A CLINICAL TRIAL IN HEALTHY VOLUNTEERS WITH ECZEMA PRONE SKIN TO EVALUATE THE MOISTURISATION EFFICACY OF TWO TEST ARTICLES PLUS TWO CONTROLS AS MEASURED BY CORNEOMETER® ASSESSMENT AND THE REDUCTION IN SKIN REDNESS EFFICACY, AND THE RELATIVE DEGREE OF IMPROVEMENT TO SKIN BARRIER FUNCTIONALITY OF THREE TEST ARTICLES AS MEASURED BY TEWAMETER® AND CHROMAMETER CR300® ASSESSMENTS, AND SELF-PERCEPTION QUESTIONNAIRE (SPQ).

Prepared for:
Arete Labs
Unit 1B, 137-139 Silverwater Road
Silverwater
NSW 2128
Australia

Prepared by:
PCR Corp
8 Richmond Road
Dukes Park
Chelmsford
Essex
CM2 6UA
United Kingdom

Draft Report v1: 17th March 2023
Final Report: 31st March 2023

A CLINICAL TRIAL IN HEALTHY VOLUNTEERS WITH ECZEMA PRONE SKIN TO EVALUATE THE MOISTURISATION EFFICACY OF TWO TEST ARTICLES PLUS TWO CONTROLS AS MEASURED BY CORNEOMETER® ASSESSMENT AND THE REDUCTION IN SKIN REDNESS EFFICACY, AND THE RELATIVE DEGREE OF IMPROVEMENT TO SKIN BARRIER FUNCTIONALITY OF THREE TEST ARTICLES AS MEASURED BY TEWAMETER® AND CHROMAMETER CR300® ASSESSMENTS, AND SELF-PERCEPTION QUESTIONNAIRE (SPQ).

PCR CORP REPORT NO: ATLCLI1M

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by PCR Corp were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt
(Principal Investigator)

B Drewitt .....

Date 31 / 03 / 2023 .....

Sophie Ellis
(Project Manager)

Sophie Ellis .....

Date 31 / 03 / 2023 .....

Dr. David Wrone, MD
(Consultant Dermatologist)

Dr. David Wrone .....

Date 31 / 03 / 2023 .....

QUALITY ASSURANCE STATEMENT

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

Bryan Baker
(Quality Assurance)

Bryan Baker .....

Date 31 / 03 / 2023 .....

SUMMARY

Title: A clinical trial in healthy volunteers with eczema prone skin to evaluate the moisturisation efficacy of two test articles plus two controls as measured by Corneometer® assessment and the reduction in skin redness efficacy, and the relative degree of improvement to skin barrier functionality of three test articles as measured by Tewameter® and Chromameter CR300® assessments, and Self-perception questionnaire (SPQ).

Study design: Randomised, single-blind, single-centre study.

Test Articles:
1 - Anti-inflammatory Barrier Repair Serum (Used as a regime)
2 - Anti-inflammatory Ointment Gel (Used as a regime)
3 - Anti-Flare Oil (Used as a regime)
4 - Negative Control (Untreated - Site 2)
5 - Positive Control (Glycerine Site - 3)

Observations:

- 3-day wash down from all moisturizing products with a standard bar of soap (legs and face).
- Corneometer® assessments of skin hydration – 3 replicates on the lower leg at baseline (i.e. prior to test article application), a single application of test articles 1 and 2 to the same test site 1 on the lower leg (2 minutes to be allowed between the application of test articles for absorption into the skin) with further Corneometer® assessments done immediately (15 minutes) after application of test article 2, and at 12 hours and at day 5 following test article application.
- Tewameter® assessments of Trans-epidermal water loss – 1 assessment on the face at baseline (i.e. prior to test article application), application of test articles 1, 2 and 3 to the same area on the face (2 minutes to be allowed between the application of test articles for absorption into the skin) with further Tewameter® assessments done immediately (15 minutes) after application of test article 3 and at 12 hours following test article application. Subjects then used the issued products (test article 1, 2 and 3) at home, as directed and had a final Tewameter® assessment on day 5.

