GLOBAL PRODUCT TESTING

SUMMARY REPORT

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 107 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF THREE TEST ARTICLES FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

CONDUCTED ACCORDING TO PCR MASTER PROTOCOL: PCRRIP1 (20JAN2022)

PCR Corp. Study Number: **ATLRIP1M**

TEST ARTICLES: 1. Eczema Barrier Repair Serum: AL-22-010
2. Eczema Ointment Gel: AL-21-113
3. Eczema Foaming Cleanser: AL-21-111
(DILUTED TO 8% W/V DEIONIZED WATER)

Please Note: PCR Corp is an abbreviation for Princeton Consumer Research Corp.

Prepared for:

Arete Labs
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Silverwater
NSW 2128

Prepared by:

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Draft Report v1: 18th November 2022
Final Report: 25th November 2022

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 107 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF THREE TEST ARTICLES FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

CONDUCTED ACCORDING TO PCR MASTER PROTOCOL: PCRRIP1(20JAN2022)

PCR Corp. Study Number: **ATLRIP1M**

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 28 / 11 / 2022

Sophie Ellis
(Project Manager)

Sophie Ellis

Date 28 / 11 / 2022

Dr. David Wrone, MD
(Consultant Dermatologist)

David Wrone, M.D.

Date 28 / 11 / 2022

Dr. Geetha Kugan, MRCP, DCH, FRCPCH
(Consultant Paediatrician)

Geetha Kugan

Date 28 / 11 / 2022

Dr. Anita Saha, MD
(Consultant Gynaecologist)

Date 28 / 11 / 2022

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)

R. Statham

(p.p. Reece Statham)

Date 28 / 11 / 2022

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, FL 33702 Tel: +1 (727) 576 7300	The Principal Investigator (PI) responsible for ensuring sufficient resources were available to conduct the study and was responsible for the study design, review of the study protocol, authorization and summary report.
Study Supervisor (SS) Andrew King PCR Corp 164A Plymouth Grove Manchester M13 0AF United Kingdom Tel: +44(0)161 791 1797	The Study Supervisor (SS) 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 (0)1245 934050	The Project Manager (PM) involved with the study authorization, compilation of study results and summary report.
Consulting Dermatologist Dr. David Wrone, MD	The Consulting Dermatologist has reviewed the study results and concurs with the study result conclusions.
Consulting Paediatrician Dr. Geetha Kugan, MRCP, DCH, FRCPCH	The Consulting Paediatrician has reviewed the study results and concurs with the study result conclusions.
Consulting Gynaecologist Dr. Anita Saha MD	The Consulting Gynaecologist has reviewed the study results and concurs with the study result conclusions.
Sponsor Contact Aditi Mamtani / Shaakila Nordien Arete Labs Unit 1B, 137-139 Silverwater Road Silverwater NSW 2128 Email: aditi@arete-labs.com / shaakila@arete-labs.com	

2. INTRODUCTION AND OBJECTIVE

The objective of this study was to investigate the irritation and sensitisation potential of cosmetic test articles, in a shared panel of 100 healthy volunteers by means of repeated cutaneous occlusive patch applications based on the modified Draize method of Jordan and King (1977)1 to support claims such as "Dermatologically Tested", "Clinically Tested", "Clinically Proven", "Kind to Skin", "Mild for Skin", "Safe for Skin", "Hypoallergenic", "Allergy Tested", "Suitable for all Skin Tones", "Dermatologist Approved", "Paediatrician Approved", "Gynaecologist Approved" and "Suitable for Eczema Prone Skin".

3. STUDY DESIGN

The study was conducted single blind, at a single center according to Master Protocol: PCRRIP1.
The test articles were patched under occlusive conditions using Finn chambers or equivalent occlusive patches. A total of nine inductions patches worn for 47 hours or 71 hours (patching occurred Mondays, Wednesdays, and Fridays) for three weeks (a make-up day was allowed to ensure subjects had all 9 induction patches). Subjects had a rest period of 14 days. Challenge patches were applied for 48 hours, and readings were made 1 hour, and 48 hours post removal.

4. TEST MATERIALS

4.1 TEST ARTICLES

The test articles were supplied by the Sponsor and labelled as follows:

TA#	Test Article Name/Description	ID Code (Batch/Lot #)	Dilution/special handling
1	Eczema Barrier Repair Serum	AL-22-010	Use as supplied. Occlusive patch.
2	Eczema Ointment Gel	AL-21-113	Use as supplied. Occlusive patch.
3	Eczema Foaming Cleanser	AL-21-111	Dilute to 8% with deionized water. Occlusive patch.

5. STUDY ETHICS

5.1 DECLARATION OF HELSINKI

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013)[2].

