <0.35 <0.35 | |
| Allerg,Mesquite Allerg,Cockroach Allerg,Derm, pter. | | <0.10 | 0.50 | Н | kU/L kU/L kU/L | <0.35 <0.35 <0.35 | |
| Alieig, Deilli, ptei. | The stan | dard classific | ation system util | H izes the | following | <0.35 class cutoffs. | |
| | Class | ku/L | Interpretation | | | | |
| | 0 | <0. 35 | Negative for Al | lergen | ., | | |
| | I | 0, 35-0, 69 | Positive for Al | ergen | | | |
| | II | 0. 70-3. 49 | Strongly Positiv | /e | | | |
| | III | 3. 5-17. 49 | Strongly Positiv | /e | | | |
| | IV | 17. 5-52. 49 | Strongly Positiv | /e | | | |
| | v | 52. 5-99. 99 | Strongly Positiv | /e | | | |
| | VI | >100 | Strongly Positiv | ⁄e | | | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

0.60

| Allerg,Derm. farinae |
|----------------------|
| Allerg,Clad. herb. |
| Allerg,Firebush |
| Allerg,Cat Dander Ep |
| Allerg, Dog Dander |
| Allerg,Bluegrass |
| Allerg,Pigweed |
| Allerg, Mulberry |
| Allerg,Helminth |
| Phys, Addr, Phone |
| |

| <0.10 | • | | kU/L | <0.35 |
|-----------|------|---|------|--------|
| | 1.40 | Н | kU/L | <0.35 |
| | 0.40 | Н | kU/L | < 0.35 |
| 0.10 | | | kU/L | < 0.35 |
| | 1.80 | Н | kU/L | < 0.35 |
| | 0.90 | Н | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| Not given | | | | 1 |

End of Report

~0.35 ~0.35 ~0.35 ~0.35 ~0.35 ~0.35 ~0.35 ~0.35

< 0.35

kU/L



Levelace Scientific Resources 2011 Ridgecrest Dr SE Albuquerque, NM 87108



Name: BHE,

Gender: Male Age: 61

Race:

Height(in): 77.5

Weight(lb): 282

Any Info:

Id: AKP037 Date: 12/03/13

Temp: 19

PBar: 625

Physician:

Technician: CRD

| ·, ., | | | | | I GOTHINGIA | III. UND | |
|---|----------------------------|---------------|----------------------------------|----------------------|-------------|----------------|------------------|
| Spirome | try (B | TPS) Ref | PRE-RX Pre Pre | POST-RX Post Post | Post | Flow 16 T | |
| FVC FEV1 | Liters Liters | 6.03 4.80 | Meas % Ref 4.46 74 3.06 64 | Meas % Ref | % Chg | | |
| FEV1/FV0 FEF25-75 | %L/sec | 78 4.67 | 69 88 1.86 40 | | | 12 | |
| FEF50% FEF75% | L/sec L/sec | 5.70 2.22 | ** 2.65 | | | 8 | \wedge |
| IC VC PEF | Liters Liters L/sec | 6.03 10.37 | 9.04 87 | | | + | |
| MVV PIF | L/min L/sec | 164 | 5.74 | | | 4 | |
| Lung \ | | Plethysi | 74 mography | (BTPS) | | 0 | |
| Vtg VC | Liters Liters | 6.03 | J. 242.13 | | | -4 | |
| TLC RV | Liters Liters | 8.44 2.90 | | | | | |
| RV/TLC FRC PL ERV | % Liters | 38 4.19 | | | | -8 | |
| Diffusi | Liters Liters | | | | | -12 <u>-</u> 2 | 0 2 4 6 8 |
| DITCO DL Adj DLCO/VA VA BHT | mL/mmHg/min mL/mmHg/min | 32.6 | | | | - 2 | 0 2 4 6 8 Volume |
| Resist | ance | | | | | | |

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec
 1.03

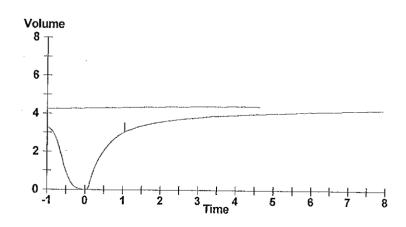
 Gaw
 L/sec/cmH2O
 1.006

 sRaw
 cmH2O/L/s/L
 4.32

 sGaw
 L/s/cmH2O/L
 0.231

Vtg (Raw) Liters

Comments:





Levelace Scientific Resources 1 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP-037,

Gender: Male

Age: 61

Race:

Height(in): 77.5

Weight(lb): 282

Any Info:

Id: AKP-037 Date: 12/10/13

Temp: 16

PBar: 637

Physician:

Technician: CRD

| | | | | | | | i Gorifficia | III. OND | | | | | |
|-------------------|----------------|----------|---------|-------------|------|-------|--------------|------------------------|--|-------------|-------------|---------------|--|
| Spiron | netry (| BTPS) | PR | E-RX | POS | ST-RX | | F1 | | | ** | | |
| Opiion | iotry | Ref | Pre | Pre | | Post | Post | Flow 16 ⊤ | | | | | |
| FVC | l Managar | 0.00 | | % Ref | Meas | % Ref | % Chg | 16. | | | | | |
| | Liters | 6.03 | 4.40 | 73 | | | | + | | | | | |
| FEV1 | Liters | 4.80 | 3.10 | 65 | | | | 40 | | | | | |
| FEV1/F | VC % | 78 | 70 | 90 | | | | 12 + | | | | | |
| FEF25-, | 75%L/sec | 4.67 | 2.20 | 47 | | | | 1 | | | | | |
| FEF50% | | 5.70 | ** 2.88 | ** 50 | | | | | | | | | |
| FEF75% | | 2.22 | 0.86 | 39 | | | | 8 + | ٨ | | | | |
| IC | Liters | | | | | | | 1 | $I\Lambda$ | | | ** | |
| VC | Liters | 6.03 | | | | | | Ť | | | | , | |
| PEF | L/sec | 10.37 | 8.35 | 80 | | | | 4- | 1 | | | | |
| MVV | L/min | 164 | | | | | | | 1 | 4 | | | |
| PIF | L/sec | | 0.30 | | | | | . + | 1 | | | | |
| FEV1/F | | | 71 | | | | | _ | j | 1 | | | |
| Luna | Volumes/ | Plethysi | നവു | nhv | (B | TPS) | | 0 | | 1-1-1-1-1-1 | | - | |
| \/ * ~ | | | ,,,,, | ⊘ πy | • | • | | 1 | | | | | |
| Vtg VC | Liters | | | | | | | | | | | | |
| V.C | Liters | 6.03 | | | | | | -4 † | | | | | |
| TLC | Liters | 8.44 | | | | | | 1 | | | | | |
| RV | Liters | 2.90 | | | | | | T | | | | | |
| RV/TLC | % | 38 | | | | | | -8 [‡] | | | | | |
| FRC PL | Liters | 4.19 | | | | | | | | | | | |
| ERV | Liters | | | | | | | + | | | | | |
| IC | Liters | | | | | | | 42 | | | | | |
| Diffus | sion | | | | | | | -12 [⊥] -2 | 0 | 2 4 | 6 | 8 | |
| DLCO | mL/mmHg/mir | 1 32.6 | | | | | | _ | • | Volume 4 | • | • | |
| DL Adj | mL/mmHg/mir | 32.6 | | | | | | | | | | | |
| DLCO/V | A mL/mHg/min/L | | | | | , | | | | | | | |
| VA VA | Liters | - 0.13 | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | | |
| | stance | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| Raw Tota | al cmH2O/L/sec | | | | | | | | | | | | |

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec
 1.03

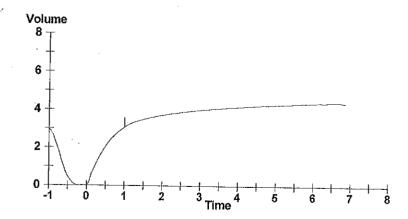
 Gaw
 L/sec/cmH2O
 1.006

 sRaw
 cmH2O/L/s/L
 4.32

 sGaw
 L/s/cmH2O/L
 0.231

 Vtg (Raw)
 Liters

Comments:





Lovelace Scientific Resources 2 11 Ridgecrest Dr SE Albuquerque, NM 87108

Name: BHE,

Gender: Male

Age: 61

Race: Caucasian

Height(in): 78.0

Weight(lb): 282

Any Info:

ld: AKP-037 Date: 12/17/13

Temp: 18

PBar: 638

Physician:

Technician: VL

| , | | | | | | 10 | CHILICIAI | un vL |
|-----------|------------------------|--------------|-------------|--------------|--------------|---------|---------------|--|
| Spirome | trv (B | TPS) | PRI | E-RX | POS | Γ-RX | | Flow |
| Ophomo | <i>y</i> | Ref | Pre Meas | Pre % Ref | Post Meas | | Post % Chg | 16 _T |
| FVC | Liters | 6.11 | 4.36 | 71 | WICES | 70 T\Q1 | 70 Orig | 1 |
| FEV1 | Liters | 4.87 | 2.96 | 61 | | | | |
| FEV1/FV0 | | 78 | 68 | 87 | | | | 12 + |
| FEF25-75 | | 4.73 | 1.68 | 35 | | | | |
| FEF50% | L/sec | 5.77 | ** 2.43 | ** 42 | | | | † |
| FEF75% | L/sec | 2.25 | ** 0.48 | ** 21 | | | | 8 + |
| IC | Liters | ~ | 0.40 | 41 | | | | |
| VC | Liters | 6.11 | | | | | | † /\ |
| PEF | L/sec | 10.49 | 7.67 | 73 | | | | 4 |
| MVV | L/min | 166 | ,,,,, | | | | | |
| PIF | L/sec | 100 | 4.96 | | | | | + / \ |
| FEV1/FEV | | | 73 | | | | | |
| | | Olothyom | | nh | (R) | PS) | | 0 |
| | √olumes/F | - ietiiyəiri | vyrap | pny | (- | , | | 1 |
| Vtg VC | Liters | | | | | | | |
| VČ | Liters | 6.11 | | | | | | -4+ |
| TLC | Liters | 8.56 | | | | | | |
| RV | Liters | 2.94 | | | | | | Ť |
| RV/TLC | % | 38 | | | | | | -8+ |
| FRC PL | Liters | 4.28 | | | | | | |
| ERV | Liters | | | | | | | † |
| IC | Liters | | | | | | | 12 |
| Diffusi | OB | | | | | | | -12 ¹ / ₋₂ 0 2 ₍₂₁₎ 4 6 8 |
| DLCO | mL/mmHg/min | 22.0 | | | | | | -2 0 2 4 6 8 Volume |
| DL Adj | | | | | | | | |
| DLCONA | mL/mmHg/min | | | | | | | |
| VA | mL/mHg/min/L Liters | 3.20 | | | | | | |
| BHT | Sec | | | | | | | |
| | | | | | | | | |
| Resist | ance | | | | | | | |
| Pow Total | cmH2O/Licon | | | | | | | |

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

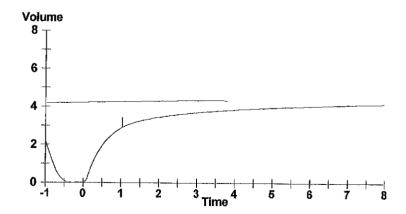
 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 SGaw
 L/s/cmH2O/L/s/L

 Vtg (Raw)
 Liters

Comments:





Loyelace Scientific Resources 241—Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP-037,

Gender: Male

Age: 61 Race:

Height(in): 77.5

Weight(lb): 282

Any Info:

ld: AKP-037

Date: 12/23/13

Temp: 18

PBar: 637

Physician:

Technician: CRD

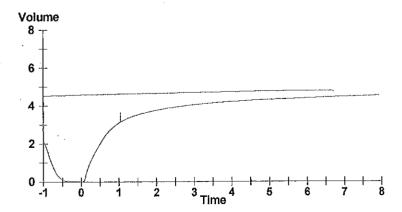
| Any imo. | | | | | | | | | - | | | | |
|---------------------|--------------|---------|-------------|--------------|----|---------------|---------------|------------------|--|--|---|---|---|
| Spirometr | v (BT | 'PS) | | E-RX | | T-RX | Dool | Flow | | | | | |
| ap. 101(1011 | , | Ref | Pre Meas | Pre % Ref | | Post % Ref | Post % Chg | 16 T | | | | | |
| FVC | Liters | 6.03 | 4.77 | 79 | | | | † | | | | | |
| FEV1 | Liters | 4.80 | 3.17 | 66 | | | | 12 | | | | | |
| FEV1/FVC | % | 78 | 66 | 85 | | | | 12 | | | | | |
| FEF25-75% | 6L/sec | 4.67 | 1.78 | 38 | | | | + | | | | | |
| FEF50% | L/sec | 5.70 | ** 2.95 | ** 52 | | | | | ۸ | | | | |
| FEF75% | L/sec | 2,22 | ** 0.54 | ** 24 | | | | 8+ | Λ | | | | |
| IC | Liters | | | | | | | 1 | | | | | |
| VC | Liters | 6.03 | | | | | | _ | 1) | _ | | | |
| PEF | | 10.37 | 8.50 | 82 | | | | 4 + | | man de la companya de | | | |
| MVV | L/min | 164 | | | | | | <u> </u> | | '\ | | | |
| PIF | L/sec | | 5.88 | | | | | | | Υ., | | | |
| FEV1/FEV | | | 72 | | ,- | TOO) | | 0 | | | | | — |
| Lung \ | /olumes/P | lethysn | nogra | phy | (E | BTPS) | | 1 | | | | | |
| Vtg | Liters | | | | | | | | | | 1 | | |
| vč | Liters | 6.03 | | | | | | -4 | | | , | | |
| TLC | Liters | 8.44 | | | | | | | | | | | |
| RV | Liters | 2.90 | | | | | | | | | | | |
| RV/TLC | % | 38 | | | | | | -8 | | | | | |
| FRC PL | l_iters | 4.19 | | | | | | 1 | | | | | |
| ERV | Liters | | | | | | | | | | | | |
| IC | Liters | | | | | | | -12 \frac{1}{-2} | _ | | | ^ | |
| Diffusi | | | | | | | | -2 | 0 | 2 Volume | | 6 | 8 |
| DLCO | mL/mmHg/min | | | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | 5 | | | | | | | |
| DLCOMA | mL/mHg/min/L | 3.19 | | | | | | | | | | | |
| VA | Liters | | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | | |
| Resist | ance | | | | | • | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | | | |
| | cmH2O/L/sec | | | | | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | | | |
| i tutt II-Ap | OE O. B 000 | | | | | | | | | | | | |



Vtg (Raw) Liters

Raw Gaw

sRaw sGaw



Interpretation:

cmH2O/L/sec 1.03

L/sec/cmH2O 1.006 cmH2O/L/s/L 4.32 L/s/cmH2O/L 0.231



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc Ific Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PAGE

1

X, BHE

PATIENT ID **AAGI4836** DOB 09/02/1952 REPORT STATUS Final

PRINT DATE & TIME

PHYSICIAN Unlisted Physician. COLLECT DATE & TIME 12/03/2013 10:25 RECEIVE DATE & TIME 12/03/2013 19:53

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

48

NO

3.0

7.6

5.30

16.1

48

90

33.9

13.8

274

NOT GIVEN

12/04/2013 06:08

14-67

2.3-5.6

4.0-10.6

4.64-6.00

14.5-17.7

42-53

81-98

31.2-35.2

11.0-14.5

150-400

30920931

0

AKP037

| COMMENTS | ; |
|----------|---|
|----------|---|

| | I | Result | | | |
|------------------------------------|---|---|---------------------------------------|---------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 140 | | mmol/L | 134-14 4 | |
| Potassium | 3.9 | | mmol/L | 3,5-5,1 | |
| Chloride | 107 | | mmol/L | 98-111 | |
| CO2 | 24 | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | 6-14 | 6 |
| Glucose | | 101 H | mg/dL | 60-100 /)/ | s imil |
| | Impaired fasting glucose 100-126 mg/dl (ADA Guidel 13 | (IFG) is defined as a ines Diabetes Care 26 | a fasting glucos 5: (3160-3167)200 | e level of /2/ | 15 |
| BUN | 13 | | mg/dL | 7-31 | |
| Creatinine | 0.72 Creatinine method is IDMS Please note new reference | traceable. EstGFR Ca | mg/dL alculation has b | 0.62-1.66 | |
| eGFR non-African Am GFR Comment | >60 | - | ml_/min/1.73m2 | >60 | |
| | Estimated GFR values are on IV fluids, obese (BMI> | not accurate in acute 34) or underweight (| e kidney failure MI<20) people, | , inpatients | |
| | on IV fluids, obese (BMI> the very old or very youn people with acute illness | g, races other than (es, or amputations. | Caucasian or Afr | ıcan American, | |
| Calcium | 9.3 | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.4 | | gm/dL | 6.1-8.2 | |
| Albumin | 4.2 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.5 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 48 | | Ú/L | 38-150 | |
| AST(SGOT) | 24 | | Ų/L | 6-58 | |

Many

End of Report

ALT(SGPT)

Fasting

CBC WBC

Phosphorus

RBC

Hgb

Hct

MCV

MCHC

Platelets

Eos, Respiratory

Phys. Addr. Phone

RDW

Mon 2013

Ũ/L

mg/dL

x10E3

x10E6

gm/dL

%

fL.

gm/dL

%

x10E3

NS NOG WORK

2) 24/14. - Subject shibted day on " |24/13, date of Dig -7 veat.
He who inadvertends often the Day! dury. Data was collected correctly.

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

ന ന ന ന m ന ന 8 9 11/24/13 11/27/13 11/28/13 11/29/13 11/30/13 12/11 [13 12/213 12/3/13 12/4/13 2 2 ~ 2 N 2 ~ 7 ~ \vdash \vdash \vdash Н с | ↤ YES YES YES 0 0 0 Ó Ö 0 9 ന ന 0.1(2/3)2 ന ന m 9 9 1 (2) $1(\overline{2})$ 7 7 ~ 2 ш YES SES) ᠳ YES ΧES 0 0 0 0 0 0 0 (1/2 3 0 1/2 3 0 (1)2 3 0 (1/2 3 0 (1) 2 3 0 (1) 2 3 0 (1) 2 3 ന <u>ත</u> ON. 0(1/2 3 0 1 (2/3 <u>(S</u>) ന S S $1 \bigcirc 3$ 0 1 (2 0 (1) 2 2 7 YES Œ YES YES , (NO) YES 0 0 0 0 1 2 3 0(1)23 9 ന 0(1)232(3) 0 1 2 (3) 0 1 2 (3) 0 1 (2) 3 | 0 1 2 (3) 0 1 (2) 3 3 ന (NO YES (NO) YES (NO 2 0 1(2) 0 1 (2) N YES \leftarrow YES YES 0 0 1 2 3 0 1 2 3 0 1/2 3 0 1/2 3 <u>\$</u> 0 1 0 3 0 1(2)3 0 1 2(3) MO YES (NO ന 0 7 0 (1) YES NO YES (ON) 0 1 2/3 0 (D) 2 3 ന 0 1 2 3 ~ YES (NO) YES Ø 1 YES YES 0 1/2/3 0 1 2 3 0 1 2 3 0 1)23 0 1 2/3 <u>S</u> YES (NO) ന (<u>S</u>) 7 MQ YES $\overline{}$ YES (NO) YES YES Q 0 🐧 2 3 0 (1) 2 3 (0N) 0 1 (2)3 12/3 0 1 (2) 3 YES (NO) m ~ NO YES Н YES 0 0 (1) 2 3 No 1 2 (3) 0 11 /2 3 Ñ. 12/3 (NO) ന 1 2 7 YES \vdash YES YES YES Ó 0 0 0 0 Throat Clearing Throat Clearing Voice Hoarse Voice Hoarse Runny Nose DAY PM Runny Nose Congestion Congestion Itchy Nose Itchy Nose Sneezing Sneezing 0 to 3 0 to 3 0 to 3 0 to 3

W P 1001 SCALE 0 to 3 $(6.00)^{\circ}$ ($(9.0)^{\circ}$ (SCALE 0 to 3

\$ OF

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

DATE COMPLETED: 12/0/3/13 SUBJECT NUMBER: PIK POST

SUBJECT INITIALS AND DATE:

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

0 to 3 Sneezing 0 to 3 0 to 3 Sneezing 0 to 3 Runny Nose 0 to 3 Voice Hoarse Throat Clearing Voice Hoarse Congestion Runny Nose Throat Clearing Itchy Nose SCALE 0 to 3 ltchy Nose Congestion DAY PM Ř YES (NO 12/03/13 12/04/13 12/05/13 YES YES 0 0 0 0 0 0 1(2)3<u>§</u> N Ö w YES (NO YES | 0 1(2)3 | 0/1*)*2 0/1 YES (NO) 0 1 (2) 3 0 1 (2) 3 0 1 (2) 3 0 1 (2) 3 0 1 (2) 3 0 (1) 2 3 0/1 2 3 0/1 2 3 0 1 /2 3 0 1 (2) 3 0 0 YES 0 1 3 0/1 0 (1) 2 3 | 0 /1/2 3 0 1/2/3 0 (3) (NO) YES ω 0 1(2 B YES VES NO KES NO YES (NO) YES (NO) YES <u>f</u>) 2 S S (NÓ YES (NO) YES (NÓ) YES W 3 0 1 2 3 0 1 2 3 0 1 2 12/04/13 12/07/13 12/08/13 12/09/13 12/10/13 12/10 0 (1/2 3 0 0/1)23 0(1)23 0(1)23 0/1)23 0 (1)2 YES (NO) 0 1/2/3 0 (1)2 0/1/2 3 YES (NO) YES YES) NO YES (NO NO YES (NO) ω 0 1 3 0/1/2 N 0 ω ω ω 0 D2 0 (1) 2 YES (NO) YES YES (NO) YES YES 0 (1)2 (1)2 (NO ω w ω ω ω 0/1/2 YES ΥES 0 YES 0 0 0 0 1/2 щ \vdash <u>ب</u> Н œ Ν N 2 2 NO **Z**0 **€** Q w ω ω W 12:6 woke up coasping 0 YES ΥES ΥES 0 0 0 0 0 0 ᅩ <u>سا</u> Н **|--**3 \vdash |-- N N N Ŋ

12-6

SUBJECT INITIALS AND DATE: paton colognet 975 12-10-13

DATE COMPLETED: 1310113

SUBJECT NUMBER: A KP037

Y=Yes N= No

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc fic Resources Leslie Byatt, Unn Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

PAGE

24664

PATIENT NAME BHE, BHE

PHYSICIAN Unlisted Physician,

REQUISITION NO.

Test

31033178 COMMENTS:

0

PT. PHONE NO.

80G 09/02/1952 **AAGI8221**

SEX M

REPORT STATUS

Final

RECEIVE DATE & TIME 12/10/2013 20:14 PRINT DATE & TIME 12/11/2013 09:17

PATIENT NO. **AKP037**

PATIENT ID

COLLECT DATE & TIME

12/10/2013 10:45

In Range

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone

NOT INDICATED

Rare

NS

End of Report

/ Dec 2013

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

ന m ന ന ന <u>S</u> NO. 9 9 0/1/2 2 2 N 2 2 N 15 0/1) \mathcal{I} √-1 ₩ \vdash YES YES YES YES 0 0 Q 0 0 (0N) ന ന ന 3 m Ŝ. N Q 2 0 (1) 2 \mathbb{T}) 2 2 0 (1) 2 2 N N 14 $\overline{\mathbb{C}}$ Ţ É 1 YES YES YES 0 o 0 0 0 12/12/3 ന 2 ന ന m ന m 2 3 S N 1 (2) ~ (T) *1*/2 7 3 0 YES YES YES YES 0 Ö 0 0 0 0 @ 2 (C) (3)ന ന ന ന 9 9 <u>\$</u> (C) 0 (1) 2 ~ 7 141/61 81/61 Ę (F) 0 Ä \leftarrow YES YES YES YES 0 0 0 0 0 ന 3 ന ന <u>Q</u> ന ო 2 g m Š 0 1 10 1/2 7 N d E) (T) €° Н YES YES YES YES 0 0 0 0 0 10 10 13 1,23 <u>S</u> 0/1/2 3 ന NO. 9 ന ന E) ന 10 0/1/2 0 0 2 0 1 2 d 7 N 70 YES YES \leftarrow ш YES YES 0 0 0 63 0.1(2)3 $0 \ 1(2)3$ § 9 \$ ന <u>≸</u> က 0 1(2)3 12/09/13/12/10/13 12/11/13 12 B <u>§</u> <u>S</u> $\sqrt{1}$ N CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS თ Ð \leftarrow YES YES YES YES 0 0 0 0 0 9 ന ന (S) m ന ന Ę Ó 0/1/2 (1) 2 7 7 \sim ∞ \bigcirc Second 0 1 **V**ES YES YES 0 0 0 0 0 0 ന ന ന ന 9 9 9 g 1 2 N 2 d \vdash \vdash $\overline{}$ ┰┤ \vdash YES YES XES 0 0 0 0 0 0 Throat Clearing Throat Clearing Voice Hoarse Voice Hoarse DAY PM Runny Nose Runny Nose Congestion Congestion Itchy Nose Itchy Nose DAY AΜ Sneezing Sneezing 0 to 3 0 to 3 0 to 3 0 to 3 0 to 3 0 to 3 0 to 3

0= No symptoms (no symptoms detected)

SCALE 0 to 3

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: PKF637 DATE COMPLETED: 12/17/1

sex wte some elet of sneeding the sneeding t

SUBJECT INITIALS AND DATE: M. 1.2 -(



Lovelace Sc ific Resources Leslie Byatt, Jin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME BHE, BHE

PHYSICIAN Unlisted Physician,

REQUISITION NO. 31033185

PT. PHONE NO.

0

PATIENT ID **AAGI8221** DOB 09/02/1952 SEX M

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

12/17/2013 10:00

RECEIVE DATE & TIME 12/17/2013 19:27 PRINT DATE & TIME 12/18/2013 07:01

PATIENT NO.

AKP037

COMMENTS:

Test

Result

In Range

Out of Range

Rare

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

Not given

End of Report

Mutrice mo 18 Dec 2013

| | | | Investigator Initials/Date | Man Worth | | | | | | | | | * | • |
|-----------------------|-------------------------|-------------------|---|----------------------|-------------------|------------------|------------------|---|--|-------|--|--|--|---|
| LSR Study#: 274/0 | Subject Initials: 13H S | | Action Taken | 3 NOVE | からいの | NOVE | Neve | 7 | | | | | e as specific as possible | Date: 22 /2013 |
| 4S7 | luS. | 90 | ** End Date (DD/MMM/YYYY) | Sylvericas NORE | BU/DOC SOR NOWE | 1 100 POOLS NONE | 19/DEC/2013 NONE | | | | | | t should be made to b | O Date: |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | Super Ted | M | NA LUMBELE | Suspelled | | | 9,000 | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | Mustain 4 |
| | | | SEVERITY | Mod | Lild | S S S | mod | | | | | | te UNK in space | |
| 5749 | AKP037 | | ** Start Date (DD/MMM/YYYY) | 08000 3013 | tof Dec 2013 | 5 10c/20/3 | 12/Dec/2013 | | | | | | day is <u>unknown,</u> wri | Investigator Signature (at end of study): |
| Study Identification: | Subject Number: | | Adverse Event | 50007000 50007000 | THE STREET STREET | nus postion | DOF SMILZING | | | | | | ** | Investigator Signa |

14

Lovelace Scientific Resources, Inc - AdverseEvents 04/2013



Lovelace (ntific Resources Leslie Byatı, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

X, BHE PHYSICIAN

PATIENT ID **AAGJ4038**

09/02/1952

M

REPORT STATUS Final

PAGE 1

Unlisted Physician, REQUISITION NO.

COLLECT DATE & TIME 12/23/2013 09:59

RECEIVE DATE & TIME

PRINT DATE & TIME

0

PT. PHONE NO.

PATIENT NO.

12/23/2013 19:01

12/24/2013 06:03

31033196

AKP037

COMMENTS:

NO PHYSICIAN LISTED

| | R | esult | | | | |
|----------------------|---|---|---------------------|-------------------------|---------------------------|-----------------------|
| Test | in Range | Out of Ran | ge- | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 14 1 | | | mmol/L | 134-1 44 | |
| Potassium | 3.6 | | | mmol/L | 3.5-5.1 | |
| Chloride | 109 | | | mmol/L | 98-111 | |
| CO2 | 22 | | | mmol/L | 20-30 | |
| Anion Gap | 10 | | | | 6-14 | |
| Glucose | | /a\ | | mg/dl_ | 60-100 | |
| PU IN | Impaired fasting glucose (100-126 mg/dl.(ADA Guideli | nes Diabetes | ed as a Care 26: | (3160-3167)200 | 3) | |
| BUN | 15 | | | mg/dL | 7-31 | |
| Creatinine | 0.82 Creatinine method is IDMS | traceable. Es | tGFR Cal | mg/dL culation has b | 0.62-1.66 een adjusted | |
| | Please note new reference | range effecti | ve 5/23/ | 2013. | | |
| eGFR non-African Am | >60 | | | mL/min/1.73m2 | >60 | |
| GFR Comment | Estimated GFR values are ron IV fluids, obese (BMI>3 the very old or very young people with acute illness | (4) on underwe | iaht (RM | T-20) naan a | | |
| Calcium | 9.0 | , | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.0 | | | gm/dL | 6.1-8.2 | |
| Albumin | 4.1 | | | gm/dL | 3.4-4.7 | |
| Globulin | 2.9 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.6 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 49 | | | U/L | 38-150 | |
| AST(SGOT) | 36 | | | U/L | 6-58 | |
| ALT(SGPT) | 63 | | | U/L | 14-67 | |
| Fasting | NO | | | | | |
| Phosphorus | 3.4 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | 4050 | | |
| WBC | 7.1 | | | x10E3 | 4.0-10.6 | |
| RBC | 5.13 | | | x10E6 | 4.64-6.00 | |
| Hgb | 16.0 | | | gm/dL | 14.5-17.7 | |
| Hct | 45 | | | % | 42-53 | |
| MCV | 88 | 05.4 | | fL | 81-98 | 0/10/10 |
| MCHC | 40.0 | 35.4 | Н | gm/dL | 31.2-35.2 // | "> 1040/1 |
| RDW | 13.3 | | | % ~10E3 | 11.0-14.5 | TO THE REAL PROPERTY. |
| Platelets | 244 | Many | * | x10E3 | 150-400 1/6 | y WALL |
| Eos, Respiratory | | Many | - | | NS NS | ζ., |
| Phys, Addr, Phone | NO DHYSTOTAN LITSTED | | | | | |

End of Report

Museriew Sub I 2 Ian 2014

Ongoing at EOS (for Clinic use) Subject Initials: \mathcal{OH} List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. Stop Date LSR #: (Day/Month/Year) UNK/AUG/1999 2010 2010 E * Start Date 5700101 10/11/13 2012 200F \$110 B 2010 7011 CONCOMITANT MEDICATION LOG Oral Route 0 Ø, 00 0 2 2 Tabs per 20 Frequency BB 80 10/2 10/2 20 BO **β** 90 8 MG 200 Unit mi 3 20 Ž Z 12.51 500 2013 300 Dose 150 20 0 73 Study Identification: At Pharma SUPPLEMENT (What you take it for) SUPPHEMENT Diabetes Indication Supplement A lipido Shir Ider G01/ たた Name of Medication Meio pre Flu scasine thastead Subject Number: Dichtnac SIMINSTATIO Amlodogina EXAMPLE Alloouring Bensapa 5 [}

L Date: 12/26/13 Eriena

* If day or month of medication date is <u>unknown,</u> write UNK in space provided

M 54/WK

5

Allegizs

11/4/13

10/4/13

122

4-5 X WEL

C

Allerance

2012

Lovelace Scientific Resources, Inc - ConMeds 04/2013

SC Signature (at end of study):

stigator Signature (at end of study):_

Date: 12/93/13

| Study Identification: | AL Pharma | | | | | | LSR#: | 2749 |
|--|---|----------------------|-----------------|--|--------------|--|-------------------|---------------------|
| Subject Number: | ALPUST | | | | | | Subject Initials: | S. BH |
| List all <u>pres</u> | CONCOMITANT MEDICATION LOG List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements | CONC ou are takir | OMITA | CONCOMITANT MEDICATION LOG | ATION L | OG medications, vitamin | and subnieme | 1 |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Dav/Month/Year) | Stop Date | Ongoing at EOS |
| EXAMPLE | Diabetes | 500 | MG | 2 Tabs per dav | o Fig | UNIÇ/AUG/1999 | | (Jest Dalling to A) |
| Testations | 1 | 7.5 | % | 00 | 00 | 2012 | | Ì |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | - | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or mor | oth of medi | cation dat | e is <u>unknow</u> | n, write UN | * If day or month of medication date is unknown, write UNK in space provided | | |
| Investigator Signature (at end of study): (SC Signature (at end of study) | or Signature (at end of study): | | In C | in 100 5 | Sale | L Date: 12/20/13 | 21/0 | |
| 1 | | Lovelace S | kilentific Reso | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | leds 04/2013 | Date: | 5 K | PAGE: A of A |

| Study Identification: | Arthuma | | | | | | LSR#: | 2749 | <u> </u> |
|-----------------------|---|----------------------|---------------|--|--------------|--|---------------------|------------------------------------|------------|
| Subject Number: | ALPUST | | , | | | , | Subject Initials: _ | S: BHE | |
| List all | CONCOMITANT MEDICATION LOG List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. | CONC ou are takir | OMITA | CONCOMITANT MEDICATION LOG | ATION L | OG medications, vitamin | s and suppleme | ints. | |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS (for Clinic use) | 300 034 |
| EXAMPLE | Drabetes | 500 | MG | 2 Tabs per day | Orat | UNK/AUG/1999 | | | |
| Testakone | 17 | 7.5 | % | 00 | 00 | 2012 | | | - Jane 1 |
| | | | | | | | | | r risiggaa |
| | | | | | | | | | District |
| | | | : | | | | | | 1 1000 |
| | | | | | | | | | g top P |
| | | | | | | | | | · Integri |
| | | | | | | | | | a sygia- |
| | | | | | | | | | o Porvers |
| | | | | | | | | | d series |
| | | | | | | | | | a area cal |
| | | | | | | | | | |
| | * If day or mo | nth of medi | cation da | ite is <u>unknow</u> | n, write UN | * If day or month of medication date is unknown, write UNK in space provided | 9. | | 1 |
| Investigator Signatu | Investigator Signature (at end of study): | | | 100 00 C | Salt | L Date: 12/26/13 | 6/13 | | 7 |
| SC Signati | SC Signature (at end of study) |) ovelave | r l | Y | | Date: 0/ | 3250 | | |
| | | רסעמומנים | Scientific ne | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | Meds 04/2013 | | PA | SE SE | |

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| Thrc | Y/N Voic | o ñ | <u>ο</u> ῦ | o 글 | O Z | | Thra | Y/N Voic | o ñ | ဝ ဂ | o 큐 | 0 2 | | | 15 |
|-----------------|---------------------------------------|---------------------------------|-------------------|----------------------|----------------------|----------|--|--|--------------------|----------------------|----------------------|----------------------|----------------------|-----|--|
| Throat Clearing | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DA. | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | > | D | なした |
| Clea | - loar: |] % | stion | lose | Nose | DAY PM | Clea | loars | 36 | stion | ose | Nose | АМ | DAY | APP |
| iring | se | | | | נו | _ | ring | Se Se | | | | '" | | | XOX |
| YES | YES | 0 | 0, | 0 | 0 | | YES | YES | ه_ | | -0 | 6 | ū | | MAI |
| | \sim | 5 | 0 4 2 | (b) 2 | (D)2 | 14 | ر ا | | 1 2 | 1 2 | 1 2 | 1 2 3 | 12/17/13 | 14 | ERE |
| (No |) ⟨₹ | ω | ω | ω | ω | | ₹ | o S | ω | w | ω | | | | SPOR |
| YES | YES | 0 1 | 0(<u>1</u>)2 | 0 D | 0 @ 2 | | YES | YES | | 0 (7) |)© | O | 12/18/13 | | CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS |
| (N) | \(\vec{\vec{\vec{\vec{\vec{\vec{\vec{ | 16 | | 2 | 2 | 15 | (§ | | 2 | 1/2 | N | 2 3 | <u>%</u> | 15 | VEKY |
| | _ | $\mathcal{V}\widetilde{\omega}$ | ω | ω | ω | | | | | w | ω | † | <u> </u> | | 12 + |
| YES | ¿YEŚ | 0 1 | 0 1 | 0 1(| 0 1 | | YES | YES | (<u>17</u> 22 |) (<u>1</u>) | 0 (E) 2 | 0 (1) 2 3 | 12/19/13 | _ | HOUN |
| (Z) | 13 | | 1 (2)3 | (2)3 | $\frac{1}{2}$ 3 | 16 | Ê | | ⊕ 2 | 2 | 1 | 2 | 19/ | 16 | IV. |
| | - |) 3 | 3 0 | 3 0 | 3 0 | | 79000 | Salara | クω 。 | ω 0 | ω 0 | ļ | | | |
| YES | YES | |) 1(| | 1 /3 | 17 | YES | YES | (J) | 30 | > C | | 2 | 17 | |
| (S) | J 6 | 1/2/3 | 1(2) 3 | 1 ② 3 | 3 | 7 | (Š | DZŞ | Σ ω | 2 3 | 2 3 | 0 (1) 2 3 | 12/20/13 | 7 | |
| | YES | , | | -0 | 0 | | YES | | 0 | 0 | 0 | 0 | | | |
| YES | l | 1 | 0 (1) 2 | XD) | C | <u>)</u> | 25500 | YES | (<u>h</u>) 2 | $\hat{\mathbb{D}}^2$ | ① 2 | , (J | 7 | 18 | |
| (8) | \S S | 2)3 | D 2 | 2 3 | 2 3 | - | | | 2 3 | 2 3 | 2 3 | 2 3 | 21/12 | | İ |
| YES | YES | 0 | 20 | 0 | | | YES | YES | 0 | 0 | 0 | 0 | 12/13/142413 | | |
| i | 1 | 10 | 0 🕭 2 | (1)2 | 0 🖉 2 | 19 | | | 2 | 1/2 | 75 | 0 1)2 3 | 22 | 19 | |
| S | (§ |) ω | ω | ω | ω | | <\\circ\circ\circ\circ\circ\circ\circ\ci | >(§ |) ω | 3 | ω | ω | W | | |
| YES | YES | 0 | 0 1 | 0 1 | 0 | | YES | YES | 0 (1 | 0 | 0 | 0 | 12 | | |
| 1 | | 2 | 2 | ١ 2 | 1 2 | 20 | |)(3 | [)2 | <u>)</u> | アク | D (F) 2 | | 20 | |
| NO NO | NO | ω | ω | ω | ω | | | | | 3 | ω | ω | ũ | | |
| YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 3 | 12/ | | |
| NO NO | NO | 2 | N | 2 | 2 | 21 | N O | NO | 2 | . 2 | ~ | 2 | 24/ | 21 | |
| | | ω | ω | <u>υ</u> | ω | | | <u> </u> | w | 3 | ω | ω | W) | | |
| YES | YES | 0 1 | 0 1 | 0 1 | 0 | | YES | YES | 0 1 | 0 1 | 0 | 0 1 | [2] | . , | |
| NO | NO | . 2 | , | . 2 | 1 2 | 22 | N O | 8 | , 2 | . 2 | 2 | 0 1 2 3 | 113 12/24/13 12/25/0 | 22 | |
| | | ω | ω | ω | ω | L | 0 | 0 | ω | ω | ω | ω | 3 | - | |

12-18 50 m

XTRA SPRAY

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: ALAOST DATE COMPLETED: 12/23/13

SUBJECT INITIALS AND DATE: ## # 12-23-13

BHE AKPO37

12/23/13

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ☐YES ☐NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: PRODUCT Seemed to help Two help Two lefts. |
| When ground comes on Market Let me know 50 I can buy it |
| the study was easy Erica was very vice all the Time |
| Jet me know when I can buy Pil ! |
| |

[Type text] Subject initials and Date $\frac{12-3-13}{12-3113}$ Study Staff Initials and Date $\frac{2m}{12/3113}$

AKP-038

2/49 AKPharma PERENNIAL ALLER JES SCREENING/VISIT 1 SOURCE DOCUMENTS

| Initials: DRR Site # | #: Subject #: _AKP 138 |
|--|--|
| PATIENT DEMOGRAPHICS | |
| Patient Demographics | |
| Date of Birth: 09 / Oct 194 Gender: Male Fem | (dd/mmm/yyyy) |
| Gender: Male | nale |
| If female, Indicate Childbearing Potential | |
| | urgically sterilized Post-Menopausal |
| Ethnicity: Hispanic Non Hispanic Race: Asian Black Cau | ic |
| | |
| Pacific Islander Other, Sp | ecify |
| | |
| Smoking History | |
| Smoking Status: None (smoked less that | ın 100 cigarettes in lifetime) |
| <u>'</u> | oked more than 100 cigarettes in lifetime) |
| Current (smokes now) | |
| If subject is a former or current smoker, plea | se indicate: |
| Years smoked: 16 | Cigarettes per day: 20 |

Version: 02 September 2013



Lovelace Sc ific Resources Leslie Byatt, um Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME DRR, DRR

PATIENT ID **AAGH5323**

COLLECT DATE & TIME

n∩¤ 10/09/1946 SEY REPORT STATUS М Final

PAGE

PHYSICIAN

Unlisted Physician, REQUISITION NO.