- Chromameter CR300® assessments of skin redness – 4 assessments on the face at baseline (i.e. prior to test article application), application of test articles 1, 2 and 3 to the same area on the face (2 minutes to be allowed between the application of test articles for absorption into the skin) with further Chromameter CR300® assessments done immediately (15 minutes) after application of test article 3 and at 12 hours following test article application. Subjects then used the issued products (test article 1, 2 and 3) at home, as directed and had final Chromameter CR300® assessments on day 5.
- 10 subjects with the most facial redness/dry/flaky/eczema at baseline had professional high resolution clinical photographic images taken of their face (left, right and front aspects) at baseline (i.e. prior to test article application) and at the end of the study on day 5.
- Self-perception questionnaire (SPQ) completed immediately (within 1 hour) and at 12 hours following the first test article application and on day 5.

Duration of study:	3 days – Washout Phase 5 days – Active Phase
Number of subjects:	35 subjects were enrolled, and 34 subjects completed the study.
Types of subjects:	Healthy male and female subjects, aged 18 years or older with self-perceived dry/eczema/flaky prone skin.
Start Date:	w/c 27th February 2023
End Date:	w/c 6th March 2023
Study location:	PCR Corp 164A Plymouth Grove Manchester M13 0AF United Kingdom

1. KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key personnel	General responsibilities
Principal Investigator (PI) Barrie Drewitt PCR Corp Baypoint Commerce Center 9600 Koger Blvd N. St. Petersburg Florida 33702 USA Tel: (727) 576-7300	The Principal Investigator (PI) was responsible for ensuring sufficient resources were available to conduct the study and was responsible for the study design, review of the study protocol and report, and ensuring that they concurred with the study findings report.
Project Supervisor (PS) Kira Day PCR Corp 164A Plymouth Grove Manchester M13 0AF United Kingdom Tel: 0161 791 1797	The Project Supervisor (PS) was responsible for the conduct of the study on a daily basis.
Project Manager (PM) Sophie Ellis PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: +44 01245 934050	The Project Manager (PM) was involved with the study design, compilation of study results, and writing the study protocol and report.
Consulting Dermatologist Dr. David Wrone, MD	The Consulting Dermatologist has reviewed the study results and conclusions.
Project Co-ordinator (PC) Aditi Mamtani Arete Labs Unit 1B, 137-139 Silverwater Road Silverwater NSW 2128 Australia Email: Aditi@arete-labs.com Tel: +61466312655	The Project Co-ordinator (PC) was the primary point of contact on behalf of the Sponsor of this project and represented the Sponsor of this study.

2. INTRODUCTION AND OBJECTIVE

The objective of this study was to evaluate the moisturisation efficacy of two test articles plus two controls as measured by Corneometer® assessment and the reduction in skin redness efficacy, and the relative degree of improvement to skin barrier functionality of three test articles as measured by Tewameter® and Chromameter CR300® assessments, and Self-perception questionnaire (SPQ) when tested in approximately 30 healthy male and female subjects with self-perceived dry/eczema/flaky prone skin.

To substantiate the following claims:

- Clinically proven to moisturise the skin up to hours/100
- Clinically proven to improve skin barrier protection in 5 days
- Clinically proven to reduce skin redness up to 12 hours
- Approved by Dermatologist
- Suitable for dry/flaky skin**
- Suitable for skin that may be prone to eczema or dermatitis***
- Moisturizing formula that relieves and protects a compromised skin barrier/dry/flaky skin
- Helps strengthen the skin's protective barrier
- Skin protectant
- Locks-in moisture
- x% of panel of 30 subjects agree that:
  skin is feeling hydrated/softer
  skin redness is looking reduced
  product application is pleasant/easily absorbed/leaves a comfortable skin feel
  skin feels relieved from dry itchy* sensation

3. STUDY DESIGN

The study was conducted randomised, single blind, in a single centre.

