CLINICAL EVALUATION OF THE EFFICACY OF A SKIN CARE PRODUCT IN IMPROVING SKIN CONDITIONS

FINAL REPORT

March 16, 2020

SPONSOR:	Cosmetic Skin Solutions LLC 10580 North McCarran Boulevard 115-275 Reno, NV 89503
TEST PRODUCT:	Supreme Serum CE; Formula Number: CE-043019A, Lot/Batch# 300874 Expiry 9/3/2021
STUDY NUMBER:	BCS 19-142
PROJECT NUMBER:	1123049

RESEARCH STANDARD

This clinical study was conducted in accordance with the International Conference of Harmonization Tripartite Guideline on Good Clinical Practice, applicable FDA regulations/guidelines set forth in 21 CFR Parts 11, and 50 and standard practices of BioScreen Testing Services.

TABLE OF CONTENTS

I. SUMMARY OF RESULTS

Under conditions of the study a total of 28 healthy female subjects, 36-65 years of age, completed the clinical study evaluating the effectiveness of Test Product: Supreme Serum CE; Formula Number: CE-043019A, Lot/Batch# 300874 Expiry 9/3/2021 to improve skin conditions.

A. Skin Barrier Function - TEWL

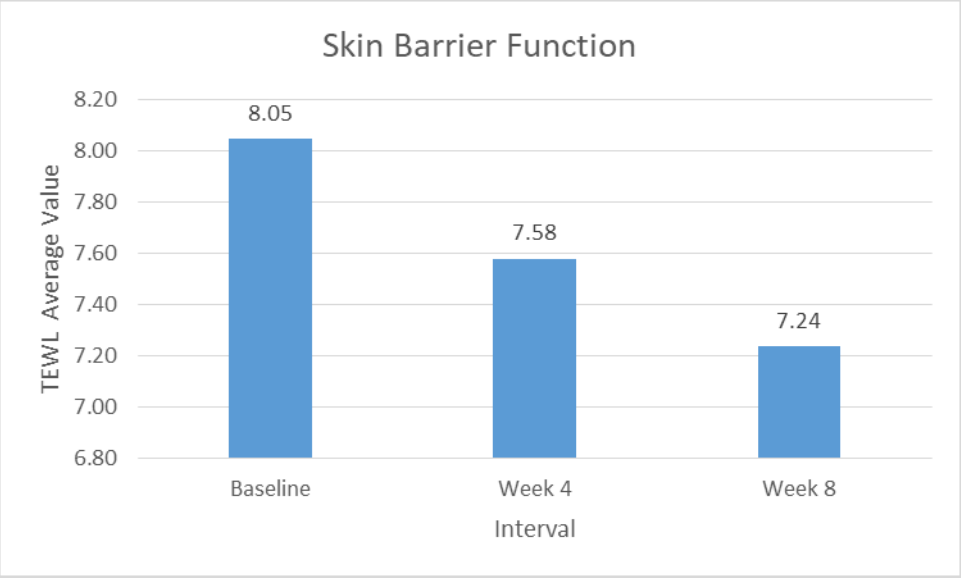
Negative difference indicates an improvement in skin barrier function.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	**-5.81%**	**-10.05%**
Percent of Subjects Improved	75.00%	**85.71%**

Bold values indicate statistical significance ($p \leq 0.05$).

Clinical Findings:

- There was a statistically significant improvement in skin barrier function from baseline at the week 4 and week 8 post-treatment intervals.
- A statistically significant number of subjects demonstrated an improvement in skin barrier function from baseline at the week 8 post-treatment interval.



B. Skin Brightness - Chromameter

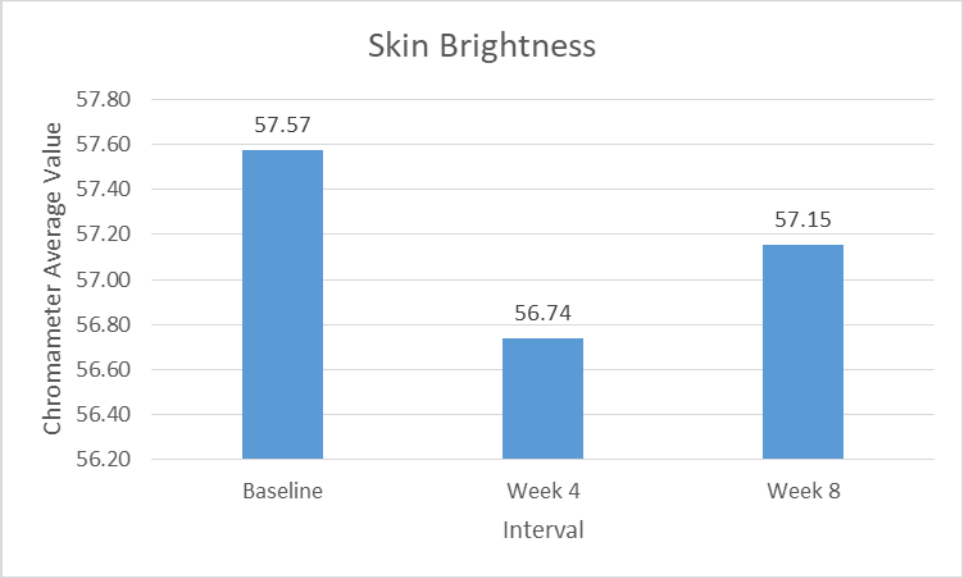
Positive difference indicates an improvement in appearance of skin brightness.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	**-1.45%**	-0.73%
Percent of Subjects Improved	28.57%	32.14%

Bold values indicate statistical significance ($p \leq 0.05$).