11/12/2013 10:30

RECEIVE DATE & TIME

PRINT DATE & TIME

PT. PHONE NO.

PATIENT NO.

11/12/2013 20:12

11/14/2013 06:10

30920945

AKP038

COMMENTS:

| | | | Result | | | |
|--------------------------------------|-----------|----------------|-------------------|--|-----------------|-----------|
| Test | • | In Range | Out of Ran | nge Units | Reference Range | Site Code |
| Allerg,Panel 18 Allerg,Juniper | | | (9.70) | S gh 11/18/13 kU/L cs Hgh 11/18/13 kU/L cs Hgh 11/18/13 kU/L cs Hgh 11/18/13/13/13/13 | <0,35 | |
| Allerg,Cottonwood | | <0.10 | Ne | s ga iilialio ku/L | <0.35 | |
| Allerg,West.Ragweed | | <0.10 | The second second | an of wirelia kU/L | <0.35 | |
| Allerg,Russian This | | | (14.40 M | kU/L | <0.35 | |
| Allerg, Bermuda Grass | | 0.00 | (Q_70) NO | GZ H XourauskU/L | <0.35 | |
| Allerg,Alternaria Allerg,Mesquite | | 0.30 | (0.80) NO | kU/L LS HganlisluskU/L | <0.35 | |
| Allerg,Cockroach | | <0.10 | Q.00 / 11 | kU/L | <0.35 | |
| Allerg, Derm. pter. | | <0.10 | | kU/L | <0.35 <0.35 | |
| 1 912 2 p. 251 | The stan | | ation system util | lizes the following | class cutoffs. | |
| | Class | ku/L | Interpretation | • | | |
| | 0 | <0. 35 | Negative for Al | llergen | | |
| · | I | 0. 35-0. 69 | Positive for A | llergen | | |
| | <u>II</u> | 0. 70-3. 49 | Strongly Positi | ive | | |
| | III | 3. 5-17. 49 | Strongly Positi | ive | | |
| | īv | 17. 5-52. 49 | Strongly Positi | ive | | |
| | v | 52. 5-99. 99 | Strongly Positi | ive | | |
| | VI | >100 | Strongly Positi | ive | | |
| | Results | with allergens | scoring in Class | s 1 should be consid | ered weakly | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allerov.

| | ciinicai ailergy. | | |
|------------------------|---------------------|-----------------------------|--------|
| Allerg,Derm. farinae | <0.10 | kU/L | <0.35 |
| Allerg, Clad. herb. | <0.10 | kU/L | < 0.35 |
| Allerg, Firebush | . 1 14. | 3.90 NCS HONNIER KULL | < 0.35 |
| (Allerg, Cat Dander Ep | Inclusion Criteria | (3.60) NGS HXIMINIS KU/L | < 0.35 |
| (Allerg, Dog Dander) | In clusion Creteria | 0.40 NCS H OS HI 18/13 KU/L | <0.35 |
| Allerg, Bluegrass | | 0.60 Nes HOU W/18/12 KU/L | < 0.35 |
| Allerg, Pigweed | | 12.10 Nes Had with ku/L | < 0.35 |
| Allerg, Mulberry | 0.10 | kU/L | < 0.35 |
| Allerg,Helminth | <0.10 | kU/L | < 0.35 |
| Phys, Addr, Phone | Not given | | |

Callback Accession Comments:

T3463932

EALTTE, EBERGR, ECATDA, ECLAHE, ECOCKR, ECOTTO, EDERFA, EDERPT, EDOGDA, EFIREB, EHELHA, EJUNIP, EKENBL.

EMESQU, EMULBE, EROUPI, ERUSTH, EWESRA

11/13/2013 08:13 pm FAXED TO 11/13/2013 08:14 pm FAXED TO

3488546 NC CS11630 3488546NC CS1/1630

Continued on next page

DRR, DRR

11/14/2013 06:10

FAX24664



Lovelace S tific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME DRR, DRR

PATIENT ID

DOB 10/09/1946 REPORT STATUS Final

PAGE 2

PHYSICIAN

Unlisted Physician,

PT. PHONE NO.

AAGH5323 COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

11/12/2013 10:30 PATIENT NO.

11/12/2013 20:12

SEX

11/14/2013 06:10

30920945

Test

AKP038

COMMENTS:

Result

In Range

Out of Range

Units

Jsalyer PI 18 Nov 2013

Reference Range

Site Code

End of Report



Lovelace Scientific Resources 2 1 Ridgecrest Dr SE Amuquerque, NM 87108



Name: DRR,

Gender: Male

Age: 67

Race: Caucasian

Height(in): 72.0

Weight(lb): 195

Any Info:

Id: AKP038 Date: 11/27/13

Temp: 19

PBar: 637

Physician:

Technician: CRD

| | | | | | | i e crimicia | in; CRD |
|-----------|--------------|----------|-------------|--------------|-------------------------|-------------------------|---|
| Spirome | trv (E | TPS) | PR | E-RX | POST-RX | , ens.c | Flow |
| | , | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post | 16₩ 16 _T |
| FVC | Liters | 4.67 | 5.49 | 118 | Meda 10 1761 | % Chg | |
| FEV1 | Liters | 3.70 | 3.35 | 90 | | | Ī |
| FEV1/FV0 | C % | 78 | 61 | 78 | | | 12 |
| FEF25-75 | %L/sec | 3.65 | 1.27 | 35 | | | |
| FEF50% | L/sec | 4.52 | 2.12 | 47 | | | † |
| FEF75% | L/sec | 1.65 | 0.33 | 20 | | | 8 - |
| IC | Liters | | 5.00 | 20 | | | |
| VC | Liters | 4.67 | | | | | + / "\ |
| PEF | L/sec | 8.85 | 9.20 | 104 | | | |
| MVV | L/min | 138 | 0.20 | 104 | | | 4 \ |
| PIF | L/sec | 100 | 6.26 | | | | 1 1 |
| FEV1/FEV | /6% | | 71 | | | | |
| | Volumes/F | Plethysn | | nhv | (BTPS) | | 0 + + + + + + + + + + + + + + + + + + + |
| | | | .09,0 | ~,,, | | | + |
| Vtg VC | Liters | 4.07 | | | | | |
| TLC | Liters | 4.67 | | | | | 4 |
| RV | Liters | 7.03 | | | | | |
| RV/TLC | Liters | 2.63 | | | | | |
| FRC PL | % | 40 | | | | | -8 ⁻ |
| | Liters | 3.94 | | | | | |
| ERV IC | Liters | | | | | | Ī |
| 10:cc : | Liters | | | | | | -12 [⊥] |
| Diffusi | on | | | | | | -12 1 2 Volume 6 8 |
| DLCO | mL/mmHg/min | 23.5 | | | | | volume |
| DL Adj | mL/mmHg/min | 23.5 | | | | | |
| DLCO/VA | mL/mHg/min/L | 3.07 | | | | | |
| VA | Liters | | | | | | |
| ВНТ | Sec | | | | | | |
| Resist | ance | | | | | | |
| | cmH2O/L/sec | | | | • | | |
| | cmH2O/L/sec | | | | | | |
| - ' | | | | | | | |

Comments:

Vtg (Raw) Liters

Raw Exp

Raw

Gaw

sRaw

sGaw

cmH2O/L/sec

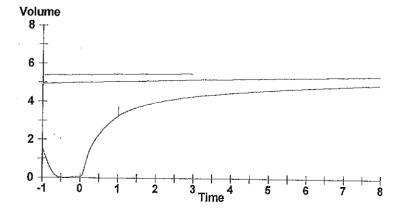
cmH2O/L/sec

cmH2O/L/s/L

L/sec/cmH2O 0.947

L/s/cmH2O/L 0.228

4.38





Lavelace Scientific Resources 101 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP,

Gender: Male

Age: 67

Race:

Height(in): 72.0

Weight(lb): 195

Any Info:

ld: 038

Date: 12/04/13

Temp: 19

PBar: 622

Physician:

Technician: CRD

| 7 triy irii Q. | | | | | | GOIIIIGIS | III. UKD | , | | | | |
|----------------|-----------------|----------|-------------|--------------|-------------------------|---------------|------------------|--------|-------------|---------------|---|--|
| Spirome | trv (B | TPS) | PR | E-RX | POST-RX | | Flow | | | | | |
| ориото | иу | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 _T | | | | | |
| FVC | Liters | 4.67 | 4.89 | 105 | 70 1101 | 70 Ong | 1 | | | | | |
| FEV1 | Liters | 3.70 | 3.10 | 84 | | | | | | | | |
| FEV1/FV0 | > 0 <u>/</u> | 78 | 64 | 81 | | | 12 + | | | | | |
| FEF25-75 | | | | | | | | | | | | |
| FEF50% | L/sec | 3.65 | 1.22 | 34 | | | + | | | | | |
| | | 4.52 | 2.19 | 48 | | | 0 | | | | | |
| FEF75% | L/sec | 1.65 | 0.35 | 21 | | | 8† | \cap | | | | |
| IC. | Liters | | | | | | 1 | - / N | \ | | | |
| VC_ | Liters | 4.67 | | | | | | - [| | | | |
| PEF | L/sec | 8.85 | 8.22 | 93 | | | 4 + | - 1 | | | | |
| MVV | L/min | 138 | | | | | - { | | \ | | | |
| PIF | L/sec | | | | | | ŧ | - 1 | λ. | | | |
| FEV1/FEV | /6% | | 71 | | | | . ام | 1. | | | | |
| Lung \ | Volumes/F | Plethysn | nogra | phy | (BTPS) | | 0 | 1 | · | J | + | |
| Vtg | Liters | • | • | . , | | | † | | | | | |
| vč | Liters | 4.67 | | | | | -4 + | | | | | |
| TLC | Liters | | | | | | - | | | | | |
| | | 7.03 | | | | | + | | | | | |
| RV | Liters | 2.63 | | | | | | | | | | |
| RV/TLC | % | 40 | | | | | -8 | | | | | |
| FRC PL | Liters | 3.94 | | | | | | | | | | |
| ERV | Liters | | | | | | Ţ | | | | | |
| <u>10</u> | Liters | | | | | | -12 ¹ | | | | | |
| Diffusi | on | | | | | | -12 -2 | 0 | 2 Volume | 6 | 8 | |
| DLCO | mL/mmHg/min | 23.5 | | | | | | | Volume | | | |
| DL Adi | mL/mmHg/min | | | | | | | | | | | |
| DLCO/VA | | | | | | | | | | | | |
| VA | mL/mHg/min/L | 2.99 | | | | | | | | | | |
| | Liters | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | |
| Resist | ance | | | | • | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | | |
| | cmH2O/L/sec | | | | - | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | | |
| | 3111 IL 31L1300 | | | | | | | | | | | |

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec

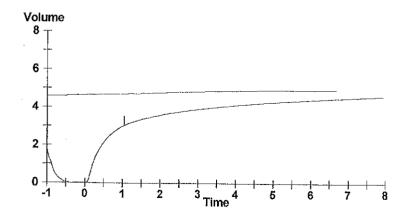
 Gaw
 L/sec/cmH2O

 sRaw
 cmH2O/L/s/L
 4.38

 sGaw
 L/s/cmH2O/L
 0.228

 Vtg (Raw)
 Liters

Comments:





velace Scientific Resources 41 Ridgecrest Dr SE Albuquerque, NM 87108



Name: DRR,

Gender: Male

Age: 67

Race: Caucasian

Height(in): 72.0

Weight(lb): 195

Any Info:

ld: AKP-038 Date: 12/11/13

Temp: 17

PBar: 634

Physician:

Technician: VL

| Spirome | trv (E | STPS) | PRI | E-RX | POST-RX | | | | | | |
|--------------|-----------------|-----------|-------|--------------|-------------------------|-------|--------------|--------------|----------|---------------|---------------|
| | u y | Ref | Pre | Pre % Ref | Post Post Meas % Ref | Post | Flow 16 ⊤ | | | | |
| FVC | Liters | 4.67 | 4.75 | 102 | weas wikei | % Chg | ľ | | | | |
| FEV1 | Liters | 3.70 | 3.16 | 85 | | | † | | | | |
| FEV1/FV0 | C % | 78 | 66 | 85 | | | 12 | | | | |
| FEF25-75 | %L/sec | 3.65 | 1.77 | 48 | | | | | | | |
| FEF50% | L/sec | 4.52 | 2.48 | 55 | | | † | | | | |
| FEF75% IC | L/sec Liters | 1.65 | 0.55 | 33 | | | 8 + | \sim | | | |
| VC | Liters | 4.67 | | | | | + | / \ | | | |
| PEF | L/sec | 8.85 | 9.34 | 106 | | | | | | | |
| MVV | L/min | 138 | , | ,00 | | | 4 🕂 | | | | |
| PIF | L/sec | | 1.48 | | | | ļ | 1 4 | | | |
| FEV1/FEV | 6% | | 72 | | | | _ | 1 | <u> </u> | | |
| Lung \ | Volumes/F | Plethysmo | ograp | ohy | (BTPS) | | 0 | | | -1 | 1 |
| Vtg VC | Liters | | | | | | † | | 1. | | |
| VC | Liters | 4.67 | | | | | -4 \ | | | | |
| TLC | Liters | 7.03 | | | | | " [| | | | |
| RV | Liters | 2.63 | | | | | † | | | | |
| RV/TLC | % | 40 | | | | | -8+ | | | | |
| FRC PL | Liters | 3.94 | | | | | -0 | | | | |
| ERV | Liters | | | | | | f | | | | |
| IC . | Liters | | | | | | 40 | | | | |
| Diffusi | on | | | | | - | ·12 | 0 2 | 4 | 6 | 0 |
| DLCO | mL/mmHg/min | 23.5 | | | | | - | ັ່√vo | lume | O. | 8 |
| DL Adj | mL/mmHg/min | 23.5 | | | | | | | | | |
| DLCO/VA | mL/mHg/min/L | 3.06 | | | | | | | | | |
| VA | Liters | - | | | | | | | | | |
| BHT | Sec | | | | | | | | | | |
| f*3 * - t | | | | | | | | | | | |

Resistance

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

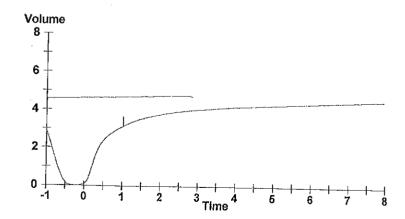
 Raw
 cmH2O/L/sec

 Gaw
 L/sec/cmH2O

 SGaw
 L/s/cmH2O/Ls/L

 Vtg (Raw)
 Liters

Comments:





Lovelace Scientific Resources 11 Ridgecrest Dr SE Abouquerque, NM 87108



Name: AKP-038,

Gender: Male

Age: 67

Race:

Height(in): 72.0

Weight(lb): 195

Any Info:

ld: AKP-038 Date: 12/18/13

Temp: 20

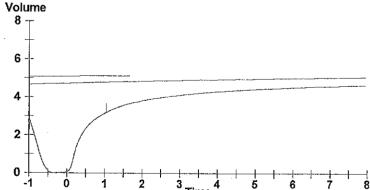
PBar: 634

Physician:

Technician: CRD

| ruly uno. | | | | | | COMMO | III. URD | , | | | | |
|-----------|--------------|-----------|--------|-----|---------------|-------------|-------------|--------------|---------------------------------------|------------------|---------------|--|
| Spirome | tne | (BTPS) | PRE | -RX | POST-RX | | Flow | | · · · · · · · · · · · · · · · · · · · | | | |
| Ophome | zu y | Ref | Pre | Pre | Post Post | Post | 16 T | | | | | |
| | | | Meas | | Meas % Ref | % Chg | 10 | | | | | |
| FVC | Liters | 4.67 | 5.12 | 110 | | _ | + | | | | | |
| FEV1 | Liters | 3.70 | 3.21 | 87 | | | 40 | | | | | |
| FEV1/FV | | 78 | 63 | 80 | | | 12 - | | | | | |
| FEF25-78 | | 3.65 | 1.38 | 38 | | | 1 | | | | | |
| FEF50% | L/sec | 4.52 | 2.23 | 49 | | | - | | | | | |
| FEF75% | L∕sec | 1.65 | 0.38 | 23 | | | 8 - | $\sqrt{1}$ | | | • | |
| IC | Liters | | | | | | 1 | - / | \ | | | |
| VC_ | Liters | 4.67 | | | | | İ | - 1 | | | | |
| PEF | L/sec | 8.85 | 9.00 | 102 | | | 4+ | - 1 | | | | |
| MVV | L/min | 138 | | | | | | - 1 | 4 | | | |
| PIF | L/sec | | | | | | Ť | ł | \ | | | |
| FEV1/FE | | | 71 | | / | | 0 | | J 77 L | -1, 1 | | |
| Lung | Volumes | s/Plethys | mograp | bhy | (BTPS) | | | | | | | |
| Vtg | Liters | | | | | | | | | | | |
| VČ | Liters | 4.67 | | | | | -4 + | | | | | |
| TLC | Liters | 7.03 | | | | | į | | | | | |
| RV | Liters | 2.63 | | | | | T | | | | | |
| RV/TLC | % | 40 | | | | | -8+ | | | | | |
| FRC PL | Liters | 3.94 | | | | | | | | | | |
| ERV | Liters | | | | | | † | | | | | |
| IC | Liters | | | | | | -12 l | | | | | |
| Diffus | ion | | | | | | -12 -2 | 0 | 2 Volume | 6 | 8 | |
| DLCO | mL/mmHg/r | min 235 | | | | | | | Volume | | | |
| DL Adj | mL/mmHg/r | | | | | | | | | | | |
| DLCO/VA | mL/mHg/mi | | | | W | | | | | | | |
| VA | Liters | 0.00 | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | |
| Resis | | | | | | | | | | | | |
| | | | | | • | | | | | | | |
| | I cmH2O/L/se | | | | | | | | | | | |
| Raw Insp | | | | | | | | | | | | |
| Raw Exp | cmH2O/L/se | | | | | | | | | | | |
| Raw | cmH2O/L/se | | | | | | | | | | | |
| Gaw | L/sec/cmH2 | | | | | | | | | | | |
| sRaw | cmH2O/L/s/ | | | | | | | | | | | |
| sGaw | L/s/cmH2O/ | L 0.228 | | | | | | | | | | |
| Vtg (Raw) | Liters | | | , | | | | | | | | |
| | | | | | A death and a | | | | | | | |





EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| AN | NAT- | | Ι | r | - | Τ | | Г | I | T | Τ | T | T | Ι |
|--|-------------|-------------------------|--------------|----------------------|--------------|---------------------|------------------------|---------|----------------------|------------------|----------------------|--------------------|---------------------|-----------------|
| Nose $0.1(2.3) \cdot 1/3 \cdot $ | \$ C | | | | | 8 | ON O | | | | | | 9 | ON NO |
| Nose $(1/20)(3)(3)(3/20)(3)(3/20$ | > | | | | | YES | YES | | | | ŀ | | YES | YES |
| AN -7 -6 -5 -1 -5 -4 -5 -4 -3 -4 -3 -4 -3 -4 -5 -1 -5 -4 -4 -5 -4 -5 -4 -5 -4 -5 -4 -5 -5 -4 -5 -5 -4 -5 -5 -4 -5 -5 -4 -5 -5 -4 -5 -5 -5 -4 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 -5 | 7/13 | | Į. | | 1 | 9 | ON | | | | ļ | 1 | 9 | S S |
| Nose $0.1 \bigcirc 3$ | =//; | $\overline{\mathbb{C}}$ | → ' | Η , | \leftarrow | YES | (ES) | 0 | | | | 1 | YES | YES |
| NAV -7 -6 -5 -4 -3 (1/23/13 11/23/13/13 11/23/13/13 11/23/13/13 11/23/13/13/13/13/13/13/13/13/13/13/13/13/13 | , e (27 | | m | | 1 | 9 | 9 | | | | 1 | 1 6 | <u>Q</u> | 9 |
| NAV -7 -6 -5 -5 -4 -3 -3 -4 -3 -7 -5 -6 -5 -5 -4 -3 -4 -3 -3 -1 -5 -5 -4 -3 -3 -1 -5 -5 -4 -3 -3 -1 -3 -4 -3 -3 -1 -3 -4 -3 -3 -1 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -5 -4 -3 -5 -5 -4 -3 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -5 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 -4 -3 -3 - | = 0 | ₹) | l | Ð, | 71 | YES | (ES) | 17, | () | - | H | - | l | (YES |
| NAV | ري س | | l | | , | | S | 6 | | | , | | (2) | 9 |
| Nose $(-1/20)_{1/2} = (-1/23)_{1/2} = (-1/23)_{1/2} = (-1/23)_{1/2} = (-1/23)_{1/2} = (-1/2)_{1$ | | | ₩ | (E) | | } | (ES) | -2 | ₽ | 01 | Η- | 0 | YES | (YES) |
| Nose 0.1 (2) 0.1 (2) 0.1 (2) 0.1 (2) 0.1 (2) 0.1 (3) 0.1 (3) 0.1 (4) 0.1 (5) 0.1 (5) 0.1 (7) 0.1 (1) (1) (1) (1) (1) (1) (1) (1) (1 | 2 (| | l | | ε (| S | 9 | | | | 1 | , | <u></u> | <u>8</u> |
| ANY -7 -6 -5 -4 Nose 0 1(2) 3 0 1(2) 3 0 1 2(3) 0 1(2) 3 Insection 0 (1) 2 3 0 1(2) 3 0 1(2) 3 0 1(2) 3 Hoarse VES (NO) VES (NO) VES (NO) VES (NO) Stion 0 (1) 2 3 0 1 2 3 0 (1) 2 3 0 1(2) 3 Hoarse VES (NO) VES (NO) VES (NO) VES (NO) Stion 0 (1) 2 3 0 1 2 3 0 1(2) 3 0 (1) 2 3 Hoarse (0) 2 3 0 1 2 3 0 1(2) 3 0 (1) 2 3 Stion 0 (1) 2 3 0 1 2 3 0 1 2 3 0 (1) 2 3 Hoarse VES (NO) VES (NO) VES (NO) VES (NO) Hoarse VES (NO) VES (NO) VES (NO) VES (NO) RES (NO) VES (NO) VES (NO) VES (NO) VES (NO) RES (NO) VES (NO) VES (NO) VES (NO) VES (NO) RES (NO) VES (NO) VES (NO) VES (NO) VES (NO) | Ž = 2 | | | ₩. | ₹-1 | l . | (ES) | ļ. Ţ | \supset | ~ - | | | YES | (FS) |
| ANY -7 -6 -5 -5 -1/23/12 11/23/12 11/23/12 11/23/13 11/23/13 11/23/13 11/23/13 11/23/13 11/23/13 11/23 11/23 11/23 10/10 cse 0.1 2 3 0 1 2 3 0 1 2 3 0 1 1 | 20 " | m | т | 1 | | ② | 8 | | | | | E | NON NON | ON) |
| AN | | | Θ | ₩ | | | (ES) | 4, | Ð | H . | (J) | \vdash | - | YES (|
| ANY -7 -6 -6 -6 -6 -6 -6 -6 -6 -6 -6 -6 -6 -6 | | | l | <u></u> | m | (2) | SN SN | | | | | | | ON O |
| ANY -7 -6 Nose 0 1(2) 3 0 1(2) 3 Nose 0 1(2) 3 0 1(2) 3 Stion 0 (1) 2 3 0 1 2 3 Hoarse YES (NO YES | 7 - 67 | | \bigcirc | ⊣ | Đ | YES | (TES) | - | | t . | (D) | | | YES |
| AM (1/20/13 11) Nose 0 1(2) 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 VPM -7 Nose 0 1 2 3 0 1 Stion 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Hoarse YES (NO YES Hoarse YES (NO YES Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 Iose 0 1 2 3 0 1 | 200 | 1 | 1 | | | P | ON | (| | _ | | m (| 9 | ON |
| AN | | 1 |] ← | ⊣ | | YES | (ES) | φ | | | $\overline{\Theta}$ | 1 | ΥES | |
| Nose Iose Iose Hoarse Nose Nose Iose Hoarse Iose Hoarse Hoarse | | | 2 3 (| 12 3 | | | S S | 7 | 1 | | 12 3 | | 9 | (S) |
| AN Nose Iose Iose Hoarse Hoarse Nose Nose Nose | 2/2 | 0 1(| \bigcirc_1 | 0 | \bigcirc_1 | | (KES) | 11 | 0 | (O) ₁ | 0 | \bigcirc_1 | YES | YES |
| Runr Runr 1 Thro O to | AM you | Runny Nose 0 to 3 | lose | Congestion 0 to 3 | ng | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 |) eso | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N=No

SUBJECT NUMBER:

DATE COMPLETED: [[[87]

SUBJECT INITIALS AND DATE:



Lovelace Sc ific Resources Leslie Byatt, ∪iin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME X, DRR

PHYSICIAN

Test

Unlisted Physician, REQUISITION NO.

30920902 COMMENTS: PT, PHONE NO. 0

PATIENT ID **AAGI3116** DOB 10/09/1946 SEX М

REPORT STATUS Final

PAGE

COLLECT DATE & TIME 11/27/2013 10:20 RECEIVE DATE & TIME 11/27/2013 18:44 PRINT DATE & TIME 11/28/2013 06:11

PATIENT NO.

AKP038

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr. Phone None seen Not given

in Range

NS

End of Report

Nes MMm. 03 Der 2013

SUBJECT INITIALS AND DATE: $\frac{1}{2}$

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY 1 1 2 3 | 1 | , 2 | 3 | 4 | τυ. | 9 | 7 | 00 | 6 | |
|----------------------|-------------|----------|-----------|------------|-------------|------------------|----------|---------|-------|---------|
| | <u> </u> | 11/29(13 | 11/29/13 | 11/30/13 | 12/1/13 | (येया ३ | 12/3/13 | 12/1/13 | 12/5 | (3 |
| Runny Nose | 10, 1, 2, 3 | 0(1) 2 3 | 0 1 Ø 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 (1)2 3 | ε z 🛈 o | 0 1 2 | က |
| 0 to 3 | _ | G | Ų, | Ç | | | (20) | Ç | | |
| Itchy Nose | 0 1 2 3 | 0123 | 0 (1) 2 3 | 0123 | 6 1 2 3 | (0)123 | 0 (1/2 3 | 6/123 | 0 1 2 | က |
| 0 to 3 | | (| , | Ç |) | , | | | | |
| Congestion | 0 1 2 3 | 0 1 (2/3 | 0 1 63 | 0 1 6/3 | 0 1 6 3 | 0 1 (2) 3 | 0 10 2 3 | 0 1 Ø 3 | 0 1 2 | m |
| 0 to 3 | | (| , , |) |) | | | · | | |
| Sneezing | 0 1 2 3 | (0)123 | 0123 | 0 (11) 2 3 | $(6)_{123}$ | (6) 123 | 6/123 | 60123 | 0 1 2 | ო |
| 0 to 3 | _ | | | , | (|)) |) | • | | |
| Voice Hoarse | YES \ NO | YES (VO) | YES (16) | YES (VO) | YES NO | YES (VO) | YES MO | YES NO | YES | 9 |
| N/Y | | |) (|) (|) |) | <u> </u> | (| | |
| Throat Clearing Y/N | YES NO | YES NO | (KES NO | KES/ NO | MES NO | KES NO | (FS) NO | YES NO | YES | 9 |
| DAY PM | T | ~ | 8 | 4 | ß | 9 | 7 | ∞ | 6 | |
| Runny Nose | 0123 | 0 | 0 (1)2 3 | 0 (1) 2 3 | 0 1 (2/3 | 0 1 (2) 3 | 0 ①23 | 0 1 2 3 | 0 1 2 | 3 |
| 0 to 3 | , (| | | | | | • | | | |
| Itchy Nose 0 to 3 | 0123 | Ø 1 2 3 | 0 🗘 2 3 | Ø1 2 3 | (0) 1 2 3 | 0 1 2 3 | 6/123 | 0 1 2 3 | 0 1 2 | m |
| Congestion | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 🖉 3 | 0 102 3 | 0 1 2 3 | 0 1 2 | က |
| 0 to 3 | | • | | | | (| ٧. | | | |
| Sneezing | (0)123 | 0123 | 0123 | 0 (1) 2 3 | 0123 | (0)123 | (C)1 2 3 | 0 1 2 3 | 0 1 2 | ო |
| 0 to 3 |) | (| |) | 4 | (| (| | | |
| Voice Hoarse | YES (NO) | YES (NO) | YES (NO) | YES MO | VES (NO) | ρ ί ν saλ | (ON) SEX | YES NO | YES | NO |
| N/N |) |) | |) |) | |) | | | |
| Throat Clearing Y/N | (ES) NO | XES NO | (KES) NO | (ES) NO | YES NO | ν̃€S) NO | YES NO | YES NO | YES | ON O |
| SCALE 0 to 3 | | | | | | | | | | 1 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N=No

SUBJECT NUMBER:

ALPO 38 DATE COMPLETED: 12/4/13



COLLECT DATE & TIME

Lovelace S iffic Resources Leslie Byatt, crin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME **DRR, DRR**

PATIENT ID **AAGI5588** DOB 10/09/1946

REPORT STATUS Final SEX М

PAGE

PHYSICIAN Unlisted Physician,

12/04/2013 10:16

RECEIVE DATE & TIME 12/04/2013 20:05 PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

12/05/2013 06:16

31033175

0

AKP038

| COMMENTS | : | |
|----------|---|--|
| | | |

| | F | Result | | | |
|----------------------|--|------------------------|----------------|-----------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 140 | | mmol/L | 134-144 | |
| Potassium | 4.3 | | mmol/L | 3.5-5.1 | |
| Chloride | 106 | | mmol/L | 98-111 | |
| CO2 | 26 | | mmol/L | 20-30 | |
| Anion Gap | 8 | | - | 6-14 | |
| Glucose | 63 | | mg/dL | 60-100 | |
| BUN | 31 | | mg/dL | 7-31 | |
| Creatinine | 1.05 | | _ mg/dL | 0,62-1.66 | |
| | Creatinine method is IDMS | | | een adjusted | |
| | Please note new reference | = | | | |
| eGFR non-African Am | >60 | | mL/min/1.73m2 | >60 | |
| GFR Comment | Estimated CED values and a | not accurate in acuto | kidnov foiluma | innationta | |
| | Estimated GFR values are on IV fluids, obese (BMI>) the very old or very young | 34) or underweight (BM | I<20) people. | , inharients | |
| | the very old or very youn | g, races other than Ca | ucasian or Afr | ican American, | |
| Calcium | people with acute illness | es, or amputations. | | | |
| Total Protein | 9.0 7.0 | | mg/dL | 8.4-10.4 | |
| Albumin | 4.1 | | gm/dL | 6.1-8,2 | |
| Globulin | 2.9 | | gm/dL gm/dL | 3.4-4.7 | |
| Bilirubin, total | 0.9 | | | 2.4-4.2 | |
| Alk Phos | 107 | | mg/dL U/L | 0.3-1.2 | |
| AST(SGOT) | 32 | | U/L | 38-150 | |
| AST(SGPT) | 53 | | U/L | 6-58 | |
| Fasting | NO NO | | U/L | 14-67 | |
| • | 2.3 | | mg/dL | 2.3-5.6 | |
| Phosphorus | 2.0 | | mgrac | 2.3-0.0 | |
| CBC WBC | 7.3 | | x10E3 | 4.0-10.6 | |
| RBC | 4.83 | | x10E6 | 4.64-6.00 | |
| Hgb | 15.5 | | gm/dL | 14.5-17.7 | |
| Hct | 46 | | % | 42-53 | |
| MCV | 94 | | fĽ | 81-98 | |
| MCHC | 34.1 | | gm/dL | 31,2-35,2 | |
| RDW | 13.0 | | % | 11.0-14.5 | |
| Platelets | 269 | | x10E3 | 150-400 | |
| Eos, Respiratory | None seen | | A10-0 | NS | |
| Phys. Addr. Phone | NOT GIVEN | | | 110 | |
| LING MUNICIPALITY | 1401 011011 | | | | |

End of Report

10 Dec 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| CIRCLE APPROXIMATE ACSPORSE | WALE ALST S | MAC LVENT IL MOONE | | | | | | ļ | 1 | _ |
|-----------------------------|-------------|--------------------|----------|----------|----------------|-----------------|---------------------|----------------|---------|-------------|
| ΛΔΠ | 7 | 60 | മ | 10 | 11 | 12 | E | , H4 | | |
| AM | [भिष्यात्र | 5)/Solei | 17/04/3 | 51/LOPC! | \overline{g} | 1 2/00/13 | । भव्यात्र ।भावात्र | 51/11/ei | ाम । जा | <u> </u> |
| Runny Nose | 0 1 2 3 | 0 1 2 3 | 0 (T)2 3 | 0 10 2 3 | 0 1 (2) 3 | $0 \ 1 \ 2 \ 3$ | $0 \ 1(2) \ 3$ | O 1 2 3 | 0 1 2 3 | <u></u> |
| 0 to 3 | |) |) |) | | , | , | | , | — [] |
| Itchy Nose | 0 1 2 3 | 6)123 | V1 2 3 | (0)123 | $(6)_{123}$ | 0123 | 0 1 2/3 | 0/1 2 3 | 0 1 2 | M |
| 0 to 3 | | > | • |) |) | , | (| (| | Τ. |
| Congestion | 0 1 2 3 | 0 (02 3 | 0 (1/2 3 | 0 (L)2 3 | 0 1 (2) 3 | 0 (0) 2 3 | 0 1 (2) 3 | 0 (C/2 3 | 0 1 2 | |
| 0 to 3 | | , | ę |) | , (| | | | | Τ, |
| Sneezing | 0 1 2 3 | (6)123 | 0123 | (0)123 | 0/1 2 3 | O1 2 3 | 0 (1/2 3 | 0123 | 0 1 2 | m |
| 0 to 3 | | · (| • | | | 1 | | | | Τ. |
| Voice Hoarse | YES NO | YES (NO | YES (0) | YES (NO) | YES (NO | YES (NO) | YES (NO) | YES (Ng | YES NO | |
| N/A | |) | 6 |) | (1 | |) (| | | - T |
| Throat Clearing | YES NO | WES NO | YES NO | KES NO | (YES NO | (ES) NO | (res) NO | (FE) NO | YES NO | |
| V/V | | , | | • | 4 | 12 | 7 | 14 | 15 | |
| DAY PM | 7 | × | D) | OT . | - 1 | | 3 | 1 | , | 7 |
| Runny Nose | 0 \$ 2 3 | 0 1 (2)3 | 0 1 2 3 | 0 1/2 3 | 0(1)2 3 | 0 (1) 2 3 | 0 1(2/3 | 0 1 2 3 | 0 1 7 | n |
| 0.10.5 | | (| ļ | | 1 | , | 1 | , | , | n |
| Itchy Nose | Ø123 | 0123 | 0 1 2 3 | 0123 | 0 1 2 3 | 0/1/2/3 | 0(1) 2 3 | 0 I 2 3 | 7 1 0 | n |
| Congestion | 0 (T)2 3 | 0 1 (2)3 | 0/1/23 | 0 (1)2 3 | 0 (1) 2 3 | 0 1(2) 3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 | 6 |
| 0 to 3 |) (|) | 2 |) | | | | | | Τ, |
| Sneezing | 0123 | 0)123 | 0123 | 0123 | (0)123 | 0123 | 0(1)2 3 | 0 1 2 3 | 0 1 2 | რ |
| 0 to 3 | (4 |) | , | | | | | | l | Τ, |
| Voice Hoarse | YES (NO | / YES MO | YES (NO) | YES NO | YES (KG) | YES (NO | YES NO | YES NO | YES NO | |
| N/X |) |) _ _ |) |) (|) (| | | | 1 | ٦, |
| Throat Clearing | YES NO | YES) NO | (YES) NO | (ES) NO | YES (NO | (YES NO | (FES NO | YES NO | YES NO | |
| V/V | | |) | | | | | | | 1 |
| C 0+ 0 1 1 0 1 0 | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

DATE COMPLETED: (2/11/3 SUBJECT NUMBER: AKPO38

SUBJECT INITIALS AND DATE:



fic Resources Lovelace Sc Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME DRR, DRR

PHYSICIAN Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

31033180

COMMENTS:

Test

0

PATIENT ID **AAGH5323**

DOB 10/09/1946 SEX M

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

12/11/2013 13:00

RECEIVE DATE & TIME 12/11/2013 19:14

MM 12 Dec 13

PRINT DATE & TIME

12/12/2013 06:13

PATIENT NO.