5.2 INDEMNITY PROVISION

The Sponsor was responsible, without regard to legal liability, and shall indemnify PCR Corp, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury arising out of the administration or use of the test article, or of any procedure required under this

protocol as a result of a subject participating in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

5.3 ICH GCP

The study was conducted in accordance with applicable International Council for Harmonization. 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)3 in as much as they apply to cosmetic and consumer product testing/research.

6. QUALITY ASSURANCE

The study was conducted according to the Sponsor Authorization, the master protocol, the Standard Operating Procedures of PCR Corp and according to the applicable ICH Guidelines on Good Clinical Practice, and other recognised guidelines. An audit of the final report was completed, for accuracy and completeness of presentation. Additionally, the study may be subject to the following Quality Assurance procedures:

- Review of protocol and protocol amendments for completeness, clarity and adequacy.
- Inspection and/or audit of critical phases of study conduct for compliance with protocol and PCR Corp procedures.

PCR Corp Quality Assurance would have informed PCR Corp management of any findings that may have affected the integrity of the study.

7. RETENTION OF DATA

All raw data generated by PCR Corp during the course of the study, including the sponsor authorization form and final summary report, will be retained in the PCR Corp Archive for a minimum period of three years from study completion as is PCR Corp policy for cosmetic products. In the event of original data being transferred to the Sponsor at their request, exact copies will be so retained. At no time will archived data be destroyed without prior written approval of the Sponsor. All study data will be available at any time, by appointment, for inspection by the Sponsor or their authorized representative. The study master protocol will be archived and retained indefinitely at PCR Corp.

8. REFERENCES

1. Jordan W.P. and King S. E. (1977) Contact Dermatitis 3, 19-26.
2. World Medical Association (2013). "Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects". JAMA 310 (20): 2191–2194. doi:10.1001/jama.2013.281053
3. ICH E6_R2, INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE, Current Step 4 version dated 9 November 2016

9. RESULTS

9.1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, located in Manchester between w/c 26th September 2022 and w/e 4th November 2022.

9.2 SUBJECTS

112 male and female subjects were enrolled into the study. 107 subjects completed the study. The age & gender of these subjects is presented in table in Appendix 2. 50% of subject panel had self-assessed Eczema prone skin. All skin tones were included (Fitzpatrick I-VI).

9.3 ADVERSE EVENTS / REACTIONS, SUBJECTS NOT COMPLETING THE STUDY AND DEVIATIONS

No adverse events or reactions were reported.

5 subjects withdrew for personal reasons.

There were no deviations that occurred during the conduct of the study.

10. CONCLUSIONS

The test articles can be considered as safe for use under the conditions of the study and claims such as "Dermatologically Tested", "Clinically Tested", "Clinically Proven", "Kind to Skin", "Mild for Skin", "Safe for Skin", "Hypoallergenic", "Allergy Tested", "Suitable for all Skin Tones", "Dermatologist Approved", "Paediatrician Approved", "Gynaecologist Approved" and "Suitable for Eczema Prone Skin" are substantiated.

SUMMARY REPORT

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 106 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF ONE (1) TEST ARTICLE FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

CONDUCTED ACCORDING TO PCR MASTER PROTOCOL: PCRRIP1(20JAN2022)

PCR Corp. Study Number: **ATLRIP2M**

TEST ARTICLE: **1. Anti-flare oil AL-21- 023**

Please Note: PCR Corp is an abbreviation for Princeton Consumer Research Corp.

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Draft Report v1: 29th December 2022
Draft Report v2: 17th January 2023
Final Report: 25th January 2023

A MODIFIED DRAIZE REPEAT INSULT PATCH TEST IN A SHARED PANEL OF 106 HEALTHY VOLUNTEERS, TO INVESTIGATE THE IRRITATION AND SENSITISATION POTENTIAL OF ONE (1) TEST ARTICLE FOLLOWING REPEATED CUTANEOUS PATCH APPLICATIONS

CONDUCTED ACCORDING TO PCR MASTER PROTOCOL: PCRRIP1(20JAN2022)

PCR Corp. Study Number: **ATLRIP2M**

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 30 / 01 / 2023

Ashley Clarke
(Project Manager)
Date 25 / 01 / 2023

Dr David Wrone, MD
(Consulting Dermatologist)
David Wrone, M.D.
Date 25 / 01 / 2023

Dr. Anita Saha, MD
(Consulting Gynaecologist)
Date 25 / 01 / 2023

Dr. Geetha Kugan, MRCP, DCH, FRCPCH
(Consultant Paediatrician)
Geetha Kugan
Date 26 / 01 / 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 25 / 01 / 2023