Clinical Findings:

- There was a statistically significant decrease in appearance skin brightness from baseline at the week 4 post-treatment interval.



C. Fine Lines and Wrinkles (Global) - Clinical Grading

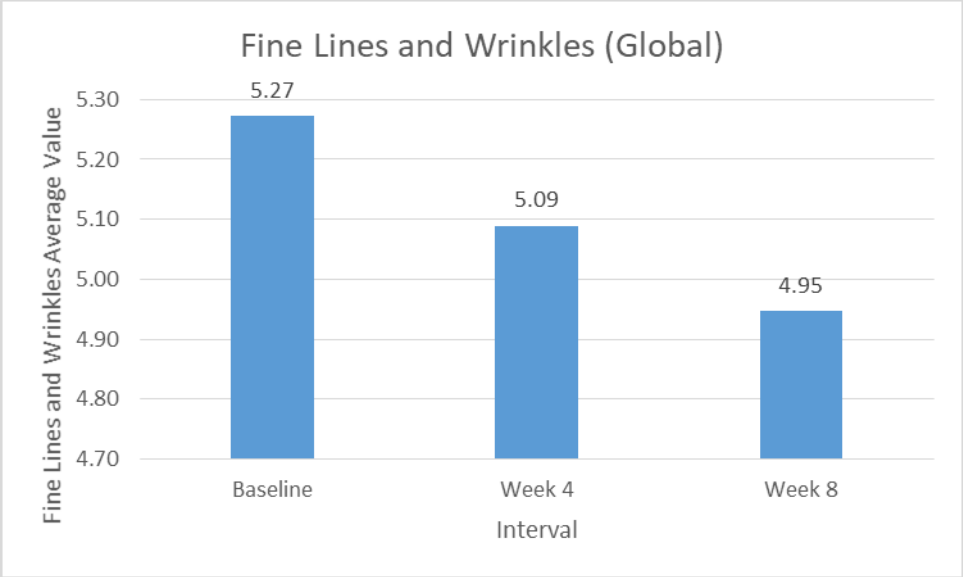
Negative difference indicates an improvement in appearance of fine lines and wrinkles globally.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	**-3.49%**	**-6.20%**
Percent of Subjects Improved	35.71%	64.29%

Bold values indicate statistical significance ($p \leq 0.05$).

Clinical Findings:

- There was a statistically significant improvement in appearance of fine lines and wrinkles globally from baseline at the week 4 and week 8 post-treatment intervals.



D. Post-Treatment Questionnaire (Week 4)

Statement	% of Subjects with Favorable Responses
1. My skin looks smoother	71.43%
2. The appearance of fine lines and wrinkles look smoother.	75.00%
3. My skin feels smoother.	**78.57%**
4. My skin feels more moisturized.	67.86%
5. My skin feels more hydrated.	64.29%
6. My skin feels more refreshed.	71.43%
7. My skin looks more radiant.	67.86%
8. My skin tone looks more even.	60.71%
9. My skin looks brighter.	71.43%
10. My skin looks revitalized.	67.86%
11. My skin looks more youthful.	57.14%
12. I would recommend this product to family and/or friends.	71.43%

Bold values indicate statistical significance ($p \leq 0.05$).

E. Post-Treatment Questionnaire (Week 8)

Statement	% of Subjects with Favorable Responses
1. My skin looks smoother	**89.29%**
2. The appearance of fine lines and wrinkles look smoother.	**78.57%**
3. My skin feels smoother.	**92.86%**
4. My skin feels more moisturized.	71.43%
5. My skin feels more hydrated.	71.43%
6. My skin feels more refreshed.	**78.57%**
7. My skin looks more radiant.	60.71%
8. My skin tone looks more even.	60.71%
9. My skin looks brighter.	67.86%
10. My skin looks revitalized.	**82.14%**
11. My skin looks more youthful.	67.86%
12. I would recommend this product to family and/or friends.	75.00%

Bold values indicate statistical significance ($p \leq 0.05$).

II. STUDY OBJECTIVE

To evaluate the effectiveness of a skin care product to/for:

- Improve skin barrier
- Improve skin brightness
- Improve appearance of fine lines and wrinkles (global)

III. STUDY DATES

The study began on December 12, 2019 and ended on February 12, 2020.

IV. TESTING FACILITY

BioScreen Clinical Services Division
BioScreen Testing Services, Inc.
3301 N. 2nd Street
Phoenix, AZ 85012

V. TEST PRODUCT

Product Name	Number of Samples	Date Received	Accession Number
Supreme Serum CE; Formula Number: CE-043019A, Lot/Batch# 300874 Expiry 9/3/2021	40	01 Nov 2019	1123049
Broad Spectrum UV Defense Advanced Formula SPF 30*	80	26 Nov 2019; 18 Dec 2019	1131061

*****Supporting Product

VI. TEST PRODUCT HANDLING

Test products that have been reviewed and approved for use by the Regulatory and Safety representatives of Cosmetic Skin Solutions LLC was tested. A sufficient quantity of samples of the above test product to allow for 40 subjects to use for the entire study duration was received from Cosmetic Skin Solutions LLC prior to start of the study.

Upon arrival at BioScreen Clinical Services (BCS) the test product was assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested. Each individual sample of the test product was weighed before and after use by the subject. This information was recorded on the test product log-in form. Samples were retained for a period of 30 days beyond submission of final report. Sample disposition was conducted in compliance with appropriate federal, state and local ordinances.