4. SELECTION OF SUBJECTS

4.1 SCREENING

A sufficient number of subjects were recruited into the study to allow for a minimum of thirty subjects to enter the active phase. Subjects satisfied the following inclusion and exclusion criteria, were prepared to accept the prohibitions and restrictions and gave written informed consent (*Appendices 1 & 2*).

The suitability of each potential subject was confirmed before their acceptance by review of a study specific pre-treatment questionnaire (*Appendix 3*).

4.2 INCLUSION CRITERIA

a. Subject is a healthy male or female, aged 18 years or older with self-perceived dry/eczema/flaky prone skin.
b. No use of any skin treatment products on the lower legs or face for three days before the active phase (other than the soap provided).
c. No washing of the lower legs or face for three hours prior to coming to the test centre.
d. Willing to use the test articles as instructed following the directions for usage provided by the sponsor and to attend all study visits.
e. Willing to withhold all facial treatments during the course of the study including toxins, fillers, microdermabrasion, peels, facials, laser treatments, IPL, tightening treatments.
f. Subject has signed a written Informed Consent.
g. Subject has signed the photography model release authorisation form.

4.3 EXCLUSION CRITERIA

a. Subject is pregnant, nursing, or planning to become pregnant.
b. Inadequate precautions/procedures to prevent pregnancy (women of childbearing potential only).
c. Subject is currently using concurrent medication likely to affect the response to the test article or confuse the results of the study including Botox/collagen fillers, anti-inflammatory medications, antihistamines, and steroids.
d. Any conditions on the test site that would interfere with evaluations (i.e. tattoos, scars, open cuts, sunburn, piercings, excessive hair, etc.).
e. A fever in the last 12 hours, prior to start of the study.
f. A current skin disease of any type or under the treatment of a doctor for any skin condition (exceptions for dry/eczema/flaky prone skin).
g. Heavy alcohol consumption (i.e. more than 14 units per week or 4 units a day).
h. Significant past medical history of hepatic, cancerous, multiple sclerosis, high blood pressure, renal, Thrombosis/Phlebitis, cardiac, pulmonary, digestive, haematological, neurological, locomotor or psychiatric disease, which in the opinion of the Investigator would compromise the safety of the subject.
i. History of asthma requiring regular medication.
j. Insulin-dependent diabetes.
k. Use of topical treatments such OTC (over the counter) acne medication or hydrocortisone on the test sites (lower legs and face) in the last month.
l. Facial chemical peel in the last 14 days.
m. Microdermabrasion treatment on the face within 6 months of the study start.
n. Cosmetic medical procedures in the test area such as injectable anti-wrinkle products, facial cosmetic surgery, etc. in the last year.
o. Current use or history of repeated use of illicit drugs.
p. Known sensitivity to the test articles, similar materials, or their constituents.
q. Subject has participated in any clinical study which involved the test sites within 21 days or is currently participating at PCR or other clinical testing facility, in a study utilizing the same test sites (face/lower leg area) or product or with conflicting inclusion/exclusion criteria.

4.4 PROHIBITIONS AND RESTRICTIONS FOR THE DURATION OF THE STUDY

a. Subjects must not touch the areas where the test articles have been applied.
b. Subjects must refrain from smoking throughout their visit to the Test Centre.
c. Subjects need to have been in the environmentally controlled room for at least 30 minutes before any assessment. Toilet visits are acceptable, but subjects need to have been in the environmentally controlled room for at least 30 minutes before any assessment.
d. No consumption of hot beverages at any time whilst in the controlled room, or any product containing caffeine in the one hour preceding each assessment.
e. No treatment to the lower legs or face for three hours before all visits.
f. Subject agrees to use the test articles as instructed for the duration of the study following the directions for usage provided by the sponsor and to replace their usual facial serum, moisturizer/ointment and anti-flare regime products with the test articles provided.
g. Subject agrees not to introduce any new skincare treatments or products to their legs or face for the duration of the study (e.g. moisturizer, serums etc.) other than the test articles provided.
h. Subject agrees to avoid excessive sun exposure and any form of tanning for the duration of the study.

