A CLINICAL STUDY IN 22 HEALTHY FEMALE PANELISTS AGES 40-70 YEARS

Prepared for:

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A clinical study in 22 healthy female panelists ages 40-70 years

Princeton Consumer Research Corp. Report No: PHBCLI1P

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 Princeton Consumer Research Corp. were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

Barrie Drewitt, DipSW, CertHE, MICR
(Principal Investigator)

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Date 2nd March 2017

Cassandra Starr
(Project Manager)

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Date 2nd March 2017

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.

Anne Campbell, BS
(Quality Assurance Manager)

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Date 2nd March 2017

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1 SUMMARY

Protocol Title:	A clinical study in 22 healthy female panelists ages 40-70 years
Study design:	Single-center, home use study design
Test Article:	1. Illuminating Serum
Number of subjects:	Twenty-two subjects were enrolled and twenty (20) completed the study
Type of subjects:	Healthy female subjects between the ages 40-70 years old with self-assessed fine lines and wrinkles, uneven skin tone.
Method:	Subjects reported to the testing facility for baseline screening at which time Informed Consent and demographics were obtained and Inclusion/Exclusion criteria were verified. Once eligibility was confirmed subjects underwent baseline (before product use) Chromameter, Corneomter, Cutometer measurements and visual evaluations on their face. Subjects were issued product and instructions for use at home for the next 28 days. After 14 days (visit 2) and 28 days (visit 3), subjects returned to testing facility to have visual evaluations, instrument measurements of the face and completed a questionnaire. Subjects were asked to return used product at visit 3.
Conclusion:	Under the conditions of this study, results of corneometer measurements on the face indicate that the hydration of the skin at baseline (average of 56.3) significantly increased after 14 (average 75.5) and 28 days (average 70.2) of product use, with statistical significance (p-value > 0.05).

Results of visual evaluations of skins texture (tactile/touch) indicate when comparing to baseline (moderately rough, average 3.75) that after 28 days of serum use the skins texture significantly improved (average 2.7) indicating skin was smoother. Results for skin tone significantly decreased after 28 days (average 3.35) of product use when compared to baseline (average 4.7) indicating an improvement in skin tone indicating skin appears less dull.

As demonstrated in the results of the 28 day SPQ, the product performed highly favorably over the testing period (28 days), (Top 2 responses + ½ the neither agree nor disagree responses) with ≥80% value being regarded as highly favorable).

- 87.5% of subjects agreed their skin appeared healthier looking and more even toned after using the serum
- 85% of subjects agreed that their dry lines and wrinkles appeared less noticeable after using the serum.
- 85% of subjects agreed their skin looked and felt firmer and more elastic after using the serum.
- 85% of subjects agreed their skin appeared more youthful after using the serum.
- 82.5% of subjects agreed the serum significantly reduced the appearance of dull skin
- 82.5% of subjects agreed they were satisfied with the serum.

- 80% of subjects agreed the serum significantly improved their skins softness and smoothness
- 80% of subjects agreed the serum significantly improved the radiance of their skin
- 80% of subjects agreed their face appeared more luminous after using the serum
- 80% of subjects agreed their skin's suppleness was visibly restored after using the serum
- 80% of subjects agreed the serum significantly improved their skin's overall appearance
- 80% of subjects agreed they would recommend the serum to a friend

Duration of study: Study Started: 24 January 2017
Study Ended: 21 February 2017

Location: Princeton Consumer Research Corp.
Princeton Forrestal Center
307 College Road East
Princeton, New Jersey 08540