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 FL 33702 USA Tel: +1(727) 576 7300	The Principal Investigator (PI) responsible for ensuring sufficient resources were available to conduct the study and was responsible for the study design, review of the study protocol, authorisation and summary report.
Study Supervisor (SS) Andy King PCR Corp 164A Plymouth Grove Manchester M13 0AF United Kingdom Tel: +44(0)161 791 1797	The Study Supervisor (SS) responsible for the conduct of the study on a daily basis.
Project Manager (PM) Ashley Clarke PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom Tel: +44 (0)1245 934050	The Project Manager (PM) involved with the study authorisation, compilation of study results and summary report.
Consulting Dermatologist David Wrone, MD	The Consulting Dermatologist has reviewed the study results and concurs with the study result conclusions.
Consulting Gynaecologist Dr. Anita Saha MD	The Consulting Gynaecologist has reviewed the study results and concurs with the study result conclusions.
Consulting Paediatrician Dr. Geetha Kugan, MRCP, DCH, FRCPCH	The Consulting Paediatrician has reviewed the study results and concurs with the study result conclusions.
Sponsor Contact Aditi Mamtani / Shaakila Nordien Arete Labs Unit 1B 137-139 Silverwater road Silverwater NSW 2128 Australia Email: aditi@arete-labs.com / Shaakila@arete-labs.com Tel: +61466312655	

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The objective of this study was to investigate the irritation and sensitisation potential of one (1) cosmetic test article, in a shared panel of 106 healthy volunteers by means of repeated cutaneous occlusive patch applications based on the modified Draize method of Jordan and King (1977)[1] to support claims such as "Dermatologically tested", "Clinically tested", "Clinically proven", "Kind to skin", "Mild for skin", "Safe for skin", "Suitable for all skin tones", "Dermatologist Approved", "Paediatrician Approved", "Gynaecologist approved", "Hypoallergenic", "Allergy tested" and "Suitable for Eczema prone skin".

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The study was conducted single blind, at a single centre according to Master Protocol: PCRRIP1.
The test article was patched under occlusive conditions using Finn chambers or equivalent occlusive patches. A total of nine inductions patches worn for 47 hours or 71 hours (patching occurred Mondays, Wednesdays, and Fridays) for three weeks (a make-up day was allowed to ensure subjects had all 9 induction patches). Subjects had a rest period of 14 days. Challenge patches were applied for 48 hours, and readings were made 1 hour, and 48 hours post removal.

4. TEST MATERIALS

4.1 TEST ARTICLE

The test article was supplied by the Sponsor and labelled as follow:

TA#	Test Article Name/Description	ID Code (Batch/Lot #)	Dilution/special handling*
1	Anti-Flare Oil	AL-21- 023	Use as supplied by Sponsor.

5. STUDY ETHICS

5.1 DECLARATION OF HELSINKI

The study conformed to the requirements of the 1964 Declaration of Helsinki and its subsequent amendments (World Medical Association; 2013)[2].

5.2 INDEMNITY PROVISION

The Sponsor was responsible, without regard to legal liability, and shall indemnify PCR Corp, or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury arising out of the administration or use of the test article, or of any procedure required under this protocol as a result of a subject participating in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of PCR Corp employees or any persons undertaking or involved in the study by arrangement with PCR Corp.

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The study was conducted in accordance with applicable International Council for Harmonization. 2016. Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)3 in as much as they apply to cosmetic and consumer product testing/research.

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1. Jordan W.P. and King S. E. (1977) Contact Dermatitis 3, 19-26.
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3. ICH E6_R2, INTEGRATED ADDENDUM TO ICH E6(R1): GUIDELINE FOR GOOD CLINICAL PRACTICE, Current Step 4 version dated 9 November 2016

9. RESULTS

9.1 LOCATION AND DATES OF THE STUDY

The study was performed at PCR Corp, located in Manchester between w/c 14th November 2022 and w/e 23rd December 2022.

9.2 SUBJECTS

110 male and female subjects were enrolled into the study. 106 subjects completed the study. The age and gender of these subjects is presented in table in Appendix 2. 50% of subject panel had eczema prone skin.

9.3 ADVERSE EVENTS, ADVERSE REACTIONS, SUBJECTS NOT COMPLETING THE STUDY AND DEVIATIONS

No adverse events or reactions were reported.

4 subjects withdrew for personal reasons.

There were no deviations that occurred during the conduct of the study.

9.4 ASSESSMENTS

Individual reactions to the test article are presented in Appendix 1.

As demonstrated by the individual skin responses to the test article:

Test Article 1 – Anti-flare oil AL-21- 023

Elicited no visible erythematous reactions during the induction phase of the study.

There were no questionable reactions observed during the Challenge Phase (Days 38 and 40) by any of the subjects to the test article. These results support the assessment that under the conditions of the study, the test article has demonstrated a low potential for irritation and sensitization.

10. CONCLUSIONS

The test article can be considered as safe for use under the conditions of the study, and claims such as, "Dermatologically tested", "Clinically tested", "Clinically proven", "Kind to skin", "Mild for skin", "Safe for skin", "Suitable for all skin tones", "Dermatologist Approved", "Paediatrician Approved", "Gynaecologist approved", "Hypoallergenic", "Allergy tested" and "Suitable for Eczema prone skin" are substantiated.