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

FINAL REPORT

September 11, 2020

SPONSOR:

Cosmetic Skin Solutions LLC
10580 North McCarran Boulevard
Reno, NV 89503

TEST PRODUCT:

Supreme Olive Serum; Formula Number: 50-300831,
Lot/Batch# 300949 Expiry 4/20/2022

STUDY NUMBER:

BCS 20-046

PROJECT NUMBER:

1136642

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.....	4
II. Study Objective.....	8
III. Study Dates.....	8
IV. Testing Facility.....	8
V. Test Products.....	8
VI. Test Product Handling.....	8
VII. Adverse Events.....	9
VIII. Protocol Deviations.....	9
IX. Study Results and Analysis	
A. Study Subjects.....	10
B. Skin Barrier Function - TEWL.....	11
C. Skin Redness (a* value) – Chromameter.....	12
D. Skin Complexion - Clinical Grading.....	13
Appendix A.....	14
Appendix B.....	24

I. SUMMARY OF RESULTS

Under conditions of the study a total of 31 healthy female subjects, 43-65 years of age, completed the clinical study evaluating the effectiveness of Test Product: Supreme Olive Serum; Formula Number: 50-300831, Lot/Batch# 300949 Expiry 4/20/2022 to improve skin conditions.

A. Skin Barrier Function - TEWL

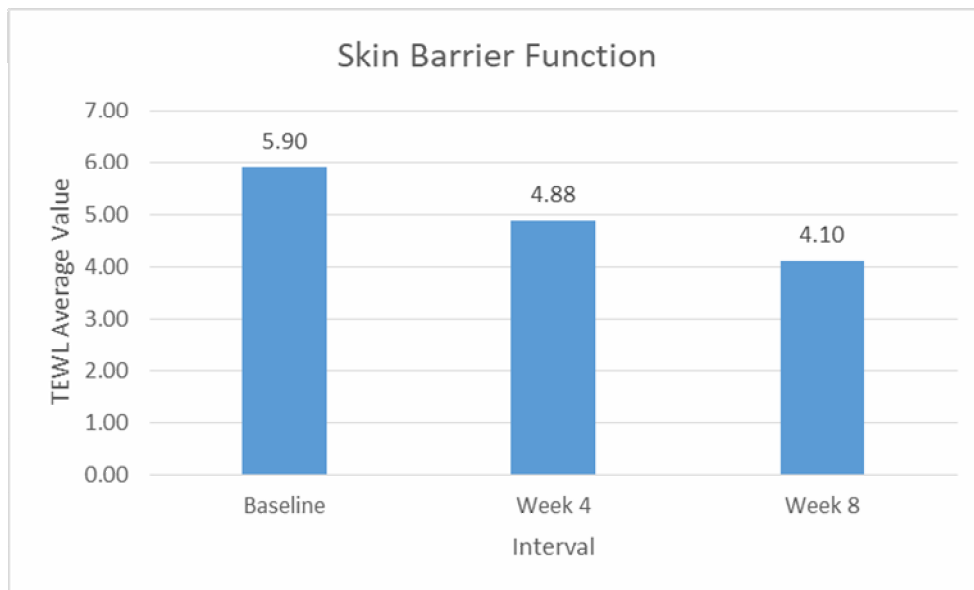
Negative difference indicates an improvement in skin barrier function.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	-17.29%	-30.53%
Percent of Subjects Improved	83.87%	93.55%

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 4 and week 8 post-treatment intervals.