Test Product Use Instructions

Morning Use: Each morning after cleansing, apply 5-6 drops to a dry face, neck and décolleté. Apply sponsor provided sunscreen 15 minutes prior to sun exposure and reply every hour while outdoors. Follow with cosmetics (if applicable).

Evening Use: Allowed to wash face with provided Neutrogena cleansing bar.

VII. ADVERSE EVENTS

Subject ID: 1033
Subject Initials: CNB
Adverse Event Date: 04 Feb 2020

The subject, a 60 year old African American female, reported to the test facility on 12Feb2020. She indicated on 04Feb2020 she was leaving an office and tripped on the stairs. She fell on the ground landing on her right side (from shoulder to hand) obtaining a minor scrape on her head. She continued to use test product and felt the sunscreen helped heal the scrape. She did not seek medical attention, but did set up a doctor's appointment the week of Feb 17th as follow-up. Subject completed study. No follow-up was necessary.

It is in the opinion of the Principal Investigator that the adverse event was not product related.

Subject ID: 30215
Subject Initials: AML
Adverse Event Date: 15 Jan 2020

On 15Jan2020 the subject was at her husband's neurology appointment and her body started feeling funny. She went to the office water fountain to get water to drink and sat down. When she returned to the exam room with her husband she felt faint, so the neurologist had her lay down. This is when she blacked out for a while; she was talking to the doctor but didn't remember doing so. Two hours after the appointment she napped for about two hours straight. She went to urgent care after the nap and when they swabbed her mouth the tests results said she had Influenza B. Pharmacy was closed that night but she got the medicine and started taking it on 16Jan2019. No follow-up was necessary.

It is in the opinion of the Principal Investigator that the adverse event was not product related

VIII. PROTOCOL DEVIATIONS

The following deviations occurred during the study, but did not impact clinical findings.

Subject ID	Deviation
1033	Used serum twice daily from Baseline to Week 4 interval
27338	Used more than 8 drops of product from Baseline to Week 4 interval

IX. STUDY RESULTS AND ANALYSIS

A. Study Subjects

A total of 28 healthy female subjects consented, enrolled and completed the 8 week clinical study.

Table 1. Subject Demographics.

No.	Subject ID	Subject Initials	Age	Race
1	1033	CNB	60	AA
2	1068	MRD	63	H
3	1298	L-C	65	C
4	1478	TLN	54	AA
5	5107	GMK	58	C
6	6836	HAC	45	C
7	7326	MIO	64	C
8	7379	ALC	65	AA
9	8594	LMM	65	H
10	9711	MAN	51	C
11	11852	KEN	64	C
12	13315	EAO	49	C
13	16677	BMW	36	C
14	17030	TLH	44	C
15	18520	R-G	55	H
16	21050	SMH	65	NA
17	21475	LMK	54	NA
18	21518	NAO	54	H
19	22931	HAC	51	C
20	25237	COS	38	C
21	25312	GCG	60	H
22	25810	JMR	40	C
23	27338	LMC	60	C
24	29053	ERS	57	C
25	33608	E-L	49	A/PI
26	34106	M-L	50	C
27	34732	R-D	54	H
28	35644	C-G	60	C

AA= African American, A= Asian, C= Caucasian, H= Hispanic, NA= Native American, PI= Pacific Islander

B. Skin Barrier Function - TEWL

Table 2. Mean skin barrier function values.

Interval	Mean ± SD
Baseline	8.05 ± 2.25
Week 4	7.58 ± 1.94
Week 8	7.24 ± 1.86

Table 3. Descriptive statistics of skin barrier function differences from baseline.

Note: Negative difference indicates improvement in skin barrier function.

Interval	Parameter	Skin Redness Differences from Baseline
Week 4	**Mean**	-0.47
	SD	0.72
	% Change	**-5.81%**
	p	**≤0.001**
	%Improvers	75.00%
	p	NS
Week 8	**Mean**	-0.81
	SD	0.98
	% Change	**-10.05%**
	p	**≤0.001**
	%Improvers	**85.71%**
	p	**≤0.001**

Bold values indicate statistical significance ($p \leq 0.05$).

C. Skin Brightness (L value) - Chromameter

Table 4. Mean skin brightness values.

Interval	Mean ± SD
Baseline	57.57 ± 5.72
Week 4	56.74 ± 5.95
Week 8	57.15 ± 5.44

Table 5. Descriptive statistics of skin brightness differences from baseline.

Note: Positive difference indicates improvement in skin brightness.

Interval	Parameter	Skin Brightness Differences from Baseline
Week 4	**Mean**	-0.83
	SD	1.56
	% Change	**-1.45%**
	p	**≤0.009**
	%Improvers	28.57%
	p	NS
Week 8	**Mean**	-0.42
	SD	1.66
	% Change	-0.73%
	p	NS
	%Improvers	32.14%
	p	NS

Bold values indicate statistical significance ($p \leq 0.05$).

D. Fine Lines and Wrinkles (Globally) – Clinical Grading

Table 6. Mean fine lines and wrinkles values.

Interval	Mean ± SD
Baseline	5.27 ± 1.32
Week 4	5.09 ± 1.35
Week 8	4.95 ± 1.32

Table 7. Descriptive statistics of appearance of fine lines and wrinkles differences from baseline.

Note: Negative difference indicates improvement in appearance of fine lines and wrinkles.