2 KEY STUDY PERSONNEL AND RESPONSIBILITIES

Key Personnel	General Responsibilities
Principal Investigator (PI) Barrie Drewitt, DipSW, CertHE, MICR Princeton Consumer Research Corp. Princeton Forrestal Center 307 College Road East Princeton, New Jersey 08540 Tel: 609.455.1112	The Principal Investigator (PI) is responsible for ensuring sufficient resources are available to conduct the study and is responsible for the study design and conduct, subject safety, review of the study protocol and study report.
Study Supervisor (SS) Diane Benevento Princeton Consumer Research Corp. Princeton Forrestal Center 307 College Road East Princeton, New Jersey 08540 Tel: 609.455.1112	The Study Supervisor (SS) will be responsible for the conduct of the study on a daily basis.
Project Manager (PM) Cassandra Starr Princeton Consumer Research Corp. 9600 Koger Blvd. N, Suite 120 St. Petersburg, FL 33702 Tel: 727.576.7300	The Project Manager will be the primary point of contact and will represent the site (Princeton Consumer Research) for this study.
Project Coordinator (PC) Marisa Arredondo Phace Bioactive 50 Sound View Drive, Suite 3 South Greenwich, CT 06830 Tel: 203.769.1117	The Project Coordinator (PC) is the primary point of contact on behalf of the sponsor of this study and will represent the Sponsor of this study (Phace Bioactive).

3 OBJECTIVE

The objective of this study was to determine the perceived effectiveness and acceptability of an illuminating serum to improve the texture, skin tone and health of the skin, all by utilizing self-perception questionnaire (SPQ) and instrumentation (Chromameter, Corneometer and Cutometer).

4 STUDY DESIGN

This study was conducted at a single testing facility. Subjects were given instructions to use the product once daily for 28 days. Targeted claims proposed by sponsor are as follows but not limited to:

- Brightens Skin
- Skin Firming
- Smooths Skin
- Improves firmness/elasticity
- Improves skin texture

- Improves age spots/skin tone
- Hydrating/moisturising

Please note that it was the responsibility of the sponsor to determine the testing and study designs required for submission to entities such as the Home Shopping Network, QVC, etc.

5 SELECTION OF SUBJECTS

5.1 Screening

An adequate number of subjects were screened and enrolled so that twenty (20) subjects would complete the study. Subjects satisfied the following inclusion and exclusion criteria, accepted the prohibitions and restrictions and gave written informed consent.

The suitability of potential subjects was confirmed before their acceptance by review of a study specific pre-treatment questionnaire.

5.2 Inclusion criteria

a) Subject is a healthy female between ages 40 – 70 years;

b) Subject has signed a written Informed Consent/HIPAA;

c) Subject is willing to use the serum as directed (i.e. twice daily) and complete all study related requirements;

d) Subject has self-assessed fine lines and wrinkles and/or uneven skin tone

e) Subject is skin Fitzpatrick I- IV

5.3 Exclusion criteria

a) Subject is pregnant, nursing, or planning to become pregnant;

b) Subject has a skin disease which, in the opinion of the Investigator, would compromise the safety of the subject or the validity of the study outcome;

c) Subject has known allergies to consumer products in the same product category as the test product.

5.4 Prohibitions and restrictions

a) Subject agrees to discontinue their current face serums, lotions and/or moisturizers for the duration of the study;

b) Subject agrees to apply the serum the night before visits 2 and 3, and apply the product the day of visits 2 and 3, after the instrument readings are taken

5.5 Subject withdrawal

The participation of a subject in this study may have been discontinued for any of the following reasons:

- the subject wished to withdraw from study participation;
- if, in the opinion of the Investigator, it was in the best interest of the subject;
- suspected adverse effects from the test article;
- inter-current illness;
- violation of the prohibitions and restrictions;
- development of an exclusion criteria;

Subjects were free to withdraw at any time and did not need to give a reason, however, every reasonable attempt was made to ascertain such reasons. The data for those subjects who were withdrawn will be included in the final clinical report, but may be excluded from final data analysis.

Subjects were not followed up with after their withdrawal from the study, except in the case of a serious adverse event. Withdrawn subjects were not replaced.

6 TEST ARTICLES

To the best of the Sponsor's knowledge, the test article has been formulated and tested to comply with applicable regulations. Following consultation with the Sponsor, Princeton Consumer Research Corp. considered the test article to be safe for human use.

The test article was supplied by the Sponsor:

- Illuminating Serum

The test article was used as supplied by the Sponsor, and according to the use instructions provided by the Sponsor.