B. Skin Redness (a*) - Chromameter

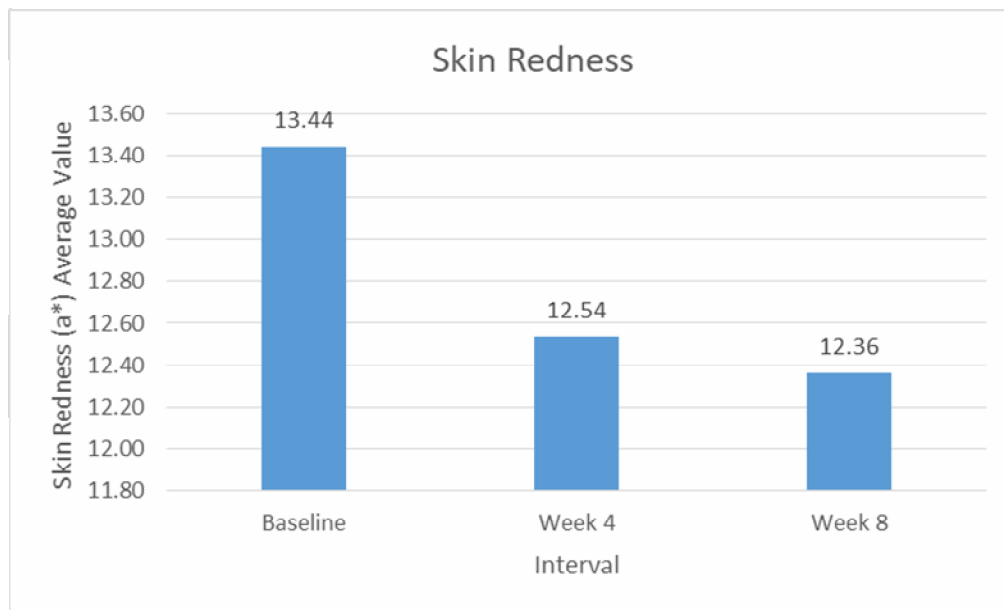
Negative difference indicates an improvement in skin redness.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	-6.72%	-8.01%
Percent of Subjects Improved	83.87%	80.65%

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

Clinical Findings:

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



C. Skin Complexion - Clinical Grading

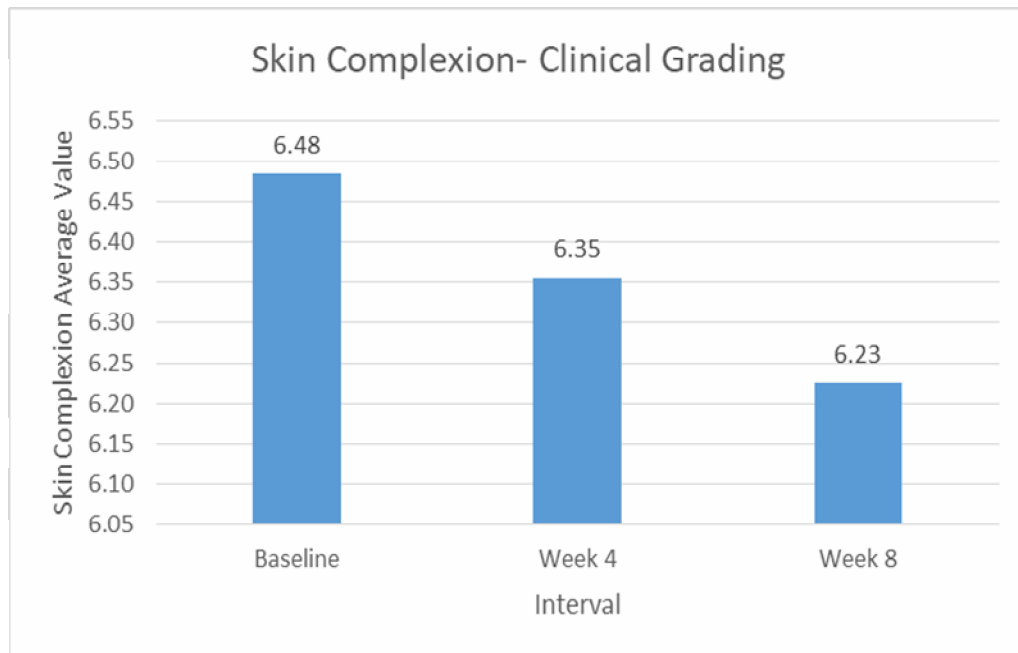
Negative difference indicates an improvement in appearance of skin complexion.

Parameter	Week 4	Week 8
Mean Percent Difference from Baseline	-1.99%	-3.98%
Percent of Subjects Improved	32.26%	48.39%

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

Clinical Findings:

- There was a statistically significant improvement in appearance of skin complexion from baseline at the week 8 post-treatment interval.