AKP038

Result

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr. Phone None seen Not given

in Range

NS

End of Report

| LSR Study #: ORR | ovided. * | Relationship to Study Investigator Drug Initials / Date | * wated Willy 12 Jan 14 | | | 1 | / | PAGE: of F |
|---|---|---|------------------------------------|--|--|---|---|---|
| | ADVERSE EVENT LOG * Use DD/MMM/YYYY format for dates. If day is unknown, write UNK in the space provided. * | Action Taken * End Date Rela | the his pet 5 Jan 2014 | | | | | how; to record) affy activities. If y activities. Lovelace Scientific Resources, Inc AdverseEvents 11/2013 |
| Study Identification: 2749 Subject Number: $Akpo38$ | ADV * Use DD/MMM/YYYY format for date: | Adverse Event an "Start Date Severity SAE? | poglycentia No 18/Dec/13 Wild with | | | | | SEVERITY KEY (If severity changes in intensity, refer to protocol on how to reside causes minimal discomfort does not interfere with normal cally activity. Moderate: causes sufficent discomfort to interfere with normal daily activities. Severe: prevents normal daily—tivities. My My My My My London Double Company of the Lovelace Scient Company of the Company of |

| Study Identification _ | 2749 | Subject Initials | _ DRR |
|------------------------|---------|------------------|-------|
| Subject Number: | AKP OSF | Date | 12/B |

Concomitant Medication Sheet

List all medications, including over the counter vitamins & supplements, that you currently take:

| Name Of Medication | Indication | Dose/Unit Frequency | Route | Start Date | Stop Date |
|--|--|--|--|--|--|
| Atendol | HBP, | 50 Mg/dA | PO | 2000 | eng |
| Atorvastatin | Cholesterol | 40mg day | PO | 2013 | ong |
| Azelastina HCI | Itchy oyes | Idrop dis | Eye | 2013 | ong |
| HCTZ | HBP' | 25mg/m | 40 | 2000 | ong |
| LUSARTAN POTASSIUM | HBP | 25 mg/drg | P0 | 2013 | one |
| sultavitymin, | supplement | 1 days | <u>70</u> | 2000 | ong |
| | CAD prophlakus | 1 gurn oth | PU | 2000 | ong |
| Therein TEDIES | Italy Eyes | -PPN | Eye | 2000 | ono_{0} |
| Ч то от техня ператителя и м «М техня то Мато то маке и сруд функту и и принценирова и передования и принцени | · · | энн тай байн тай бүүн ар маган 19 он он тайгаан айсаасын армындары маган ар | endas aktalabeks erroksakserilandas da samusa kapana a agang | | |
| Names — many many many many mine 110 m days or a hall a not many base a many many many many many many many ma | | and (all which the party of manifest which is defined as the contract of the c | · · · · · · · · · · · · · · · · · · · | | |
| tenneriquisgissyn is — is by Mangoning to globally individual physical phys | | Market Market Market Market Market Market Market Market Market Market Market Market Market Market Market Market | (ANIANANI PANIA - PANIA - Propries and secundary and secun | | alle chendracement surren unaspanyassissis 4 visid |
| | : | ow dend to buildings resument the commences the complete and and | politica a companione a menter a contra proprio e con Priblich (P) - cop i com | | معطعات ثبات تجرب المراجعة المراجعة ومراجعة المرا |
| other water experience on the characteristic contribution of the c | PSEARCE Volves, and observe translated to homeet return or exercise. | t Wr 18 yyk hondydd dyndlei fyldar (h Marmonn y dannau y yr 18 _{97) e} ngg gy | array of National VS Salar Carries and assure (addition in the surgeous | ter toperang emploritymentementementementementementementemen | on the confidence of the common property and the condition of the conditions of the |
| nn ann an 1964, ann thair i de 1940 (1960 an 1940). The Beat State and Committee and Adel State And State and Adel State and A | | on homer own) remarks traction to deliver numerops by tracks by a consequence to be a | and and the court of the second court of the s | | Oliva Maria Maria Maria (ang tanggan manang manang manang manang manang manang manang manang manang manang man |
| trokket (damphi na paga kanggar prilik) — gal b Pr. p Walth finda a ana katha a kanggar kahala a ani kahan a kanggar k | an in-farth under der der der der der der der der der | aminanan ilapoilmana padjigan sprijija padjir - ko mode www.nomina-i-je-ford | ð sændaru við jöldir í heljussen eifn viðskrena erns í kvan ha ja neillið se helsindi þjá hjed sjö | | NO let transplante es comment solliere le di a sociali approvene e comme |
| (中で中央大学の大学の1984年)) mg (1950年 かたたけが) k ー サラ がまえがめる は ("511年)gar になっぱ ((かんかけだけ がかっかる a sono) | Androne - Angel Par Class Conference and Colored Spring Print (1997) in the Angel An | n of the state of | kanna dar danda pisaran sadda annigi kajada 378, anal mada add ar da | | dere ver manne with the land that the many pilling have t |
| THE OPERATOR AND ADDRESS OF THE STREET AND ADDRESS OF THE STREET AND ADDRESS OF THE STREET ADDRESS OF THE STRE | | | nggan Padalifah ni Inga Pedialan masasasa samaan iyyan iyyiyi. | | ووسلسو داود الاوليد ووجيدينيس واسترار مناود والعقود داور والإستروب ما الادادات |
| | | | | 1 | gody halls develop the of his property broken as a wideful to the |
| -9)- (Винавыкы попункция инфикатуры) — 19- (Винавыкы инфикатуры) — 19- (Винавыкы инфикатуры) — 19- (Винавыкы и | | | MARKERIAN SOURCEMBER OF STATE TO SECURISE STATE | | arrante afrontesione meso arquitatques (commessandon |
| ttieren gegleigtereid hat demock op tein (d. 180 v.) 16 daarste reikkanskanskan jarok historioon deskrifterst taansk | - Clause - Aller of a referral - Autoback 1974) and ref. 1866 have below read - Autoback 1974 and 1974 and 197 | - Address of the first first for a first for a first first for a first first for a first first for a first first for a first first for a first first for a first first for a first f | andicidina degração servição inter hé histologumble conseste provides de consequent a servi | | diala ferrora sudra a milas an frafator super super a masa mada ber a series |
| And the second s | | The control of the control of the book control of the control of t | en en en en en en en en en en en en en e | The other hands were some some on the state of the | ann an artis de lago sur l'illiga en guitel desse que l'optic |
| | | | institutional the complete desirable for the consideration consideration is a sec | | ورامينات فأراد و ورود المراد والأنوان والأوموارات والمراد والمراد والمراد والمراد والمراد والمراد و |
| | ر و المرافق المرافق المرافق المرافق و المرافق و المرافق في مرافق المرافق في مرافق المرافق المرافق المرافق المرافق | The latest and the same of the | وي موجود و الإنجاب و الإنجاب و الإنجاب و الإنجاب والأناس والإنجاب والمناطق المالية | amus (Q-100) pilot-10 gitisis dapo garan pilothar ay par (1914) saga (1914). | - Bir bal o perghyang perkyahada (The STORM) [Nyapy 1924 perghilik terbanya |
| | INT | Musica Musica | MA Cul. | I IS NO | 2013 |

| INVESTIGATOR SIG | NATURE:/ | 1/XI Mul | funcie | DATE: / | 2 Nov-2013 |
|------------------|----------|----------|--------|-----------|------------|
| CRC SIGNATURE: _ | Erick | mal | duncor | _ DATE: _ | 18/Dec/13 |

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | | 15 | 16 | 17 | 18 | 19 | $\frac{1}{20}$, $\frac{1}{1}$, $\frac{21}{1}$, $\frac{22}{1}$ | , 21, | 22 |
|----------------------|----------|-----------|----------|-----------|----------------------------|-----------|--|---------|---------|
| | 1411/13 | 5/12/13 | 2/13/13 | 12/11/21 | 12/14/13 12/15/13 12/16/13 | 12/10/13 | 17/1/13 | 1918/13 | 12/19 |
| Runny Nose | 0 1 2 3 | 0 10 2 3 | 0 10 2 3 | 0 (1)2 3 | 010300023 | 0 (1) 2 3 | 0 (1) 3 | 0(1)2 3 | 0 1 2 3 |
| Itchy Nose | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | Ø1 2 3 | 0123 | Ó123 | ()1 2 3 | Ó1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1 (2) 3 | 0 (1)2 3 | 0 1 (2) 3 | 0 (023 | 0 (1)23 | 0 (02 3 | 0 (023 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0123 | 0123 | 0123 | 0 (1)2 3 | 0123 | 6)123 | Ø1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (80 | YES (NO | YES (NO) | YES (NO) | YES (NO) | YES MO | YES (NO | YES NO |
| Throat Clearing Y/N | YES NO | (YES) NO | (VE)S NO | (KES) NO | (YES) NO | YES NO | XES NO | (F) NO | YES NO |
| DAY PM | 14 | <u>\$</u> | 16 | 17 | 718 | 19 | σ | 21 | 22 |
| Runny Nose 0 to 3 | 0 1/2 3 | 0 (1/2 3 | 0 1(2)3 | 0 1 (2) 3 | 0(1) 2 3 | 0 (£ z 3 | 0(1/2 3 | 0 1.2.3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 6/123 | 0123 | 0 1 2 3 | 0123 | 0123 | 6/1/2/3 | 0123 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 (1)2 3 | 0 (1/2 3 | 0(1)2 3 | 0 (02 3 | 0 (£) 2 3 | 0 (1)2 3 | 0 (1)2 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0123 | 0/123 | 01 2 3 | 0123 | 0)123 | (0) 1 2 3 | 6/123 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (VO | YES NO | YES (NO) | YES (VO) | VES (NO) | VES NO | YES (NO) | YES NO | YES NO |
| Throat Clearing Y/N | (YES NO | (YES NO | YES NO | (ES) NO | (YES) NO | (Es) NO | KES / NO | YES NO | YES NO |
| | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N=No

SUBJECT NUMBER: ALL

 $3\overline{S}$ date completed:_

SUBJECT INITIALS AND DATE:



Lovelace Sci Ic Resources Leslie Byatt, Can Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME DRR, DRR

PATIENT ID **AAGJ2119**

10/09/1946

REPORT STATUS SEX Final

PAGE

PHYSICIAN Unlisted Physician,

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

12/18/2013 10:15 PATIENT NO.

12/18/2013 18:54

12/19/2013 06:09

31033198

0

COMMENTS:

AKP038

| | Res | ult | | | | |
|------------------------------------|---|---|-----------------------------------|----------------------------------|----------------|----|
| Test | In Range | Out of Range | Units | Reference Range | Site Code | |
| Comp Metabolic Panel | | | | | | |
| Sodium | 142 | | mmol/L | 13 4 -1 44 | | |
| Potassium | 4.2 | | mmol/L | 3.5-5.1 | | |
| Chloride | 107 | | mmol/L | 98-111 | | |
| CO2 | 29 | | mmol/L | 20-30 | | |
| Anion Gap | 6 | | | 6-14 🔏 | 1000 115 | |
| Glucose | voulfied by manual 1i- | 44 , *L | mg/dL | 60-100 // /X | PUNS DECOIS | |
| PM 4 1 k 1 | Verified by repeat analysis | See below | | 10 | 1 DOC 2013 | |
| BUN | 29 | Tee vice | mg/dL | 7-31 | 1 | |
| Creatinine | U.98 | | mg/dL | 0.62-1.66 | | -2 |
| | Creatinine method is IDMS to | | | een adjusted. | | |
| | Please note new reference r | ange effective 5/23, | | | | |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | | |
| | Estimated GFR values are no | t accurate in acute | kidney failure, | inpatients | | |
| | Estimated GFR values are no on IV fluids, obese (BMI>34 the very old or very young, people with acute illnesses, |) or underweight (BM races other than Ca or amoutations | 41<20) people, aucasian or Afr | ican American, | | |
| Calcium | 9.5 | | mg/dL | 8.4-10.4 | | |
| Total Protein | 7.2 | | gm/dL | 6.1-8.2 | | |
| Albumin | 4.3 | | gm/dL | 3.4-4.7 | | |
| Globulin | 2.9 | | gm/dL | 2.4-4.2 | | |
| Bilirubin, total | 0.8 | | mg/dL | 0.3-1.2 | | |
| Alk Phos | 116 | | Ŭ/L | 38-150 | | |
| AST(SGOT) | 33 | | U/L | 6-58 | | |
| ALT(SGPT) | 51 | | U/L | 14-67 | | |
| Fasting | NO | | | | | |
| Phosphorus | 3,1 | | mg/dL | 2.3-5.6 | | |
| CBC | | | | | | |
| WBC | 7.9 | | x10E3 | 4.0-10.6 | | |
| RBC | 4.91 | | x10E6 | 4.64-6.00 | | |
| l-lgb | 16.0 | | grn/dL | 14.5-17.7 | | |
| Hct | 46 | | % | 42-53 | | |
| MCV | 94 | | fL | 81-98 | | |
| MCHC | 34.9 | | gm/dL | 31.2-35.2 | | |
| RDW | 12.9 | | % | 11.0-14.5 | | |
| Platelets | 284 | | x10E3 | 150-400 | | |
| Eos, Respiratory | None seen | | | NS | | |
| Phys, Addr, Phone | Not given | | | | | |

Callback Accession Comments:

W3494863

GLU

12/18/2013 08:10 pm GIVEN TO luchi s NC CS11630

End of Report

nudication likely to decrease blood glucose. Will contact patient, who was asymptomatic in office for exam yesTerday, 18 Dec 2013.

12/19/2013 06:09

19 Dec 2013

FAX24664

DRR, DRR

DRR/AKP038

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE: Would you use / purchase this nasal wash product in the future?" ☐YES ☑NO You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary:

[Type text]
Subject initials and Date DWR 12/18/13 and Date PM 12/18/13

AKP-039

2,49 AKPharma PERENNIAL ALLERGIES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIENT | DEMOGRAPHICS | |
|---------------|------------------------------|--|
| Patient I | Demographics | |
| Date of B | irth: 13 , Feb, 4 | 962 (dd/mmm/yyyy) |
| Gender: | irth: 13 , Feb , 16 | Female |
| If female, | Indicate Childbearing Potent | tial |
| | Childbearing [| Surgically sterilized Post-Menopausal |
| Ethnicity: | Hispanic Non Hi | ispanic |
| Race: |] Asian 🔲 Black 🔲 | Caucasian American Indian |
| | Pacific Islander Othe | er, Specify |
| | | |
| Smoking. | History | |
| Smoking S | tatus: None (smoked les | ss than 100 cigarettes in lifetime) |
| | Former (previous | ely smoked more than 100 cigarettes in lifetime) |
| | Current (smokes r. | now) |
| If subject is | a former or current smoker, | , please indicate: |
| | s smoked: | Cigarettes per day: |

Version: 02 September 2013



DAB

Lovelace Sc ific Resources Leslie Byatt, Cun Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME EAW, EAW

PATIENT ID **AAGH8333**

SEX 02/13/1962 F

REPORT STATUS Final

PAGE

PHYSICIAN

COLLECT DATE & TIME 11/18/2013 10:05 RECEIVE DATE & TIME 11/18/2013 20:28 PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

11/20/2013 06:09

30920942

AKP039

COMMENTS:

| Test |
|--|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach |
| Allerg,Derm. pter. |

| | Result | | | | |
|--|------------|----|-------|-----------------|-----------|
| In Range | Out of Ran | ge | Units | Reference Range | Site Code |
| <0.10 | | | kU/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| NCS | 0.90 | Н | kŲ/L | <0.35 | |
| <0.10 Of 11 | 22/13 | | kU/L | < 0.35 | |
| <0.10 \T \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | | | kU/L | <0.35 | |
| MAS | (0.70 | Н | kU/L | < 0.35 | |
| <0.10 06/1/2 | 2/12 | | kU/L | <0,35 | |
| <0.10 | 413 | | kU/L | <0.35 | |
| <0.10 (0.10) <0.10 | | | kU/L | <0.35 | |

The standard classification system utilizes the following class cutoffs. class ku/L Interpretation

| 0 | <0. 35 | Negative for Allergen |
|-------|--------------|-----------------------|
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| V | 52. 5-99. 99 | Strongly Positive |
| VI VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-vI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| <0.35 |
|--------|
| <0.35 |
| <0.35 |
| <0.35 |
| <0.35 |
| < 0.35 |
| < 0.35 |
| <0.35 |
| < 0.35 |
| |

End of Report

Jahrer PI 22/1/00 2013



Lovelace Scientific Resources 2 11 Ridgecrest Dr SF 2 /1 Ridgecrest Dr SE Albuquerque, NM 87108

Name: EAW,

Gender: Female

Age: 51

Race: Black

Height(in): 66.0

Weight(lb): 281

Any

Id: AKP-039

Date: 12/03/13

Flow

6

2

0

-2

-6

0

3

1_{Volume} 2

Temp: 19

PBar: 625

Physician:

Post % Chg

| Info: | | | | Technician: VL |
|-------|--------|--------|---------|----------------|
| | (BTPS) | PRE-RX | POST-RX | Flore |

| 0.1 | (BTPS | 3) | PRE | -RX | POS | T-RX |
|-------------|---------|-----|---------|-------|------|-------|
| Spirometry | F | Ref | Pre | Pre | Post | Post |
| | | N | ∕leas % | 6 Ref | Meas | % Ref |
| FVC Lit | ters 3. | 40 | 2.02 | 59 | | |
| FEV1 Lit | ters 2. | 79 | 1.92 | 69 | | |
| FEV1/FVC % | | 83 | 95 | 114 | | |
| FEF25-75%L/ | sec 3. | 06 | 3.73 | 122 | | |
| FEF50% L/ | sec 3. | 73 | 5.53 | 148 | | |
| FEF75% L/ | sec 1. | 45 | 2.08 | 144 | | |
| IC Li | ters | | | | | |
| VC Li | ters 3. | 40 | | | | |
| PEF U | sec 6. | 20 | 6.89 | 111 | | |
| | | 99 | | | | |
| | sec | | 2.42 | | | |
| FEV1/FEV6% | • | | 98 | | | |
| Lung Vo | hy | (E | TPS) | | | |

| Vtg | Liters . | |
|--------|----------|------|
| vč | Liters | 3.40 |
| TLC | Liters | 5.37 |
| RV | Liters | 1.92 |
| RV/TLC | % | 35 |
| FRC PL | Liters | 2.01 |
| ERV | Liters | |
| IC | Liters | |

Diffusion

DLCO mL/mmHg/min 30.4
DL Adj mL/mmHg/min 30.4
DLCO/VA mL/mHg/min/L 3.33 Liters VΑ

BHT

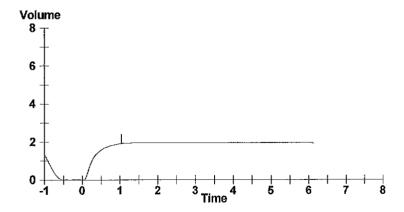
Sec Resistance

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec

Raw cmH2O/L/sec L/sec/cmH2O 0.481 Gaw sRaw cmH2O/L/s/L 3.99 L/s/cmH2O/L 0.251 sGaw

Vtg (Raw) Liters

Comments:







Levelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP-039,

Gender: Female

Age: 51

Race:

Height(in): 66.0

Weight(lb): 281

Any Info:

Id: AKP-039 Date: 12/10/13

Temp: 16

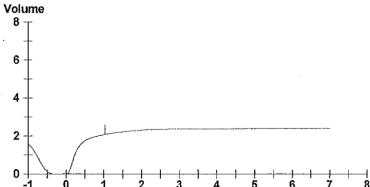
PBar: 637

Physician:

Technician: CRD

| Any Info: | | | | | | l echniciar | n: CRD | |
|--|--|------------------------------------|---|-------------------------------------|------------------------------|---------------|------------------------|-----------------------------|
| Spirometry | (BT | PS) Ref | PRE-R Pre Meas % | Pre | POST-RX Post Post Meas % Ref | Post % Chg | Flow 8 _T | |
| FEV1 L FEV1/FVC % FEF25-75%L FEF50% L IC L VC L PEF L MVV L PIF L FEV1/FEV6% | iters 6 /sec /sec /sec /sec liters /sec /min /sec | 1.45 3.40 6.20 99 | 2:40 2:12 88 3:11 ** 5:79 1:26 6:76 2:76 89 | 71 76 106 102 155 87 | (BTPS) | , | 6 4 2 2 0 | |
| Vtg L VC L TLC L RV L RV/TLC 9 FRC PL L ERV L IC L Diffusio DLCO n DL Adj n DLCO/VA n | iters iters iters iters iters iters iters iters iters on iters on iters on iters | 3.40 5.37 1.92 35 2.01 | | • | | | -4 -6 -1 | 0 1 _{Volume} 2 3 4 |
| Resista Raw Total of Raw Insp of Raw Congress Co | mH2O/L/sec mH2O/L/sec mH2O/L/sec mH2O/L/sec /sec/cmH2O 0 mH2O/L/s/L | 1.99 .481 3.99 .251 | | | | | | |
| Vtg (Raw) L | ıters | | | , | | | | |





Version: IVS-0101-20-5B



Lovelace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108

Name: EAW,

Gender: Female

Age: 51

Race: Black

Height(in): 66.0

Weight(lb): 281

Any Info:

Id: AKP-039

Date: 12/17/13

Temp: 18

PBar: 638

Physician:

Technician: VL

| Oi | (B) | TPS) | PR | E-RX | POST-RX | <u> </u> | Flow | | | | |
|-----------|--------------|----------|------|-------|-------------|----------|-----------------------|-------------|---------------|---|---------------|
| Spiromet | ry | Ref | Pre | Pre | Post Post | Post | 8 ∓ | | | | |
| | | | | % Ref | Meas: % Ref | % Chg | | | | | |
| FVC | Liters | 3.40 | 2.34 | 69 | | | † | \wedge | | | |
| FEV1 | Liters | 2.79 | 2.11 | 76 | | | 6 | / \ | | | |
| FEV1/FV0 | ; % | 83 | 90 | 109 | | | • | / / | | | |
| FEF25-75 | %L/sec | 3.06 | 2,94 | 96 | | | + | / / | | | |
| FEF50% | L/sec | 3.73 | 4.68 | 125 | | | | - 1 | \ | | |
| FEF75% | L/sec | 1.45 | 1.29 | 90 | | | 4 🕆 | - 1 | | | |
| IC | Liters | | | | | | 1 | 1 | \ | | |
| VC | Liters | 3.40 | | | • | | | | \ | | |
| PEF | L/sec | 6.20 | 7.05 | 114 | | | 2 + | l | \ | | |
| MVV | L/min | 99 | | | | | | | X | | |
| PIF | L/sec | | 2.63 | | | | Ť | - 1 | \ \ | | |
| FEV1/FEV | | | 93 | | | | 0 | | - | | 1 |
| Luna \ | /olumes/F | Plethysm | ogra | phv | (BTPS) | | - | / | ~~~ | | |
| | Liters | • | 9 | , , | | | T | | | | |
| Vtg VC | Liters | 3.40 | | | | | -2 | | \ | | |
| TLC | Liters | 5.37 | | | | | ľ | | V | | |
| RV | Liters | 1.92 | | | | | † | | | | |
| RV/TLC | % | 35 | | | • | | -4 | | | | |
| FRC PL | 70 Liters | 2.01 | | | | | , | | | | |
| ERV | Liters | 2.01 | | | | | † | | | | |
| IC ERV | Liters | | | | • | | 6 | | | | |
| | | | | | | | -6 [⊥] -1 | 0 : | 1 2 | 3 | 4 |
| Diffusi | | | | | | | -• | • | l 2 Volume | • | • |
| DLCO | mL/mmHg/min | | | | • | | | | | | |
| DL Adj | mL/mmHg/min | | | | | • | | | | | |
| | mL/mHg/min/L | 3.40 | | | | | | | | | |
| 1.7.6 | 1.74 | | | | | | | | | | |

Resistance

VA

BHT

 Raw Total
 cmH2O/L/sec

 Raw Insp
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec

 Raw
 cmH2O/L/sec
 1.99

 Gaw
 L/sec/cmH2O
 0.481

 sRaw
 cmH2O/L/s/L
 3.99

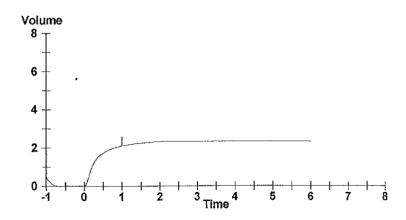
 sGaw
 L/s/cmH2O/L
 0.251

Liters

Sec

Vtg (Raw) Liters

Comments:



Interpretation:

() = OUTSIDE 95% CONFIDENCE INTERVAL

Norm Set: Knudson (1983)

Version: IVS-0101-20-5B







Lovelace Scientific Resources 1 Ridgecrest Dr SE Arouquerque, NM 87108



Name: AKP-039,

Gender: Female

Age: 51

Race:

Height(in): 66.0

Weight(lb): 281

Any Info:

ld: AKP-039 Date: 12/23/13

Temp: 18

PBar: 637

Physician:

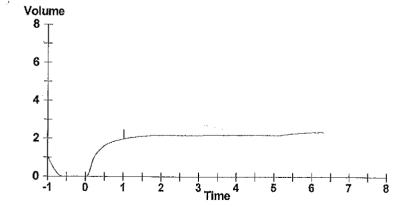
Technician: CRD

| Spirometr | , (B | TPS) | PRE | E-RX | POS | T-RX | • | Flow | The state of the s |
|--------------------------------------|---|----------------------------|------------------------------------|--------------------------------|------|-------|-------|------------|--|
| obitomen | у | Ref | Pre | Pre | | Post | Post | Flow 8⊤ | |
| FVC FEV1 FEV1/FVC FEF25-75% | | 3.40 2.79 83 3.06 | Meas 2.36 2.03 86 2.43 | % Ref 69 73 103 79 | Meas | % Ref | % Chg | 6 | |
| | L/sec L/sec Liters | 3.73 1.45 | 3.88 0.87 | 104 60 | | | | 4 | |
| VC PEF MVV P(F | Liters L/sec L/min L/sec | 3.40 6.20 99 | 6.92 2.18 | 112 | | | | 2 | |
| Lung V | ™ ′olumes/F | ethysmo | 86 grap | ohy | (B | TPS) | | 0 | |
| Vtg VC TLC | Liters Liters Liters | 3.40 5.37 | | | | | | -2 | |
| FRC PL | Liters % Liters | 1.92 35 2.01 | | | | | | -4 | |
| Diffusio | | | | | | | | -6-1 0 | Volume 3 4 |
| DL Adj DLCO/VA VA | mL/mmHg/min mL/mmHg/min/L mL/mHg/min/L Liters Sec | 30.4 30.4 3.40 | | | | N. | | | VOIGHIS |

Resistance

 Raw Total Raw Insp
 cmH2O/L/sec c

Comments:



EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

| | - Next-Joseph | # | m | m | | 3 Mon 3 | | <u> </u> | | | г о | ന | m | ON | ON |
|--|---|----------------------------|----------------------|----------|-------------|--------------------|--------------|-----------------|--------|------------|------------|-------------|-----------------|---------------------|-----------------|
| | 5 | 12/3 | 7 (0) | (C) 2 | 0 1(2)3 | 0 5 | (YES) NO | VES NO | 0 | 0 1 2 | 0 1 2 | 0 1 2 | 0 1 2 | YES | YES N |
| | ÷ | 7/7/ | 1 2 3 | ന | 0 1(2)3 | Ot 2 3 | (YES) NO | (YES) NO | | 0 (1)2 3 | 0(1)2 3 | 0 1(2)B | | YES (NO) | (YES) NO |
| OMFORT | | $\left(\frac{1}{2}\right)$ | 0 1 2 3 | 0)123 | 0 1(2) | 0)123 | NO (YES) NO | (YES) NO | -1 | 0 (1)2 3 | 0(1)2 3 | 0 1(2) | <u></u> | YES (NO | (YES) NO |
| ATHING CO | | 11 3 0 | 0 1 2 3 | 0 (1)2 3 | 0 1(2)3 | 0 2 3 | YES | (YES) NO | -2 | 0 1 2 3 | 01 2 3 | 0 1(2)3 | 0 2 3 | YES (10 | (YES) NO |
| CEIVED BRE | | 13 | O 123 | (C)1 2 3 | 0 1 (2)3 | 6 1 2 3 | YES (NO) | (ES) NO | -3 | 0 D2 3 | 01 2 3 | $0 \ 1(2)3$ | 01 2 3 | YES (NO) | (YES) NO |
| ON PATIENT-PERCEIVED BREATHING COMFORT | ç | 4-11 | 0 (1)2 3 | 0)123 | $0 \ 1(2)3$ | 01 2 3 | (ES) NO | YES) NO | 4 | 0(1)2 3 | 0 2 3 | 0 1(2)3 | 0123 | YES (NO | (YES) NO |
| ON P | REEN DIARY <i>HOURS</i> | 1,57 | O123 | 0123 | $0.1(2)^3$ | 0123 | (YES) NO | (ES) NO (| Ţ. | 0123 | 01 2 3 | 0 1 (2) B | 6 2 3 0 2 3 | YES NO | (YES) NO |
| IS OF ANY | : SHEET (SC USE EVERY 12 | 11/2.12 | 0123 | 0123 | 0 1 (2) 3 | O _{1 2 3} | YES (NO) | (FES) NO | 9- | 0 (1)2 3 | 0 (1)2 3 | 0 1(2)3 | 0123 | YES (NO) | (YES) NO |
| 7111 | OMS SCORE | 11 25 | 0 1 2 3 | O1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO | YES NO | -7 | $0(1)^2$ 3 | 0123 | 0 1(2)3 | 0123 | YES (NO | (YES) NO |
| | DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY) | DAY | Runny Nose 0 to 3 | lose | Congestion | Sneezing 0 to 3 | Voice Hoarse | Throat Clearing | DAY PM | Runny Nose | lose | Congestion | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes $\,$ N= No $\,$

SUBJECT NUMBER: ALP DS 7 DATE COMPLETED: 12/3/13

SUBJECT INITIALS AND DATE:



Lovelace S tific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME X, EAW

PATIENT ID **AAGI4838** ^{DOB} **02/13/1962**

F

REPORT STATUS Final

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO. PT. PHONE NO. COLLECT DATE & TIME 12/03/2013 14:30 RECEIVE DATE & TIME

PRINT DATE & TIME

0

PATIENT NO.

12/03/2013 19:55

12/04/2013 06:08

30920933

AKP039

| Result | | | | | | |
|------------------------------------|--|---|------------------------------------|--|------------------------------|--------------------|
| Test | In Range | Out of Rang | jo | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 142 | | | mmol/L | 134-144 | |
| Potassium | 4.0 | | | mmol/L | 3,5-5,1 | |
| Chloride | 108 | | | mmol/L | 98-111 | |
| CO2 | 27 | | | mmol/L | 20-30 | |
| Anion Gap | 7 | | | | 6-14 | |
| Glucose | 99 | | | mg/dL | 60-100 | |
| BUN | 13 | | | mg/dL | 7-31 | |
| Creatinine | 0.73 | | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | traceable. Est | tGFR Cal | culation has be | een adjusted | |
| | Please note new reference | range effectiv | ve 5/23/ | 2013. | | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| O. IX OVIDAIGH | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | ot accurate in 4) or underwer , races other s. or amoutate | n acute i ight (BM) than Car | kidney failure, I<20) people, ucasian or Afr | inpatients ican American, | |
| Calcium | 9.1 | o, or unpucat | 101134 | mg/dL | 8.4-10.4 | |
| Total Protein | 7.3 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.7 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.6 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.3 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 100 | | | U/L | 38-150 | |
| AST(SGOT) | 18 | | | Ú/L | 6-58 | |
| ALT(SGPT) | 29 | | | U/L | 14-67 | |
| Fasting | NO | | | 4,- | 17-01 | |
| Phosphorus | 4.3 | | | mg/dL | 2.3-5.6 | |
| CBC | * | | | | 2.0 0.0 | |
| WBC | 8.6 | | | x10E3 | 4.0-10.6 | |
| RBC | 4.47 | | | x10E6 | 4.00-5.36 | |
| Hgb | •••• | 11.8 | L | gm/dL | | sad idada |
| Hct | 39 | 11.0 | <u> </u> | % | 36-48 | Com Mari |
| MCV | 86 | | | fL. | 81-98 | ۸ |
| MCHC | 50 | 30.6 | t_ | gm/dL | 31.2-35.2 | Me inan |
| RDW | | 15.3 | H | 9117GL % | | 14 - 26) |
| Platelets | 310 | 1010 | £1 | x10E3 | 150-400 | CG WWW |
| Eos, Respiratory | VIU | Few | * | VIACO | NS | -y + 6, |
| Phys, Addr, Phone | NOT GIVEN | 1. GAA | | | 51 BN | cs Mini. Dec 13 |
| | | | | | | |

End of Report

MM 2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| CINCLE APPROAINIAIE RESPONSE EVENT 12 HOURS | VIAIL ALSE | ואסר דעיווי זב | 2000 | | | | | | | [|
|---|------------|----------------------|--------------|----------------|--------------------|------------------|-------------------|-----------|----------------|----|
| DAY | H | 7 | m. | 4. | 2 | | ۲. | ∞ | ත _් | |
| AM | 12/3/13 | 12/4/13 | 12/5/13 | 12/10/13 | 12/7/13 | | 12/8/13/12/9/13/2 | 12/10/13 | 1/11/21 | 3 |
| Runny Nose 0 to 3 | 10 1 2 3 | 0 1 2 3 | 0123 | 0123 | G _{1 2 3} | (O) 1 2 3 (O) | 0123 | (U123 | 0 1 2 | ń |
| Itchy Nose 0 to 3 | 0 1 2 3 | Ø1 2 3 | 1 2 3 | 0123 | 0,123 | 0123 | 0123 | O1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0 1 2 3 | 0 1(2)3 | 0 1(2)3 | 0 1(2)3 | 0 1(2)3 | 0 1 2 3 | 0(1)2 3 | 0 (1.72 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1 2 3 | 2 3 | O1 2 3 | (O)1 2 3 () | O1 2 3(| 0123 | Q 2 3 (| 0/1 2 3 | 0 1 2 | 33 |
| Voice Hoarse Y/N | YES NO | (ES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (ES) NO | (YES) NO | YES NO | 0 |
| Throat Clearing Y/N | YES NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | VES NO | YES NO | 0 |
| DAY PM | τ- | 7 | 3 | 4 | 5 | . 9 | 7 | ∞ | 6 | |
| Runny Nose 0 to 3 | 0(1)2 3 | 0(T) 2 3 | 0 1 2 3 | 0 2 3 | (O)1 2 3 | 0(1)2 3 | 0(1)2 3 | 0 1 2 3 | 0 1 2 | က |
| Itchy Nose 0 to 3 | 0(1)2 3 | $\bigcirc^{1\ 2\ 3}$ | 0 1 2 3 | 0 2 3 | (0) 2 3(| 0)123 | (0) 2 3 | 0 1 2 3 | 0 1 2 | 33 |
| Congestion 0 to 3 | 9 1 (2) 3 | 0 1(2)3 | 0 1 (2)3 | 0 1(2)3 | 0(1)2 3 | 0(1)2 3 | 0 1(2)8 | 0 1 2 3 | 0 1 2 | က |
| Sneezing 0 to 3 | 0123 | (0)123 | 0123 | (O) 1 2 3(| 0 2 3 | \bigcirc 1 2 3 | (0) 23 | 0 1 2 3 | 0 1 2 | 3 |
| Voice Hoarse Y/N | YES (NO | YES NO | YES (NO) | YES (NO | YES (NO) | YES (NO | YES (NO | YES NO | YES NO | 0 |
| Throat Clearing Y/N | YES NO | (YES) NO | (YES) NO | (VES) NO | (YES) NO | (YES)NO (| YES NO | YES NO | YES NO | 0 |
| C -+ 0 L 1 V J J | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) 2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

Y=Yes N= No

SUBJECT NUMBER:

DATE COMPLETED: 13/10/13

SUBJECT INITIALS AND DATE: EAW 12/10/2017



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sci ic Resources Leslie Byatt, Cun Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME EAW, EAW

PATIENT ID

AAGH8333

DOB SEX 02/13/1962

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

31033179

COMMENTS:

PT. PHONE NO.