It was the responsibility of the Sponsor to determine, for each batch of test article, the identity, strength, purity, composition, and other characteristics which appropriately define the test article before its use in the study. The determination of its stability and documentation of methods of synthesis and derivation were also the Sponsor's responsibility.

It was the responsibility of the Sponsor that the test article met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty were fully met by the Sponsor prior to receipt of the test article at Princeton Consumer Research Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any Princeton Consumer Research Corp. site was accepted.

On study completion any remaining unused/used test articles will be disposed of by site, unless otherwise requested by the Sponsor after issuance of final report or 28 days after study completion, whichever comes first.

7 STUDY PROCEDURE

Visit 1 Baseline

Study participants reported to the testing facility with a clean face where Informed Consent was obtained, demographics collected and study eligibility was confirmed. Upon verification of eligibility, subjects were asked to acclimate in a temperature controlled room for 15 minutes before having visual evaluations of the face and instrumentation readings taken (Cutometer, Chromameter and Corneomter). Subjects were issued product and instructions for use. Adverse Event were recorded and reviewed.

Visit 2 (14 days after Visit 1)

Subjects were instructed to return to the test facility at their scheduled visit time after 14 days of home product use. Adverse events were reviewed and recorded. Subjects acclimated for 15 minutes, underwent visual evaluations, instrumentation taken on the face (Chromameter, Corneometer and Cutometer) and completed the fourteen-day product use questionnaire which was reviewed by the staff for completeness.

Visit 3 (28 days after Visit 1)

Subjects were instructed to return to the test facility at their scheduled visit time after 28 days of home product use. Adverse events were reviewed and recorded. Subjects were asked to return used product, acclimated for 15 minutes, had a final visual evaluation, instrumentation taken on their face (Chromameter, Corneometer and Cutometer) and completed the twenty-eight-day product use questionnaire which was reviewed by the staff for completeness.

7.1 CUTOMETER® MPA 580 ASSESSMENT FOR SKIN ELASTICITY/FIRMNESS

Measurements to study any changes in the viscoelastic properties of the skin by the test article was performed using the Cutometer® MPA 580 (Courage and Khazaka, Germany). The measuring principle is based on the suction method. Negative pressure is created in the device and the skin is drawn into the aperture of the probe. Inside the probe, the penetration depth is determined by a non-contact optical measuring system. This optical measuring system consists of a light source and a light receptor, as well as two prisms facing each other, which project the light from transmitter to receptor. The light intensity varies due to the penetration depth of the skin. The resistance of the skin to be sucked up by the negative pressure (firmness) and its ability to return into its original position (elasticity) are displayed as curves at the end of each measurement using Windows® based software. The instrument was used on the right cheek bone area (highest point) of the face.

7.2 CORNEOMETER® ASSESSMENTS OF SKIN HYDRATION

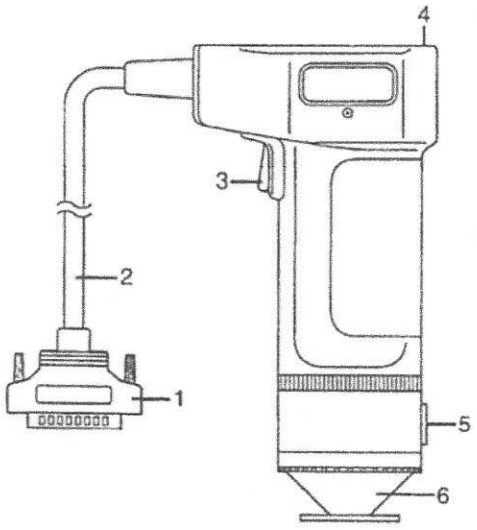
Moisturization measurements to study the humectant properties of the test articles were performed using the Corneometer CM825 (Courage and Khazaka, Germany). This instrument relies on the dielectric constant, a physical property of water, which is relatively high and as such will affect the capacitance of a capacitor. Any change in the dielectric constant due to skin moisture variations will alter the capacitance of the precision capacitor in the instrument. These variations are detected electronically and are converted into a value by the Corneometer. A 15-minute warm-up period will be allowed before using the Corneometer.