Interval	Parameter	Skin Brightness Differences from Baseline
Week 4	**Mean**	-0.18
	SD	0.25
	% Change	**-3.49%**
	p	**0.002**
	%Improvers	35.71%
	p	NS
Week 8	**Mean**	-0.33
	SD	0.25
	% Change	**-6.20%**
	p	**≤0.001**
	%Improvers	64.29%
	p	NS

Bold values indicate statistical significance ($p \leq 0.05$).

APPENDIX A

CLINICAL EVALUATION OF THE EFFICACY OF A SKIN CARE PRODUCT IN IMPROVING SKIN CONDITIONS

Study Number:	BCS 19-142
Principal Investigator:	Rania Ibrahim, Ph.D.
Sub-Investigator:	Brochelle Yazzie, B.S.
Sub-Investigator:	Jordan DeSantis, MHI
Sub-Investigator:	Livia Shoshani, B.S.
Testing Facility:	BioScreen Clinical Services Division BioScreen Testing Services, Inc. 3301 North 2nd Street Phoenix, AZ 85012
Sponsor:	Cosmetic Skin Solutions LLC 10580 North McCarran Boulevard Reno, NV 89503

RESEARCH STANDARD

The conduct of this study will comply with the International Conference of Harmonization Tripartite Guidelines on Good Clinical Practice, applicable FDA regulations/guidelines set forth in 21 CFR Parts 11 and 50 and standard practices of BioScreen.

I. OBJECTIVE

To evaluate the effectiveness of a skin care product to/for:

- Improve skin barrier
- Improve skin brightness
- Improve appearance of fine lines and wrinkles (global)

II. TESTING FACILITY

BioScreen Clinical Services Division
BioScreen Testing Services, Inc.
3301 North 2nd Street
Phoenix, AZ 85012

Investigator: Rania Ibrahim, Ph.D.
PH: 602-277-1154

III. STUDY DURATION

The study will be completed within a 9-week period (including an approximate 1 week washout period and an 8 week product usage).

IV. STUDY DESIGN AND METHODS

Test Product

Supreme Serum CE

Test Product Handling

Test products that have been reviewed and approved for use by the Regulatory and Safety representatives of Cosmetic Skin Solutions LLC will be tested. A sufficient quantity of samples of the above test product to allow for 40 subjects to use for the entire study duration will be received from Cosmetic Skin Solutions LLC prior to start of the study.

Upon arrival at BioScreen Clinical Services (BCS) the test product will be assigned a unique laboratory code number and entered into a daily log identifying the lot number, sample description, sponsor, date received and tests requested. Each individual sample of the test product will be weighed before and after use by the subject. This information will be recorded on the test product log-in form. Samples will be retained for a period of 30 days beyond submission of final report. Sample disposition will be conducted in compliance with appropriate federal, state and local ordinances.

Test Product Use Instructions

Morning Use: Each morning after cleansing, apply 5-6 drops to a dry face, neck and décolleté. Apply sponsor provided sunscreen 15 minutes prior to sun exposure and reply every hour while outdoors. Follow with cosmetics (if applicable).

Evening Use: Allowed to wash face with provided Neutrogena cleansing bar.

V. INFORMED CONSENT FORM, PHOTOGRAPHY RELEASE FORM, AND MEDICAL HISTORY FORM

Informed consent will be obtained from each volunteer prior to initiating the study describing reasons for the study, possible adverse effects, associated risks and potential benefits of the treatment and their limits of liability. Panelists will sign and date the informed consent document and a photography release form to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject will be assigned a permanent identification number and complete an extensive medical history form. These forms along with the signed consent forms will be available for inspection on the premises of BioScreen Clinical Services only. [21 CFR. Ch.1. Part 50, Subpart B.]

VI. SUBJECT SELECTION

Panel selection will be accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof. Individuals will be admitted to study at the discretion of the Investigator or his designee based on medical history and findings on the pre-study interview and examination.

1. Number of Subjects: Approximately 33 healthy subjects meeting inclusion/exclusion criteria listed below will be enrolled to complete the study with a minimum of 25 subjects.
2. Age: 35-65
3. Sex: Female
4. Race: Unrestricted
5. Inclusion Criteria:
    a. Individuals who, at baseline, are free of any dermatological or systemic disorder, which would interfere with the results, at the discretion of the Investigator.
    b. Individuals in good general health.
    c. Individuals who complete a preliminary medical history.
    d. Individuals who will read, understand and sign an informed consent document.
    e. Individuals who will be able to cooperate with the Investigator and research staff, have the test product applied according to the protocol and complete the full course of the study.
    f. Individuals who have not participated in any study involving the same test site for the past 15 days.
    g. Individuals who will agree to discontinue use of personal care products (e.g. lotions, creams, serums) for the washout period and duration of the study, with the exception of those provided by BCS.

h. Individuals who will agree to continue using approved cosmetics (e.g. foundation, blush) for the washout period and duration so long as they do not contain anti-aging ingredients. BCS staff will review cosmetics for approval.
i. Individuals with mild/moderate/severe fine lines and wrinkles globally (score 1-9 on a 10-point scale).
j. Individuals with visible skin dullness.
k. Individuals who agree not to sunbathe/tan and agree to avoid sun (UV) exposure as much as possible for the duration of the study.
l. Individuals who agree to apply the sponsor provided sunscreen a minimum of 15 minutes prior to sun exposure, and to reapply every hour they remain outdoors (exposed to UV).