0

COLLECT DATE & TIME 12/10/2013 14:12 RECEIVE DATE & TIME 12/10/2013 20:09

PRINT DATE & TIME 12/11/2013 09:17

PATIENT NO.

AKP039

Result

Test

In Range

Out of Range

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

NOT INDICATED

Rare

End of Report

1000 13 11 Dec 2013

FAX24664

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | 7 | m | m | m | m | _ | | | m | m | က | 3 | | |
|----------|--------------------------|----------------|--------------|----------------------|--------------------|---------------------|------------------------|--------|----------------------|------------------------|----------------------|--------------------|---------------------|-------------------|
| 2 | × | 7 | 7 | 7 | 7 | 8 | NO NO | 22 | 7 | 7 | 2 | 7 | NO | N N |
| 4 | 11 | L | 0 1 | 0 1 | 0 1 | YES | YES | 7 | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES |
| , | 5 | <u>ო</u> | m | 3 | m | <u> </u> | | | m | m | 33 | m | | |
| 21 | \lesssim | 7 | 2 | 0 | 7 | ON Email | ON NO | 21 | 7 | 7 | 7 | 7 | NO | ON |
| ., | 141 | (5) | 0 | 0 1 | 6 | (YES | (ES) | | 0 1 | 0 1 | 0 1 | 0 1 | YES | YES |
| , | IJ | m | m | 2 | m | ON | N ON | | m | m | m | m (| <u>S</u>) | NO |
| 20/ | 9 | 11 2 | 1 2 | | 1 2 | - | our of | 20 | | $\widehat{\mathbb{Q}}$ | | | | |
| | 1 | <u> </u> | (e) | 0 | 0 | (E) | () | |) O | 0 | 0 | (e) | YES | (YES |
| 7 | $\widetilde{\mathbb{Z}}$ | 2.3 | 2 3 | (Z) | 2 3 | NO | 8 | | الا 3 | 2 3 | 2 3 | 2 3 | <u></u> 9) | NO |
| 19 | 7 | -1 | | H / | 77 (| (E) | YES. | 13 | (\exists) | 1 | 7 | 7 | YES (| YES |
| | 3/2 | 3(0) | 3 | 8 | ر ا ا | | | | 3 | 3(0) | 0 (| 9) m 4 | _ | |
| 18 | 1/2 | 5. | 2 1 | 3 | 2 | ON (| ON (| 200 | 2 | 2 | 7 | ~ (| 9 | NO |
| 4 | 177 | \bigcup_1 | (<u>1</u>) | 0 / | 5 | | | -4 | 9 (| 3 |) 0 | 5 | ES V | (ES) |
| | /3 | 8 | m | R | m | ON. | S S | | m | m | т | m (| 9 | ON |
| 17 | 13/ | 1 2 | 1 2 | $\frac{1}{2}$ | 1 2 | | | 17 | $\frac{1}{2}$ | 11 2 | (1) | 7 2 | | |
| | 12 | \odot | 0 | 0 ' | (9 | (E) (| | | 0 | 9 | 9/ | (9) | YES / | (KES |
| , | 413 | ž 3(| 2 3 (| (2) | 2 3 | ON O | 9 | | 2 3 | 2 3 | 2 3 | 2 3 | (2) | 9 0 0 |
| 197 | 71: | 7 | 」 | Ψ, | | | YES | 16 | Ö, | 7 | (D) | | YES (| YES |
| <u> </u> | 3 1. | (b) | (<u>o</u>) | 0 | (e) | | | | 0 (| 9 | 0 1 | (ف | \sim | |
| 10 | US | 2 3 | 2 3 | (2) | 2 3 | S S | 8 | 12 |)2 3 | 2 3 | 3 | 2 3 | (g) | NO NO |
| Ĺ, | 7// | \int_{1}^{1} | 5 | [| 6 | | YES | 15 | 0 | \tilde{O}_1 | | 0 | YES | YES) |
| | - | 8 | 6 6 | 8 | <u>κ</u> | 1 | | | ж ж | 3 | 8 | 3 | (S) | |
| 14 | 20 | 0 1 2 3 | 2 | 7 | 2 | ON | <u>Q</u> | 14 | 1 | 1 | | 2 | 1 | ON (|
| , 14 | 12/1 | 0 1 | 0 1 | T | 10 | YES | YES | | 012 | 0(1)2 | 0(1)2 | 0)1 2 | YES | YES |
| | -11 | - Similare | | | 1 | ۵ | | | | | | | ۵ | Throat Clearing / |
| DAY | AM | Vose | ose | tion | <u>∞</u> | loars | Clear | PM | Nose | ose | tion | B | loars | Clear |
| ۵ | Ā | Runny Nose | Itchy Nose | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | roat |
| | | Ru | Itcl | ပြီး င် | Snic | % \{ \ | Throa Y/N | | Ru O t | ltc. | ် ဂိ | Sn | Voice Y/N | F > |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable) 3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

g date completed: SUBJECT NUMBER:

SUBJECT INITIALS AND DATE: EHW (2417/2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scie Resources Leslie Byatt, Chin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME EAW, EAW

PATIENT ID DOR **AAGH8333** 02/13/1962 SEX F

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 12/17/2013 13:30

RECEIVE DATE & TIME 12/17/2013 19:17

PRINT DATE & TIME 12/18/2013 07:01

31033199

0

PATIENT NO.

COMMENTS:

AKP039

Result

Test

In Range

Out of Range

Norm Sub-I 18 Dec 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Not given

NS

End of Report

| LSR Study #: | Subject Initials: | | Action Taken Investigator Initials/Date | | | | | | | | e as specific as possible** | 23 Jae 2013 | de 12/3/13, | PAGE: |
|----------------------------|-------------------|-------------------|---|--|----|----|---|--|--|---|--|---|---------------------------------|--|
| 57 | วร | (7) | ** End Date (DD/MMM/YYYY) | | | | 2 | | | | ould be made to b | Date: 2 | k) | ints 04/2013 |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | | | 9) | | | | | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | Mutino no | che ma | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 |
| | 0 | | SEVERITY | | 5/ | - | | | | | ite UNK in space | 1/100 × (A | 8 | LOV |
| 5710 | AKP039 | | ** Start Date (DD/MMM/YYYY) | | | | | | | - | day is <u>unknown,</u> w | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: 2749 | Subject Number: | | Adverse Event | | | | | | | | ** | Investigator Signa | SC Signa | |

ij

1

Study Identification: <u>ALPhum</u> Subject Number:

LSR #:

Subject Initials:

CONCOMITANT MEDICATION LOG

List all prescription medications you are taking. Also include over-the-counter medications, vitamins and supplements,

| Ongoing at EOS (for Clinicuse) | | X | X | X | S | | Ž | X | | | X | |
|--------------------------------------|-------------------------|-------------|------------|------------|------------|-----------------------|--------------|------------|----------|------------|--------------|----------|
| Stop Date | | | | | | | | | 5102/01 | 11/11/2013 | | |
| * Start Date (Day/Month/Year) | UNK/AUG/1999 | 2008. | 2002 | colo | 2002 | 2002 | 5000 | 2005 | 2010. | 2010. | 2010. | |
| Route | Öral | O d | 00 | Po | PB | 00 | Po | 00 | 60 | 60 | dos. | |
| Frequency | 2 Tabs per Graday Am | QQ | QO. | 20 | QD | an | 00 | QO | - Pro | pen | pro | • |
| Unit | MG | £ | tab | Ę | 76 | 44 | MG | , & | SW | MY | drog | , |
| Dose | 500 | 2 | - | 0001 | 1.001 | ĺ | 400 | 00 / | 10 | 40 | 1 | |
| Indication (What you take it for) | Diabetes | CADPROPAGES | Sugalement | Supplement | Sigolement | per Bungly Sugglement | In delicency | swaplement | allegics | allusies | or alleges | D |
| Name of Medication | EXAMPLE | £2# | MVI | Both | V.t. D3 | Super Bangle | Folic Aced | 6010. | 2xtec | Allega | Zachbroyedap | |

)

* If day or month of medication date is unknown, write UNK in space provided

Investigator Signature (at end of study):

SC Signature (at end of study): 人人

ţ

Lovelace Scientific Resources, Inc - ConMeds 04/2013

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| ۸۷۷ | 17 | 1, | 16 | 17 | 18 | 10 | 20 | 7.2 | | 22 |
|----------------------|-----------------------|--------------------|----------------|------------------|------------------|------------------|---------------|--------|---------|--------|
| AM | 12/11/3 | 12/18/19 | 12/19/12 | 12 | 7 | 13/22/13 | 12/23/2 | 1/2/21 | 14 | 125/1 |
| Runny Nose | 0 1 2 3/ | (0)123/ | 0)123 | (6)123 | $(0)_{123}$ | 0)123 | (0)123 | 0 1 2 | 3 | 1 2 3 |
| 0 to 3 | _ |) (|) (|) { |)(|) |) (| | | |
| Itchy Nose | 0 1 2/3 | $(0)_1 \ 2 \ 3($ | (0)123 | L 2 3 | 6 2 1 2 3 | 0123 | (0123 | 0 1 2 | 3 0 | 123 |
| 0 to 3 | _ |) |) | (| (| () | | | | |
| Congestion | $0.1\ \frac{1}{2}\ 3$ | 0.1(2) | 0.1(2) | $0(1)^{2}$ 3 | 0 1(2)3 | $0.1 \bigcirc 3$ | 0 1(2)3 | 0 1 2 | 3 0 | 123 |
| 0 to 3 | anne. |) |) |)(| | 4 | | | | |
| Sneezing | 0 1/2 3 | $\bigcirc 1 2 3 ($ | 0 1 2 3 | (0)123 | $(0)^{1}$ 2 3 (| 0123 | (0)123 | 0 1 2 | 3 0 | 123 |
| 0 to 3 | | , - (| <u> </u> |) (|) (| (| 9 | | | |
| Voice Hoarse | YEŚ NO | (YES) NO | (YES) NO | (YES) NO | (VES) NO | (YES) NO | (KES) NO | YES NO |) YES | ON |
| N/N | - | (|) (| (| (| * | (| | | |
| Throat Clearing | YES NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO (| YES) NO | (YES) NO | YES NO |) YES | 9 |
| N/N | ~7. |) |) |) |) |) |) | | | |
| DAY PM | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | | 22 |
| Runny Nose 0 to 3 | (O)1 2 3 | 0(1)2 3 | (b)1 2 3 | 0(1)2 3 | 0(1)23 | 0(1)23 | 0 1 2 3 | 0 1 2 | 3 0 | 123 |
| Itchy Nose 0 to 3 | 0(1)2 3 | 0(1)2 3 | O <u>1</u> 2 3 | 6)123 | O 1 2 3 | 0 2 3 | 0 1 2 3 | 0 1 2 | 3 0 | 1 2 3 |
| Congestion 0 to 3 | 0 (2 3 | O 1 2 3 | 0(1)2 3 | 0 (1)2 3 | 0 (02 3 | $0(1)^2$ 3 | 0 1 2 3 | 0 1 2 | 3 0 | 1 2 3 |
| Sneezing (| 0)123 | O 2 3 | 0123 | $\bigcirc 1 2 3$ | () 2 3 l | (<u>)</u> 2 3 | 0 1 2 3 | 0 1 2 | 3 0 | 123 |
| 2010 | | İ | ľ | | - | | | | | |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO | YES NO | VES NO | YES (NO) | YES NO | YES NO |) YES | ON |
| Throat Clearing Y/N | (YES) NO | (YES) NO | (YES) NO | (YES)NO | (ES) NO | (YES) NO | YES NO | YES NO |) YES | N S |
| COALCIONS | | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER:

DATE COMPLETED:

13/22/13

SUBJECT INITIALS AND DATE: EHW 12/23/2013



Lovelace Sc fic Resources Leslie Byatt, um Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME EAW, EAW

PATIENT ID **AAGH8333** DOR. 02/13/1962 SEX REPORT STATUS Final F

PAGE 1

Site Code

PHYSICIAN

Unlisted Physician, PT, PHONE NO. **COLLECT DATE & TIME** RECEIVE DATE & TIME 12/23/2013 11:30 12/23/2013 18:38

Result

PRINT DATE & TIME 12/24/2013 06:03

REQUISITION NO.

PATIENT NO.

31033188 O

AKP039

| COMMENTS: |
|-----------|
|-----------|

| Test | In Range | Out of Range | Units | Reference Range |
|----------------------|----------|--------------|--------|---------------------|
| Comp Metabolic Panel | | | | |
| Sodium | 142 | | mmol/L | 134-1 44 |
| Potassium | 4.3 | | mmol/L | 3.5-5.1 |
| Chloride | 107 | | mmol/L | 98-111 |
| CO2 | 26 | | mmol/L | 20-30 |
| Anion Gap | 9 | | | 6-14 |
| Glucose | 94 | | mg/dL | 60-100 |
| BUN | 13 | | mg/dL | 7-31 |

0.63 mg/dL 0.50-1.40 Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

Please note new reference range effective 5/23/2013.

eGFR non-African Am **GFR Comment**

Creatinine

mL/min/1.73m2

>60

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium 9.7 mg/dL 8.4-10.4 gm/dL **Total Protein** 7.6 6.1-8.2 gm/dL 3.4-4.7 3.8 Albumin Globulin 3.8 am/dL 2.4-4.2 0.3-1.2 NCS WAM 0.2 mg/dL Bllirubin, total L

38-150 101 U/L Alk Phos U/L 6-58 AST(SGOT) 16 U/L 30 14-67 ALT(SGPT) Not given

Fasting Phosphorus 3.2 mg/dL 2.3-5.6 CBC WBC x10E3 4.0-10.6 8.6 4.00-5.36 x10E6 4.62 **RBC** am/dL 12.4 12.0-16.0 Hgb % 36-48 39 Hct fL 85 81-98 MCV gm/dL 31.2-35.2 MCHC 31.5 % **RDW** 14.6

31.2-35.2 11.0-14.5 WC MAR 150-400 NS WCS MAR Н x10E3 315 **Platelets** Rare Eos, Respiratory

Not given Phys, Addr. Phone

End of Report

Montaine of Sub-I 2 Jan 2014

EAW AKPO39

12/23/13

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ☐YES ☐NO |
|---|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: This nasal wash did decrease my symptoms of runny nose, itchy nose and congestion. I would suggest a different bottle, may a pump spray bottle for ease of use. My nasal passages were dry most of the day after my morning use. |
| |
| |
| |
| |

AKP-040

2,49 AKPharma PERENNIAL ALLER TES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIENT | DEMOGRAPHICS | |
|--------------|--------------------------|---|
| Patient D | Demographics | |
| Date of Bi | irth: 14 / N DV | / 198] (dd/mmm/yyyy) |
| Gender: | Male Male | / 198] (dd/mmm/yyyy) [Female |
| If female, | Indicate Childbearing I | Potential |
| | Childbearin | ng Surgically sterilized Post-Menopausal |
| Ethnicity: | Hispanic N | Non Hispanic |
| Race: | Asian Black | Caucasian |
| | Pacific Islander | Other, Specify |
| | | |
| Smoking | History | |
| Smoking S | Status: None (smooth | ked less than 100 cigarettes in lifetime) |
| | Former (pre | eviously smoked more than 100 cigarettes in lifetime) |
| | Current (sm | nokes now) |
| If subject i | s a former or current si | moker, please indicate: |
| Vesi | rs smoked: | Cigarettes per day: |

Version: 02 September 2013

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: Medical Record: DOB:11/14/1981

AMC, AMC AAGH9651

Age: 32Y Sex:M

30920961

Account Number:

Attending MD: Patient ID:AKP040 Unlisted Physician

Patient Phone: 0

W3426315 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician Reg#: 30920961

| Allerg, Panel 18 | | | 11/22/13 |
|-----------------------|---------|---------|----------------------|
| Allerg, Juniper | H 52.10 | [<0.35] | kU/L NCS 0 11/22/13 |
| Allerg, Cottonwood | H 18.80 | [<0.35] | VII/I |
| Allerg, West. Ragweed | н 8.00 | [<0.35] | kU/L NCSON 11/22/13 |
| Allerg, Russian This | H 48.00 | [<0.35] | kU/L NO. 11/22/13 |
| Allerg, Bermuda Grass | H 31.50 | [<0.35] | kU/L NEW MINE |
| Allerg,Alternaria | H 47.30 | [<0.35] | kU/L / 1/22/13 |
| Allerg,Mesquite | H 12.30 | [<0.35] | kU/L NGS 91 11/22/13 |
| Allerg,Cockroach | H 1.10 | [<0.35] | kU/L NG9 & 11/22/13 |
| Allerg, Derm. pter. | <0.10 | [<0.35] | kU/L |

The standard classification system utilizes the following class cutoffs.

| Class | kU/L | Interpretation |
|-------|------------|-----------------------|
| 0 | <0.35 | Negative for Allergen |
| Ī | 0.35-0.69 | Positive for Allergen |
| II | 0.70-3.49 | Strongly Positive |
| III | 3.5-17.49 | Strongly Positive |
| VI | 17.5-52.49 | Strongly Positive |
| V | 52.5-99.99 | Strongly Positive |
| VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal, Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Allerg, Derm. farinae Allerg, Clad. herb.

0.10 <0.10

[<0.35][<0.35]

kU/L

CONTINUED

Printed: 11/22/2013 15:28

Patient Name: AMC, AMC

Medical Record #: AAGH9651

Location: CORE

Page: 1

INTERIM REPORT

Halyer- Aut PI 22 May 2013

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: AMC, AMC Medical Record: AAGH9651

DOB:11/14/1981 Age:32Y Sex:M 30920961

Account Number:

Attending MD: Unlisted Physician

Patient ID:AKP040 Patient Phone: 0

W3426315 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician Req#: 30920961

| Allerg, Panel 18 | (CONTINUED) | | NC5 9 11/22/13 |
|--------------------|-----------------|---------|------------------------------|
| Allerg, Firebush | H 9.50 | [<0.35] | kii/Ti Tana ON 11 (dhami 12) |
| Allerg, Cat Dander | Epvil 42 80 | [<0.35] | kU/L WAS & 11/22/13 |
| Allerg, Dog Dander | Æ 2.40 V | [<0.35] | kU/L NOS S 11/22/13 |
| Allerg,Bluegrass | H 21.80 | [<0.35] | kU/L NOS OF 11/22/13 |
| Allerg, Pigweed | н 31.50, | [<0.35] | kU/L ACS |
| Allerg, Mulberry | H 4.30 | [<0.35] | kU/L NESS 11/23/13 |
| Allerg, Helminth | 0.30 | [<0.35] | kU/L // |

W3426316 COLL: 11/20/2013 11:49 REC: 11/20/2013 20:13 PHYS: Unlisted Physician Req#: 30920961

Phys, Addr, Phone

NO PHYSICIAN GIVEN

END OF REPORT

Printed: 11/22/2013 15:28

INTERIM REPORT

Patient Name: AMC, AMC

Halyn PI 22 Nov 2013

Location: CORE

Medical Record #: AAGH9651

Page: 2



Lavelace Scientific Resources 2 /1 Ridgecrest Dr SE Albuquerque, NM 87108

Name: AMC,

Gender: Male

Age: 32 Race: Caucasian

Height(in): 72.0

Weight(lb): 308

ld: AKP-040 Date: 12/11/13

Temp: 17

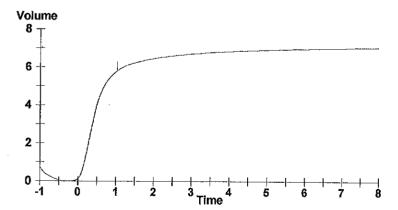
PBar: 634

Physician:

| Any Info: | | | T | echnician | : VL |
|--|---|--|----------------------|-----------|---|
| Spirometry | (BTPS) Ref | PRE-RX Pre Pre | POST-RX Post Post | Post . | Flow 16 _T |
| FVC Liter FEV1 Liter FEV1/FVC % FEF25-75%L/se FEF50% L/se FEF75% L/se IC Liter VC Liter VC Liter PEF L/se MVV L/mi PIF L/se FEV1/FEV6% | 18 4.72 83 10 4.92 10 5.81 10 2.45 18 5.71 10 10.07 11 182 | Meas % Ref 7.06 124 5.80 123 82 99 6.38 130 ** 9.24 ** 159 2.88 117 10.10 100 3.89 83 | Meas % Ref | % Chg | 12 8 4 |
| Vtg Liter VC Liter TLC Liter RV Liter RV/TLC % FRC PL Liter ERV Liter ERV Liter IC Liter | 5.71 7.56 5 2.03 28 5 3.13 | smograpny | (BTF3) | | -4 -8 -12-2 0 7 ₇₀₁₋₁₂₋₄ 6 8 |
| DLCO mL/r DL Adj mL/r | mmHg/min 38.9 nmHg/min 38.9 nHg/min/L 3.77 s | | | | -2 0 2 4 6 8 Volume |
| Resistanc | е | | | | |
| Raw Exp cmH Raw cmH Gaw L/se sRaw cmH | 2O/L/sec 2O/L/sec 2O/L/sec 1.48 c/cmH2O 0.752 2O/L/s/L 4.65 mH2O/L 0.215 | | | | |



Vtg (Raw) Liters





yelace Scientific Resources 11 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP-040,

Gender: Male

Age: 32

Race:

Height(in): 71.5

Weight(lb): 308

Any Info:

ld: AKP-040 Date: 12/18/13

Temp: 20

PBar: 634

Physician:

Technician: CRD

| | | · · · · · · · · · · · · · · · · · · · | | | | 1 OOI II II OIG | II. OND | | |
|----------------|-----------------|---------------------------------------|--------------|--------------|------------|-----------------|-------------|---------------------------------------|---------|
| Spirometry | (B | TPS) | PR | E-RX | POST-RX | | Flow | · · · · · · · · · · · · · · · · · · · | |
| op.romony | | Ref | Pre | Pre | Post Post | Post | 16 ⊤ | | |
| FVC Lite | ere | 5.63 | Meas 7.28 | % Ref 129 | Meas % Ref | % Chg | | | |
| FEV1 Lite | are | 4.65 | 5.95 | 128 | | | 1 | | |
| FEV1/FVC % | 510 | 83 | 82 | 98 | | | 12 | | |
| FEF25-75%L/s | er | 4.86 | 6.20 | 128 | | | | / | |
| FEF50% L/s | | 5.74 | 8.14 | 142 | | | + | / | |
| FEF75% L/s | | 2.42 | 2.35 | 97 | | | | | |
| IC Lite | | 2.72 | 2.30 | 97 | | | 8 † | 1 | |
| VC Lite | | 5.63 | | | | | 4 1 | | |
| PEF L/s | | | ** 15.04 | ** 151 | | | | ' | |
| MVV ∐m | | 181 | 13.04 | 131 | | | 4+ | | |
| PIF L/s | | 101 | 6.92 | | | | 1 | \ \ | |
| FEV1/FEV6% | - | | 84 | | | | İ | "\ | |
| | umaa/E | lathuan | | | (BTPS) | | 0 + | | <u></u> |
| Lung Vol | umes/r | remysm | iograf | ony | (BIFS) | | | | - 1 |
| Vtg Lite | ers | | | | | | 7 | | 1 |
| VC Lite | ers | 5.63 | | | | | -4+ | Lucy | } |
| TLC Lite | ers | 7.44 | | | | | - | | - 1 |
| RV Lite | rs | 2.00 | | | | | † | _ | . / |
| RV/TLC % | | 28 | | | | | -8 ↓ | | \sim |
| FRC PL Lite | rs | 3.05 | | | | | -0 | | |
| ERV Lite | rs | | | | | | + | | |
| IC Lite | rs | | | | | | 40 | | |
| Diffusion | | | | | | • | -12 | 2 4 6 | • |
| | /mmHg/min | 29.7 | | | | | -2 0 | Volume 6 | 8 |
| | mmHg/min | | | | | | | | |
| DLCO/VA mL/ | mHalmin/I | 20.7 | | | š. 1 | | | | |
| VA Liter | rin igritiiiir. | 3.77 | | | | | | | |
| BHT Sec | | | | | | | | | |
| | | | | | | | | | |
| Resistance | ce | | | | , | | | | |
| Raw Total cml- | 12O/L/sec | | | | | | | | |
| Raw Insp cml- | | | | | | • | | | |
| | 12O/L/sec | | | | | | | | |
| | | 4.54 | | | | | | | |



Vtg (Raw) Liters

Raw Gaw sRaw

sGaw

Interpretation:

cmH2O/L/sec 1.54 L/sec/cmH2O 0.732

cmH2O/L/s/L 4.69

L/s/cmH2O/L 0.213

Volume



Lovelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AMC,

Gender: Male

Age: 32

Race: Hispanic

Height(in): 72.0

Weight(lb): 308

Any Info:

ld: AKP-040

Date: 12/26/13

Temp: 17

PBar: 637

Physician:

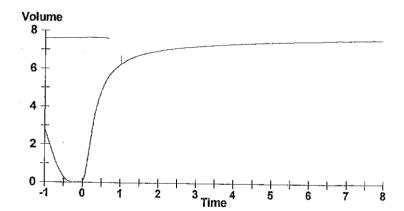
Technician: VL

| Any into: | | | | l echnicia | ın: VL | | | |
|---|--|---|----------------------|------------|--------------------------|-------------|-------------|----|
| Spirometry | (BTPS) Ref | PRE-RX Pre Pre | POST-RX Post Post | Post | Flow 16 _T | | | |
| FVC Liters FEV1 Liters FEV1/FVC % FEF25-75%L/sec | 5.71 4.72 83 4.92 | Meas % Ref 7.64 134 6.22 132 81 98 6.61 134 | Meas % Ref | % Chg | 12 | | | |
| FEF50% L/sec FEF75% L/sec IC Liters VC Liters | 5.81 2.45 5.71 | ** 8.96 ** 154 2.57 105 | | | 8 | | | |
| PEF L/sec MVV L/min PIF L/sec FEV1/FEV6% | 10.07 182 | ** 15.11 ** 150 2.09 83 | | | 4 | | | |
| Lung Volun Vtg Liters | nes/Plethys | smography | (BTPS) | | | and and | | Γ' |
| VC Liters TLC Liters RV Liters RV/TLC % FRC PL Liters ERV Liters | 5.71 7.56 2.03 28 3.13 | | | | -8 | | | |
| Diffusion | | | | | -12 [⊥] -2 0 | 2 Volume | 6 | 8 |
| DL Adj mL/mm | iHg/min 38.9 iHg/min 38.9 g/min/L 3.79 | | | | | volume | | |
| Resistance | | | | | | | | |
| Raw Total cmH2C Raw Insp cmH2C Raw Exp cmH2C Raw cmH2C Gaw L/sec/ci sRaw cmH2C | /L/sec /L/sec /L/sec 1.48 mH2O 0.752 /L/s/L 4.65 | | • | 4 4 | | | | |

Comments:

Vtg (Raw) Liters

sGaw



Interpretation:

L/s/cmH2O/L 0.215



Lovelace Scientific Resources 41 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AMC,

Gender: Male

Age: 32 Race:

Height(in): 71.5

Weight(lb): 308

Any Info:

ld: AKP-040 Date: 01/02/14

Temp: 18

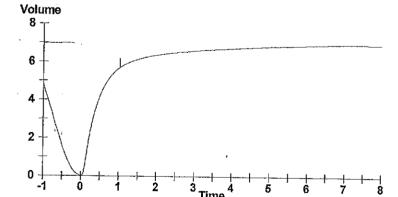
PBar: 637

Physician:

Technician: CRD

| 7 Wiy IIIIO. | | | | ecnniciar | 1; CRD | | |
|---|--|--|------------------------------|---------------|--|-------------|------------|
| Spirometry FVC Liters FEV1 Liters FEV1/FVC % FEF25-75%L/sec FEF50% L/sec FEF75% L/sec IC Liters VC Liters PEF L/sec MVV L/min PIF L/sec FEV1/FEV6% | (BTPS) Ref 5.63 4.65 83 4.86 5.74 2.42 5.63 9.95 181 | PRE-RX Pre Pre Meas % Ref 7.00 124 5.70 122 82 98 5.74 118 7.33 128 2.56 106 | POST-RX Post Post Meas % Ref | Post % Chg | Flow 16 - 12 - 4 - 4 - 4 - 4 - 4 - 4 - 4 - 4 - 4 - | | |
| Lung Volume | es/Plethver | | (BTPS) | | 0 + | | |
| Vtg Liters VC Liters VC Liters TLC Liters RV Liters RV/TLC % FRC PL Liters ERV Liters IC Liters Diffusion DLCO ml/mmH DLCO/VA ml/mHg/ VA Liters BHT Sec | 5.63 7.44 2.00 28 3.05 g/min 38.7 g/min 38.7 min/L 3.79 | | | ۔ | -4 -8 -12 -2 0 | ₹Volume 4 | S 8 |
| Resistance | | | • | | | | |
| Raw Total cmH2O/L Raw Insp cmH2O/L Raw Exp cmH2O/L Raw cmH2O/L Gaw L/sec/cml sRaw cmH2O/L | /sec /sec /sec 1.54 120 0.732 | | | . 3 | | | |





EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 0 | 12/14B | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO | ON SE | 0 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO |
|--------|--|-------------|------------|----------------------|--------------|--------------|-----------------|--------|----------------------|----------------------|----------------------|--------------------|--------------|
| 1 | - 1 | 123 | 1(2)3 | 1 2 3 | 2 3 | (<u>P</u>) | NO | 0 | 1 2 3 | 1 2 3 | 123 | 123 | 9 |
| 1 | 1/13/12 | 0 1 🖉 3 0 1 | 1(2) 3 0 | 230 |)2 3 OA | (NO) YES | NO (FES | -1 | <u>(2</u>) 3 0 | 1(2)3 0 | 2(3) 0 | 2 3 0 | (NQV) YES |
| ' | 1/21 [2] | m | 3 | 2301 | 3 0 🗘 | (NO) YES | NO KES | | ③ 0 1 | 3 0 | ②3 0 1 | 3001 | (ND) YES |
| -2 | 312109 | 0 1 | 0 1(2) | 0 1 | Q 1 2 | YES | ES) | -5 | 0 1 2 | 0 1 | 0 1 | 91 2 | YES |
| ကု | 1/80/21 | 0 1 🖎 3 | 0 ① 2 3 | 0 1 2 ③ | Ø1 2 3 | YES (N) | (ES) NO | ကု | 0 1(2)3 | O1 2 3 | 0 1 (2)3 | 0 1(2) 3 | VES NO |
| 4 | 12/07/13 12/08/13 12/09/13 12/10/13 12/11/13 | 0 🗇 2 3 | 00/2 3 | 0 1(2)3 | 1 2 3 | YES (NO) | (YES) NO | -4 | 0 1 (2) 3 | 0@23 | 0 1 2(3) | (D)1 2 3 | YES (NO. |
| | 2/13 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | Ø1 2 3 (| YES (NO) | (YES) NO | rὑ | 0 1 2 | 0 (D 2 3 | 0 (1) 3 | © 1 2 3 (| YES (NO) |
| 5- 9- | 12/05/13 | 0 1 (2) 3 | 0 1(2)3 | 0 1 2 3 | 1 2 3 | YES (NO) | (YES) NO | မှ | 0 1(2)3 | 0 (1)2 3 | 0 1 2(3) | 0123 | YES (NO) |
| 7- | 12/04/13 | 0 (1)2 3 | 0 1(2) 3 | 0123 | O1 2 3 © | YES (NO) | (VES) NO | 7- | o(I)2 3 | 0 1(2)3 | 0 1 2 ③ | O 123 | YES (NO) |
| DAY -7 | AM | Runny Nose | Itchy Nose | Congestion 0 to 3 | Sneezing | Voice Hoarse | Throat Clearing | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: AKPOHD DATE COMPLETED: 12/11/13

SUBJECT INITIALS AND DATE:



Lovelace S tific Resources Leslie Byatt, viin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME AMC, AMC PATIENT ID **AAGH9651** DOB 11/14/1981 SEX REPORT STATUS Final

gm/dL

%

x10E3

31.2-35,2

11.0-14.5

150-400

NS

PAGE

PHYSICIAN

Unlisted Physician.

COLLECT DATE & TIME 12/11/2013 11:30

M RECEIVE DATE & TIME 12/11/2013 19:31

PRINT DATE & TIME 12/12/2013 06:13

REQUISITION NO. 31033170

PT, PHONE NO. 0

PATIENT NO.

34.1

12.6

191

None seen

Not given

COMMENTS:

AKP040

| COMMENTS. | | | | | | |
|------------------------------------|---|---------------|---|----------------|---------------------|------------------|
| | F | Result | | | | |
| Test | In Range | Out of Ra | nge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 138 | | | mmol/L | 134-1 44 | |
| Potassium | 4.2 | | | mmol/L | 3.5-5.1 | |
| Chloride | 106 | | | mmol/L | 98-111 | |
| CO2 | 23 | | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | | 6-14 | |
| Glucose | | 105 | ·Η | mg/dL | 60-100 <i>以(</i> | S MM |
| | Impaired fasting glucose (100-126 mg/dl (ADA Guidel | (IFG) is defi | ned as a | fasting gluck | ose level of | - \ - |
| BUN | 7 | mes brabetes | care zo. | mg/dL | 7-31 | 2 ()DEC 15 |
| Creatinine | 0.92 | | | mg/dL | 0.62-1.66 | • |
| 0.020.00 | Creatinine method is IDMS | traceable. E | stGFR Cal | | | |
| | Please note new reference | range effect | ive 5/23/ | 2013. | | |
| eGFR non-African Am GFR Comment | >60 | - | | mL/min/1.73m3 | 2 >60 | |
| Of It Comment | Estimated GFR values are n | not accurate | in acute | kidnev failu | re, inpatients | |
| | on IV fluids, obese (BMI>3 | 34) or underw | reiaht (BM | II<20) people. | | |
| | the very old or very young people with acute illness | g, races othe | r than Ca | ucasian or Ai | frican American, | |
| Calcium | B.9 | es, or amputa | L TOIIS. | mg/dL | 8,4-10,4 | |
| Total Protein | 7.0 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.8 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | | am/dL | 2.4-4.2 | |
| Bilirubin, total | 0.4 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 79 | | | U/L | 38-150 | |
| AST(SGOT) | 28 | | | U/L | A HA | |
| ALT(SGPT) | | 80 | Н | Ú/L | 14-67 A | 0.5 1 BW. |
| Fasting | ΝΌ | | • | 0/2 | יאן זיט-דיו | or may |
| Phosphorus | 2.9 | | | mg/dL | 2.3-5.6 | cs Man |
| CBC | | | | | /· | 00- |
| ŬWВС | 4.9 | | | x10E3 | 4.0-10.6 | |
| RBC | 5.82 | | | x10E6 | 4.64-6.00 | |
| Hgb | 17.0 | | | gm/dL | 14.5-17.7 | <i>^</i> |
| Hct | 50 | | | % | 42-53 | |
| MCV | 86 | | | fL | 81-98 | |
| 140110 | | | | | | |

End of Report

Phys. Addr. Phone

MCHC

Platelets

Eos, Respiratory

RDW

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 290 | | | | • | | , | | • | | Γ |
|------------------------|-------------------------|-----------------|---|------------------|----------------|-----------------|----------------|----------------|--------|----------|
| AM | 1यां/13 | 12/ | विषय विश्वासी क्षा में अन्ति । जी जी अपी क्षा अपी अपी अपी अपी | 1यापै।ड | 17/15/13 | त्रीत्या | इ गर्यम्पि | ३ ग्वि/श्राउ | • | N |
| Runny Nose 0 to 3 | 0 1 2 3 | (C) 2 3 | O _{1 2 3} | Ø1 2 3 | © 123 | © 123 | O 1 2 3 | O 123 | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1 2 3 | © 1 2 3 | 0①2 3 | © 1 2 3 | © 1 2 3 | 3 1 2 3 | © 123 | O 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0 1 2 3 | | o∰2 3 | 0 T 2 3 | 1 2 3 | ©1 2 3 | © 123 | Ø123 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1 2 3 | © 123 | © 1 2 3 | a 1 2 3 | Q 123 | © 123 | © 123 | 0.123 | 0 1 2 | m |
| Voice Hoarse Y/N | YES NO | YES (NO) | YES (NO | YES (NO | YES MO | YES 🚳 | YES (ND) | YES (NO | YES NO | |
| Throat Clearing Y/N | YES NO | √ES NO | (FE) NO | (ES) NO | (YES) NO | (TES) NO | (YES) NO (| YES / NO | YES NO | Ι_ |
| DAY PM | T | 2 | 8 | 7 | 2 | 9 | 7 | 8 | 6 | 1 |
| Runny Nose 0 to 3 | Ø1230 | © 123 | 6)1 2 3 | Ø123 | Ø1 2 3 | Ø1 2 3 | © 1 2 3 | 0 1 2 3 | 0 1 2 | <u>س</u> |
| Itchy Nose 0 to 3 | 0 © 23 | 6)1 2 3 | 1 2 3 | (1) 1 2 3 | O 123 | \emptyset 123 | @1 2 3 | 0 1 2 3 | 0 1 2 | · π |
| Congestion 0 to 3 | 0 1 🖎 | 0 🗘 2 3 | 0 10 3 | 0(1)2 3 | 0 ⊕ 23 | 0 D 23 | 0 🗘 2 3 | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 1 2 3 1 1 | 2 3 | 1 2 3 | O 1 2 3 | O1 2 3(| Ø1 2 3 | Q 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO | (ES) NO | (VES) NO | YES NO | YES NO | |
| Throat Clearing Y/N | NO (SE) | √€€ NO | ON SEA |) ON (SA) | YES NO | YES NO | (ES) NO | YES NO | YES NO | I _ |
| | | | | | | | | | | 1 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) $Y=Yes\ N=No$

DATE COMPLETED: $/\mathcal{E}-/\mathcal{S}-/$ SUBJECT NUMBER: AMCPOH

SUBJECT INITIALS AND DATE: /2-/8-/3



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Sc ific Resources Leslie Byatt, n Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME AMC, AMC

PATIENT ID **AAGH9651**

DÔB 11/14/1981 \$EX REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO. 31033200

PT. PHONE NO.