Three measurements were made using the probe attachment of the Corneometer at each of the test sites (right cheek area), between each assessment the probe attachment of the Corneometer was pressed onto a dry tissue. The next assessment would not have been performed until a value of 5 or less is displayed by the instrument. Subjects were in a controlled environment (at a temperature of 22°C ± 2°C and at a relative humidity of 45% ± 5%) for at least 15 minutes prior to any assessments being performed.

7.3 CHROMAMETER® CR300 MEASUREMENTS ASSESSMENTS FOR SKIN TONE/COLOR

Instrumental measurements of skin tone and color were performed using a Chromameter CR300® (Courage and Khazaka, Germany) on the right cheek area of the face. The measuring head of the CR-300 uses diffuse illumination/0° viewing geometry. A pulsed xenon arc (PXA) lamp inside a mixing chamber provides diffuse, uniform lighting over the 8mm-diameter specimen area. Only the light reflected perpendicular to the specimen surface is collected by the optical-fiber cable for color analysis. A representative diagram of the CR-300 measuring probe is shown below:

CR-300



1. Cable connector
2. Cable
3. Measuring button
4. Ready lamp
5. Tripod socket
6. Light-projection tube

This instrument measures the amount of light reflected from the skin and quantifies this into a numerical value using the L*a*b* color scale, where L*(100) equates to total white and L*(0) equates to total black. Therefore, the L* value is inversely proportional to the Fitzpatrick visual scale of skin tone. The instrument will be allowed to warm up for 30 minutes prior to use.

7.4 Visual Evaluations

The Expert Grader assessed the subject's face at all visits (Baseline, Day 14 and Day 28) using the same lighting and same global scoring scale. The Grader used the following scale:

Clinical Sign	Absent	Mild	Moderate	Severe
Texture (tactile)	**0** *Smooth*	**1 2 3**	**4 5 6**	**7 8 9** *Rough*
Uneven Skin tone	**0** *Bright/Clear*	**1 2 3**	**4 5 6**	**7 8 9** *Dull/Blotchy*

7.5 Self- Perception Questionnaire

Self-Perception Questionnaires (SPQ) was provided to the subjects at Day 14 (Visit 2) and Day 28 (Visit 3) to gather information on the perceived effectiveness and acceptability of the test product

8 STUDY ETHICS

8.1 Subject consent

Subjects were informed of the nature, purpose and known risk of the study both orally and in writing and gave their written informed consent before participating in the study. Subjects were advised that they were free to withdraw from the study at any time without being obliged to give a reason. They were compensated for their time and participation.

8.2 Indemnity provision

The Sponsor was responsible, without regard to legal liability, and would indemnify Princeton Consumer Research Corp., or any of their respective officers or employees in the event of claims for compensation from subjects suffering injury or other deterioration

in health or well-being as a result of participation in this study, except and insofar as such claims arise as a result of any negligent act or omission on the part of Princeton Consumer Research Corp. employees or any persons undertaking or involved in the study by arrangement with Princeton Consumer Research Corp.