5. METHOD

5.1 TEST ARTICLE

The following test articles were supplied by the Sponsor as follows:

1 - Anti-inflammatory Barrier Repair Serum (Used as a regime)
2 - Anti-inflammatory Ointment Gel (Used as a regime)
3 - Anti-Flare Oil (Used as a regime)

Test articles 1, 2 and 3 were used as a regime on the face, as supplied and according to the usage instructions provided by the sponsor.

15. CONCLUSIONS

The data from the Corneometer® measurements demonstrate there were no statistically significant differences ($p > 0.05$) between the test site and the untreated site prior to application of the test articles which confirms the validity of the study. After a single application, test articles 1 and 2 (applied as a regime) produced statistically significant hydration (moisturisation) of the skin ($p < 0.05$) when compared to the untreated site for all of the timepoints up to and including Day 5. Therefore, it can be concluded that under the conditions of this study claims of "Moisturising/Hydrating", "Combats dehydration", and "Clinically proven to moisturise the skin up to 100 hours" can be substantiated for test articles 1 and 2 (applied as a regime).

The data from the Tewameter® measurements demonstrate test articles 1, 2 and 3 (applied as a regime) performed statistically significantly at improving the skin barrier function measured via Trans epidermal water loss readings of the skin ($p < 0.05$) when compared to baseline (untreated site) for all of the timepoints; up to and including 12-hours and within 5 days of test article usage. Therefore, it can be concluded that under the conditions of this study claims of "Improves skin's barrier protection in 5 days", "Moisturizing formula that relieves and protects a compromised skin barrier/dry/flaky skin", "Helps strengthen the skin's protective barrier", "Skin protectant" and "Locks-in moisture" can be substantiated for test articles 1, 2 and 3 (applied as a regime).

The data from the Chromameter CR300® a* measurements demonstrate test articles 1, 2 and 3 (applied as a regime) performed statistically significantly at reducing skin redness when compared to baseline (untreated site) for all of the timepoints; up to and including 12-hours and within 5 days of test article usage. Therefore, it can be concluded that under the conditions of this study claims of "Clinically proven to reduced skin redness up to 12 hours" and "Clinically proven to reduced skin redness within 5 days" can be substantiated for test articles 1, 2 and 3 (applied as a regime).

The subject panel of this study was made up of subjects with self-perceived dry/eczema/flaky prone skin therefore it can be concluded that under the conditions of this study, claims of "Suitable for dry/flaky skin" and "Suitable for skin that may be prone to eczema or dermatitis" can be substantiated for test articles 1, 2 and 3 (applied as a regime).

The study results and conclusions in this report have been reviewed by a consultant dermatologist (M.D.) therefore it can be concluded that under the conditions of this study, the claim of "Approved by Dermatologist" can be substantiated for test articles 1, 2 and 3 (applied as a regime).