COLLECT DATE & TIME 12/18/2013 11:10

RECEIVE DATE & TIME

PRINT DATE & TIME

12/18/2013 18:49

12/19/2013 06:09

PATIENT NO.

AKP040

Test

COMMENTS:

0

In Range

Out of Range

Manhenne no 19 Dec 2013

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone None seen Unknown

NS

End of Report

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DΔV | 7 | α | σ | 10 | 11 | 12 | 13 | 14 | 15 |
|----------------------|----------------|----------------|----------------|---------------------------|----------------|----------------|-------------------------------------|----------------|----------------|
| AM | 1418/13 | | 1420/13 | 12/18/13 1420/13 12/21/13 | 13/22/13 | 1423/13 | 142413 142413 12/24(13 142413 1424) | 13/20/13 | 12/24/13 |
| Runny Nose 0 to 3 | 0 1 2 3 | Ø123 | Ø123 | © 123 | © 1 2 3 | 6 123 | © 123 | ©123 | G 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0 62 3 | Ø123 | Ø1 2 3 | Ø123 | © 123 | 6 123 | Ø1 2 3 | 0 (2 3 |
| Congestion 0 to 3 | 0 1 2 3 | ©1 2 3 | 0 (17) 3 | Ø 1 2 3 | © 123 | O1 2 3 | Q 123 | 6 123 | 0 6 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | © 1 2 3 | Ø 123 | © 1 2 3 | ©1 2 3 | 6 123 | OI 2 3 | Q 1 2 3 | C 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES 🚳 | YES 🐠 | YES (NO | YES (| YES 🚱 | YES 🐠 | YES (P) | YES 🐠 |
| Throat Clearing Y/N | YES NO | (VEŠ NO | (ES) NO | (YES) NO | YES NO | Œŷ NO | (ES) NO | (E) NO | NO Æ |
| DAY PM | | 00 | 6 | 10 | 11 | 12 | 13 | 14 | 15 |
| Runny Nose 0 to 3 | 0 D 2 3 | Ø 123 | ©1 2 3 | © 123 | © 123 | © 123 | @ 123 | Ø 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 🗇 2 3 | 1 2 3 | O 1 2 3 | © 123 | © 123 | 0 C 2 3 | Ø 123 | Q 123 | 0 1 2 3 |
| Congestion 0 to 3 | 0 D 2 3 | 1 2 3 | © 123 | Q 123 | ©1 2 3 | 0 © 2 3 | 0 Q 723 | © 123 | 0 23 |
| Sneezing 0 to 3 | Ø123 | ©1 2 3 | 1 2 3 | © 123 | Q1 2 3 | E 7 VD | C /1 2 3 | 66/123 | 0 1/2 3 |
| Voice Hoarse Y/N | YES 🐠 | YES (NO) | YES 🐠 | YES (10) | YES (NO | ON SE | YES (NO) | YES (1) | YES NO |
| Throat Clearing Y/N | KES NO | (YES) NO | (YEŚ) NO | WES NO | (ES) NO | VES/ NO | MES NO | YES NO | YES NO |
| SCALEDTA | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: $\frac{AMC}{HKDU4D}$ DATE COMPLETED: $\frac{12}{L}$

SUBJECT INITIALS AND DATE: 1226-13



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scir Tic Resources Leslie Byatt, (Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

AMC, AMC

PATIENT ID

DOB 11/14/1981 SEX

REPORT STATUS

PAGE

PHYSICIAN

Unlisted Physician,

REQUISITION NO.

PT. PHONE NO.

COLLECT DATE & TIME 12/26/2013 11:09

AAGH9651

RECEIVE DATE & TIME

Final

PRINT DATE & TIME

12/26/2013 18:42

12/27/2013 06:03

PATIENT NO.

AKP040

COMMENTS:

Test

In Range

Out of Range

Manufaire m Sult

Units

Reference Range

Site Code

Eos, Respiratory Phys, Addr, Phone

None seen **NOT INDICATED** NS

End of Report

** If day is <u>unknown</u>, write UNK in space provided, but every effort should be made to be as specific as possible** LSR Study #: 2749 Action Taken Subject Initials: Date: 27 (DD/MMM/YYYY) 29/Dec/2 ** End Date ADVERSE EVENT LOG (Suspected/Not Suspected) Relationship to Study Drug SEVERITY Study Identification: AKP humme Investigator Signature (at end of study): _ 240ec/2013 (DD/MMM/YYYY) ** Start Date 11 catelon 3 treaty mack- any Subject Number: Adverse Event

Lovelace Scientific Resources, Inc. AdverseEvents 04/2013

SC Signature (at end of study): _

Ongoing at EOS (forclinic use) i D List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. Subject Initials: 129 hears 7105-01/2013 Stop Date 5/00/6 11/18/13 LSR#: Date: 2/27/14 Date: 27 FM Oral UNK/AUG/1999 26/020/2013 (Day/Month/Year) * If day or month of medication date is <u>unknown,</u> write UNK in space provided * Start Date 9/2013 8/2013 1990 201 CONCOMITANT MEDICATION LOG \mathcal{D} Route Lovelace Scientific Resources, Inc - ConMeds 04/2013 CO C 2 Tabs per Frequency PRN B 00 2 ΜG 3 Unit Ty. 2002 Dose 325 62 64 Diabetes Study Identification: All Musma (What you take it for) Indication Headache-SC Signature (at end of study): Investigator Signature (at end of study): Alergue Allogo Allega EXAMPLE Name of Medication pmypazil Subject Number: Bundar Aspirun Stroid in

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A) ON PATIENT-PERCEIVED BREATHING COMFORT

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| Γ | Γ. | <u></u> | ı | _ | | ı — | 1. | | I - | l <u> </u> | · · · · · · | T | Т | | ٦ |
|---------------------|--------------|--------------------|----------------------|----------------------|------------------------|----------|---------------------|---------------------|--------------------|----------------------|----------------------|-----------|----------------|--|---|
| Throat Clearing Y/N | Voice Hoarse | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose (0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Υ/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | 0 to 3 | AIVI | DAY | |
| YES | YES | (8) | <u>@</u> | @1 2 | ©1 2 | | YES | YES | 0 | 0 | <u>0</u> 1 | e | 5 1 | 17/1 | 1 |
| NO | (NO) | 2 3 | 2 3 | 2 3 | 2 3 | 14 | 8 | NO | 2 3 | 2 | 2 3 | 1 2 3 | 51107 | 14 | |
| YES | YES | 9 | 0.0 | 0 🗘 2 | 0 (7) | 1 | (FS) | YES | © 123 | 0 Ф2 | 0 D 2 | | |)) 1 | |
| NO | 6 | 2 3 | ω |)2 3 | 3 | 15 | NO | 3 | | ω | ω | (A) 2 3 | 1401113 | 15 | |
| (KES) | | | · 6 | © 1 2 | @1 2 | 1 | YES |) YES | Q 123 | 0 | 9 | | | 12/2 | |
| NO | YES 餐 | رد س | 2 3 | 2 3 | 2 3 (| 16 | NO | 8 | 2 3 | 2 3 | 2 3 | 0 1 6/3 | | 16 />/> _ | 1 |
| (YES | YES (NO | @1 2 | Q 1 | @1 2 | © 1 2 | 17 | | YES | @ 1 2 3 | @ 1 2 | 0 <u>@</u> 2 | 0 2 3 | | 17/20 | |
| NO. | 8 | | 2 3 | 2 3 | 2 3 | 7 | NO | (A) | | <u>ω</u> | 2 3 | ۷. | 3/2 | 0/2 | l |
| KES. | YES | 9 | 8 | © 1 2 | 0 43 2 | 18 | (ES) | YES | @ 1 2 3 | . 6 | 02 | M 7 2 3 | , (1 1, (1) | 18 | |
| NO | É | | 2 3 | ω | 2 3 | 8 | NO O | 8 | | 2 3 | 2 3 | ۷. | | | I |
| YES | YES (NO | @1 | 9 | 9 | 0 1 | 19 | (YES) | YES | <u>(</u> 01 2 3 | 6 | 6 | (| 701/3 | 19/2/ | |
| NO | 8 | 2 3 | 2 3 | 2 3 | 1003 | 9 | NO | 6 | | 2 3 | ν. 3 | 2 2 | 7/2 | ا ر | 1 |
| (A) | YES | 0.7 | 9 1 | © 1 | (T) | 20 | (SZ) | YES (| 9 | 62 | 0,1 | 7 (3) | | 20 | |
| NO | 8 | 2 3 | 2 3 | 2 3 | 2 3 | 0 | NO | NO) | 1 | 2 3 | 2 3 | Ú | 7 / 7 | | 1 |
| YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 21 | (YES) | YES | 9 | 0 1 | 0 (1) | F | | 1.11 5/2/2/2/5 | |
| NO NO | NO | 2 3 | 2 3 | 2 3 | 2 | <u> </u> | NO | NQ. | | 2 3 | N 3 | | 1 | | |
| YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 22 | YES | YES | 0 1 | 0 1 | 0 1 | 0 0 1 2 0 | 2 0 | 0/ | , |
| NO O | NO NO | 2 3 | 2 3 | 2 3 | رم س | 2 | o O | O O | 2 3 | 2 3 | 2 3 | 0 | 2 (| \\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\ | 1 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No \mathcal{ANC} AKPD4D DATE COMPLETED: 1-2-14

SUBJECT NUMBER:

SUBJECT INITIALS AND DATE:



Resources Lovelace Scie Leslie Byatt, Chu Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME AMC, AMC

PATIENT ID **AAGH9651** DOB 11/14/1981

REPORT STATUS SEX Final

PAGE

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME 01/02/2014 10:00

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

01/02/2014 19:08

01/03/2014 06:02

30920925

0

x10E3

150-400 NCS MAPUL

PATIENT NO. **AKP040**

COMMENTS:

| COMMENTS; | | | | | | |
|----------------------|--|---------------------------------|------------------------|---|------------------------------------|-------------|
| | R | esult | | | | |
| Test | In Range | Out of Rai | nge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 140 | | | mmol/L | 134-144 | |
| Potassium | 4.0 | | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | | mmol/L | 98-111 | |
| CO2 | 24 | | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | | 6-14 | a Jana |
| Glucose | | 149 | Н | mg/dL | 60-100 NZ | SIMM |
| BUN | 9 | | | mg/dL | 7-31 | 1001 |
| Creatinine | 0.91 | | | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDMS | | | | been adjusted. | |
| | Please note new reference | range effect | ive 5/23/ | 2013. | | |
| eGFR non-African Am | >60 | | | mL/min/1.73m2 | 2 >60 | |
| GFR Comment | | | | | | |
| | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | 34) or underwa L races other | eight (BM r than Ca | kidney failur I<20) people, ucasian or Af | re, inpatients frican American, | |
| Calcium | 8.5 | b, or ampaca | L 1 4/101 | mg/dL | 8.4-10.4 | |
| Total Protein | 6.9 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.7 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.2 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.3 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 90 | | | Ŭ/L | 38-150 | |
| AST(SGOT) | 24 | | | U/L | 6-58 | 2. 11. |
| ALT(SGPT) | | 74 | Н | U/L | 14-67 (1) | SINM |
| Fasting | YES | | | | 70 - | |
| Phosphorus | 2.4 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | | | |
| WBC | 5.0 | | | x10E3 | 4.0-10.6 | 5.00 |
| RBC | | 6.01 | Н | x10E6 | 4.64-6.00 | 15 1811/12. |
| Hgb | 17.2 | | | gm/dL | 14.5-17.7 | 2 - W-M |
| Hct | 51 | | | % | 42-53 | |
| MCV | 84 | | | fL | 81-98 | |
| MCHC | 33.9 | | | gm/dL | 31.2-35.2 | |
| RDW | 12.6 | | | % | 11.0-14.5 | |

End of Report

Platelets

Eos, Respiratory

Phys. Addr. Phone

MM Sob I Jours 14

Moderate

197

NOT GIVEN

AMC/040 1/2/14

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" ☐ YES ☐ NO |
| i v |
| You are also encouraged to make any free comments regarding your experience |
| in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| I didn't Hotice a buge Change |
| It did seem to dry out me |
| These which people I would |
| period to see u/hat other benitits it |
| period to see what other benities it |
| May after. |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

[Type text] Subject initials and Date 2m 1-2-14

AKP-041

4,49 AKPharma PERENNIAL ALLER JES SCREENING/VISIT 1 SOURCE DOCUMENTS

| PATIENT | DEMOGRAPHI | <u>CS</u> | | |
|---------------|---------------------|---------------------|----------------------------------|---------|
| Patient D | emographics | | | |
| Date of Bir | th: 00/Fe | 26 1988 | o (dd/mmm/yyyy) | |
| Gender: | Male Male | Female | | |
| If female, I | ndicate Childbearir | ng Potential | | |
| , | Childbea | aring 🗌 Surgi | cally sterilized Post-Men | opausal |
| Ethnicity: | Hispanic [|] Non Hispanic | | |
| Race: | Asian 🗌 Blac | ck Caucas | ian 🔲 American Indian | |
| | Pacific Islander | Other, Speci | fy | |
| | | | | |
| Smoking I | Hstory | | | |
| Smoking St | atus: None (si | moked less than 1 | 00 cigarettes in lifetime) | |
| | Former (| (previously smoke | ed more than 100 cigarettes in l | fetime) |
| | Current | (smokes now) | | |
| If subject is | a former or curren | at smoker, please i | ndicate: | |
| | | | | |

Version: 02 September 2013



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace S atific Resources Leslie Byatt, Jin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr

24664

PATIENT NAME NLD, NLD PHYSICIAN

PATIENT ID **AAGH8310**

OOB 02/02/1988

REPORT STATUS Final

PAGE 1

Site Code

Unlisted Physician. REQUISITION NO.

COLLECT DATE & TIME 11/15/2013 14:16

RECEIVE DATE & TIME 11/18/2013 19:56 PRINT DATE & TIME 11/20/2013 06:09

PT. PHONE NO.

PATIENT NO.

30920941

O

AKP041

COMMENTS:

Test Allerg,Panel 18 Allerg,Juniper Allerg, Cottonwood Allerg, West. Ragweed Allerg, Russian This Allerg, Bermuda Grass Allerg Alternaria Allerg, Mesquite Allerg, Cockroach

Allerg Derm. pter.

| | Result | | | | |
|----------|--------------|---|-------|-----------------|--|
| In Range | Out of Range | | Units | Reference Range | |
| | 31.20 | Н | kU/L | <0.35 | |
| | 1.50 | Ĥ | kÜ/L | <0.35 | |
| <0.10 | | | kU/L | <0.35 | |
| | 2.60 | Н | kU/L | <0.35 | |
| <0.10 | | | kU/L | < 0.35 | |
| | ₹5:30 ¥ | Н | kU/L | < 0.35 | |
| | 0.90 | Н | kU/L | < 0.35 | |
| | ©0.90 | Н | kU/L | < 0.35 | |
| | 0.40 | н | kU/L | < 0.35 | |

The standard classification system utilizes the following class cutoffs. class Interpretation

| Ciass | KU/ L | Titel bi eracion |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3, 5-17, 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| v | 52. 5-99. 99 | Strongly Positive |
| VI VI | >100 | Strongly Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| Allerg,Derm. farinae | | (0.40) | Н | kU/L |
|----------------------|---------|----------------|---|-------|
| Allerg,Clad. herb. | <0.10 | ~ | | kU/L |
| Allerg,Firebush | | 0.50 | Н | kU/L |
| Allerg,Cat Dander Ep | | ₹3.70 | Н | kU/L. |
| Allerg,Dog Dander | 0.30 | #10.1.5.1 3/J# | | kU/L |
| Allerg,Bluegrass | | 0.40 | Н | kU/L |
| Allerg, Pigweed | 0.30 | | | kU/L |
| Allerg, Mulberry | | 0.50 | Н | kU/L |
| Allerg,Heiminth | <0.10 | | | kU/L |
| Phys, Addr, Phone | Unknown | | | |

End of Report

1000 ro13

<0.35 <0.35 < 0.35 < 0.35 < 0.35 < 0.35 < 0.35 < 0.35 < 0.35



Lovelace Scientific Resources 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: NLD,

Gender: Female

Age: 25

Race: Hispanic

Height(in): 63.0

Weight(lb): 162

Id: AKP-041 Date: 11/27/13

Temp: 19

PBar: 637

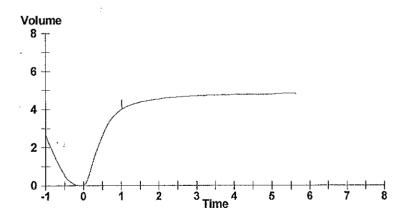
Physician: Technician:

| Any Info: | | | | i ecnnicia | an: |
|---|---|---|------------------------------|---------------|---|
| Spirometry | (BTPS) Ref | PRE-RX Pre Pre Meas % Ref | POST-RX Post Post Meas % Ref | Post % Chg | Flow 16 _T |
| FVC Liters FEV1 Liters FEV1/FVC % FEF25-75%L/sec FEF50% L/sec IC Liters VC Liters VC Liters PEF L/sec MVV L/min PIF L/sec FEV1/FEV6% | 3.49 3.02 87 3.62 4.10 1.97 3.49 6.48 119 | 4.84 139 4.03 134 83 96 4.30 119 4.98 122 2.43 123 6.83 106 2.44 | | , ong | 12 8 4 0 |
| Lung Volus Vtg Liters VC Liters TLC Liters RV Liters RV/TLC % FRC PL Liters ERV Liters IC Liters Diffusion DLCO mL/ms DL Adj mL/ms | 3.49 4.97 1.45 28 2.52 mHg/min 25.0 mHg/min/L 3.93 | mography | (BTPS) | | -4 -8 -12-2 0 2 _{Volume} 6 8 |
| Resistance | 9 | | | | |

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec Raw Exp cmH2O/L/sec cmH2O/L/sec Raw L/sec/cmH2O 0.604 Gaw cmH2O/L/s/L 3.86 sRaw L/s/cmH2O/L 0.259 sGaw

Vtg (Raw) Liters

Comments:





Lor lace Scientific Resources 244 Ridgecrest Dr SE Albuquerque, NM 87108

Name: NLD,

Gender: Female

Age: 25

Height(in): 63.0

Race: Hispanic

Weight(lb): 162

Any Info:

ld: AKP-041

Date: 12/06/13

Temp: 19

PBar: 631

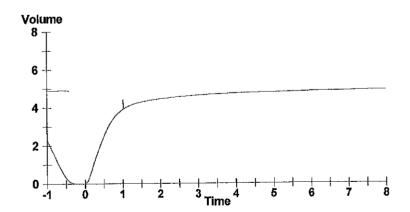
Physician:

Technician: VL

| Ally IIIO. | (BT | PS) | PRE | -RX | POST | -RX | | Flow | | | | |
|------------|------------------|-----------|--------------|-----------|----------------|-------|---------------|-------------|-----|---------------------------------------|--------------|---|
| Spirometr | у ` | Ref | Pre | Pre | Post Meas % | Post | Post % Chg | 16 T | | | | |
| | | | Meas | % Rei | Weas / | i Vei | 70 Ong | 1 | | | | |
| FVC | Liters | 3.49 | 4.91 | 131 | | | | | | | | |
| FEV1 | Liters | 3.02 | 3.95 80 | 93 | | | | 12 + | | | | |
| FEV1/FVC | | 87 | | 93 109 | | | | | | | | |
| FEF25-759 | | 3.62 | 3.94 4.84 | 118 | | | | | | | | |
| FEF50% | L/sec | 4.10 | 2.00 | 101 | | | | 8∤ | | | | |
| FEF75% | L/sec | 1.97 | 2.00 | 101 | | | | | • | | | |
| IC VO | Liters | 3.49 | | | | | | 1 | | | | |
| VC | Liters L/sec | 6,48 | 6.25 | 96 | | | | 4 | - 1 | , ' | | |
| PEF MVV | L/sec L/min | 119 | 0.20 | • | | | | Ĭ, | - 1 | | | |
| PIF MVV | L/IIIII L/sec | 119 | 2.26 | | | | | † | ĺ | M | | |
| FEV1/FEV | | | 82 | | | | | 0 | | | | |
| | | lathyama | | nhv | (BT | 'PS) | | • | | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | | |
| Lung v | /olumes/P | leniyan i | Jyraj | PHY | , | - | | † | | - And | | |
| Vta | Liters | | | | | | | -4 | | | | |
| Vtg VC | Liters | 3.49 | | | | | | | | | | |
| TLC | Liters | 4.97 | | | | | | + | | | | |
| RV | Liters | 1.45 | | | | | | -8 | | | | |
| RV/TLC | % | 28 | | | | | | -0 T | | | | |
| FRC PL | Liters | 2.52 | | | | | | + | | | | |
| ERV | Liters | | | | | | | | | | | |
| IC | Liters | | | | | | | -12 -2 | 0 | 2 4 | 6 | 8 |
| Diffusi | on | | | | | | | -24 | v | 2 Volume | - | • |
| DLCO | mL/mmHg/min | 25.0 | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | | |
| DLCO/VA | mL/mHg/min/L | 3.89 | | | | | | | | | | |
| VA | Liters | | | | | | | | | | | |
| BHT | Sec | | | | | | | | | | | |
| Resist | ance | | | | | | | | | | | |
| 1700100 | ando | | | | | | | | | | | |

Raw Total cmH2O/L/sec Raw Insp cmH2O/L/sec cmH2O/L/sec Raw Exp 1,53 cmH2O/L/sec Raw L/sec/cmH2O 0.604 Gaw cmH2O/L/s/L 3.86 sRaw L/s/cmH2O/L 0.259 sGaw Vtg (Raw) Liters

Comments:





ovelace Scientific Resources 141 Ridgecrest Dr SE Albuquerque, NM 87108



Name: NLD,

Gender: Female

Age: 25

Race: Hispanic

Height(in): 63.0

Weight(lb): 162

ld: AKP-041 Date: 12/13/13

Temp: 22

PBar: 630

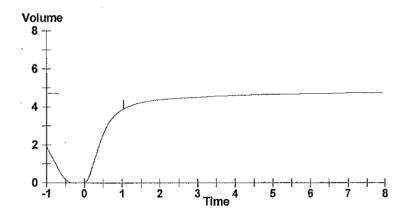
Physician:

Technician: VI

| Any Info: | | | | | | Lechnicia | ın: VL | | | | |
|------------|--------------|---------|-------------|--------------|-------------------------|---------------|------------------|-----|---------------|---|---|
| Spiromet | (B | TPS) | | E-RX | POST-RX | | Flow | | | | |
| opilomet | ıy | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 | | | | |
| FVC | Liters | 3.49 | 4.71 | 135 | | | † | | | | |
| FEV1 | Liters | 3.02 | 3.90 | 129 | | | 12 | | | | |
| FEV1/FVC | % | 87 | 83 | 95 | | | 14 | | | | |
| FEF25-759 | %L/sec | 3.62 | 4.31 | 119 | | | + | | | | |
| FEF50% | L/sec | 4.10 | 5.31 | 130 | | | | | | | |
| FEF75% | L/sec | 1.97 | 2.08 | 106 | | | 8 🛉 | | | | |
| IC | Liters | | | | | | 1 | 1 | | | |
| VC | Liters | 3.49 | | | | |] | | \mathcal{N} | | |
| PEF | L/sec | 6.48 | 7.10 | 110 | | | 4+ | | | | |
| MVV | L/min | 119 | | | | | | | \ | | |
| PIF | L/sec | | 2.36 | | | | T T | - 1 | \mathcal{N} | | |
| FEV1/FEV | | | 84 | | | | 0 | | | + | + |
| Lung \ | /olumes/l | Plethys | mogra | phy | (BTPS) | | _ | | men | | |
| Vta | Liters | | | | | | | | | | |
| Vtg VC | Liters | 3.49 | | | | | -4 | | | | |
| TLC | Liters | 4.97 | | | | | 1 | | | | |
| RV | Liters | 1.45 | | | | | | | | | |
| RV/TLC | % | 28 | | | | | -8+ | | | | |
| FRC PL | Liters | 2.52 | | | | | } | | | | |
| ERV | Liters | | | | | | † | | | | |
| iĊ | Liters | | | | | | -12 ¹ | | | | |
| Ďiffusi | | | | | | | -12 -2 | 0 | 2 Volume | 6 | 8 |
| | | 250 | | | | | | | volume | | |
| DLCO | ml./mmHg/min | | | | | | | | | | |
| DL Adj | mL/mmHg/min | | | | | | | | | | |
| DLCOVA | mL/mHg/min/L | . 3.00 | | | | | | | | | |
| VA | Liters | | | | | | | | | | |
| BHT. | Sec | | | | | | | | | | |
| Resist | ance | | | | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | • | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| Raw | cmH2O/L/sec | 1.53 | • | | | , . | | | | | |
| Gaw | L/sec/cmH2O | | | | | • | | | | | |
| sRaw | cmH2O/L/s/L | 3.86 | | | | | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | | | | | |
| Vta (Paul) | | | | | | | | | | | |



Vtg (Raw) Liters





Loy lace Scientific Resources 244 Ridgecrest Dr SE Albuquerque, NM 87108

lame: AKP-041,

∂ender: Female

\ge: 25

Race:

leight(in): 63.0

Weight(lb): 162

ld: AKP-041

Date: 12/20/13

Temp: 19

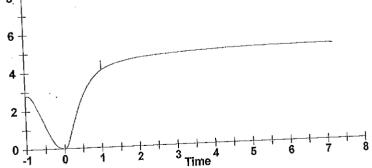
PBar: 624

100000000

Physician:

Technician: CRD

| Height(in): 63.0 | MACIBLICATION. | | | Technicia | n: CRD | |
|---------------------------|----------------------------------|-----------------------|------------|-----------|--------------|---------------------|
| Any Info: | | | POST-RX | | Flow | |
| | (BTPS) | PRE-RX | Post Post | Post | 710₩ 16 T | |
| Spirometry | Ref | Pre Pre Meas % Ref | Meas % Ref | % Chg | 10 | |
| FVC Liters | 3.49 3.02 | 5.04 145 4.07 135 | | | 12 | |
| FEV1 Liters FEV1/FVC % | 87 | 81 93 3.99 110 | | | † | |
| FEF25-75%L/sec | 3.62 | 3,99 110 4,94 121 | | | 8 | |
| FEF50% L/sec | 4.10 | 2.07 105 | | | ~ \ | |
| FEF75% L/sec | 1.97 | 2.01 | | | ŧ | |
| IC Liters | 3.49 | | | | 4 + | |
| VC Liters | 6.48 | 7.90 122 | | | | |
| 1 - | 4.40 | | | | Ť | |
| MVV L/min PIF L/sec | | 2.98 | | | 0 + | |
| | | 81 | (BTPS) | | 1 | ~ |
| Lung Volu | mes/Plethysr | nograpny | , | | j | |
| | | | | | -4 † | |
| Vtg Liters VC Liters | | | | | ļ | |
| VC Liters | 4 07 | | | | _ | |
| TLC Liters RV Liters | 4 4 5 | | | | -8- | |
| RV/TLC % | 28 | | | | 1 | |
| FRC PL Liter | s 2.52 | | | | 40 | - 0 |
| ERV Liter | | | | | -12 -2 | 0 2 4 6 8 Volume |
| IC Liter | 'S | | | | _ | AOIMHE |
| Diffusion | 050 | | | | | |
| | mmHg/min 25.0 | | | | | |
| | mmHg/min 25.0 mHg/min/L 3.84 | | | | | |
| | MHQAIIIIII 0.0-1 | | | | | |
| VA Liter BHT Sec | | | • | - | | |
| 5, | | | | | | |
| Resistan | ce | | • | | | |
| Raw Total cml | H2O/L/sec | | | | | |
| Paw inso CM | H2O/L/sec | | | | | |
| Raw Exp cm | H2O/L/sec H2O/L/sec 1.53 | | | | | |
| Raw cm | H2O/L/sec 1.53 ec/cmH2O 0.604 | | | | | |
| | H2O/L/s/L 3.86 | | | | | |
| sRaw cm sGaw L/s | /cmH2O/L 0.259 | | 1 | | | |
| Vtg (Raw) Lite | | | Valumo | | | |
| y (g (, (2,1)) = 10 | | | Volume | | | |
| | | | 8 — | | | |
| Comments: | | | + | | | |





Lovelace Sc tific Resources Leslie Byatt, clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME X, NLD

PATIENT ID **AAGI3129**

02/02/1988

SEX F

REPORT STATUS Final

PAGE 1

PHYSICIAN

Unlisted Physician,

COLLECT DATE & TIME 11/27/2013 13:20 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

11/27/2013 18:53

11/28/2013 06:11

30920924

0

PATIENT NO.

COMMENTS:

AKP041

Result

| | ŀ | (esuit | | | |
|------------------------------------|---|--|-------------------|----------------------|-----------|
| Test | In Range | Out of Range | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | |
| Sodium | 138 | | mmol/L | 134-144 | |
| Potassium | 3.9 | | mmol/L | 3.5-5.1 | |
| Chloride | 104 | | mmol/L | 98-111 | |
| CO2 | 25 | | mmol/L | 20-30 | |
| Anion Gap | 9 | | | 6-14 | |
| Glucose | 72 | | mg/dL | 60-100 | |
| BUN | 13 | | mg/dL | 7-31 | |
| Creatinine | 0.56 | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | | | een adjusted. | |
| | Please note new reference | range effective 5/23 | 3/2013. | | |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 | |
| Of It Common | Estimated GFR values are i | not accurate in acute | e kidnev failure. | inpatients | |
| | on IV fluids, obese (BMI> | 34) or underweight (£ | BMI<20) people, | | |
| | Estimated GFR values are mon IV fluids, obese (BMI>: the Very old or very young people with acute illness | g, races other than (es, or amputations. | Caucasian or Afr | ican American, | |
| Calcium | 9.0 | | rng/dL | 8.4-10.4 | |
| Total Protein | 7.3 | | gm/dL | 6.1-8.2 | |
| Albumin | 3.9 | | gm/dL | 3.4-4.7 | |
| Globulin | 3.4 | | gm/dL | 2.4-4,2 | |
| Bilirubin, total | 0.4 | | mg/dL | 0.3-1.2 | |
| Alk Phos | 91 | | U/L | 38-150 | |
| AST(SGOT) | 10 | | U/L | 6-58 | |
| ALT(SGPT) | 19 | | U/L | 14-67 | |
| Fasting | NO | | | | |
| Phosphorus | 4.1 | | mg/dL | 2.3-5.6 | |
| CBC | | | | | |
| WBC | 7.4 | | x10E3 | 4.0-10.6 | |
| RBC | 4.55 | | x10E6 | 4.00-5.36 | |
| Hgb | 13.3 | | gm/dL | 12.0-16.0 | |
| Hct | 43 | | % | 36-48 | |
| MCV | 94 | | fL | 81-98 | |
| MCHC | 31.2 | | gm/dL | 31.2-35.2 | |
| RDW | 12.6 | | % | 11.0-14.5 | ~ |
| Platelets | 284 | | x10E3 | 150 -4 00 | UCS NOW |
| Eos, Respiratory | | Rare * | | NS A | UUS MAN |
| Phys, Addr, Phone | Not given | | | | |
| | | | | | |

End of Report

03 Dec 2013 Montaine 10

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

ì

Congestion 0 to 3 Runny Nose Voice Hoarse Sneezing Itchy Nose Runny Nose CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS Throat Clearing Voice Hoarse Sneezing Congestion **Itchy Nose** Throat Clearing DAY PM DAY AΜ 0 (0)12ΥES 0 0 0 7 0(少 YES 0 YES YES $0(1)^{2}$ <u>---</u> 1 ب N 2 N N 8 Z 0 Ö 8 3(0)123 w ω ω w ω ω ω (0)12(0)10 1(2) 3 0 (1) 2 3 0 (4) YES) 0 0 (YES YES 0 ÝES) 0(1)231(2)3 1(2)3 $1 \ 2(3)$ NO NO 8 S NO 3 (0)12 ω (0)12 YES 0/1/2 (0)1 0/1)2 0 1 2 3 (0) 1 0(1)2 ŠŦ YES YES NO N (NO) YES 8 (NO) w ω w w ω w (0)126 YES) 0)1 2 0 0 YES 9 YES 1)2 E N 2 3 N O 6 <u>N</u> ω 3(0)12ω ω ω ω w 0 (T) 2 (0)1(0) 1 (YES) YES (NO 0(1)20(1)2YES Ϋ́ΕS 2 Ö **N**O 8 ψ ω ယ w w ω ω (YES) (0)1(0)1 (0)120)1 012YES 0 0 YES YES (1) 21(2/3 $(1)^2$ 'n S Q 2 N) NQ 8 0 S w w w ω ω ω 0)12 0 (O) 1 YES) 0 0(1)2 YES 0 0(1) /YES ΥES 0(1)(1)2N Ν N N <u>N</u> ON S <u>N</u> w ω ω w w ω w (SEV) /YES Ō 0 0 0 0 YES ΥES 0 0 O T \vdash щ \vdash 1 0 N 2 N N 2 N S 8 <u>2</u>0 N O Ś w w ω ω W ω ω YES 0 0 YES 0 0 0 YES 0 YES 0 0 ــــ 1 H 44 د ا 4ـــا 128. 0 2 Ν 2 Ν 2 2 <u>Z</u>

ψ

ω

w

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

DATE COMPLETED: 1 1 20 - 13

SUBJECT NUMBER: ARP 041

SUBJECT INITIALS AND DATE: NLD 11/27/13

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | - | 2 | ٣ | 4 | ır | 9 | , , | 00 | |
|------------------------|-------------|-----------|---|----------------------|-------------------------|----------|--------------|-------------|-----------------|
| | 6112/11 | 11/28/113 | 11/20/13 | (13 | 12/01/13 | 12/0413 | 12/09/13 | 5/10/27 | 12/09/3 |
| Runny Nose 0 to 3 | 0 1 2 3 | 01 2 3 | O1 2 3 | 0123 | 0123 | 0 1 2 3 | O 123 | 0 1 2 3 $($ | (01 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0)1 2 3 | $\begin{array}{cc} 0 & 1 \\ \end{array} \begin{array}{c} 3 \end{array}$ | 0 10 2 3 | 0 1(2) 3 | 0 1 2 3 | 0123 | 0 (1) 2 3 | 0 (1) 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1(2)3 | 0 1(2) 3 | © 123 | 0 (1) 2 3 | 0(1)2 3 | 0(1) 2 3 | $0(1)^{23}$ | 0(1)2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 (| 0123 | 0 1 2 3 | 0 1 2 3 | 0123 | (O) 1 2 3(| 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES NO | (YES NO | YES (NO | YES (NO | YES (NO | VES (NO | YES (NO) | YES (NO |
| Throat Clearing Y/N | YES NO | (YES) NO | YES NO | (YES) NO | YES NO | YES (NO | YES (NO) | (YES) NO | (YES) NO |
| DAY PM | - - (| 2 | 3 | 4 | 5 | 9 (| 7 | 8 | 6 |
| Runny Nose 0 to 3 | 0 h 2 3 | (0 A 2 3, | (g) 1 2 3 | $\bigcirc 1 \ 2 \ 3$ | 0)123 | 9123 | (0)123 | (O) 1 2 3 (| 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1(2)3 | 0 1 (2) 3 | 0 1 2 3 | 0123 | 0 1 2 3 | 0 1(2) 3 | $0(1)^2$ 3 | 0 1 2 3 | 01 2 3 |
| Congestion 0 to 3 | 0 (1) 2 3 | 0(1)23 | 0 (1) 2 3 | 0(1) 2 3 | 0(1) 2 3 | 0(1)23 | 0(1)23 | 0(1)2 3 | 0(1)2 3 |
| Sneezing 0 to 3 | 9123 | (0 1 2 3 | (0) 1 2 3 | 0)123 | $0\left(1\right)^{2}$ 3 | 0)123 | 0(1) 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | ves (NO | YES (NO) | YES(^C NO) | YES (NO) | YES (NO) | YES (NO | YES (NO | WES NO | YES (NO) |
| Throat Clearing Y/N | YES (NO | YES NO | YES NO | (YES) NO | (KES) NO | VES) NO | KES) NO | (YES/ NO | YES) NO |
| SCALE 0 to 3 | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

DATE COMPLETED: 11/27/13 - 12/5/13 SUBJECT INITIALS AND DATE: NLD 12/06/13 SUBJECT NUMBER: AICPOU

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: Medical Record: DOB: 02/02/1988

NLD, NLD AAGI 6777

Age:25Y Sex:F

31033172

Account Number: Attending MD:

Unlisted Physician

Patient ID:AKP041 Patient Phone: 0

F3332962 COLL: 12/06/2013 11:15 REC: 12/06/2013 18:12 PHYS: Unlisted Physician Req#: 31033172

2/07/2013 07:17 am FAXED TO 488546NCCS11533

Eos, Respiratory

* Rare

[NS]

Phys, Addr, Phone

NOT GIVEN

10 Dec 2013

END OF REPORT

Printed: 12/07/2013 07:14

INTERIM REPORT

Patient Name: NLD, NLD Medical Record #: AAGI6777

Location: CORE

Page: 1

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| γVQ | 7 | α | σ | 10 | 11 | 13 | 13 | 7.7 | 7 |
|------------------------|-----------------|-----------|-----------|-------------------|-------------|----------------|-----------|-----------|----------|
| AM | 12/0/13 | [2/07/13 | 8(3 | [युष्याह | (2/10/13 | 12/11/13 | 12/12/13 | 12/13/13 | 12/14/18 |
| Runny Nose 0 to 3 | 0123 | 0123(| 0 1 2 3 | 0)123 | 01 2 3 | O 1 2 3 | 0123 | 0123 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0(1) 2 3 | 0123 | 0 1 2 3 | 0(1)2 3 | 0 (1) 2 3 | 01 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1(2) 3 | 0(1) 2 3 | 0(1)2 3 | 0(1)23 | 0(1)23 | 0(1)2 3 | 0(1) 2 3 | 0(1) 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | $0^{1 \ 2 \ 3}$ | | 0(1)23(| 0 1 2 3 | 0 (1) 2 3 (| 0 1 2 3 | 0/1 2.3 | 01 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO | YES (NO | YES (NO) | YES (NO | YES (NO | YES (NO | yes (NO) | YES) YNO | YES NO |
| Throat Clearing Y/N | (YES / NO | YES (NO | (YES/ NO | ON (YE) | (YES) NO | YES (NO | (YES) NO | VES NO | YES NO |
| DAY PM | 7 | ∞ • | 6 | ر بر 10 | 11 | 12 | 13 | 14 | 15 |
| Runny Nose 0 to 3 | $(0)_1$ 2 3 | (0)123 | (0) 1 2 3 | (v) 1 2 3 (| 0123 | 0)123(| 0 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0(1) 2 3 | 0123 | 0 1 2 3 | (<u>0</u>)1 2 3 | 0(1) 2 3 (| 0123 | 0(1) 2 3 | 0 1 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0(1)23 | 0(1) 2 3 | 0(1)2 3 | 0 1 2 3 | 0(1)23 | 0(1)2 3(| 0 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0^{123} | 0123 | 0 1 2 3(| 0 1 2 3 | $0(1)^{2}$ 3 | 0)1 2 3 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | (YES) NO | VES (NQ) | YES (NO) | YES (NO | YES (NQ | YES NO | YES NO |
| Throat Clearing Y/N | VES NO | YES NO | (ÝĖS) NO | YES (NO) | VES (NO) | VES (NO) | VES (NO) | YES NO | YES NO |
| | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3≈ Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

DATE COMPLETED: $i \frac{2}{13}$ SUBJECT NUMBER: PKPD4

SUBJECT INITIALS AND DATE: 74 12-13-13



Lovelace Scie: Resources Leslie Byatt, Clnr Frials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 **Client Nbr**

24664

PATIENT NAME NLD, NLD

PHYSICIAN

Unlisted Physician, REQUISITION NO.