6. Exclusion Criteria:
   a. Individuals who have had a history of any acute or chronic disease that could interfere with or increase the risk on study participation.
   b. Individuals with an active (flaring) disease or chronic skin allergies (atopic dermatitis, eczema, psoriasis, acne), or had recently treated skin cancer (within the last 12 months).
   c. Individuals with a history of immunosuppression/immune deficiency disorders or currently using immunosuppressive medications (e.g., azathioprine, belimumab, cyclophosphamide, Enbrel, Imuran, Humira, mycophenolate mofetil, methotrexate, prednisone, Remicade, Stelara.) and/or radiation as determined by study documentation.
   d. Individuals with damaged skin at or in close proximity to test sites (e.g., sunburn, tattoos, scars, or other disfigurations).
   e. Individuals who have any history, which, in the Investigator's opinion, indicates the potential for harm to the subject or could place the validity of the study in jeopardy.
   f. Individuals who indicate that they are pregnant, planning a pregnancy or nursing.
   g. Individuals who have been medically diagnosed with Type I Diabetes.
   h. Individuals who have had any medical procedure, such as laser resurfacing, or plastic surgery to the test sites within the last 12 months (including Botox, Restylyn, or other fillers).
   i. Individuals who are currently using or during the last 3 months have used, Retin A, or other Rx/OTC Retinyl A, or other astringent derived products or alpha hydroxyl acid treatments for photo-aging and fine lines/wrinkles.
   j. Individuals who have a known history of hypersensitivity to any cosmetics, personal care products, and/or fragrances.
   k. Individuals who are employees of BioScreen.

VII. EXPERIMENTAL TECHNIQUES

Bioinstrumental Method to Measure Skin Barrier Function [2, 3]

Transepidermal water loss (TEWL) is a measure of skin barrier function. The evaporimeter probe has two sensors, which measures the vapor pressure gradient arising within the chamber and between the skin and the surrounding air. TEWL will be measured using DermaLab Evaporimeter (Cortex Technology, Hadsund, Denmark). Decreases in TEWL post barrier

disruption indicate an improvement in skin barrier function, such that less water is lost through the skin barrier.

TEWL measurements will be taken from the designated sites at each measurement interval.

Bioinstrumental Method to Measure Skin Brightness

Skin color is measured quantitatively with a Chromameter. The instrument reports the color of reflected light in terms of L* (dark-light axis), a* (green-red axis) and b* (blue-yellow axis).

CR-400 Chromameter, Konica Minolta or Smart Probe 400 (IMS Inc, USA) will be used to measure skin brightness (L*). All 3 values, L*, a* and b* will be recorded and the L* values provided to the Sponsor. One measurement will be taken from the designated treatment site at each measurement interval. All test sites will be averaged.

Clinical Photography for Expert Grading for Appearance of Fine Lines and Wrinkles (Global) [4-6]

Photographs are taken in accordance with regulations provided by consumer protection agencies such as the Federal Trade Commission, the Food and Drug Administration and several other regulatory authorities. The following guidelines are followed: 1) Head position is the same in before and after photos, 2) Same lighting conditions are used and the distance from the camera is same for both, before and after picture, and 3) Same room and background is used for both before and after picture.

Clinical photographs of subjects' faces (frontal, left lateral and right lateral) will be taken and evaluated with Canfield VISIA CR system using the Standard 1 modality.

Photographs obtained will be evaluated for the appearance of fine lines and wrinkles using the following scale (half point increments will be allowed):

Overall Scale: 0= None, 1-3= Mild, 4-6= Moderate, 7-9= Severe

Self-Assessment Questionnaire

Each subject will be instructed to complete a self-assessment questionnaire provided by the Sponsor at the week 4 and week 8 post-treatment intervals.

VIII. PROCEDURE

1. Subjects will report to the facility a minimum of five (5) days prior to study start.
2. Prior to beginning any study related activities, subjects will be given an informed consent form, photography release form, HIPAA form, and code of conduct form to read.
3. Once subject has completed reading they will be interviewed, in private, by BioScreen to

ensure their understanding of the aforementioned forms and be given the opportunity to ask any study related questions.

4. Subjects who agree to sign the aforementioned forms will be asked to complete a medical history form. Subjects declining to sign any of the forms will be dismissed from the study.
5. Subjects will be enrolled on the basis of the subject selection criteria. Subjects failing to meet criteria will be dismissed from the study.
6. Enrolled subjects will be given specific instructions prohibiting use of all personal care products (i.e. lotions, creams, serums, cleansers) on the test sites (face) for the entire study duration, including washout period.
7. Subjects will be instructed to continue use all cosmetics (e.g. foundation, blush), if applicable, as long as they do not contain anti-aging ingredients. Cosmetics will be inspected and approved by BCS staff to confirm it does not contain anti-aging ingredients.
8. Enrolled subjects will begin the washout period using only the provided soap (Neutrogena), sponsor provided sunscreen and approved cosmetics.
9. Following the 5 day washout period, subjects will return to the testing facility.
10. Subjects will be instructed to clean their face with a neutral cleanser and pat dry.
11. Thereafter, subjects will equilibrate by remaining quietly seated for a minimum of fifteen (15) minutes in a room maintained at approximately 20-24°C and 30%-50% relative humidity. Temperature and humidity will be recorded during subject testing.
12. Following equilibration, subjects will have the below procedures/ measurements performed by trained BCS staff:

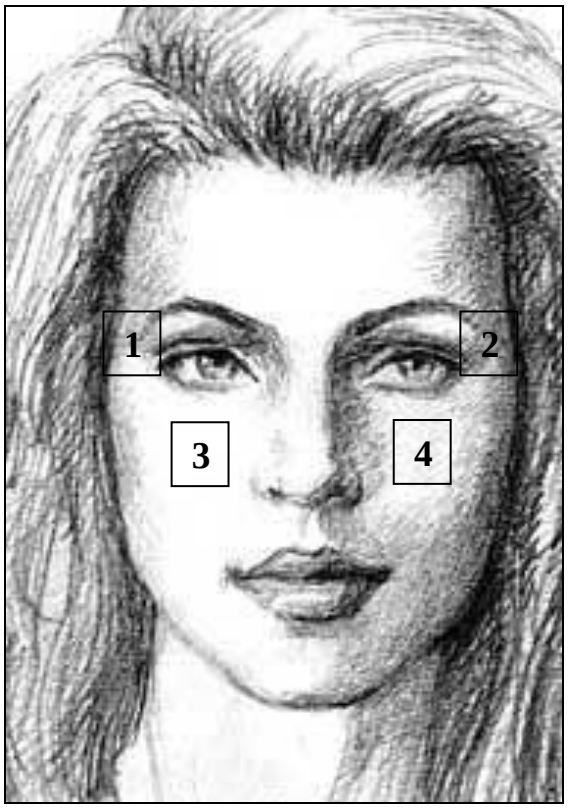
    Baseline (pre-treatment)
    a. Clinical photography (frontal, left lateral, right lateral)
    b. Skin barrier function measurement at site 1 and 2
    c. Skin brightness measurement at site 3 and 4
    See Figure 1 for schematic representation of test sites
13. Following baseline measurements, subjects will be given the test product with product use instructions as directed by the Sponsor to use for the duration of the study.
14. Subjects will be dismissed from the testing facility and informed to return 4 weeks (±3 days) and 8 weeks (±3 days) post-treatment. Test product will be weighed for compliance. Subjects suspected of non-compliance will be dismissed from study participation. Subjects will be instructed not to use test product on the day of their scheduled visit.
15. Subjects will be instructed to clean their face with a neutral cleanser and pat dry.
16. Thereafter, subjects will equilibrate by remaining quietly seated for a minimum of fifteen (15) minutes in a room maintained at approximately 20-24°C and 30%-50% relative humidity. Temperature and humidity will be recorded during subject testing.
17. Following equilibration, subjects will have the below procedures/ measurements performed by trained BCS staff:

    Week 4 (±3 days) / Week 8 (±3 days) Post-treatment

a. Clinical photography (frontal, left lateral, right lateral)
b. Skin barrier function measurement at site 1 and 2
c. Skin brightness measurement at site 3 and 4
d. Post-treatment questionnaire

18. Subjects will return the remaining test product at week 8 and will be dismissed from the study.

Figure 1: Schematic representation of test sites



IX. ADVERSE EVENTS

An adverse event is any untoward medical occurrence, whether or not it is considered study related, including death, experienced by a subject. An event may consist of a disease, an exacerbation of a pre-existing illness or condition, an occurrence of an intermittent illness or condition, a set of related symptoms or signs, or a single symptom or sign.

A serious adverse event (SAE) as defined in the CFR 312.32 is "any experience that is fatal or life threatening, is permanently disabling, requires inpatient hospitalization, or is a congenital anomaly, cancer, or overdose". All serious adverse events will be reported to the sponsor within 24 hours of BCS notification.

Each adverse event must be promptly recorded and sufficiently documented by the Study Director in the source documentation and case report form even if the adverse event is assessed by the Study Director as unlikely to be related to the study. Adverse events are graded on a scale

of severity (mild, moderate, severe, or lift threatening) and on a scale of relationship to the product (unknown, unrelated, unlikely, possible, probable, or definite). All adverse events will be reported to the Sponsor within five business days. All adverse events will be followed up until resolved, stabilized, the subject is lost to follow-up or the event is otherwise explained. All follow-up information should be reported to the Sponsor.

If, according to the Investigator, medical care is warranted, appropriate referrals will be made. BCS will follow all adverse events until resolution.

The contact information to report SAE is:

Rania Ibrahim, Ph.D.
ribrahim@bioscreen.com
Work: (602) 227-1154
Cell: (602) 689-2829

X. RISKS / DISCOMFORTS

Burning, stinging, itching, redness or irritation may occur at the test sites. There also may be risks and discomforts, which are not yet known.

XI. SUBJECT DISCONTINUATION

Criteria for the discontinuation of a subject during the study will include the following:

1. Significant protocol violation
2. Serious adverse experience
3. Request of the subject
4. Any unmanageable factor, in the Investigator's opinion, that may significantly interfere with the protocol or interpretation of results.

XII. PROTOCOL AMENDMENT

Any changes to the study protocol will be approved in writing by the client and BCS prior to implementation in the study.

XIII. DATA ANALYSES

Statistical analyses will test the hypothesis that the pre-treatment values of each parameter are statistically different from its post-treatment values. Statistical significance will be declared if the two-tailed p-value is ≤ 0.05.

Subject scores for each parameter in questionnaires will be presented in a tabular format. The percentage of subjects responding in favor of the test product will be reported. Statistical analysis will be performed using a z-test. Statistical significance will be declared if the p-value is ≤ 0.05.

XIV. STUDY REPORT

Final report will be issued to the sponsor within four weeks of study completion.

XV. DATA ARCHIVES

All original samples, raw data sheets, technician's notebooks, correspondence files, a copy of final report and remaining specimens will be maintained on the premises of the clinic in limited access marked storage files. A duplicate copy of the final report will be separately archived at BioScreen Testing Laboratories, Torrance, CA.