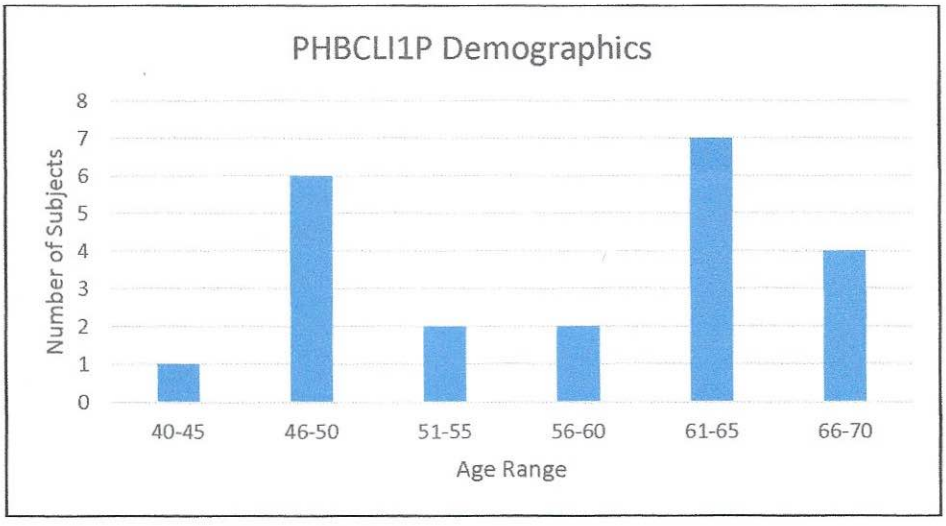
9 STUDY DATA

9.1 Location and dates of the study

The study was conducted at Princeton Consumer Research Corp. between 24th January 2016 and 21st February 2017.

9.2 Subjects

Twenty-Two (22) subjects were screened and enrolled onto the study. Twenty (20) subjects completed all phases of the study. Please see Appendix 2 for more details on the demographics.



9.3 Adverse events (AE's) and severe adverse events (SAE's)

There were no Adverse Events reported. No SAE's were reported.

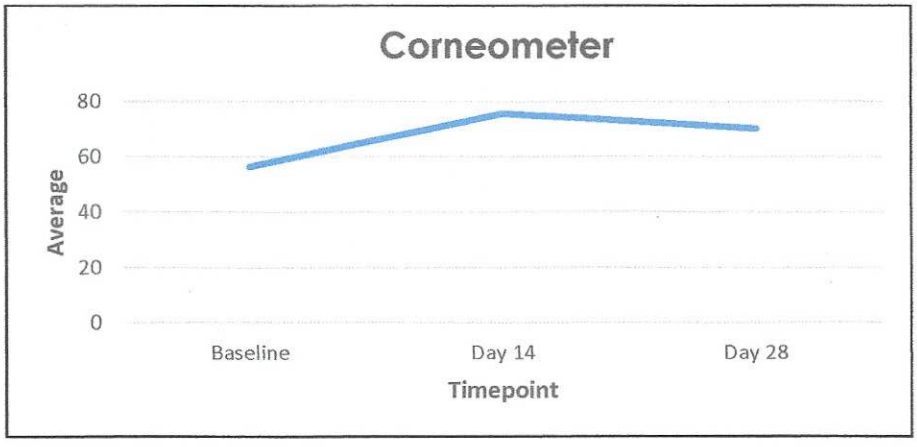
9.4 Discontinued Subject

Subjects number 12 and 13 were discontinued from the study due to personal reasons.

10 RESULTS

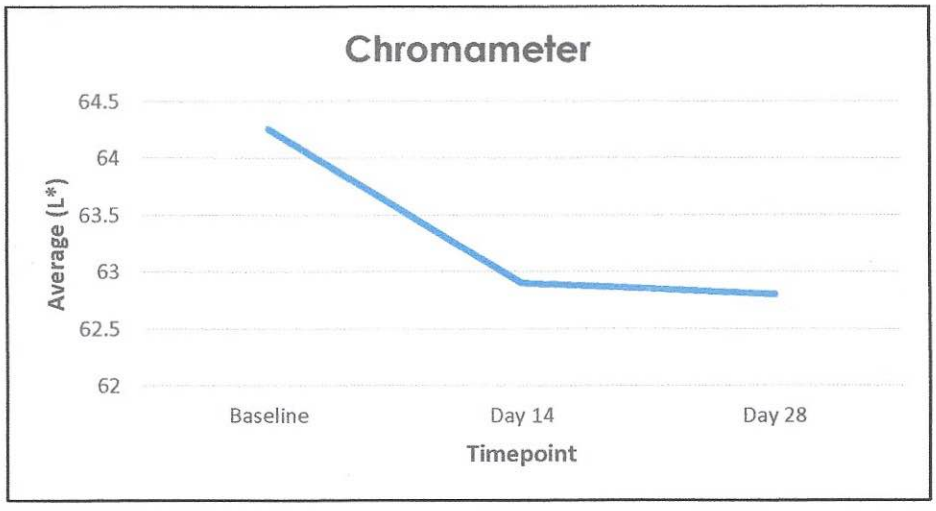
Corneometer:

Corneometer	Baseline	Day 14	Day 28
Average	56.3	75.46666667	70.1833333
% change from baseline		34.04%	24.66%
p-value		1.22E-04	2.10E-03



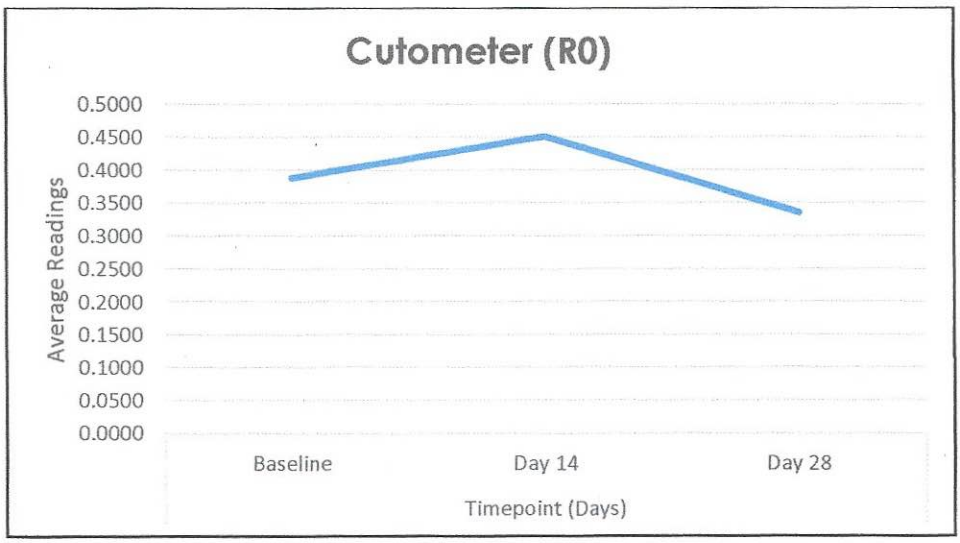
Chromameter:

Chromameter	Baseline	Day 14	Day 28
Average	64.25	62.89616667	62.796
% change from baseline		-2.11%	-2.26%
p-value		1.64E-03	2.71E-04

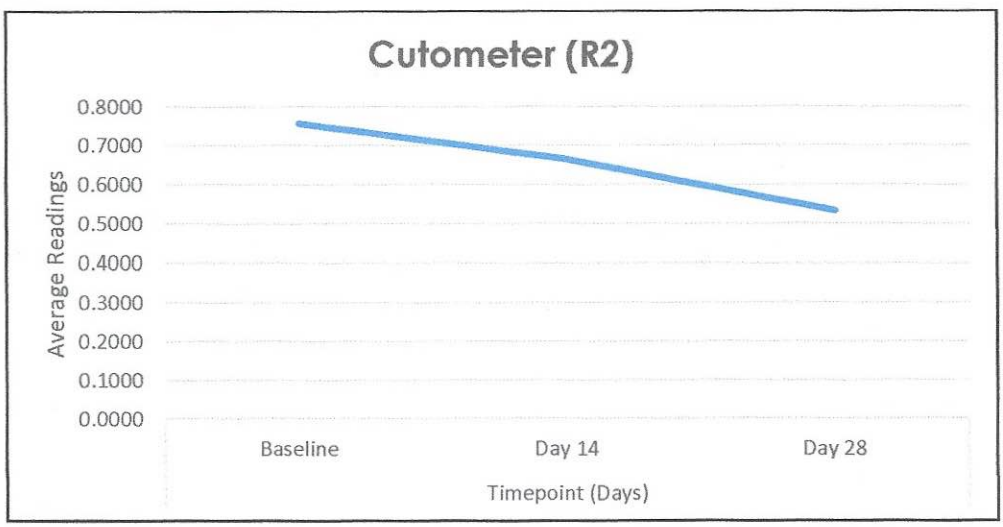


Cutometer:

R0 Firmness	Baseline	Day 14	Day 28
Average	0.38745	0.45045	0.33535
% Change from Baseline		16.26%	-13.45%
p-value		1.23E-05	1.05E-03

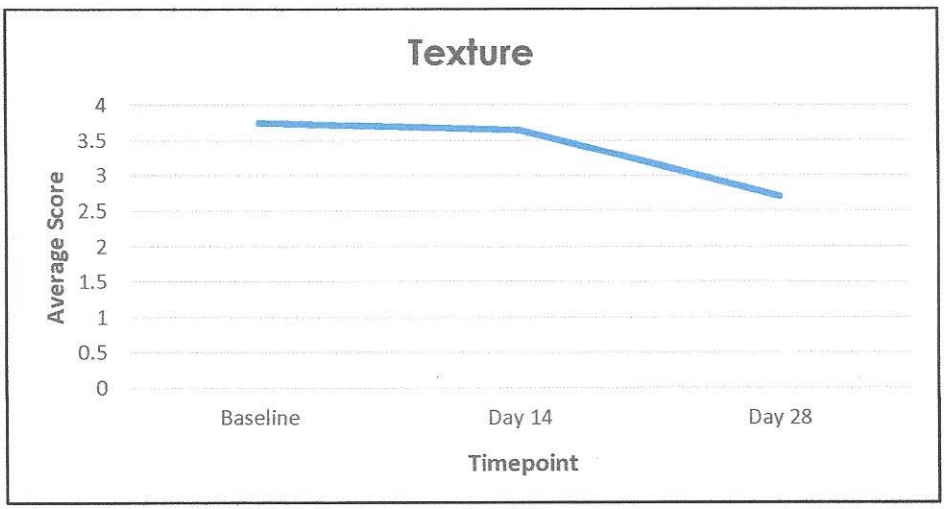


R2 Elasticity	Baseline	Day 14	Day 28
Average	0.756305	0.66452	0.53347
% Change from Baseline		-12.14%	-29.46%
p-value		5.66E-05	1.52E-08

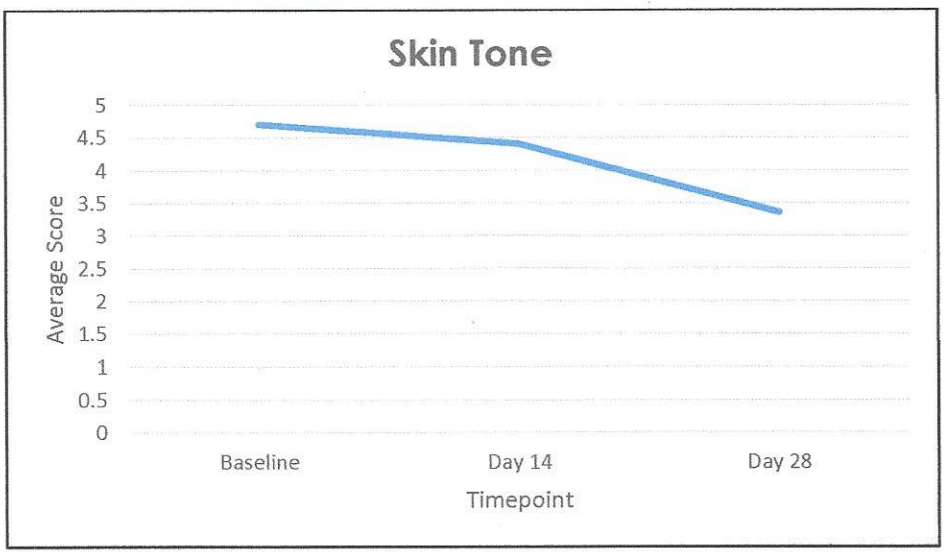


Visual Evaluations:

Texture	Baseline	Day 14	Day 28
Average	3.75	3.65	2.7
% change from Baseline		-2.67%	-28.00%
p-value		1.63E-01	2.91E-10



Skin Tone	Baseline	Day 14	Day 28
Average	4.7	4.4	3.35
% change from baseline		-6.38%	-28.72%
p-value		1.02E-02	1.62E-10



The grading scale used for visual evaluations was on a 10-point scale where 0 means Absent and 10 means severe. Individual scores can be found in Appendix 4.

Self-Perception Questionnaire- Day 14 and 28:

Questions	Top 2 + 1/2 Neither responses	
	Day 14 N=21	Day 28 N=20
Q1. My skin appears healthier-looking and more even-toned after using this serum	78.6	87.5
Q2. Dry lines and wrinkles appeared less noticeable after using the serum	76.2	85.0
Q5. My skin looks and feels firmer and more elastic after using this serum	81.0	85.0
Q13. My skin appears more youthful after using this serum	69.0	85.0
Q14. This serum significantly reduces the appearance of dull skin	81.0	82.5
Q17. I am very satisfied with this serum	66.7	82.5
Q6. This serum significantly improved my skin's softness and smoothness	71.4	80.0
Q7. This serum significantly improved the radiance of my skin	71.4	80.0
Q11. My face appears more luminous after using this serum	78.6	80.0
Q12. My skin's suppleness is visibly restored after using this serum	69.0	80.0
Q16. This serum significantly improves my skin's overall appearance	81.0	80.0
Q18. I would recommend this serum to a friend	66.7	80.0
Q8. The appearance of my skin's texture is visibly improved after using this serum	78.6	77.5
Q9. This serum significantly reduced roughness and dryness	73.8	77.5
Q10. My pore size appears smaller after using this serum	71.4	77.5
Q15. My skin has a more youthful glow after using this serum	78.6	77.5
Q4. My skin appears plumper after using this serum	73.8	72.5
Q3. My skin feels significantly more hydrated after using this serum	59.5	67.5

All SPQ individual subject responses are presented in Appendix 5.

11 CONCLUSION

Under the conditions of this study, results of corneometer measurements on the face indicate that the hydration of the skin at baseline (average of 56.3) significantly increased after 14 (average 75.5) and 28 days (average 70.2) of product use, with statistical significance (p-value > 0.05).

Results of visual evaluations of skins texture (tactile/touch) indicate when comparing to baseline (moderately rough, average 3.75) that after 28 days of serum use the skins texture significantly improved (average 2.7) indicating skin was smoother. Results for skin tone significantly decreased after 28 days (average 3.35) of product use when compared to baseline (average 4.7) indicating an improvement in skin tone indicating skin appears less dull.

As demonstrated in the results of the 28 day SPQ, the product performed highly favorably over the testing period (28 days), (Top 2 responses + ½ the neither agree nor disagree responses) with ≥80% value being regarded as highly favorable).

- 87.5% of subjects agreed their skin appeared healthier looking and more even toned after using the serum
- 85% of subjects agreed that their dry lines and wrinkles appeared less noticeable after using the serum.
- 85% of subjects agreed their skin looked and felt firmer and more elastic after using the serum.
- 85% of subjects agreed their skin appeared more youthful after using the serum.
- 82.5% of subjects agreed the serum significantly reduced the appearance of dull skin
- 82.5% of subjects agreed they were satisfied with the serum.
- 80% of subjects agreed the serum significantly improved their skins softness and smoothness
- 80% of subjects agreed the serum significantly improved the radiance of their skin
- 80% of subjects agreed their face appeared more luminous after using the serum
- 80% of subjects agreed their skin's suppleness was visibly restored after using the serum
- 80% of subjects agreed the serum significantly improved their skin's overall appearance.
- 80% of subjects agreed they would recommend the serum to a friend