31033184

0

PT. PHONE NO.

PATIENT ID

AAGH8310

DOB 02/02/1988 SEX

REPORT STATUS Final

PAGE

COLLECT DATE & TIME

12/13/2013 11:25

RECEIVE DATE & TIME 12/13/2013 19:28 PRINT DATE & TIME

12/16/2013 06:13

PATIENT NO.

COMMENTS:

AKP041

Test

Eos, Respiratory Phys. Addr. Phone

None seen Not given

In Range

Result

Out of Range

Units

Reference Range

NS

Site Code

ppn Gab I

End of Report

FAX24664

| | | | | <u>5</u> | <u>_</u> | て _ | | | | | | | _ | | |
|--------------------------------|----------------------|-------------------|---|---------------|------------|-----------|--------|------|--|------|------|---|---|---------------------------------|--|
| | | | Investigator Initials/Date | Marie | 1 2 2 W | Ma staly | income | | | | | * | | | PAGE: L of |
| LSR Study #: 2749 | Subject Initials: ML | | Action Taken | none | none | | | | | | | e as specific as possible* | Date: 27 Febro14 | 71/10/0 | |
| RSI | Sub | (5) | ** End Date (DD/MIMIM/YYYY) | 08/Dec/2013 | "/Dec/2013 | | | | | | | nould be made to be | Date: | Date; | |
| | | ADVERSE EVENT LOG | Relationship to Study Drug (Suspected/Not Suspected) | the suspected | Suspected | rested | | | | | | ** If day is unknown, write UNK in space provided, but every effort should be made to be as specific as possible ** | Mustainson | by Brand | Lovelace Scientific Rasources, Inc - AdverseEvents 04/2013 |
| 3 | | | SEVERITY | inld. | pull | mod | | | | | | rite UNK in spac | [A]: | dy): | 07) |
| Study Identification: ALPHNING | HERMI | | ** Start Date (DD/MMM/YYYY) | Ocelocelis | 27/NOV/13 | 17/08c/13 | | | | | | If day is unknown, w | Investigator Signature (at end of study): | SC Signature (at end of study): | |
| Study Identification: | Subject Number: | | Adverse Event | Simulatis | Work Borns | Wespirato | | | | | | ** | Investigator Sign | SC Sig | |



Lovelace S: tific Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

PATIENT NAME X, NLD

PATIENT ID **AAGJ3404** DOB 02/02/1988 SEX F

REPORT STATUS Final

PAGE

Site Code

PHYSICIAN Unlisted Physician, COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

12/20/2013 11:26 PATIENT NO.

12/20/2013 20:15

12/23/2013 06:08

30920953

COMMENTS:

AKP041

| | Resu | ilt | | |
|---|---|--------------------|------------------|-----------------|
| Test | In Range | Out of Range | Units | Reference Range |
| Comp Metabolic Panel | | | | |
| Sodium | 137 | | mmol/L | 134-144 |
| Potassium | 3.9 | | mmol/L | 3.5-5.1 |
| Chloride | 105 | | mmol/L | 98-111 |
| CO2 | 26 | | mmol/L | 20-30 |
| Anion Gap | 6 | | | 6-14 |
| Glucose | 76 | | mg/dL | 60-100 |
| BUN | 10 | | mg/dL | 7-31 |
| Creatinine | 0.71 | | ma/dL | 0.50-1.40 |
| | Creatinine method is IDMS tr | aceable. EstGFR Ca | | |
| | Please note new reference ra | nge effective 5/23 | /2013. | - |
| eGFR non-African Am GFR Comment | >60 | | mL/min/1.73m2 | >60 |
| -,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | Estimated GFR values are not on IV fluids, obese (BMI>34) | or underweicht (B | MI<20) people. | |
| | the very old or very young, people with acute illnesses, | races other than C | aucasian or Afri | lcan American, |
| Calcium | 8.8 | • | mg/dL | 8.4-10.4 |

Total Protein 7.2 gm/dL 6.1-8.2 Albumin 3.9 gm/dL 3.4-4.7 gm/dL Globulin 3.3 2.4-4.2 Billrubin, total 0.8 mg/dL 0.3 - 1.2Ū/L 100 38-150 Alk Phos 13 U/L AST(SGOT) 6-58 ALT(SGPT) 19 U/L 14-67

Fasting YE\$ 3.6 mg/dL 2.3-5.6 Phosphorus CBC WBC 6.6 x10E3 4.0-10.6 **RBC** 4.52 x10E6 4.00-5.36 gm/dL 13.6 12.0-16.0 Hgb 42 % 36-48 Hct MCV 93 fL 81-98 32,5 MCHC gm/dL 31.2-35.2 % 12.8 RDW 11.0-14.5 150-400 NCS MM **Platelets** 281 x10E3 Eos, Respiratory Few

Phys, Addr, Phone NO PHYSICIAN LISTED

End of Report

Museine no Sub-I 12/24/17

| Study Identification: | Akthama | Allers | 8 | | | | LSR#: | 2749 |
|-----------------------|--|----------------------|------------|--|--------------|---|-------------------|----------------|
| Subject Number: | AKPOYI | | , | | | | Subject Initials: | s: NLD |
| List all J | List all <u>prescription</u> medications you | CONC ou are takir | OMITA | CONCOMITANT MEDICATION LOG | ATION L | CONCOMITANT MEDICATION LOG are taking. Also include over-the-counter medications, vitamins and supplements. | s and suppleme | nts, |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS |
| Example | Diabetes | 200 | .∜MG | 12 Tabs per day 📶 | Oral | | | |
| nore | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | , | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or mo | nth of medi | cation da | te is <u>unknow</u> | n, write UN | * If day or month of medication date is unknown, write UNK in space provided | | |
| Investigator Signatu | Investigator Signature (at end of study): | | Jank | anlin | | Date: 27 Feb 2014 | 1102-8 | |
| SC Signatu | SC Signature (at end of study): | alle | Br | The state of the s | | Date: $2/\hat{c}$ | 71/10 | |
| | | Lovelace | Scientific | Lovelace Scientified Resources, Inc - ConMeds 04/2013 | Aeds 04/2013 | | ` 1 | PAGE: |

EFFECTS OF AKPharma's CALCIUM GLYCEROPHOSPHATE NASAL SPRAY WASH (AKP010112A)

| | | _ | | | - | , | | | | | | | | | | | | | | | | | | | | |
|--|--|-----|----------|------------|--------|------------|--------|----------------|------------|----------|--------|--------------|------------|------------------------|---|--------|----------------------|------------|---------------|------------|--------|----------|--------|--------------|-----------------|-----------|
| | | | 121/12 | 3 2 | | 2 3 | | 2 3 | | 2 2 | | SN ON | | NO | | 7 | 2 3 | | 5 3 | 7 % | | 7 | | ON | | 9 |
| | | 22 | 7 | 0 | | 0 | | 0 | | C | | YES | | YES | | 22 | 0 1 | f | ⊣ ⊃ | C | | 1 | | YES | | YES |
| | | | 20/13 | 2 3 | • | 2 3 | | 2 3 | | 2 3 | | ON ON | | 8 | | · | 2 3 | | ი 7 | 7 | | 2 3 | | SN ON | | 9 |
| | (interest | 7 | 12/2 | 0 |) (| 0 | | 0)1 |) (| 0 | . 1 | VES) |)(| YES) | | 21 | 0 1 | - | - - | 6 | | 0 | | YES | | YES |
| ΕŢ | | | 1/12 | 2, | | 2 3(| | 2 3(| | 12 37 | | | , \ | 9 | |) | 2 3 | 0 | | 2 3 | | 2 | | 9 Q | | <u>§</u> |
| OMFO | | 20 | 12/10 | 0(1) |) (| 0)1 |) (| 0)1 |) | 0 (1/2 | | YES | | YES) | | 20 | 0 | | - | | | 0/1 |)(| YES | | YES (|
| NG CC | | 6 | 18/12 | 233 |) | 2 3 | | 2 3 | | 2 3 | ٧ | ON) |) | ON O | İ | |) 3 (| 0 | | 2 3 |) | 2 3 | • | ON ON | | 0 0 |
| ON PATIENT-PERCEIVED BREATHING COMFORT | | 19 | 121 | 0 1(| • | 0 (1) |) | 0 1 |) | (T) 0 | | YES (| (| (YES) |) | 19 | 0 1(| 1 | _ | 0 | | 0 | 5 | YES (| 4 | YES |
| D BRE | | 80 | 1/13 | 2)3 | _) | 2 3 | | 2 3 | | 2 3 | | 9 | | ON | | 20 | 23 | 0 | | 2 3 | | 2 3 | - 1 | (N) | | 2 |
| CEIVE | | 18 | 12/ | 0 1(| (| 0)1 |)) | (T) o |) (i | 0)1 | χ | YES | W | YES | \ | 138 | 0 1(| 6 | | 0 1 | | 0 | | YES (| | (1) |
| T-PER | | 7 | 6/13 | 2 3 | | 2 3 (| |)2 3 | i | 2 3 | | 2 | |) 0N | | | 2 3 | 7 | | 2 3 | | 2 3 | - (| (NO) | | 2 |
| \TIEN | 33 | +-1 | Z D | 0 |) (| $(0)_1$ |) | 0 T) |) (| (0)1 |) | YES | | YES_ | ŀ | 11 | $\frac{0}{2}$ | 6 | | 0(1) |) (| 0(1) | > ` | YES (| | |
| 7d NO | DIAR | 9 | 5/13 | 2 3 (| , | 2 3 | | 2 3 | | 2 3 | | S S | |) 8 | | | 2 3 | 2 |) | 2 3 | | 2 3 | (| 2 | | 2 |
| | E SHEET (RHINITIS INSE EVERY 12 HOURS | 16 | 13/15 | $(0)_1$ |) (| 0 | (| 9 | 4 | (T) 0 |)(| YES) | | YES) | | 16 | 0 | | _ | 0)1 | 70 | 0)1 | ` | YES | 7.2.7 | , ES |
| | ET (RH | 15 | 113 | 2 3 | | 2 3 | | 2 3 | | 2 3 | (| (ON) | | 9 0 0 0 | | | 2 3 | 7 | | 2 3 | دیم | 2 3(| (| ON | | |
| | SHE! | 1 | 70 | 0 |) (| $(0)_{1}$ | | (1) |) (| 0) 1 |) | YES | | (KES) | | 15 | , (©1 | - c | , | 0(1) |) (| 0 1 |) | YES (| 777 | i i |
| | SCOR! | l . | <u>.</u> | 2 3(| | 2 3 | | 2 3 | | 2 3(| _ | ON_ | - | 2 | | | 2 3 | 75 | | 2 3 | | 2 3 (| | <u>0</u> 2 | (2 | 2 |
| | OMS: | T | 13/13 | <u>δ</u> ~ | _ | 0/1 | _ | | | 0 | | YES | | YES | | 14 | 0 | 0 11 2 | 5 | 0 (1) |) (| 0)1 |) | YES (| V V | 3 |
| | DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY) <u>CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS</u> | | | Se | | aı. | | <u>c</u> | | | | ırse | | aring | | Σ | Se | 4 | | _ | | | | rse | r. | 20 20 |
| | AILY S | DAY | AM | Runny Nose | 0 to 3 | Itchy Nose | 0 to 3 | Congestion | U to 3 | Sneezing | 0 to 3 | Voice Hoarse | | Throat Clearing V/N | | DAY PM | Runny Nose 0 to 3 | Itchy Nose | 0 to 3 | Congestion | 3 | Sneezing | 23 | Voice Hoarse | Throat Cloaning | ים ו ה |
| | | | | Ru | O t | 돧 | | 8 8 | 5 | Sn | O ţ | Vojo | 5 | Thro | - | | Runny 0 to 3 | Itc | 0 tc | S | 0 to 3 | Sne | 0 to 3 | Voic | Ė | X X |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)
3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)
Y=Yes N= No

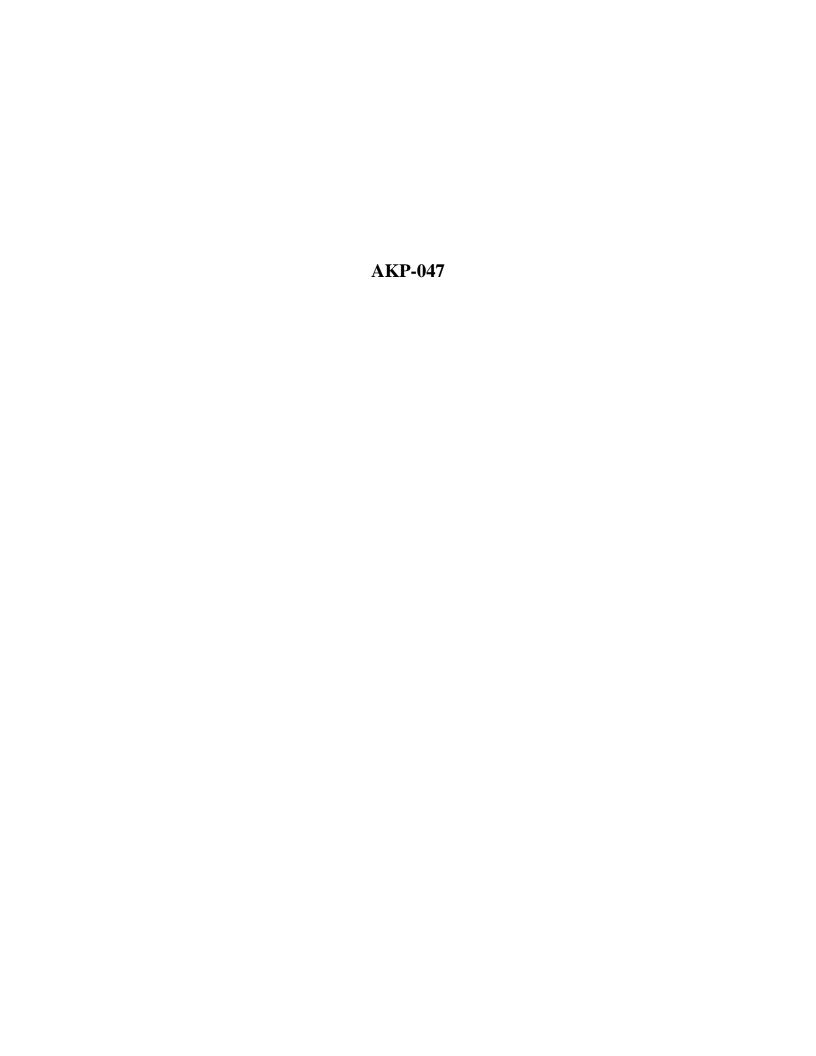
DATE COMPLETED:_ SUBJECT NUMBER: AKP DU

Effects of AkPharma's Calcium Glycerophosphate
Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

| SATISFACTION QUESTIONAIRRE: |
|--|
| Would you use / purchase this nasal wash product in the future?" ☐YES ☐NO |
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| IF the flavor was better I would buy |
| IF the flavor was better I would buy it. It also doesn't squirt very well. |
| V. Ø |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

[Type text]
Subject initials and Date_NID 12/20/13

Study Staff Initials and Date EM 1212013



2,49 AKPharma PERENNIAL ALLER JES SCREENING/VISIT 1 SOURCE DOCUMENTS

| Patient Demographics Date of Birth: OG Feb! 1947 (dd/mmm/yyyy) Gender: Male Female If female, Indicate Childbearing Potential Post-Menopausal Ethnicity: Hispanic Non Hispanic Race: Asian Black Caucasian American Indian Pacific Islander Other, Specify Smoking History Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) | Initials: LDR Site #:Subject #: ACT |
|--|--|
| Date of Birth: OG Febisaying (dd/mmm/yyyy) Gender: Male | PATIENT DEMOGRAPHICS |
| Gender: Male | Patient Demographics |
| If female, Indicate Childbearing Potential Childbearing Surgically sterilized Post-Menopausal Ethnicity: Hispanic Non Hispanic Race: Asian Black Caucasian American Indian Pacific Islander Other, Specify Smoking History Smoking History None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Date of Birth: 06 1Feb/1947 (dd/mmm/yyyy) |
| Childbearing Surgically sterilized Post-Menopausal Ethnicity: Hispanic Non Hispanic Race: Asian Black Caucasian American Indian Pacific Islander Other, Specify Smoking History Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Gender: |
| Ethnicity: | If female, Indicate Childbearing Potential |
| Race: Asian Black Caucasian American Indian Pacific Islander Other, Specify Smoking History Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Childbearing Surgically sterilized Post-Menopausal |
| Smoking History Dever to Noked In the Past | |
| Smoking History Never 5 moked in the Past Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Race: Asian Black Caucasian American Indian |
| Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Pacific Islander Other, Specify |
| Smoking Status: None (smoked less than 100 cigarettes in lifetime) Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | |
| Former (previously smoked more than 100 cigarettes in lifetime) Current (smokes now) If subject is a former or current smoker, please indicate: | Smoking History |
| Current (smokes now) If subject is a former or current smoker, please indicate: | Smoking Status: None (smoked less than 100 cigarettes in lifetime) |
| If subject is a former or current smoker, please indicate: | Former (previously smoked more than 100 cigarettes in lifetime) |
| | Current (smokes now) |
| Years smoked: Cigarettes per day: | If subject is a former or current smoker, please indicate: |
| | Years smoked: Cigarettes per day: |
| | |

Version: 02 September 2013

CRC



COLLECT DATE & TIME

Lovelace Scir Ic Resources Leslie Byatt, Cmi Trials 2441 Ridgecrest Dr SE Albuquerque, NM87108-5129

Client Nbr 24664

LDR, LDR

PATIENT NAME

PATIENT ID **AAGJ4034**

02/06/1947

М

REPORT STATUS Final

PAGE 1

Site Code

PHYSICIAN

Unlisted Physician. REQUISITION NO. PT. PHONE NO. 12/23/2013 09:41

RECEIVE DATE & TIME 12/23/2013 18:55 PRINT DATE & TIME 12/24/2013 06:03

31033191

0

PATIENT NO.

AKP047

COMMENTS:

Test Allerg,Panel 18 Allerg,Juniper Allerg, Cottonwood

Allerg, West. Ragweed Allerg, Russian This Allerg, Bermuda Grass Allerg, Alternaria Allerg, Mesquite Allerg, Cockroach

Allerg, Derm. pter.

| Kesui | |
|-------|---|
| | _ |

In Range Out of Range Units Reference Range kŲ/L 5.30 < 0.35 kU/L 0.40 <0.35 Н 0.20 kU/L < 0.35 4.30 kU/L. < 0.35 kU/L 3,60 < 0.35 Н kU/L 2.30 Н < 0.35 0.20 kU/L < 0.35 <0.10 kU/L <0.35

< 0.10 kU/L <0.35 The standard classification system utilizes the following class cutoffs. Class ku/i Interpretation

| Class | KU/L | Interpretation |
|-------|--------------|-----------------------|
| 0 | <0. 35 | Negative for Allergen |
| I | 0. 35-0. 69 | Positive for Allergen |
| II | 0. 70-3. 49 | Strongly Positive |
| III | 3. 5-17. 49 | Strongly Positive |
| IV | 17. 5-52. 49 | Strongly Positive |
| v | 52. 5-99. 99 | Strongly Positive |
| | | |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

Strongly Positive

0.40

1.30

0.90

6.80

1.60

2.20

| Allerg,Derm. farinae | <0.10 |
|----------------------|-----------|
| Allerg, Clad. herb. | <0.10 |
| Allerg, Firebush | |
| Allerg Cat Dander Ep | |
| Allerg, Dog Dander | |
| Allerg, Bluegrass | |
| Allerg, Pigweed | |
| Allerg, Mulberry | |
| Allerg, Helminth | <0.10 |
| Phys. Addr. Phone | Not given |

VI

>100

Amulaine sub I Z Jan 2014

Н

Н

Н

H

Н

kU/L kU/L

kU/L

kU/L

kU/L

kU/L

kU/L

kU/L

<0.35

< 0.35

< 0.35

<0.35

< 0.35

< 0.35

< 0.35 <0.35

End of Report



evelace Scientific Resources 41 Ridgecrest Dr SE Albuquerque, NM 87108



PBar: 636

Name: LDR,

Gender: Male

Age: 66

Race: Caucasian

Height(in): 68.0

Weight(lb): 172

Any Info:

Id: AKP-047

Date: 01/14/14

Temp: 21 Physician:

Technician: VL

| | | | | | | | | | | | | |
|--------------|-------------|-----------|-------------|--------------|-----|---------------|---------------|------------------------|-----------------|-------------|-------------|---|
| Culuanas | (B | TPS) | PR | E-RX | POS | ST-RX | | Flow | | | | |
| Spiromet | ry - | Ref | Pre Meas | Pre % Ref | | Post % Ref | Post % Chg | 16 _T | | | | |
| FVC | Liters | 3.85 | 4.29 | 111 | | | ū | + | | | | |
| FEV1 | Liters | 3.06 | 3.14 | 103 | | | | 40 | | | | |
| FEV1/FVC | % | 79 | 73 | 92 | | | | 12+ | | | | |
| FEF25-759 | | 3.10 | 2.21 | 71 | | | | + | • | | | |
| FEF50% | L/sec | 3.88 | 2.61 | 67 | | | | | /'\ | | | |
| FEF75% | L∕sec | 1.36 | 0.71 | 52 | | | | 8 + | / \ | | | |
| IC | Liters | | | | | | | 1 | $I \setminus I$ | | | |
| VC | Liters | 3.85 | | | | | | | [] | | | |
| PEF | L/sec | 7.93 | 10.45 | 132 | | | | 4 † | \ | \ | | |
| MVV . | L/min | 126 | | | | | | 1 | 1 | my de | | |
| PIF | L/sec | | 2,42 | | | | | Ī | 1 , | Vinner | | |
| FEV1/FEV | | | 80 | | | | | 0 + | + | 1 1 | | |
| Lung \ | /olumes/F | ³lethysm∘ | ogra | phy | (E | TPS) | | 1 | Ĺ | | | |
| Vtg : | Liters | · | ~ | • | | | | | | 7 | | |
| vč | Liters | 3.85 | | | | | | -4+ | | | | |
| TLC | Liters | 6.09 | | | | | | [| | | | |
| RV | Liters | 2.34 | | | | | | T | | | | |
| RV/TLC | % | 39 | | | | | | -8+ | | | | |
| FRC PL | Liters | 3.46 | | | | | | | | | | |
| ERV | Liters | | | | | | | Ť | | | | |
| IC | Liters | | | | | | | -12 1 | | | | |
| Diffusi | on | | | | | | | -12 [⊥] -2 | 0 | 2 Volume | 6 | 8 |
| DLCO | mL/mmHg/min | | | | | | | | | VOIGITIE | | |
| DL Adj | mL/mmHg/min | 20.8 | | | | | | | | | | |
| DLCONA | | | | | | | | | | | | |
| 174 | Litana | | | | | | | | | | | |

Resistance

VΑ

BHT

 Raw Total Raw Insp
 cmH2O/L/sec cmH2O/L/sec
 cmH2O/L/sec

 Raw Exp
 cmH2O/L/sec
 1.31

 Gaw
 cmH2O/L/s/L
 0.830

 sRaw
 cmH2O/L/s/L
 4.52

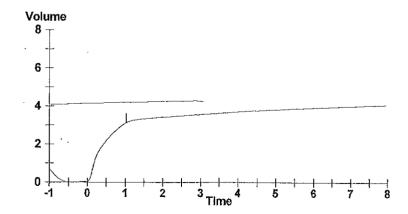
 sGaw
 L/s/cmH2O/L
 0.221

 Vtg (Raw)
 Liters

Liters

Sec

Comments:





Levelace Scientific Resources 201 Ridgecrest Dr SE Albuquerque, NM 87108



Name: LDR.

Gender: Male

Age: 66

Race: Caucasian

Height(in): 78.0

Weight(lb): 171

Any Info:

ld: AKP-047 Date: 01/23/14

Temp: 24

PBar: 633

Physician: Technician:

| ~ | | (B | TPS) | PR | E-RX | POST-RX | | Flow | | | *** | |
|-----|--------------|--------------|-----------------|---------|-------------|------------|-------|-----------------|-------|--------------------|-----------------|----------------|
| 5 | piromet | ry · | Ref | Pre | Pre | Post Post | Post | 16 T | | | | |
| F۱ | /C | Liters | 5.96 | 4.06 | % Ref 68 | Meas % Ref | % Chg | 1 | | | | |
| | EV1 | Liters | 4.73 | 2.90 | 61 | | | 40 | | | | |
| | EV1/FVC | % | 77 | 72 | 93 | | | 12 | | | | |
| FE | EF25-759 | %L/sec | 4.55 | 1.99 | 44 | | | 4 | _ | | | |
| | EF50% | L/sec | 5,59 | 3.09 | 55 | | | | | | | |
| | EF75% | L/sec | 2.14 | ** 0.61 | ** 28 | | | 8 + | - / \ | | | |
| IC | | Liters | | | | | | 1 | 1 | \ | | |
| VC | | Liters | 5.96 | | | | | Í | 1 | 1 | | |
| PE | | L/sec | 10.32 | 11.31 | 110 | | | 4 † | | /^ | | |
| | ŽΛ | L/min | 160 | | | | | | [| V | | |
| Pli | r EV1/FEV | L/sec | | 79 | | | | | } | my | | |
| | | | 73.1 (1. | | | /paral/ | | 0 | | () } } | - | - |
| | | /olumes/f | letny | /smogra | pny | (BTPS) | | 1 | | | | |
| Vt(| g | Liters | | | | | | | | | | |
| VC | | Liters | 5.96 | | | | | -4 + | | | | |
| TL | | Liters | 8.4 8 | | | | | 1 | | | | |
| R۱ | | Liters | 3.02 | | | | | _ | | | | |
| | //TLC | % | 39 | | | | | -8 | | | | |
| | RC PL | Liters | 5.18 | | | | |] | | | | |
| EF | | Liters | | | | | | | | | | |
| ic | :cc : | Liters | | | | | | -12 -2 | _ | • | _ | _ |
| | iffusi | | | | | | | -2 | 0 | Volume 4 | 6 | 8 |
| | .CO | mL/mmHg/min | 23.8 | | | | | | | VOIGING | | |
| | . Adj | mL/mmHg/min | | | | | | | | | | |
| | .CO/VA | mL/mHg/min/L | 3.07 | | | | | | | | | |
| VA | | Liters | | | | | | | | | | |
| BH | 打 | Sec | | | | | | | | | | |
| R | esista | ance | | | | | | | | | | |
| | | cmH2O/L/sec | | | | | | | | | | |



Vtg (Raw) Liters

Raw Exp

Raw

Gaw

sRaw

sGaw

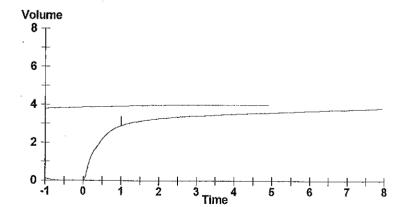
Raw Insp cmH2O/L/sec

cmH2O/L/sec

cmH2O/L/sec L/sec/cmH2O 1.242

cmH2O/L/s/L 4.16 L/s/cmH2O/L 0.241

4.16





Lovelace Scientific Resources 2 1 Ridgecrest Dr SE Albuquerque, NM 87108



Name: LDR,

Gender: Male

Age: 66

Race: Caucasian

Height(in): 68.0 Weight(lb): 170

Any Info:

Id: AKP-047

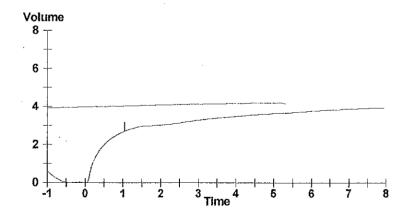
Date: 01/28/14 Temp: 19

PBar: 631

Physician: Technician:

| | (E | TPS) | PR | E-RX | POST-RX | | Flow |
|-----------|--------------|--------|-------------|--------------|-------------------------|---------------|---|
| Spirometr | ry | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 16 |
| FVC | Liters | 3.85 | 4.26 | 111 | | • | + |
| FEV1 | Liters | 3.06 | 2.73 | 89 | | | 12 |
| FEV1/FVC | % | 79 | 64 | 81 | | | 12. Τ |
| FEF25-75% | %L/sec | 3,10 | 0.90 | 29 | | | + /\ |
| | L/sec | 3.88 | 2.03 | 52 | | | _ |
| FEF75% | L/sec | 1.36 | 0.29 | 21 | | | 8 |
| IC | Liters | | | | | | 1 |
| VC : | Liters | 3.85 | | | | | |
| PEF | L/sec | 7.93 | 11.54 | 146 | | | 4 |
| MVV | L/min | 126 | | | | | |
| PIF | L/sec | | 3.18 | | | | † |
| FEV1/FEV | 6% | | 73 | | | | 0 |
| Lunal | /olumes/l | Plethy | moara | nhv | (BTPS) | | |
| _ | | ioury. | ,,,,og,.a | P.13 | | | |
| Vtg | Liters | | | | | | -4 |
| VČ. | Liters | 3.85 | | | | | |
| TLC | Liters | 6.09 | | | | | , |
| RV | Liters | 2.34 | | | | | |
| RV/TLC | % | 39 | | | | | -8 |
| FRC PL | Liters | 3.48 | | | | | <u></u> |
| ERV | Liters | | | | | | |
| IC . | Liters | | | | | | -12 ¹ -2 0 2 ₁₀₁₁₁₁ 4 6 |
| Diffusion | on | | | | | | |
| DLCO | mL/mmHg/min | 20.7 | | | | | |
| DL Adj | mL/mmHg/mir | 20.7 | | | | | |
| DLCONA | mL/mHg/min/L | | | | | | |
| VA | Liters | | | | | | |
| BHT | Sec | | | | | | |
| Resista | ance | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | |
| | cmH2O/L/sec | | | | | | |
| | cmH2O/L/sec | | | | | | |
| Raw | cmH2O/L/sec | 1.30 | | | | | |
| Gaw | L/sec/cmH2O | | | | | | |
| sRaw | cmH2O/L/s/L | 4,52 | | | | | |
| sGaw | L/s/cmH2O/L | | | | | | |
| Vta (Raw) | | V.&& I | | | | | |







Lovelace Scientific Resources 2 Ridgecrest Dr SE Albuquerque, NM 87108



Name: AKP047,

Gender: Male

Age: 66

Race: Caucasian

Height(in): 68.0

Weight(lb): 170

Any Info:

ld: AKP047 Date: 02/05/14

Temp: 19

PBar: 631

Physician:

Technician: CRD

| Any Info: | | | | | | ecnnicia | in: CRD | | |
|-----------------------|-----------------------|------------|-------------|-----------|-------------------------|---------------|--------------|--|-------------|
| Spiromet | rv (B | TPS) | | E-RX | POST-RX | Deet | Flow | | |
| | • | Ref | Pre Meas | | Post Post Meas % Ref | Post % Chg | 16 | | |
| FVC | Liters | 3.85 | 4.48 | 116 | | | t | | |
| FEV1 | Liters | 3.06 | 3.25 73 | 106 91 | | | 12 - | | |
| FEV1/FVC FEF25-759 | | 79 3.10 | 2.18 | 70 | | | | | |
| FEF50% | /aL/sec L/sec | 3.88 | 3.29 | 85 | | | † | \wedge | |
| FEF75% | L/sec | 1.36 | 0.63 | 46 | | | 8 - | / \ | |
| IC. | Liters | 1.00 | 0,00 | •• | | | | | |
| VC . | Liters | 3.85 | | | | | 7 | | |
| PEF | L/sec | 7.93 | 10.68 | 135 | | | 4 + | 1 | |
| M∨∨ | L/min | 126 | | | | | . 1 | | |
| PIF | L/sec | | 4.35 | | | | T | | |
| FEV1/FEV | | N1 (1 | 77 | | (BTPS) | | 0 | | |
| Lung \ | /olumes/F | 'lethysm | ogra | pny | (BIPS) | | 1 | | |
| Vtg | Liters | | | | | | | | |
| VC | Liters | 3.85 | | | | | -4 † | | |
| TLC | Liters | 6.09 | | | | | | | |
| RV | Liters | 2.34 | | | | | | | |
| RV/TLC | % | 39 | | | | | -8+ | | |
| FRC PL ERV | Liters Liters | 3.48 | | | | | 4 | | |
| IC IC | Liters | | | | | | 40 | | |
| Ďiffusi | กท | | | | | | -12 -2 | 0 2 4 | 6 8 |
| DLCO | mL/mmHg/min | 20.7 | | | | | | 0 2 Volume | |
| | mL/mmHg/min | 20.7 | | | | | | | |
| DLCOVA | mL/mHg/min/L | 3.06 | | | | | | | |
| VA | Liters | | | | | | | | |
| BHT | Sec | | | | | | | | |
| Resista | ance | | | | | | | | |
| Raw Total | cmH2O/L/sec | | | | | | | | |
| Raw Insp | cmH2O/L/sec | | | | | | | | |
| Raw Exp | cmH2O/L/sec | | | | | | | | |
| Raw | cmH2O/L/sec | 1.30 | | | | . 1 | | | |
| Gaw | L/sec/cmH2O | | | | | | | | |
| sRaw | cmH2O/L/s/L | 4.52 | | | | | | | |
| sGaw Vtg (Raw) | L/s/cmH2O/L Liters | U.22T | | | | | | | |
| AIR (LICIAN) | Littera | | | w. | Valuma | | | | |
| | | | | | Volume | | | | |

Comments:

Musuire and 05 Feb 2014 Volume

8
6
4
2
0
-1
0
1
2
3
Time
4
5
6
7
8



Lovelace Scien Resources Leslie Byatt, Ch., rilals 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME LDR, LDR

PATIENT ID

DOB 02/06/1947 SEX M

REPORT STATUS Final

PAGE 1

PHYSICIAN

Unlisted Physician, REQUISITION NO.

PT. PHONE NO.

AAGJ4034 **COLLECT DATE & TIME**

01/14/2014 08:35

RECEIVE DATE & TIME

PRINT DATE & TIME

PATIENT NO.