REFERENCES

1. 21 CFR. Ch.1. Part 50, Subpart B.
2. Leveque JL, Garson JC, de Rigal J. Transepidermal Water Loss from Dry and Normal Skin. *J Soc Cosmet Chem* 1979, 30: 333-343.
3. Elsner P, Berardesca E, Wilhelm KP, Maibach, HI. In *Bioengineering of the Skin*, Skin Biomechanics 2001. CRC Press, 117.
4. Arch. Dermatol., 128: 347-351, 1992.
5. Br. J. Dermatol., 130: 167-173, 1994.
6. Skin Pharmacol. Appl. Skin Physiol., 16: 100-107, 2003

APPENDIX B

A. Skin Barrier Function - TEWL

ID	Baseline		Week 4		Week 8	
	Right PA	Left PA	Right PA	Left PA	Right PA	Left PA
1033	5.1	5.6	5.1	5.6	4.9	5.4
1068	8.4	8.2	7.8	8	7.3	7.6
1298	6.2	6.4	6.4	5.9	5.9	5.6
1478	5.8	5.3	5.3	5.4	5.6	5.2
5107	7.6	8.2	5.9	6.8	5.7	6.8
6836	7.5	7.5	7.5	7.7	7.7	7.5
7326	8.0	7.7	7.7	7.9	7.2	7.4
7379	8.7	9.0	8.5	8.0	8.2	7.6
8594	8.4	8.1	7.3	7.1	5.8	5.2
9711	5.8	6.3	5.9	6.0	5.9	5.4
11852	8.3	8.0	7.3	7.6	7.5	7.0
13315	10.4	10.2	8.9	9.1	8.7	9.4
16677	9.6	9.9	7.8	7.4	7.2	7.2
17030	13.1	13.3	12.9	12.6	12.0	12.4
18520	7.6	7.1	7.4	7.6	6.8	6.6
21050	5.1	5.2	4.2	4.7	5.0	4.9
21475	8.1	7.9	7.7	8.0	7.7	7.2
21518	5.0	4.6	5.0	5.1	5.5	5.3
22931	8.8	8.3	8.3	8.2	8.1	8.4
25237	8.2	8.4	8.5	8.8	8.8	7.9
25312	10.7	11.3	10.4	10.9	10.5	10.8
25810	12.8	13.0	10.7	9.8	8.9	8.7
27338	8.2	7.9	8.3	7.9	7.9	7.8
29053	8.6	8.2	8.2	7.6	7.9	6.9
33608	6.6	6.4	6.5	6.2	6.2	6.1
34106	4.0	4.3	5.3	4.1	4.4	4.0
34732	11.4	11.2	11.0	10.8	10.4	10.7
35644	7.6	7.5	7.1	6.7	6.8	5.8

B. Skin Brightness (L value) - Chromameter

ID	Baseline		Week 4		Week 8	
	Right Cheek	Left Cheek	Right Cheek	Left Cheek	Right Cheek	Left Cheek
1033	54.8	55.8	56.2	57	56.1	57.5
1068	61.40	59.00	58.6	56.7	60.3	58.8
1298	62.0	62.2	62.2	61.8	59.3	59.6
1478	45.8	47.0	42.7	42.9	44.2	43.6
5107	63.5	64.6	66.4	65.2	63.0	60.6
6836	57.4	58.8	55.3	58.5	57.9	58.5
7326	63.9	62.7	61.4	59.9	62.3	60.3
7379	38.5	37.1	38.4	37.3	38.1	37.7
8594	63.6	62.8	60.6	57.8	60.6	60.7
9711	60.9	61.1	60.5	61.0	60.1	61.3
11852	59.6	61.5	59.4	60.8	59.4	61.2
13315	57.9	57.3	55.6	57.4	55.2	55.4
16677	62.3	63.6	62.8	63.6	62.3	62.5
17030	55.9	53.2	56.9	54.4	57.8	57.0
18520	56.2	58.5	54.4	55.3	56.5	57.4
21050	53.3	52.7	54.8	53.2	54.1	55.5
21475	56.7	55.6	55.3	54.6	57.0	55.7
21518	61.6	62.3	62.1	61.4	59.4	60.3
22931	59.4	59.4	60.4	59.7	60.8	59.2
25237	62.9	60.2	60.4	60.3	63.0	61.3
25312	54	54.7	55.0	53.2	54.2	55.5
25810	58.10	58.20	56.6	56.0	57.0	57.0
27338	59.5	56.7	55.6	52.7	57.8	52.8
29053	63.5	62.2	63.4	63.4	62.1	63.5
33608	54.9	53.7	54.2	52.0	54.2	53.2
34106	62.0	61.2	62.0	61.6	61.8	61.3
34732	52.2	52.2	50.8	52.5	56.2	55.9
35644	55.4	52.5	53.2	52.0	53.0	53.6

C. Fine Lines and Wrinkles (Globally) – Clinical Grading

Scale: 0= None, 1-3= Mild, 4-6= Moderate, 7-9= Severe

Subject ID	Baseline	Week 4	Week 8
1033	5.0	5.0	5.0
1068	5.5	5.5	5.5
1298	7.0	7.0	6.5
1478	3.0	3.0	3.0
5107	7.0	7.0	7.0
6836	7.0	6.5	6.5
7326	5.5	5.0	5.0
7379	5.5	5.5	5.0
8594	6.5	6.0	6.0
9711	5.5	5.5	5.5
11852	5.5	5.0	5.0
13315	3.0	2.5	2.5
16677	3.5	3.5	3.0
17030	6.0	6.0	5.5
18520	5.5	5.5	5.5
21050	6.7	6.0	6.0
21475	5.5	5.5	5.0
21518	5.5	5.0	5.0
22931	4.0	4.0	4.0
25237	3.0	3.0	3.0
25312	4.5	4.5	4.0
25810	4.0	3.5	3.5
27338	6.5	6.5	6.0
29053	5.0	5.0	5.0
33608	4.5	4.0	4.0
34106	4.0	3.5	3.5
34732	5.5	5.5	5.0
35644	8.0	8.0	8.0