Day 5

Subject No.	1. Do you feel your skin appeared hydrated after application of the regime?	2. Do you perceive your skin was glowing after application of the regime?	3. How would you rate your skin's elasticity after application of the regime?	4. Do you perceive reduction in itchy skin in general after application of the regime?	5. Did you experience instant relief after using the Anti-flare oil as needed to relieve itching?	6. Do you perceive reduction in redness of your skin in general after application of the regime?
1	4	3	4	5	4	4
2	4	4	3	5	4	4
3	5	4	3	4	5	3
4	DROPOUT	DROPOUT	DROPOUT	DROPOUT	DROPOUT	DROPOUT
5	5	4	4	4	4	3
6	5	5	5	5	4	5
7	4	4	4	5	5	4
8	4	3	4	3	4	4
9	5	4	4	4	5	5
10	4	3	4	5	4	4
11	5	5	3	4	3	5
12	5	2	5	4	4	4
13	5	3	4	5	5	3
14	4	3	4	4	3	4
15	5	3	4	5	4	4
16	5	5	4	4	3	5
17	5	4	4	5	5	5
18	5	3	4	5	5	4
19	5	5	5	4	4	4
20	4	5	5	4	5	5
21	5	4	4	4	4	4
22	5	3	3	4	4	4
23	4	4	4	5	5	5
24	5	3	4	5	4	4
25	4	5	5	4	5	4
26	5	3	4	4	4	4
27	4	4	3	4	4	3
28	5	5	5	5	5	4
29	5	4	4	5	4	5
30	5	4	4	5	3	4
31	4	4	5	4	4	4
32	4	3	5	4	5	4
33	4	5	3	4	5	4
34	5	5	4	5	4	5
35	4	4	5	4	5	4
% 5 RESPONSE	58.82%	26.47%	26.47%	44.12%	38.24%	26.47%
% 4 RESPONSE	41.18%	38.24%	55.88%	52.94%	50.00%	61.76%
% 3 RESPONSE	0.00%	32.35%	17.65%	2.94%	11.76%	11.76%
% 2 RESPONSE	0.00%	2.94%	0.00%	0.00%	0.00%	0.00%
% 1 RESPONSE	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
% Top 2 Responses (4 & 5)	100.00%	64.71%	82.35%	97.06%	88.24%	88.24%

Subject No.	7. Do you perceive reduction in inflammation of your skin in general after application of the regime?	8. Did you experience instant relief after using the Anti-flare oil as needed to relieve inflammation?	9. Do you perceive reduction in dry or flaky skin in general after application of the regime?	10. How improved do you feel your skin barrier is relative to before application of the regime?	11. How would you rate the overall appearance of your skin after application of the regime?	12. How would you rate the skin feel of the regime products?
1	4	5	5	4	5	4
2	3	4	5	5	4	5
3	4	5	4	4	4	4
4	DROPOUT	DROPOUT	DROPOUT	DROPOUT	DROPOUT	DROPOUT
5	5	5	4	4	4	4
6	5	5	5	5	5	4
7	4	4	4	4	5	5
8	5	4	5	4	4	4
9	5	5	5	5	5	5
10	4	4	4	4	4	4
11	5	5	5	4	4	4
12	4	4	4	4	5	4
13	4	5	5	5	4	5
14	4	4	4	4	4	4
15	4	4	4	4	4	5
16	5	5	5	5	3	4
17	4	5	5	4	4	5
18	4	4	4	5	4	4
19	5	5	5	5	4	4
20	4	4	4	4	5	4
21	4	5	5	4	4	4
22	4	4	4	3	3	5
23	5	5	5	4	5	5
24	4	4	4	4	4	5
25	4	4	4	5	4	4
26	5	5	4	4	4	4
27	5	5	5	3	5	5
28	4	4	4	4	4	4
29	4	5	4	4	4	4
30	4	5	5	5	5	5
31	4	4	4	4	3	4
32	4	4	5	5	4	5
33	5	5	5	5	4	4
34	4	5	4	4	4	4
35	4	4	4	4	3	4
% 5 RESPONSE	32.35%	52.94%	47.06%	32.35%	26.47%	35.29%
% 4 RESPONSE	64.71%	47.06%	52.94%	61.76%	61.76%	64.71%
% 3 RESPONSE	2.94%	0.00%	0.00%	5.88%	11.76%	0.00%
% 2 RESPONSE	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
% 1 RESPONSE	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%
% Top 2 Responses (4 & 5)	97.06%	100.00%	100.00%	94.12%	88.24%	100.00%