01/14/2014 18:29

01/17/2014 22:24

31033205

0

COMMENTS:

AKP047

| | | • | | |
|--|--|---|---|--|
| | | | • | |

| | | 1104011 | | | | |
|-------------------------|---------------------------|-----------------------|----------|------------------|-----------------|-----------|
| Test | In Range | Out of Rar | ıge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 136 | | | mmol/L | 134-144 | |
| Potassium | 4.0 | | | mmol/L | 3.5-5.1 | |
| Chloride | 100 | | | mmol/L | 98-111 | |
| CO2 | 26 | | | mmo!/L | | |
| | 10 | | | MINONE | 20-30 | |
| Anion Gap Glucose | 10 | 125 | | e. [st] | 6-14 | 10 Mals |
| Glucose | Impaired fasting glucose | 120 (TEG) is doffi | . H | mg/dL mg/dL | 60-100/// | 7 Miles |
| | 100-126 mg/dl. (ADA Guide | lines Diabetes | Care 26 | 3: (3160-3167)20 | 03) | |
| BUN | 15 | | | mg/dL | 7-31 | |
| Creatinine | 0.88 | | | mg/dL | 0.62-1.66 | |
| | Creatinine method is IDM | S traceable. Es | tGFR Ca | ilculation has | been adjusted. | |
| | Please note new reference | | | | | |
| eGFR non-African Am | >60 | o range cricee | | | | |
| GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| GER Comment | Estimated GFR values are | not accurate i | in acute | kidney failur | o innotiants | |
| | on IV fluids, obese (BMI | >34) or underwa | riaht (E | MI<20) people. | e iliharielira | |
| | the very old or very you | ng, races other | than (| aucasian or Af | rican American, | |
| | people with acute illnes | ses, or amputat | cions. | | , | |
| Calcium | 9.7 | | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.9 | | | gm/dL | 6.1-8.2 | |
| Albumin | 4.6 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.3 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.6 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 66 | | | Ŭ/L | 38-150 | _ |
| AST(SGOT) | 42 | | | U/L | 0 50 | a share |
| ALT(SGPT) | | 87 | Н | U/L | 14-67 | 5 Miller |
| Fasting | NO | | • • • | | 11 31 10 | |
| Phosphorus | 3.6 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | 111291 444 | 2.0 0.0 | |
| WBC | 6.0 | | | x10E3 | 4.0-10.6 | |
| RBC | 0.0 | 4.60 | L | x10E6 | 4.64-6.00 | · S MAIN |
| Hgb | 14.7 | 4.00 | L. | gm/dL | | / WA 4 |
| Hct | 43 | | | ymrac % | 14.5-17.7 | |
| MCV | 94 | | | | 42-53 | |
| MCHC | | | | fL | 81-98 | |
| RDW | 33.9 | | | gm/dL | 31.2-35.2 | |
| | 12.6 | | | % | 11.0-14.5 | |
| Platelets | 257 | | | x10E3 | 150-400 | |
| Phys, Addr, Phone | NO DUVETCTAN CTVEN | | | | | |
| | NO PHYSICIAN GIVEN | 72 | | | | |
| | CORRECTED ON 01/14 AT 18 | 32: PREVIOUSLY | REPORTE | ED AS NO PHYSIC | IAN | |
| Allerg,Panel 18 | | | | | | |
| Allerg, Juniper | | 5.10 | Н | kU/L | < 0.35 | |
| Allerg, Cottonwood | | 0.40 | Н | kU/L | <0.35 | a |
| Allerg, West. Ragweed | 0.10 | | | kU/L | <0.35 | hM. |
| Allerg,Russian This | | 4.30 | Н | kU/L | <0.35 | |
| Allerg Bermuda Grass | | 3.20 | Ĥ | kU/L | <0.35 | • |
| Allerg,Alternaria | | 2.50 | H | kU/L | <0.35 | |
| Allerg, Mesquite | 0.20 | | •• | kU/L | <0.35 | |
| Allerg,Cockroach | <0.10 | | | kU/L | <0.35 | |
| Allerg, Derm. pter. | <0.10 | | | kU/L | <0.35 | |
| · mar Gl - arrivi brace | The standard classificat | ion system util | izes th | ne following cla | ass cutoffs. | |
| | -9 1 | | | | | |

Continued on next page

LDR, LDR

01/17/2014 22:24

Interpretation

Class

ku/L

Manhine Sub-I 21 Jan 2014

FAX24664

DAILY SYMPTOMS SCORE SHEET (SCREEN DIARY)

<u>CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS</u>

| 78.0 | ٦ | , | L | | , | | | | |
|------------------------|------------|-----------|------------|-----------|-----------|-----------|-----------|-----------|---------|
| DAY | <u>`</u> | <u>م</u> | ų. | 4 | ψ, | 7 | | 0 | 0 |
| AM | 17114 | 1814 | । वात | 7110117 | []][] | 万[2][1 | 1 13 14 | [年][1 | 1 |
| Runny Nose | 0123 | 0123 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 🕲 3 | 0 1 🔘 3 | 0 1 (2) 3 | 0 1 2 3 |
| Itchy Nose | 0 1 2 3 | 0 1 (2) 3 | 0 1 2 3 | 0 ① 2 3 | 0 (1) 2 3 | 0 ①23 | 0 🗘 2 3 | 0 (1) 2 3 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1 2 (3) | 0 1 2 3 | 0 1 2(3) | 0 1 2 3 | 0 1 2 (3) | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 1 2 3 | 0 (1) 2 3 | 0 🛈 2 3 | 0 1 2 3 | 0 ①23 | 0 (1) 2 3 | 0 10 2 3 | 0 ① 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES NO | YES (NO) | YES (NO | YES (NÔ) | YES (NO) | YES 🔞 | YES (NO) | YES (NO) | YES NO |
| Throat Clearing Y/N | YES NO | (YES) NO | VES NO | (YES) NO | (VES) NO | (YES) NO | (YES) NO | (YES) NO | YES NO |
| DAY PM | <i>L</i> - | မှ | ι - | 4 | ကု | -2 | 7 | 0 | 0 |
| Runny Nose 0 to 3 | 0 1 (2) 3 | 0 1 2 (3) | 0.1 (2) 3 | 0 1 2(3) | 0123 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0 1 🕲 3 | 0 1 (2) 3 | 0 Ø 2 3 | 0 (1) 2 3 | 0 ① 2 3 | 0 1 2 3 | (0) 1 2 3 | 0 1 2 3 | 0 1 2 3 |
| · Congestion 0 to 3 | 0 1 ② 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2(3) | 0 1 2(3) | 0 1 2 ③ | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 3 |
| Sneezing 0 to 3 | 0 (1) 2 3 | 0 1(2) 3 | 0 (1) 2 3 | 0(1) 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0123 | 0 1 2 3 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO) | YES (NO | YES (NO | YES (NO) | ves (NO) | YES NO | YES NO |
| Throat Clearing Y/N | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | VES NO | (YES) NO | YES NO | YES NO |
| SCALE 0 to 3 | | | | | | | | | |

SCALE U TO 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

リカニレニ

Y=Yes N=No

SUBJECT NUMBER: AKP D47

DATE COMPLETED:

SUBJECT INITIALS AND DATE XXXII 1-14-2014

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 2 | Throat Clearing Y/N | Voice Hoarse Y/N | 0 to 3 | Sneezing | 0 to 3 | Congestion | 0 to 3 | Itchy Nose | 0 to 3 | Runny Nose | DAY PM | Throat Clearing Y/N | Y/N | Voice Hoarse | 0 to 3 | Sneezing | 0 to 3 | Congestion | 0 to 3 | Itchy Nose | 0 to 3 | Runny Nose | AM | DAY |
|------------------------------|------------------------|---------------------|--------|--------------|--------|-------------------|--------|-----------------------|--------|---------------|---------|------------------------|-----|--------------|--------|------------------|--------|-----------------|--------|---------------------|--------|-----------------------------------|--------------------|--------|
| ֡֝֝֟֝֓֓֓֓֓֓֓֓֓֓֓֓֓֓֓֟֝֓֓֓֓֟֟ | | arse | | | | n | | ው | | Se | × | | | arse | | | | 'n | | e | | se | | _ |
| | (SEA) |) YES | (| (0) 1 2 3 | | 0 1 | (| 0 (1) 2 3 | | 0 1(2) | | YES | | YES | ŀ | 7 0 | | 0 1 | | 0 | | 0 1 2 3 | 11111 | |
| | ON | (NO) | | 2 3 | • | 1 (2) 3 | | 2 3 | | ω | | ON | | NO | I | ر ت | | 2 3 | | 23 | | | | |
| | (SEA) | YES | (| (6) 1 | | 0 1 | | 0)1 | (| 0 (1) 2 | 2 | (YES) | } | YES | (| <u>)</u> | • | 0 1 | • | 0 | • | 0 1 | <u> </u> | |
| | NO | (S) | 3 | (6) 1 2 3 | | 01(2)3 | | (D) 1 2 3 | | 2 3 | 2 | NO | (| S S |) (| (a) 1 2 3 | (| 1 (2) 3 | • | 2 3 | 1 | (ව) 3 | <u>t</u> | |
| | (SEA) | YES | (| (0) 1 2 3 | | 100 | (| 0 | | 0 1 | | (YES) |) | YES | (| 6)1 2 3 | , | 0 1 | | 01 2 | | 0 1 2 3 0 0 2 3 | 1110 | |
| | NO | YES (NO) | | 2 3 | | 2 (I) 0 | | 0123 | (| 0 1 (2) 3 | 3 | NO | (| 8 | 1 (| ر د | (| 0 1(2)3 | • | 2 3 | | 2 3 | f | w |
| | YES | YES | (| (0) 1 2 3 | , | ① o | (| (0) 1 2 3 (0) 1 2 3 | (| 0 ① 2 3 | | (YES) |) | YES | Ç |) (5) | . (| 0 (1) 2 3 | . | 0(1)23 |) | 0 1 | 11/7/14 | - |
| | ON | YES (NO) |) | 2 3 | | 0①23 | | 2 3 | | 2 3 | 4 | NO | (| 8 | 1 | 0(1) 2 3 | | 2 3 | | 23 | (| 0 1 (2) 3 0 (1) 2 3 0 (1) 2 3 | | |
| | (SE) | YES | _ | 1(0) | | 2 🛈 0 | (| (0) 1 | 1 | 0 1 | | (SEA) | • | YES | (| 9 | | 0 1 | (| (i) 1 2 | (| (I) 0 | | |
| | ON | (NO | | (0) 1 2 3 | | 2 3 | | 2 3 | (| 0 1(2) 3 | 5 | NO | (| (ON) | 1 (| (n) 1 | (| (2) 3 | | 2 3 | | 2 3 | 4) 13 | |
| | (SEA) | YES | (| (0)123 | | 0 1 | | (0)12 | | 012 | | (YES) | } | ΥES | | | | 0 1 | | 0(1) 2 |) | \mathbb{O}_{0} | | |
| | ON | NO | | 2 3 | (| 0 1 (2) 3 | | 2 3 | | 2 3 | 6 | NO | (| (N) | 1 (| 0 (1) 3 | (| 0 1(2)3 0 1(2)3 | , | 2 3 | | 2 3 | F112111 H18111 | · • |
| | (YES) | YES | (| (6) 1 | | 0 1 | | (b) 1 | (| 0 | | (YES) | } | YES | © - | <u>)</u> | | | (| 9 | | (<u>U</u>) 0 | 77 | |
| | ON | (NO | | 2 3 | (| $(2)_3$ | | 2 3 | | 2 3 | 7 | NO | (| (NO | , , | ر د | (| 0 1 (2) 3 | | 2 3 | | | 10 14 | 7 |
| | (YES) | | | 0 (1 | | | | | (| | | (VES) |) | YES | | 2 | , | 0 | (| | | 0 | | |
| | N O | YES (NO) | | 0(1)23(0)123 | | 0 ① 2 3 0 ① 2 3 | | 0 (1) 2 3 0 (1) 2 3 | ` | 0(1)23 0(1)23 | 8 | (YES) NO | (| (NO) YES |) (| 0(1)2 3 (0)1 2 3 | | 0 1(2)3 0 1(2)3 | | ε 7 (O) ε 7 (L) 0 | | 23 0 🛈 23 0 🛈 23 | 014 1/2/14 1/22/14 | - |
| | YES |) ES | (| 0 | | 0 | , | 0 (1) | (| 0 | | (YES) NO | | | 10 | 3 | , | 0 | _(| 1 | | 0 | 2 1 | |
| | (YES) NO | YES (NO) | | 2 3 | · |)2 3 | |) 2 3 | ` |) 2 3 | 9 | NO | (| (O) | 1 | ر ا | (| 2) 3 | | 2 3 | |) 2 3 | 7714 | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

SUBJECT NUMBER: ACOUTT DATE COMPLETED: 1/23/14

SUBJECT INITIALS AND DATE: X J. 1-23-2014

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

| | 1 | |
|-----|----------------|---|
| אאר | CIRCLE APPROXI | |
| 1 | MATE RESPON | |
| • | ISE EVERY 12 | • |
| > | HOURS | |
| 3 | | • |
| _ | | |

| CC41 F O +- 3 | Throat Clearing Y | Voice Hoarse Y/N | Sneezing 0 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 0 to 3 | Runny Nose 0 0 to 3 | DAY PM | Throat Clearing (Y | Voice Hoarse Y/N | Sneezing (0 0 to 3 | Congestion 0 0 to 3 | Itchy Nose (0 0 to 3 | Runny Nose Ó 0 to 3 | AM '/ | DAY | CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS |
|---------------|-------------------|------------------|----------------------|-------------------|------------------------|------------------------|--------|--------------------|------------------|-----------------------|------------------------|-------------------------|------------------------|---------|-----|--|
| | YES NO | YES NO | 123 | 123 | 123 | 1 2 3 | 7 | (YES) NO | YES (NO) | (0) 1 2 3 | 0(1)23 | 0 1 2 3 | ô (1) 2 3 | 1/23/14 | 7 | AIE KESPO |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 | 8 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 3 | 1/24/14 | ∞ | NSE EVE |
| | ON | NO | 2 3 | 2 3 | 2 3 | 2 3 | | NO | ON | 2 3 | 2 3 | 2 3 | 2 3 | 1/14 | | RY 12 |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 | 9 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 1/25/14 | 9 | HOUR. |
| | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 5/14 | • | |
| | S∃A | ΥES | 0 1 | 0 1 | 0 1 | 0 1 2 | 10 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 3 | 1/26/14 | دسر | |
| | ON | ON | 2 3 | 2 3 | 2 3 | 2 3 | 0 | NO | ON | 2 3 | 2 3 | 2 3 | 2 3 | 11/1 | 10 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 | 11 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 | 1/2 | 11 | |
| | ON | ON | 2 3 | 2 3 | 2 3 | 2 3 | 1 | NO | NO | 2 3 | 2 3 | 2 3 | ź 3 | 27/14 | 1 | |
| | YES | ΥES | 0 1 | 0 1 | 0 1 | 0 1 | 1 | YES | ΥES | 0 1 | 0 1 | 0 1 | ó 1 | 1/28/ | 12 | |
| | NO N | ON | 2 3 | 2 3 | 2 3 | 123 | 12 | NO | NO | 2 3 | 2 3 | 2 3 | 123 | 41/3 | 2 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 2 | 1 | YES | ΥES | 0 1 | 0 1 | 0 1 | 0 1 | 1/29/ | ш | |
| | N O | N O | 2 3 | 2 3 | 2 3 | 2 3 | 13 | N O | N O | 2 3 | 2 3 | 2 3 | 2 3 | h//6 | 13 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 1/30 | , 1 | |
| | N O | N O | 2 3 | 2 3 | 2 3 | 2 3 | 14 | N N | N O | 2 3 | 2 3 | 2 3 | 2 3 | 4 | 14 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 | 0 1 | 0 1 | 1/31, | | |
| | NO N | ON | 2 3 | 2 3 | 2 3 | 2 3 | 15 | ON | S S | 2 3 | 2 3 | 2 3 | 123 | 11/1 | 15 | |

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

SUBJECT NUMBER: LD R Y=Yes N= No

DATE COMPLETED:

SUBJECT INITIALS AND DATE:



Lovelace Scier Resources Leslie Byatt, Clin Trials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME X, XLDR

PATIENT ID **AAGK8068**

DOB 02/06/1947

REPORT STATUS SEX Final М

PAGE 1

PHYSICIAN

Unlisted Physician,

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

01/23/2014 09:28

01/23/2014 23:34

01/24/2014 07:05

31033210

0

PATIENT NO.

COMMENTS:

AKP047

Test

In Range

Result

Out of Range

MMuhine M Sub I 29 Jan 2014

Units

Reference Range

Site Code

Eos. Respiratory Phys, Addr. Phone None seen

NS

NO PHYSICIAN LISTED

End of Report

FAX24664

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| SINGEL OF FORMING I FINEST CIVE EVENT AT FINESTS | , ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | | **** | | | | | | | |
|--|---|-----------|-----------|-----------|-----------|-----------|---------|---------|--------|---|
| DAY | 7 | 00 | 6 | 10 | 11 | 12 | 13 | , 14 | 15 | |
| AM | 1/23/14 | 1/24/11 | 1/25/14 | 1/20/11 | h1/22/1 | 1/82/1 | h1/62/1 | 1/30/14 | 1/31/1 | Ž |
| Runny Nose | 0 (D 2 3 | 0 1 (2) 3 | 0 1 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| | 0 1 2 3 | 0(1) 2 3 | 0123 | 0123 | 0 10 2 3 | 0)123 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0(1)23 | 0 1 (2) 3 | 0 1 (2) 3 | 0 (1)2 3 | 0 1 (2) 3 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1 2 3 | 0(1)2 3 | 0 1 2 3 | 0123 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES (NO) | YES NO | YES NO | YES NO | |
| Throat Clearing Y/N | (YES) NO | YES NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | YES NO | YES NO | YES NO | |
| DAY PM | 7 | ∞3 | 6 | 10 | 11 | 12 | 13 | 14 | 15 | |
| Runny Nose 0 to 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 (1)2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0123 | 0123 | 0123 | 0123 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0(1)23 | 0 1 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0(1)23 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 1 2 3 | 0)123 | 0)123 | 0123 | 0123 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES (ÑO | YES (NO) | YES (NO | YES (NO | YES (NO | YES NO | YES NO | YES NO | YES NO | |
| Throat Clearing Y/N | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | YES NO | YES NO | YES NO | YES NO | |
| C - 1 0 1 1 0 1 2 2 3 | | | | | | | | | | 1 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=No

SUBJECT NUMBER:

DATE COMPLETED:

SUBJECT INITIALS AND DATE:



Lovelace Scien Resources Leslie Byatt, Clin frials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

LDR, LDR

PATIENT ID **AAGJ4034**

02/06/1947

REPORT STATUS SEX М Final

PAGE 1

PHYSICIAN

Unlisted Physician.

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

01/28/2014 08:45

01/28/2014 18:46

01/29/2014 06:07

31033207

Test

0

PATIENT NO.

AKP047

COMMENTS:

Result

Manufrinews 05 Feb 2014

Out of Range Units Reference Range

Site Code

Eos, Respiratory Phys. Addr. Phone Moderate

NS

NO ORDERING PHYSICIAN INDICATED

In Range

End of Report

FAX24664



Lovelace Scient Resources Leslie Byatt, Clin ...als 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr

24664

PATIENT NAME LDR, LDR

PATIENT ID AAGJ4034

02/06/1947

REPORT STATUS М Final

PAGE 1

PHYSICIAN Unlisted Physician.

COLLECT DATE & TIME 02/05/2014 08:50 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

PATIENT NO.

02/05/2014 19:47

02/06/2014 06:07

31033204

Test

0

AKP047

| COMMENTS | ; |
|----------|---|
|----------|---|

Comp Metabolic Panel Sodium Potasslum Chloride CO2

> Anion Gap Glucose

Creatinine

BUN

| | | Kesuit | | | | | |
|----|-------|------------|-----|--------|---------------|--------------|---|
| ln | Range | Out of Rar | ige | Units | Reference Ran | je Site Code | |
| 1 | 34 | | | mmol/L | 134-144 | | |
| 3 | 3.9 | | | mmol/L | 3.5-5.1 | | |
| 9 | 99 | | | mmol/L | 98-111 | | |
| 2 | 24 | | | mmol/L | 20-30 | | |
| 1 | 11 | | | | 6-14 | NOS 1802 | |
| | | 152 | Н | mg/dL | 60-100 | NOS 10412 | 7 |
| | I E | | | ma(d) | 7 04 | | |

mg/dL 1.04 0,62-1.66 Creatinine method is IDMS traceable. EstGFR Calculation has been adjusted.

Please note new reference range effective 5/23/2013.

eGFR non-African Am **GFR Comment**

15

mL/mln/1,73m2

mg/dL

>60

7-31

Estimated GFR values are not accurate in acute kidney failure, inpatients on IV fluids, obese (BMI>34) or underweight (BMI<20) people, the very old or very young, races other than Caucasian or African American, people with acute illnesses, or amputations.

Calcium 10.0 mg/dl. 8.4-10.4 **Total Protein** 7.7 gm/dL 6.1-8.2 Albumin 4.5 gm/dL 3.4-4.7 Globulin 3.2 gm/dL 2.4-4.2 mg/dL Billrubin, total 0.6 0.3-1.2 Alk Phos 61 Ü/L 38-150 AST(SGOT) U/L 37 6-58 ALT(SGPT) 67 U/L 14-67 NO Fasting 3.3 mg/dL Phosphorus 2.3-5.6 Eos, Respiratory None seen NS Unknown Phys, Addr, Phone CBC WBC 5.6 4.0-10.6

RBC Hgb Hct MCV **MCHC RDW Platelets** 4.70 15.0 44 95 33.8 12.9 233

x10E3 x10E6 gm/dL % fL gm/dL

%

x10E3

4.64-6.00 14.5-17.7 42-53 81-98 31.2-35.2 11.0-14.5

150-400

End of Report

Marshine no Sul I

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| | 14 | 15 | 16 | 117 | 18 | 119 | ,20 | 21 | 22 |
|------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|--------------|-----------|
| | 1/28 | 129 | 130 | 15. | 1 2 | 7 | 23 | 77 | 2 |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 (1) 2 3 | 0(1)2 3 | 0 ① 2 3 | 0 10 2 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 (1) 2 3 | 0 (1) 2 3 |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0(1)2 3 | 0123 | 0123 | Ø1 2 3 | 0123 | 0123 | 0123 | 0 1 2 3 |
| Congestion 0 to 3 | 0 1 2 3 | 0 1 (2) 3 | 0 1 2 3 | 0 (1) 2 3 | 0(1)23 | 0 10 2 3 | 0 1 (2) 3 | 0 1 2(3) | 0 (1) 2 3 |
| | 0 1 2 3 | 0 1 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 2 3 | 0123 | 0123 | © 123 | 0123 |
| Voice Hoarse Y/N | YES NO | YES (NO | VES (NO | YES (NO) | YES (IO | YES (NO) | YES ((O) | YES (NO) | YES (NO |
| Throat Clearing Y/N | YES NO | (YES) NO | (VES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO |
| DAY PM | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
| Runny Nose 0 to 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 ①23 | 0 ① 2 3 | 0 (1) 2 3 | 0 1 (2) 3 | o (D 2 3 | 0 1 2 3 |
| Itchy Nose 0 to 3 | 0)123 | 0 1 2 3 | 0(1) 2 3 | 0123 | 0123 | 0123 | 0123 | 0123 | 0 1 2 3 |
| Congestion 0 to 3 | 0(1)23 | 0(1) 2 3 | 0 1 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 🔯 3 | 0 10 2 3 | 0 1 2 3 |
| | 0/123 | 0 (1) 2 3 | 0123 | 0(1) 2 3 | 0123 | 0123 | 0123 | 0123 | 0 1 2 3 |
| Voice Hoarse Y/N | YES (NO) | YES (NO) | YES (NO | YES (NG) | YES (NO) | YES (NO | YES (10) | YES (NO | YES NO |
| Throat Clearing Y/N | (VES) NO | KES) NO | (YES) NO | (YES) NO | (YES) NO | (YES) NO | (ES) NO | (YES) NO | YES NO |
| SCALE O to 2 | | | | | | | | | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No コンショルン

DATE COMPLETED: SUBJECT NUMBER: AKP D4 7

SUBJECT INITIALS AND DATE: X.M. 2-5-2014

されていると

| Study Identification: 27 (9 | 2749 | | | LSR | LSR Study #: | |
|-----------------------------|---|---------------|--|---------------------------|-----------------------------|-------------------------------|
| Subject Number: | AKPOUT | 7 | | Sub | Subject Initials: CDR | |
| | | | ADVERSE EVENT LOG | (7) | | |
| Adverse Event | ** Start Date (DD/MMM/YYYY) | SEVERITY | Relationship to Study Drug (Suspected/Not Suspected) | ** End Date (DD/MMM/YYYY) | Action Taken | Investigator Initials/Date |
| wer nek | 20/5an 12074 | meld. | Vat moneted | art | Cotts on | Mile on the original of the |
| | | | , | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | TO SECURE |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | The state of the s | | | |
| | | | | | | |
| * | If day is <u>unknown,</u> write | e UNK in spac | ** If day is <u>unknown</u> , write UNK in space provided, but every effort should be made to be as specific as possible** | nould be made to be | e as specific as possible** | * |
| Investigator Sigr | Investigator Signature (at end of study): | | Mussin m | Date: | Date: 27516-2014 | |
| SC Sign | SC Signature (at end of study): _ |): Und | le brett | Date: | J-1/5/2 | |
| | | ľo. | Lovelace Scientific Resources, Inc - AdverseEvents 04/2013 | | PAGE: | GE: |

• }

. ;,

Ongoing at EOS (for Clinic use) 30/NON/24/3 201/0N/2013 List all <u>prescription</u> medications you are taking. Also include <u>over-the-counter</u> medications, vitamins and supplements. Subject Initials: Stop Date Date: 05 FU-2014 LSR #: 0/02/ 1928 200 E 5661/---UNK/AUG/1999 0100 2002 * If day or month of medication date is <u>unknown,</u> write UNK in space provided ,661 (Day/Month/Year) * Start Date CONCOMITANT MEDICATION LOG Route Oral Oral Brad oral oral 292 05.E D.C. 97.B 2 Tabs per Frequency 9 9 Warne MO MG 1746 Unit E 220 20 21 500 9 300 Dose 200 Hypercholesterolpma. 9 \otimes 10/201/00/00/00 HUDERHENSION (What you take it for) Indication Diabetes SC Signature (at end of study): _ Investigator Signature (at end of study); ロスクロコ しつのなナ カース Study Identification: Name of Medication nethorne HIODURINGE Subject Number: EXAMPLE Testor HNUTT

Date:

Lovelace Scientific Resodrces, Inc - ConMeds 04/2013

| Study Identification: | AKPhama |) | 1 | | | | LSR#: | 2749. |
|-----------------------|--|--------------|----------------|--|--------------|---|---------------------|---------------------------------|
| Subject Number: | ALPORT | | ı | | | | Subject Initials: _ | ds: LDR |
| List all | List all <u>prescription</u> medications you | _ | COMITA | CONCOMITANT MEDICATION LOG | ATION L | CONCOMITANT MEDICATION LOG are taking. Also include over-the-counter medications, vitamins and supplements. | s and suppleme | ents. |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS (for Clinic use) |
| EXAMPLE | Diabetes | 200 | MG | 2 Tabs per day | Oral | UNK/AUG/1999 | 700 | |
| brtsone | Kush | 4/2 | 45 | OAM. | Lat | 1/22/14 | - Cont | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| | * If day or n | nonth of med | ication da | te is <u>unknow</u> | n, write UN | * If day or month of medication date is unknown, write UNK in space provided | | |
| Investigator Signatu | Investigator Signature (at end of study): | MM) | this | ing (M) | | Date: 05 F-47-2014 | dr 2014 | |
| SC Signatt | SC Signature (at end of study): | wall | Α, | Brack | | Date: $2/\sqrt{2}$ | 71/2 | Y |
| | | Lovelace | Scientific Res | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | Aeds 04/2013 | 1 | id I | PAGF: 2 of 2 |

!

Effects of AkPharma's Calcium Glycerophosphate Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ズ YES □NO |
|---|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: This worked as well or better than my antihirtamines. |
| _ |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |
| |

[Type text]
Subject initials and Date

Study Staff Initials and Date____

15/14

AKP-049

2,49 AKPharma PERENNIAL ALLER JES SCREENING/VISIT 1 SOURCE DOCUMENTS

| Initials: <u>ERB</u> Site #: Subject #: <u>049</u> |
|--|
| PATIENT DEMOGRAPHICS |
| Patient Demographics |
| Date of Birth: <u>28 / Jun / 1957</u> (dd/mmm/yyyy) |
| Gender: |
| If female, Indicate Childbearing Potential |
| Childbearing Surgically sterilized Post-Menopausal |
| Ethnicity: Hispanic Non Hispanic |
| Race: Asian Black Caucasian American Indian |
| Pacific Islander Other, Specify |
| |
| Smoking History |
| Smoking Status: None (smoked less than 100 cigarettes in lifetime) |
| Former (previously smoked more than 100 cigarettes in lifetime) |
| Current (smokes now) |
| If subject is a former or current smoker, please indicate: |
| Years smoked: Cigarettes per day: |
| 5716 Kg 201 16 7 - 11 |

Version: 02 September 2013

Page 3 of 5



Lovelace Scient Resources Leslie Byatt, Clin i rials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

PATIENT NAME ERB, ERB

PATIENT ID **AAGK4096** DOB 06/28/1954

REPORT STATUS SEX F Final

PAGE

Site Code

PHYSICIAN

Unlisted Physician,

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PT. PHONE NO.

01/16/2014 10:41 PATIENT NO.

01/16/2014 18:28

01/20/2014 06:10

31033189

049

COMMENTS:

| Test |
|---|
| Allerg,Panel 18 Allerg,Juniper Allerg,Cottonwood Allerg,West.Ragweed Allerg,Russian This Allerg,Bermuda Grass Allerg,Alternaria Allerg,Mesquite Allerg,Cockroach Allerg,Derm. pter. |

| | Result | | | |
|--------------|------------|-----|-------|----------------|
| In Range | Out of Rat | nge | Units | Reference Rang |
| | 1.50 | Н | kU/L | <0.35 |
| <0.10 | | , , | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | 2.30 | Н | kÚ/L | < 0.35 |
| <0.10 | | - 4 | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | 0.40 | Н | kU/L | < 0.35 |
| | 0.40 | H | kU/L | <0.35 |
| 0.20 | | | kU/L | <0.35 |

The standard classification system utilizes the following class cutoffs. ku/L Interpretation

| 0 | <0. 35 | Negative | for Allergen |
|-----|--------------|----------|--------------|
| I | 0. 35-0. 69 | Positive | for Allergen |
| II | 0. 70-3. 49 | Strongly | Positive |
| III | 3. 5-17. 49 | Strongly | Positive |
| IV | 17. 5-52. 49 | Strongly | Positive |
| v | 52. 5-99. 99 | Strongly | Positive |
| VI | >100 | Strongly | Positive |

Results with allergens scoring in Class 1 should be considered weakly positive or equivocal. Class 2 and higher should be considered positive. Although increasing class ranges (0-VI) are reflective of increasing concentrations of allergen-specific IgE, this may not correlate with the degree of clinical response when challenged with the specific allergen. The correlation of allergy laboratory results with clinical history is essential. A negative test may not rule out clinical allergy.

| Allerg,Derm. farinae |
|----------------------|
| Allerg,Clad, herb. |
| Allerg, Firebush |
| Allerg Cat Dander Ep |
| Allerg, Dog Dander |
| Allerg,Bluegrass |
| Allerg, Pigweed |
| Allerg, Mulberry |
| Allerg, Heiminth |
| Phys, Addr, Phone |

| 0.20 | | | kU/L | < 0.35 |
|-------|-------|---|------|--------|
| | 1.60 | H | kU/L | < 0.35 |
| | 0.50 | Н | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | 1,30 | Н | kU/L | < 0.35 |
| | 12.20 | Н | kU/L | < 0.35 |
| <0.10 | | | kU/L | < 0.35 |
| | | | | |

NO ORDERING PHYSICIAN PROVIDED

0.20

< 0.10

End of Report

Manueur Sont-I 21 Jan 2014

kU/L

kU/L

<0.35

< 0.35



Levelace Scientific Resources 2. Ridgecrest Dr SE Albuquerque, NM 87108



Name: ERB,

Gender: Female

Age: 59 Ra

Race: Hispanic

Height(in): 58.6

Weight(lb): 164

Any Info:

Id: 0AKP49 Date: 01/29/14

Temp: 20

PBar: 633

Physician:

Technician: TKA

| THY ITHO. | | | | | | |
|------------------------------|--------------|-----------------------|-------------------|-------|-----------------------|-----------------------------|
| Spirometry | (BTPS) | PRE-RX Pre Pre | POST-RX Post Post | Post | Flow | |
| ophomou y | Ref | Pre Pre Meas % Ref | Meas % Ref | % Chg | 8 | |
| FVC Liters | 2.42 | 2.56 106 | | | † | \wedge |
| FEV1 Liters | 2.00 | 1.98 99 | | | 6 🕂 | / \ |
| FEV1/FVC % | 84 | 77 92 1.73 77 | | | | / \ |
| FEF25-75%L/sec | 2.24 | 1.73 77 3.38 116 | | | Ţ | |
| FEF50% L/sec FEF75% L/sec | 2.93 0.91 | 0.45 49 | | | 4 † | |
| IC Liters | 0.01 | 0.40 | | | 1 | |
| VC Liters | 2,42 | | | | _ | |
| PEF L/sec | 5.08 | 6.76 133 | | | 2 † | |
| MVV L/min | 93 | - 4- | | | . ‡ | |
| PIF L/sec | | 3.12 82 | | | _ | |
| FEV1/FEV6% | 1000 L 41 | | (BTPS) | | 0 ++ | |
| Lung Volume | es/Pietnysr | nograpny | (15 (1 0) | | + | |
| Vtg Liters | | | | | -2 | |
| VC Liters | 2.42 | | | | | |
| TLC Liters | 3.82 | | | | Ť | \checkmark |
| RV Liters RV/TLC % | 1.40 37 | | | | -4 + | |
| FRC PL Liters | 1.91 | | | | | |
| ERV Liters | 1.01 | | | | Ť | |
| IC Liters | | | | | -6 [⊥] -1 | |
| Diffusion | | | | | -1 | 0 1 _{Volume} 2 3 4 |
| DLCO mL/mmH | g/min 19.7 | | | | | |
| DL Adj mL/mmH | | | , | | | |
| DLCO/VA mL/mHg/ | | | | | | |
| 1.44 | | | | | | |

Resistance

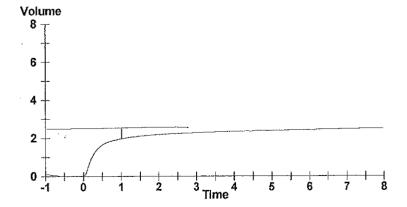
BHT

Raw Total cmH2O/L/sec
Raw Insp cmH2O/L/sec
Raw Exp cmH2O/L/sec
Raw Exp cmH2O/L/sec
Raw cmH2O/L/sec
Raw cmH2O/L/sec
Raw cmH2O/L/sec
Raw cmH2O/L/sec
Raw L/sec/cmH2O 0.458
Raw cmH2O/L/s/L 4.02
SGaw L/s/cmH2O/L 0.249
Vtg (Raw) Liters

Liters

Sec

Comments:





Lovelace Scientific Resources 2 Albuquerque, NM 87108



Name: ERB,

Gender: Female

Age: 59

Race: Hispanic

Height(in): 60.0

Weight(lb): 165

Anv Info:

ld: AKP-049 Date: 02/05/14

Temp: 19

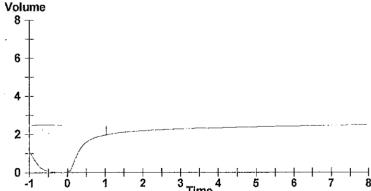
PBar: 631

Physician:

Technician: VL

| Any Info: | | | | | Į (| ecnniciai | n. VL | | |
|--|---|--|--|--|----------------------|-----------|------------------------|---|--|
| Spirometry | (В Т | r PS) Ref | Pre | E-RX Pre | POST-RX Post Post | Post | Flow 8 _T | | |
| FEV1 FEV1/FVC FEF25-75% FEF50% FEF75% IC VC PEF MVV PIF | L/sec L/sec L/sec Liters Liters L/sec L/min L/sec | 2.56 2.10 84 2.33 3.03 0.96 2.56 5.25 93 | 2.50 2.01 81 2.00 3.88 0.62 5.51 2.10 | % Ref 98 96 96 86 128 64 | Meas % Ref | % Chg | 4 | | |
| FEV1/FEV6 | " ′olumes/F | Plathvem | 83 Odra | nhv | (BTPS) | | 0 | + | |
| Vtg VC TLC RV RV/TLC FRC PL ERV IC Diffusion DLCO DLCO DLCO/VA VA | Liters Liters Liters Liters % Liters Liters Liters Liters Liters | 2.56 4.10 1.51 37 2.09 | | | | | -4 -6 -1 | 0 1 _{Volume} 2 3 4 | |
| Resista | | | | | | | | | |
| Raw Insp Raw Exp Raw Gaw sRaw sGaw | cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec cmH2O/L/sec L/sec/cmH2O cmH2O/L/s/L L/s/cmH2O/L Liters | 3.96 | | | | , | | | |
| | | | | | Volume 8 ⊤ | | | | |
| Comment | S' | | | | V | | | | |

Comments:





Logiace Scientific Resources 2441 Ridgecrest Dr SE Albuquerque, NM 87108



Name: ERB,

Gender: Female

Race: Hispanic Age: 59

Height(in): 60.0

Weight(lb): 165

Any Info:

ld: AKP-049 Date: 02/12/14

Temp: 20

PBar: 634

Physician:

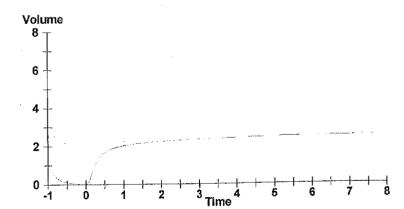
Technician: VL

| 771 | ty itho. | | | | | | | | | | | |
|---------|------------|--------------|----------|-------------|--------------|-------------------------|---------------|-------------------|-------------|-------|-------------|-------------|
| | | (B1 | PS) | PR | E-RX | POST-RX | | Flow | | | | |
| Spirome | | `y | Ref | Pre Meas | Pre % Ref | Post Post Meas % Ref | Post % Chg | 8 _T | | | | |
| | FVC | Liters | 2.56 | 2.54 | 99 | 1110000 771101 | | + | | | | |
| | FEV1 | Liters | 2,10 | 2.04 | 97 | | | 6+ | ^ | | | |
| | FEV1/FVC | | 84 | 81 | 96 | | | • 7 | - F | | | |
| | FEF25-759 | | 2.33 | 2.21 | 95 | | | + | i | | | |
| | FEF50% | L/sec | 3.03 | 4.60 | 152 | | | | ! | • | | |
| | FEF75% | L/sec | 0.96 | 0.63 | 65 | | | 4 🛉 | : | • | | |
| | iC | Liters | | | | | | 1 | i | 4 | | |
| | VC | Liters | 2.56 | | | | | _ | | | | |
| | PEF | L/sec | 5.25 | 6.19 | 118 | | | 2 + | | | | |
| | MVV | L/min | 93 | | | | | . 1 | 1 | ٠. | | |
| | PIF | L/sec | | 1.60 | | | | | 4 | , j | | |
| | FEV1/FEV | 6% | | 82 | | | | 0 ++ | | | | |
| | Lunal | /olumes/F | Plathver | noara | nhv | (BTPS) | | | | | , | |
| | | | Culyon | 110910 | ניוק | | | Ť | | 1. 1. | | |
| | Vtg | Liters | | | | | | -2 | | | | |
| | VČ | Liters | 2.56 | | | | | | | | | |
| | TLC | Liters | 4.10 | | | | | † | | | | |
| | RV | Liters | 1.51 | | | | | -4 | | | | |
| | RV/TLC | % | 37 | | | | | 7 | | | | |
| | FRC PL | Liters | 2.09 | | | | | + | | | | |
| | ERV | Liters | | | | | | -6 | | | | |
| | IC. | Liters | | | | | | -6 - 1 | 0 | 1 2 | 3 | 4 |
| | Diffusion | | | | | | | • | 1 Volume | - | | |
| | DLCO | mL/mmHg/min | 20.2 | | | | | | | | | |
| | DL Adj | mL/mmHg/min | 20.2 | | | | | | | | | |
| | DLCONA | mL/mHg/min/L | 3.22 | | | | | | | | | |
| | VA | Liters | | | | | | | | | | |
| | BHT | Sec | | | | | | | | | | |
| | Resistance | | | | | | | | | | | |
| | Raw Total | cmH2O/L/sec | | | | | | | | | | |
| | Raw Insp | cmH2O/L/sec | | | | • | | | | | | |
| | Raw Exp | cmH2O/L/sec | | | | | | | | | | |
| | Raw | cmH2O/L/sec | 1.90 | | | | 4 | | | | | |
| | Gaw | | 0.501 | | | | | | | | | |
| | sRaw | cmH2O/L/s/L | 3.96 | | | | | | | | | |
| | o/Cass | | 0.252 | | | | | | | | | |



Vtg (Raw) Liters

sGaw



Interpretation:

Norm Set: Knudson (1983)

L/s/cmH2O/L 0.252



Logalace Scientific Resources 24 Ridgecrest Dr SE Albuquerque, NM 87108





Gender: Female Age: 59 Race:

Height(in): 59.0

Weight(lb): 164

Id: AKP-049 Date: 02/19/14

Temp: 21

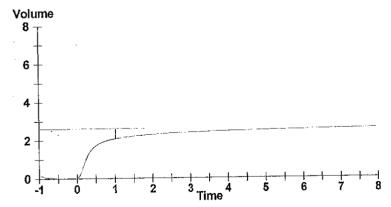
PBar: 627

Physician:

Technician, CRD

| Any Info: | | | | | | i ecnniciai | in: CRD |
|--|--|--|--|-------------------------------------|-------------------------|---------------|--|
| 1019 | (BT | PS) | PRI | -RX | POST-RX | | Flow |
| Spirometry | , (51 | Ref | Pre | Pre % Ref | Post Post Meas % Ref | Post % Chg | 8 ₇ |
| FEV1 FEV1/FVC FEF25-75% FEF50% FEF75% IC VC PEF MVV PIF | L/sec L/sec L/sec Liters Liters L/sec L/min L/sec | 2.47 2.04 84 2.27 2.96 0.93 2.47 5.13 93 | 2.63 2.09 80 2.21 4.49 0.65 6.81 | 107 103 94 97 152 70 | | | 6 4 2 |
| FEV1/FEV6 Lung V | % 'olumes/F | 'lethysm | 83 ogra | phy | (BTPS) | | 0 |
| VČ TLC RV RV/TLC FRC PL ERV IC Diffusio DLCO DL Adj | Liters Liters Liters Liters Liters Liters Liters Liters Dn mL/mmHg/min mL/mmHg/min mL/mHg/min/L Liters Sec | 19.9 | | | | | -2 -4 -6-1 0 1 _{Volume} 2 3 4 |
| Resista | ance | | | | • | | |
| Raw Total Raw Insp Raw Exp Raw Gaw sRaw sGaw Vtg (Raw) | L/sec/cmH2O cmH2O/L/s/L L/s/cmH2O/L | 4.00 | | , | Volumo | | |





Interpretation:

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| PAY | | | | | | | | | | | | | | | - | | | 1/14 |
|---|--------|---------------------|------------|----------|---------|---------------|-------|----------|---------|-------------|----------|------------|------|-------------|------------|-------------|------------|----------------------|
| DAY 1 2 3 4 5 AM 6 1/20 14 01/21 12 13 01 2 | \leq | NO | Œ | | (F) | NO | YES | O | | NO | (YES | | YES | | (<u>X</u> | | \ <u>\</u> | Throat Clearing |
| DAY 1 2 3 4 5 AM 6 1/20 14 01/21 12 13 01 2 | | | > | | | | | | | | | |) | | | | • | Y/N |
| DAY 1 2 3 4 5 AM 0 1/20/14 01/23 0123 0123 0123 0123 0123 0123 0123 01 | Ϋ́E | 5 | YES | | YES | | YES | 8 | | | YES | 8 | YES | | YE | | YES | Voice Hoarse |
| DAY 1 2 3 4 5 AM C 1/20/14 O1/21/14 C 1/23/14 O1/23/14 | |) (| | > (| | > | | (| | <u>\</u> | | (| |) } | |) | | 0 to 3 |
| DAY 1 2 3 4 5 AM C 1/20/14 O1/21/14 O1/23/14 O1/23/14 O1/23/14 O1/23/14 O1/23/14 O1/23/14 O1/24/14 my Nose 0 1/23 0 1/23 0 1/23 0 1/23 0 1/23/3 <td>O</td> <td>2 B</td> <td>0 1</td> <td>2(3)</td> <td>0</td> <td>2 (3)</td> <td>0 1</td> <td>2 B</td> <td>0</td> <td>2 (3)</td> <td></td> <td>2</td> <td>0</td> <td></td> <td>0</td> <td></td> <td></td> <td>Sneezing</td> | O | 2 B | 0 1 | 2(3) | 0 | 2 (3) | 0 1 | 2 B | 0 | 2 (3) | | 2 | 0 | | 0 | | | Sneezing |
| DAY 1 2 3 4 5 AM C 1/20 14 01/23 | | | , | | |) | (| | | > | |) | • | > | (| ر | _(| 0 to 3 |
| DAY 1 2 3 4 5 AMM 0 1/20/14 0 1/21/14 0 1/23/14 0 1/23/14 0 1/23/14 0 1/23/14 0 1/23/14 0 1/24/14 ny Nose 0 1 2/3 0 1 (2) 3 0 1 (2) 3 0 1 2/3 0 1 | G | | Q 3 | | 0)1 | | | w | <u></u> | 2 3 | 6) | 2 3 | | N | | 2 | | Congestion |
| DAY 1 2 3 4 5 AMM 0 1/20/H 0 1/20/H 0 1/21/H 0 1/21/H 0 1/22/H 0 1/23/H 0 1/23/H 0 1/24/H my Nose 0 1/2/3 0 1/2/3 0 1/2/3 0 1/2/3 0 1/23/H 0 1/24/ |) | (| | (| | . (| | | | (| | |) | | P | , | | 0 to 3 |
| DAY 1 2 3 4 5 AM 6 1/20/14 01/21/14 01/22/14 01/22/14 01/23/14 01/23/14 01/23/14 01/23/14 01/23/14 01/24/14 ny Nose 0 1 2 3 | 0 | 2 (B [*]) | 0 1 | 2 (3) | 0 1 | <u>®</u> | ᆫ | <u>6</u> | 0 1 | သ | 0 1 | (2) 3 | 0 1 | 1(2)3 | | 1(2) 3 | | Itchy Nose |
| DAY 1 2 3 4 5 AM 6 1/20/14 01/21/14 01/22/14 01/23/14 01/23/14 01/24/14 01/23/14 01/24/14 01/24/14 5 ny Nose 0 1/2 3 | | | |) | | | | | | | | < | | >< | | | | 0 to 3 |
| DAY 1 2 3 4 5 AM 6 1/20/14 01/21/14 01/22/14 01/22/14 01/23/14 01/23/14 01/23/14 01/23/14 01/23/14 01/24/14 ny Nose 0 1 2/3 | 0 | 2 (3) | 0 1 | 2 (3) | | | 0 1 | | 0 1 | | | (2) 3 | 0 1 | 1(2) 3 | 0 | 123 | | Runny Nose |
| DAY 1 2 3 4 5 AM 0 1/20 [H 01/21/H] 01/21/H 01/24/H 01/23/H 01/24/H | | 3 | ~ | 7 | | J1 | 6 | | (Ji | -4 | | ယ | | 2 | - | 1 | | DAY PM |
| DAY 1 2 3 4 5 AMM 6 1/20/14 01/21/14 01/22/14 01/23/14 01/23/14 01/24/14 0 1/23/14 01/24/14 0 1/23/14 01/24/14 0 1/24/14 | ÉŜ | NO | YES' | | (YES) | | (ES) | ON | (ES) |) NO | YES | | (ES) | | (YE | | (YES | Throat Clearing Y/N |
| $\begin{array}{cccccccccccccccccccccccccccccccccccc$ |) ; | |) [| (|) į | 8 | [| (3 | | (|) [| Ę |) [| | | | } ; | Y/N |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | 첫 | | ΥES | 3) | γFS | § | YFS | 5 | | 2 | YFS | <u>2</u>) | YFS | | - | | γFS | Voice Hoarse |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | | | (| |) (| | • (| |) (| | , | | , (| |) | | 0 to 3 |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | 0 | 2 (8) | 0 | 2 (§) | \circ | 2 <i>န</i> | 0 | 2 (3) | 0 1 | 2 [ja] | | 2 (3) | 0 1 | 1 2 (3) | 0 | | - 1 | Sneezing |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | | (| | (| | (| | (| | i |)) | | | (| | | 0 to 3 |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | 0 | 2 3 | 0/0 | 2 | 0 | N. | 0 (I) | ω | 0(1) | 2 3 | 0 (1) | 2 | 0 | 2 | 0 | 2 | 0 | Congestion |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | C | | (| | (| | (|) | (| | (| | (| | (| | 0 to 3 |
| $\begin{array}{c ccccccccccccccccccccccccccccccccccc$ | | 2/3 | 0 1 | 2(3) | 0 | | | | | | | <i>b</i> | | 1(2)3 | 0 | 1(2) 3 | | Itchy Nose |
| 01/20/14 01/21/14 01/23/14 01/23/14 01/24/14 | 0 | 2 (3) | 0 1 | 2(3) | 0 1 | 2(3) | 0 1 | 2 (3) | 0 1 | 2 (3) | | (2⁄3 √ | | 1(2/3 | | 1(2)3 | 0 1 | Runny Nose 0 to 3 |
| 2 3 4 5 | 0 | 27/19 | 110 | 11/10 | 01/2 | 11/6 | 01/2 | 4/14 | 2/10 | | | 41/22/j | 01/ | 7211 | 101/ | 720/14 | 0:/ | AM |
| | | - (3) | | 7 | | | , | , | · (J) | 4 | | ω | | 2 | |)— 2 | | DAY |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N=NO ERSSUBJECT NUMBER: AKPOY BATE COMPLETED: 1-29-14

SUBJECT INITIALS AND DATE: & 1-29-14

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| SCALE 0 to 3 | Throat Clearing | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY PM | Throat Clearing Y/N | Voice Hoarse Y/N | Sneezing 0 to 3 | Congestion 0 to 3 | Itchy Nose 0 to 3 | Runny Nose 0 to 3 | DAY AM | |
|--------------|-----------------|---------------------|--------------------|----------------------|----------------------|----------------------|--------|---------------------|---------------------|--------------------|-------------------|----------------------|----------------------|-----------|---|
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 | | (ES) | YES | 0 1 | 0 1 | 0 1 | 0 1 | | |
| | ON | NO | 2 3 | 2 3 | 2 3 | 2 3 | 7 ' | NO | NO NO | 2 (<u>3</u>) | 1(2)3 | 2 & | 2 (3) | 79/II | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | |
| | ON | ON | 2 3 | 2 3 | 2 3 | 2 3 | 00 | NO | NO | 2 3 | 2 3 | 2 3 | رم س | ∞ | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 9 | YES | YES | 0 1 | 0 1 | 0 | 0 1 | | |
| | ON | N O | 2 3 | 2 3 | 2 3 | 2 3 | • | N O | ON | 2 3 | 2 3 | 2 3 | 2 3 | 9 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 | 10 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | در | |
| | NO | ON | 2 3 | 2 3 | 2 3 | 2 3 | 0 | NO | NO | 2 3 | 2 3 | 2 3 | 2 3 | 10 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 11 | YES | YES | 0 1 | 0 1 | 0 1 | 0 | щ | |
| , | O | O | 2 3 | 2 3 | 2 3 | 2 3 | 1 | NO | NO. | 2 3 | 2 3 | 2 3 | 2 3 | 11 | ! |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 12 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 1 | |
| | NO | O | 2 3 | 2 3 | 2 3 | 2 3 | 2 | N O | NO | 2 3 | 2 3 | 2 3 | 23 | 12 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | 13 | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | <u> </u> | |
| | NO NO | NO | 2 3 | 23 | 2 3 | 2 3 | ω | O | NO O | 2 3 | 2 3 | 2 | 2 3 | 13 | |
| | YES | YES | 0 | 0 1 | 0 1 | 0 1 | | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | ы | |
| | <u>N</u> | ON | 2 3 | 2 3 | 2 3 | 2 3 | 14 | O | NO | 2 3 | 2 3 | 2 3 | 2 3 | 14 | |
| | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | احر | YES | YES | 0 1 | 0 1 | 0 1 | 0 1 | | |
| | S S | Ö | 2 3 | 2 3 | 2 3 | ν ω | 15 | ON | NO | 2 3 | 2 3 | 2 3 | 2 3 | 15 | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: _

P DATE COMPLETED: 1/29/14

SUBJECT INITIALS AND DATE: 28 /-29-14



Albuquerque, NM 87108-5129

Lovelace Scier Resources Leslie Byatt, Clin rials 2441 Ridgecrest Dr SE

Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT ID **AAGL1165** DÖB 06/28/1954

REPORT STATUS SEX Final

PAGE 1

X, XERB PHYSICIAN

COLLECT DATE & TIME

RECEIVE DATE & TIME

PRINT DATE & TIME

Unlisted Physician, REQUISITION NO.

PATIENT NAME

PT. PHONE NO.

01/29/2014 16:19 PATIENT NO.

01/29/2014 19:55

01/30/2014 06:04

0

31033194

AKP049

| COMMENTS | : |
|----------|---|
|----------|---|

| | R | esult | | | | |
|---|--|--|---|--|------------------------------|-----------|
| Test | In Range | Out of Ran | nge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Södium | 140 | | | mmol/L | 134-144 | |
| Potassium | 4.0 | | | mmol/L | 3.5-5.1 | |
| Chloride | 107 | | | mmol/L | 98-111 | |
| CO2 | 27 | | | mmol/L | 20-30 | |
| Anion Gap | 6 | | | | 6-14 | |
| Glucose | 88 | | | mg/dL | 60-100 | |
| BUN | 9 | | | mg/dL | 7-31 | |
| Creatinine | 0.63 | 15 - | | mg/dL | 0,50-1.40 | |
| | Creatinine method is IDMS | | | | en adjusted | |
| | Please note new reference | range effecti | ive 5/23/ | /2013. | | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| .,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | Estimated GFR values are n on IV fluids, obese (BMI>3 the very old or very young people with acute illnesse | ot accurate i 34) or underwa , races other es. or amoutat | in acute eight (BN r than Ca rions | kidney failure, 4I<20) people, aucasian or Afr | inpatients Ican American, | |
| Calcium | 9.6 | | | mg/dL | 8.4-10.4 | |
| Total Protein | 7.1 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.8 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.3 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.6 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 81 | | | Ü/L | 38-150 | a salana |
| AST(SGOT) | | 65 | Н | U/L | 6-58 NC | SIMPLIA |
| ALT(\$GPT) | | 91 | H | U/L | 14-67 11/1 | 5 Min |
| Fasting | NO | | | | 000 | |
| Phosphorus | 2.8 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | | | |
| WBC | 6.1 | | | x10E3 | 4.0-10.6 | |
| RBC | 4.72 | | | x10E6 | 4.00-5.36 | |
| Hgb | 13.4 | | | gm/dL | 12.0-16.0 | |
| Hct | 41 | | | % | 36-48 | |
| MCV | 88 | | | fL | 81-98 | |
| MCHC | 32,4 | | | gm/dL | 31.2-35.2 | |
| RDW | 13.7 | | | % | 11.0-14.5 | |
| Platelets | 177 | | | x10E3 | 150 -4 00 | |
| Eos, Respiratory Phys, Addr, Phone | None seen | | | • | NS | |
| i ilya, madi, i none | NO PHYSICIAN LISTED | | | | | |

End of Report

100 Feb 2014

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | , 7 | 8 | , 6 , | , 10 | ,11, | 12 / | ſ | 4/2 | | |
|------------------------|--|------------------|-----------|-----------|-----------|-----------|-----------|-----------|----------|---|
| AM | 1/29/14 | 1/30/14 | 1/21/[4 | 041/14 | 2414 | 2/3/ | 14/14 | 745/14 | 11 40/11 | 5 |
| Runny Nose 0 to 3 | 0 1 2 3 | (01(2)3 | 0 1 2 (3) | 0 1 2(3) | 012(3) | 0123 | (3) 7 0 | 0 1 2 (3) | 0 1 2 | m |
| Itchy Nose 0 to 3 | $\begin{array}{cccccccccccccccccccccccccccccccccccc$ | 0 (1) 2 3 | 0 1 (2) 3 | 0 1 (2 3 | 0 1(2/3 | 0 1(2/3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0 1 2/3 | 0 1 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1/2 3 | 0(1/23 | 0 1 2(3) | 0 1 2(3) | 0 1 2 | m |
| Sneezing 0 to 3 | $0 \frac{1}{2}$ 3 | 0 (1) 2 3 | 0 1 (2) 3 | 0 1 🖒 3 | 0 1 (2/3 | 0 1(2/3 | 0 1 2(3) | 0 1 2(3) | 0 1 2 | m |
| Voice Hoarse Y/N | YES NO | YES (NO | YES (NO | YES (NO) | YES (NO | YES (NG) | (YES) NO | (E) (E) | YES NO | 0 |
| Throat Clearing Y/N | YES NO | (YES) NO | (YES) NO | (YES NO | KES NO | (YES) NO | YES NO | VES NO | YES NO | 0 |
| DAY PIVI | 7 | ω, | 6 | 10 | 11 | 12 | 13 | 14 | 15 | |
| Runny Nose 0 to 3 | 0 1 2 3 | 0 (1) 2 3 | 0 1 2 (3) | 0 1 2(3) | 0 1 2 (3) | 0 1 2 (3) | 0 1 2 3 | 0 1 23 | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1 (2) 3 | 0 ①2 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1(2)3 | 0 1 (2) 3 | 0 1(3 3 | 0 10 3 | 0 1 2 | m |
| Congestion 0 to 3 | Ø123 | (<u>0</u> 1 2 3 | 0(1) 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 1 2 3 | 0 1 2(3) | 0 1 2 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 ①2 3 | 0 (2 3 | 0 1 🗘 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 (2) 3 | 0 1 2 3 | 0 1 /2 ③ | 0 1 2 | က |
| Voice Hoarse Y/N | YES AD | YES MO | YES (NO) | VES (NO) | YES (NO | YYES (NG) | ON SEL | (YES NO | YES NO | 0 |
| Throat Clearing Y/N | (YES) NO | (YES) NO | (YES) NO | (YE) NO | YES) NO | (YES) NO | VES NO | VES NO | YES NO | 0 |
| | | | | | | | | | ' ' ' | |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: \$\mathcal{L} \neq DO9

9 DATE COMPLETED:_

SUBJECT INITIALS AND DATE:

TriCore

Fax Number

Thu Feb 27 10:22:32 2014 Page 2 of 2

TriCore Reference Laboratories 1001 Woodward Pl NE Albuquerque, NM 87102 (505) 938-8922

Patient Name: Medical Record: DOB: 06/02/1954

ERB, ERB AAGL4964

Age:59Y Sex:F

Account Number:

Attending MD:

31033211 Unlisted Physician

Patient ID:AKP049 Patient Phone: 0

W3605701 COLL: 02/05/2014 13:18 REC: 02/05/2014 19:49 PHYS: Unlisted Physician Req#: 31033211

Eos, Respiratory

None seen

[NS]

Phys, Addr, Phone

Unknown

Musicano 27 Febro14

END OF REPORT

Printed: 02/27/2014 10:21

Location: CORE

Patient Name: ERB, ERB

Page: 1

INTERIM REPORT

Medical Record #: AAGL4964

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| DAY | 7 | œ | σ | 10 | - | | 13, | , 14 | .15 / | Γ. |
|------------------------|------------------|----------|-----------|-----------|-----------|--------------|-----------|-----------------|--------|----------|
| AM | 45/14 | 76/14 | 47/19 | 48/14 | h1/0/2 | h1/61/2 | 411/114 | h1/21/2 h1/11/2 | 7/3/19 | <u> </u> |
| Runny Nose 0 to 3 | 0123 | 0 1 2(3) | 0 1 2 3 | 0 1(2 3 | 0 1 (2) 3 | 0 🕭 2 3 | 0(3) 2 3 | 0 (1) 2 3 | 0 1 2 | ო. |
| Itchy Nose 0 to 3 | 0 1 2 3 | 0 1 2 🕲 | 0 1 2 (3) | 0 1(2) 3 | 0 1 (2) 3 | 0 (1) 2 3 | 0 \$ 2 3 | 0 (1) 2 3 | 0 1 2 | m |
| Congestion 0 to 3 | 0 1 2 3 | 0 (2 3 | 0 ① 2 3 | 0 (1) 2 3 | 0 [] 2 3 | © 123 | Ø 1 2 3 | 0 1 2 3 | 0 1 2 | т |
| Sneezing 0 to 3 | 0 1 2 3 | 0 2 3 | 0(1)23 | 00 2 3 | 0 (1) 2 3 | 0 (1) 2 3 | 0 10 2 3 | 0 (1) 2 3 | 0 1 2 | m |
| Voice Hoarse Y/N | YES NO | | YES (NO) | VES (UO) | YES (NO) | YES (NO | YES (NO) | ves (NO) | YES NO | 0 |
| Throat Clearing Y/N | YES NO | (YE) NO | (VES) NO | VES NO | (YES) NO | (YE} NO | (KES) NO | (FE) NO | YES NO | 0 |
| DAY PM | 7 | 8 | 6 | 10 | 11 | 12 | 13 | 14 | 15 | |
| Runny Nose 0 to 3 | 0 1 2 (3) | 0123 | 0 1 2 (3) | 0 1 🗘 3 | 0 1 (2) 3 | 0023 | 0 (1) 2 3 | 0(1) 2 3/ | 0 1 2 | m |
| Itchy Nose 0 to 3 | 0 1 2(3) | 012(3) | 0 1 2 (3) | 0 1 🔯 3 | 0 1 🗘 3 | 0 (1) 2 3 | 0 (4/2 3 | 0(1) 2/8 | 0 1 2 | m |
| Congestion 0 to 3 | 0 (1) 2 3 | 0 🗘 2 3 | 0(1) 2 3 | 0 (1) 2 3 | 0(223 | Ø 1 2 3 | 0 1 2 3 | ① 1 / 3 | 0 1 2 | m |
| Sneezing 0 to 3 | 0 () 2 3 | 0(1) 2 3 | 00 2 3 | 0 (2 3 | 0(1) 2 3 | e z (f) o | 0(1)23 | ε z 6 0 | 0 1 2 | က |
| Voice Hoarse Y/N | YES (NO | YES (NG | YES (NO | yes hợ | yes №Ö) | YES (NĞ | YES (NG) | OD SAX | YES NO | 0 |
| Throat Clearing Y/N | VES NO | NO (√E) | (YES) NO | KES) NO | (YES) NO | (YÈS NO | (YES NO | ON (F) | YES NO | |
| C C+ C = 1473 | | | | | | | | | | 1 |

2/12/14

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living)

Y=Yes N= No

SUBJECT NUMBER: $\frac{ERB}{AKPOY}$ GATE COMPLETED:

SUBJECT INITIALS AND DATE:



1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

Lovelace Scient ?esources Leslie Byatt, Clin ...als 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 **Client Nbr** 24664

PATIENT NAME ERB, ERB

PATIENT ID **AAGK4096** DOB 06/28/1954 SEX F

REPORT STATUS Final

PAGE

PHYSICIAN

Unlisted Physician,

PT. PHONE NO.

COLLECT DATE & TIME 02/12/2014 13:00 RECEIVE DATE & TIME

PRINT DATE & TIME

REQUISITION NO.

PATIENT NO.

02/12/2014 19:37

02/13/2014 06:06

31033206

COMMENTS:

0

049

Test

Eos, Respiratory

Phys. Addr. Phone

FAX RESULTS FAX PHONE NUMBER

Result

Out of Range

Manufacie MD 13 Feb 2014

Rare

Units

Reference Range

NS

Site Code

PHYS UNKN

In Range

8546

348

End of Report

Initials/Date Investigator Subject Initials: \mathcal{L} R** If day is <u>unknown</u>, write UNK in space provided, but every effort should be made to be as specific as possible** SC Signature (at end of study): Bucker malenders (at end of study): Bucker malenders (at end of study): Pucker malenders (at end of study) med taken Action Taken LSR Study #: (DD/MMM/YYYY) 13/Feb/2014 ** End Date ADVERSE EVENT LOG Relationship to Study Drug (Suspected/Not Suspected) h1161/2~13 SEVERITY なとのより Investigator Signature (at end of study): (DD/MMM/YYYY) ** Start Date Study Identification: Subject Number: Adverse Event

Lovelace Scientific Resources, Inc - AdverseEvents 04/2013

PAGE:

| Study Identification: | のコーの | | | | | | LSR#: | |
|-----------------------|--|------------|---------------|--|--------------|---|---|--|
| Subject Number: | UT. | | , | | | | Subject Initials: | s: ERE |
| List all | List all <u>prescription</u> medications you | CONC | OMITA | CONCOMITANT MEDICATION LOGretaking. Also include over-the-counter me | ATION I | CONCOMITANT MEDICATION LOG are taking. Also include over-the-counter medications, vitamins and supplements. | ns and suppleme | ints. |
| Name of Medication | Indication (What you take it for) | Dose | Unit | Frequency | Route | * Start Date (Day/Month/Year) | Stop Date | Ongoing at EOS (for Clinic use) |
| EXAMPLE | Diabetes | 500 | MG | 2.Tabs per day | Oral | EUNIC/AUG/1999 | 2 1 1 3 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 | |
| Abilifu | Anxiety | 5 | mg | 90 | 00 | 0102// | | |
| Clone Z epoun | Anxietu | d | 77 | 9 | 00 | 0192//- | | |
| Estrabioat | Post 1 | 1.5 | Ma | 9 | 0 | 0 bb1/2- | | K |
| Fexprendi | ne Deprossion | 1 |) (j | (DD) | 00 | 666)//- | 7 | |
| Mitazaou | 10 Anxiotin | 15 |) S | 20 | 00 | 60b) /-1/ | 0 | |
| * SIMVESTATU | 1 Hopertension | 07(| ρŽ | A 0 | 00 | 1-1//- | 0 | X |
| ZOloidem | 1 Insomic | 0 |) (S | SHO | 8 | 004/ | 5 | N STATE OF THE STA |
| Allegra | allengios | 01 | no | (0) | 5 | 100// | Noull | |
| Madil | Whitehory | d | TAB | PRN | € | 04/20/201 | 12/SO P | |
| CO LET S FILL | FIRTH OFF | | | |) | | | |
| | | | | | | | | |
| | * If day or mon | ith of med | ication da | ate is <u>unknov</u> | vn, write U | * If day or month of medication date is unknown, write UNK in space provided | | |
| Investigator Signatu | Investigator Signature (at end of study): | M | 1 Com | Ling | a | Date: 27 F | dr2014 | |
| SC Signat | SC Signature (at end of study): | tell | D | AR | | Date: 2/21 | fil | • |
| | | Lovelace | Scientific Re | Lovelace Scientific Resources, Inc - ConMeds 04/2013 | Meds 04/2013 | | P. | PAGE:of |

 $\mathbf{i} = \mathbf{j}_i$

DAILY SYMPTOMS SCORE SHEET (RHINITIS DIARY)

CIRCLE APPROXIMATE RESPONSE EVERY 12 HOURS

| 77 | | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO | YES NO | 22 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO | YES NO | |
|--------------|--------|----------------------|----------------------|----------------------|--------------------|---------------------|---------------------|--------|----------------------|----------------------|----------------------|--------------------|---------------------|------------------------|--------------|
| 21 | 2119 | 123 | 0 (1) 2 3 | 0123 | 0 (1) 2 3 | YES (NO | KES NO | 21 | ` ' | 1 2 3 | 1 2 3 | 1 2 3 | YES NO | YES NO | - |
| , 20 , 20 | | d/123 (C) | 0(3 2 3 0 | Ø 1 2 3 (0 | 0(1) 2 3 0 | YES (Ng Y | (YES) NO (| 20 | 01230 | 0 (1) 2 3 0 | 0.1230 | 0 (1230 | YES (IQ) Y | (YES NO Y | |
| | 2117 | 0123 | 0 (1) 2 3 | 0123 | 0 (1)-2 3 | YES (NØ | (YES) NO | 19 | 0123 | 0 1 2 3 | Ø 1 2 3 (| 0 7 2 3 1 | YES (NO) | (YES) NO (| |
| , /18 | 2/1 Ce | (0) 1 2 3 | 0 (1) 2 3 | 0123 | 0(1)23 | YES (NØ | (YÈS) NO | 18 | 0 1 2 3 | 0 (1) 2 3 | 6/123 | 0(1) 2 3 | YES (NO) | YES NO | |
| 17 | 2/15 | (Å 1 2 3 | 0(1)23 | 0 1 2 3 | 0(1)23 | yes (NO | (YES) NO | 17 | 0 1 2 3 | 0 (1) 2 3 | 0123 | 0(1)23 | YES (NO) | (YES) NO | |
| , 16 | ナデチ | () 1 2 3 | 0(1) 2 3 | 0 1 2 3 | 0(123 | YES (NQ | YES NO | 16 | 9123 | 0 1 2 3 | Ø 1 2 3 | 0(1) 2 3 | YES (NO) | (YE\$ NO | |
| 15 | 2/13 | 0 123 | 0 (1) 2 3 | (0) 1 2 3 | 0(1) 2 3 | YES (NG) | (YES) NO (| 15 | 9123 | 0 (1) 2 3 | Ø 123 | 0(1)23 | YES (NO | (YES) NO | |
| 14 | 4 4 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | 0 1 2 3 | YES NO | YES NO | 14 | Ø123 | 0 (1) 2 3 | m | 0(1) 2 3 | YES (NO | (YE) NO | |
| DAY | AM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | DAY PM | Runny Nose 0 to 3 | Itchy Nose 0 to 3 | Congestion 0 to 3 | Sneezing 0 to 3 | Voice Hoarse Y/N | Throat Clearing Y/N | SCALE 0 to 2 |

SCALE 0 to 3

0= No symptoms (no symptoms detected)

1= Mild symptoms (symptoms present but easily tolerated)

2= Moderate symptoms (awareness of symptoms, bothersome but tolerable)

3= Severe symptoms (symptoms hard to tolerate; symptoms interfere with activities of daily living) Y=Yes N= No

SUBJECT NUMBER: AFPO49. DATE COMPLETED:

SUBJECT INITIALS AND DATE: \mathcal{EB} $^{2}/_{19}$ / 14



Lovelace Scier. Resources Leslie Byatt, Clin (rials 2441 Ridgecrest Dr SE Albuquerque, NM 87108-5129 Client Nbr 24664

1001 Woodward Pl. N.E. Albuquerque, NM 87102 (505) 938-8922

PATIENT NAME ERB, ERB

PATIENT ID **AAGM2177** DOB 06/28/1957 SEX F REPORT STATUS Final

PAGE

PHYSICIAN Unlisted Physician.

PT. PHONE NO.

COLLECT DATE & TIME 02/19/2014 12:46

Result

RECEIVE DATE & TIME

PRINT DATE & TIME

PATIENT NO.

02/19/2014 21:52

02/20/2014 06:04

31033214

0

COMMENTS:

REQUISITION NO.

AKP049

| | Re | suit | | | | |
|------------------------------------|---|-------------------------|---------------------------------|------------------------------------|-----------------|-----------|
| Test | In Range | Out of Ra | nge | Units | Reference Range | Site Code |
| Comp Metabolic Panel | | | | | | |
| Sodium | 139 | | | mmol/L | 134-144 | |
| Potassium | 3.7 | | | mmol/L | 3.5-5.1 | _ |
| Chloride | 108 | | | mmol/L | 98-111 | |
| CO2 | 23 | | | mmol/L | 20-30 | |
| Anion Gap | 8 | | | ************ | | 200 |
| Glucose | - | 143 | Н | mg/dL | 60-100 N C | IS MAM |
| BUN | 7 | | ., | mg/dL | 7-31 | , , |
| Creatinine | 0.72 | | | mg/dL | 0.50-1.40 | |
| | Creatinine method is IDMS | traceable. E | stGFR Ca | culation has be | en adjusted | |
| | Please note new reference (| | | | | |
| eGFR non-African Am GFR Comment | >60 | | | mL/min/1.73m2 | >60 | |
| S. I. Common | Estimated GFR values are no | ot accurate | in acute | kidnev failure. | innatients | |
| | Estimated GFR values are no on IV fluids, obese (BMI>3 the very old or very young, people with acute illnesses | 4) or underw races othe | eight (B) r than C: tions | MI<20) people, aucasian or Afri | can American, | |
| Calcium | 9.6 | o, or ampaca | LIGUISI | mg/dL | 8.4-10.4 | |
| Total Protein | 7.2 | | | gm/dL | 6.1-8.2 | |
| Albumin | 3.9 | | | gm/dL | 3.4-4.7 | |
| Globulin | 3.3 | | | gm/dL | 2.4-4.2 | |
| Bilirubin, total | 0.7 | | | mg/dL | 0.3-1.2 | |
| Alk Phos | 90 | | | Ŭ/L | 38-150 | man |
| AST(SGOT) | | 71 | Н | Ū/L | 6-58 NC | SIMPLE |
| ALT(SGPT) | | 91 | H | Ü/L | 14-67 11/ | E MAN |
| Fasting | NO | | • • | | 11.01 700 | 100/100 - |
| Phosphorus | 2.5 | | | mg/dL | 2.3-5.6 | |
| CBC | | | | • | _,, _ ,, _ | |
| WBC | 6.8 | | | x10E3 | 4.0-10.6 | |
| RBC | 5.08 | | | x10E6 | 4.00-5.36 | |
| Hgb | 14.2 | | | gm/dL | 12.0-16.0 | |
| Hct | 45 | | | % | 36-48 | |
| MCV | 88 | | | fĹ | 81-98 | |
| MCHC | 31.9 | | | am/dL | 31.2-35.2 | |
| RDW | 13.6 | | | % | 11.0-14.5 | |
| Platelets | 206 | | | x10E3 | 150-400 | |
| Eos, Respiratory | None seen | | | | NS | |
| Phys, Addr, Phone | Unknown | | | | ••• | |
| | | | | | | |

End of Report

MMusician 2014

ERB
AKP049
Effects of AkPharma's Calcium Glycerophosphate

Nasal Spray wash (AkP 010112A) on Patient-Perceived Breathing Comfort

SATISFACTION QUESTIONAIRRE:

| Would you use / purchase this nasal wash product in the future?" ☑YES ☐NO |
|--|
| You are also encouraged to make any free comments regarding your experience in the use of this product regarding your opinion of any of its effects not covered specifically in the Daily Diary: |
| This product was very help for my nasal passage. Clear air born products and all ergent. Would have love to keep the romainding peroduct to see . I was able to breath at right. |
| |
| |
| |
| |

[Type text]
Subject initials and Date 6 2/19/14 Study Staff Initials and Date 2 2/19/14