D. Post-Treatment Questionnaire (Week 4)

Scale: 4= Strongly Agree, 3= Agree, 2= Disagree, 1= Strongly Disagree

ID	1. My skin looks smoother	2. The appearance of fine lines and wrinkles look smoother.	3. My skin feels smoother.	4. My skin feels more moisturized.	5. My skin feels more hydrated.	6. My skin feels more refreshed.	7. My skin looks more radiant.	8. My skin tone looks more even.	9. My skin looks brighter.	10. My skin looks revitalized.	11. My skin looks more youthful.	12. I would recommend this product to family and/or friends.
1033	2	2	2	2	2	2	2	2	2	2	2	1
1068	4	4	4	4	4	4	3	3	3	3	3	4
1298	2	2	2	3	3	3	2	2	2	2	2	2
1478	3	3	3	3	3	3	3	3	3	3	3	3
5107	3	4	4	4	4	3	3	3	4	4	4	4
6836	3	3	4	3	3	3	4	3	4	3	3	3
7326	2	3	1	1	1	2	3	3	3	2	1	1
7379	3	3	3	3	3	3	3	3	3	3	3	3
8594	3	3	3	3	3	3	2	2	2	2	2	3
9711	3	2	3	3	3	3	3	2	3	3	3	3
11852	3	3	3	2	2	3	4	4	4	4	4	3
13315	3	3	3	2	2	2	2	2	2	2	2	2
16677	3	3	3	3	3	3	3	3	2	3	3	3
17030	4	4	4	3	3	3	3	4	3	3	3	3
18520	2	3	2	2	2	2	2	2	3	2	2	2
21050	2	3	3	3	2	2	2	2	2	2	2	3
21475	2	2	2	2	2	2	2	2	2	2	2	1
21518	2	2	2	2	2	2	2	2	2	2	2	2
22931	2	2	3	3	3	3	2	3	3	3	2	2
25237	3	3	3	3	3	3	3	3	3	3	3	3
25312	3	3	3	3	3	3	3	2	3	3	2	3
25810	3	2	3	3	3	3	3	3	3	3	3	3
27338	4	3	4	4	3	4	4	4	3	3	4	4
29053	3	3	3	2	2	3	3	2	3	3	2	3
33608	3	3	3	1	1	1	3	3	3	3	3	3
34106	4	4	4	4	4	4	3	3	3	3	3	3
34732	3	3	3	3	4	4	3	3	3	3	3	3
35644	4	3	4	3	3	3	3	3	3	3	3	4

E. Post-Treatment Questionnaire (Week 8)

Scale: 4= Strongly Agree, 3= Agree, 2= Disagree, 1= Strongly Disagree

ID	1. My skin looks smoother	2. The appearance of fine lines and wrinkles look smoother.	3. My skin feels smoother.	4. My skin feels more moisturized.	5. My skin feels more hydrated.	6. My skin feels more refreshed.	7. My skin looks more radiant.	8. My skin tone looks more even.	9. My skin looks brighter.	10. My skin looks revitalized.	11. My skin looks more youthful.	12. I would recommend this product to family and/or friends.
1033	2	2	2	3	2	2	2	2	2	2	2	1
1068	4	4	4	3	3	3	3	3	3	3	3	4
1298	2	2	2	2	2	2	2	2	2	2	2	2
1478	3	3	3	3	4	3	3	3	3	3	3	3
5107	4	4	4	4	4	4	4	3	3	3	4	4
6836	3	3	3	3	3	4	4	3	4	3	3	4
7326	3	3	3	2	2	3	3	2	3	3	2	3
7379	4	4	4	4	4	4	4	3	3	3	3	4
8594	3	2	3	3	3	3	2	3	2	3	2	3
9711	3	2	3	2	2	2	2	2	3	3	2	2
11852	4	4	4	2	2	4	4	4	4	4	4	4
13315	2	3	3	2	2	2	2	2	2	2	2	2
16677	3	3	3	3	3	3	2	2	2	3	3	3
17030	3	3	3	4	4	3	3	4	3	3	3	3
18520	3	3	3	2	3	3	2	3	2	3	3	3
21050	3	2	3	3	3	3	2	2	2	2	2	3
21475	3	3	3	3	3	3	2	2	2	2	3	2
21518	3	3	3	3	3	3	3	3	3	3	3	3
22931	3	2	3	2	2	2	3	3	3	3	2	2
25237	3	3	3	3	3	2	3	2	3	3	2	2
25312	3	4	3	3	3	3	2	2	2	3	3	3
25810	4	4	4	4	4	4	4	4	4	4	4	3
27338	4	4	4	4	3	3	4	3	3	3	4	4
29053	3	3	3	3	3	3	2	2	3	3	3	3
33608	3	3	4	2	2	4	4	4	4	4	4	4
34106	3	4	4	4	4	4	3	3	3	3	3	3
34732	4	4	4	4	4	4	4	4	4	4	4	4
35644	4	3	4	4	4	4	3	3	3	3	3	4