D. Post-Treatment Questionnaire (Week 4)

Statement	% of Subjects with Favorable Responses
1. My skin looks smoother	83.87%
2. The appearance of fine lines and wrinkles look smoother.	77.42%
3. My skin feels smoother.	90.32%
4. My skin feels more moisturized.	90.32%
5. My skin feels more hydrated.	87.10%
6. My skin feels more refreshed.	83.87%
7. My skin looks more radiant.	74.19%
8. My skin tone looks more even.	80.65%
9. My skin looks brighter.	70.97%
10. My skin looks revitalized.	74.19%
11. My skin looks more youthful.	67.74%
12. I would recommend this product to family and/or friends.	80.65%

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	90.32%
2. The appearance of fine lines and wrinkles look smoother.	74.19%
3. My skin feels smoother.	87.10%
4. My skin feels more moisturized.	90.32%
5. My skin feels more hydrated.	87.10%
6. My skin feels more refreshed.	83.87%
7. My skin looks more radiant.	77.42%
8. My skin tone looks more even.	77.42%
9. My skin looks brighter.	74.19%
10. My skin looks revitalized.	74.19%
11. My skin looks more youthful.	67.74%
12. I would recommend this product to family and/or friends.	83.87%

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 function
- Improve appearance of uneven skin complexion
- Improve appearance of skin redness
- Consumer perception

III. STUDY DATES

The study began on June 19, 2020 and ended on September 3, 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 Olive Serum; Formula Number: 50-300831, Lot/Batch# 300949 Expiry 4/20/2022	60	12 May 2020; 31 Jul 2020	1136642
Sunscreen SPF 30*	40	12 May 2020	N/A

*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 will be tested. A sufficient quantity of samples of the above test product to allow for 30 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

Each morning, apply 5 to 6 drops of Supreme Olive Serum to a dry face, neck and décolleté using circular motion. Follow by applying SPF 30 Broad Spectrum sunscreen provided to face, neck and décolleté.

VII. ADVERSE EVENTS

Subject ID: 28201

Subject Initials: TRP

Adverse Event Date: 18 Jul 2020

Subject called Christina on 22Jul2020 and reported she was in the hospital. On 23Jul2020, her mother stated that the subject had an asthma attack and couldn't make her appointment. The reaction was not caused by the product.

Treatment Received: Breathing treatment. Subject stated that she was on the treatment for six days. From Saturday, 18 Jul 2020 to Friday, 24 Jul 2020.

Treatment Outcome: Subject was still in hospital the day of her appointment. She was on breathing treatment until it was safe to take her off of the treatment.

Follow-Up: On 28 Jul 2020, subject stated that she was released from the hospital on Friday, 24 Jul 2020.

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. The deviations did not impact clinical findings.

Subject ID	Deviation
3445	4 day washout
5848	4 day washout
14830	3 day washout
27611	Used a different SPF (Oil-free SPF 110) for 1 ½ days
33769	4 day washout
36841	4 day washout

IX. STUDY RESULTS AND ANALYSIS

A. Study Subjects

A total of 31 healthy female subjects consented, enrolled and completed the clinical study.

Table 1. Subject Demographics.

No.	Subject ID	Subject Initials	Age	Race
1	483	JAP	59	H
2	3445	JLR	59	C
3	4591	LCV	48	H
4	5848	PSF	62	C
5	7326	MIO	65	C
6	7716	ALW	59	C
7	7840	KSB	59	C
8	7945	TLR	43	C
9	10230	JAP	59	C
10	10353	EAW	56	NA
11	10359	G-C	44	H
12	14830	CAR	63	C
13	14977	GML	53	C
14	15309	RAM	46	C
15	17733	SAS	63	C
16	19606	DMO	56	C
17	19775	DLE	63	C
18	21938	MJD	59	C
19	22971	MWO	63	C
20	23743	CLS	45	C
21	25312	GCG	61	H
22	27611	AMD	53	H
23	27758	LAM	57	A/C
24	31867	LLP	61	C
25	33613	T-B	51	C
26	33769	K-M	64	C
27	34698	S-R	59	C
28	34729	L-S	57	NA
29	35018	S-E	51	C
30	36270	A-E	51	C
31	36841	RJB	57	H

A= Asian, C= Caucasian, H= Hispanic, NA= Native American

B. Skin Barrier Function - TEWL

Table 2. Mean skin barrier function values.

Interval	Mean ± SD
Baseline	5.90 ± 1.87
Week 4	4.88 ± 1.80
Week 8	4.10 ± 1.45

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

Note: Negative difference indicates improvement in skin barrier function.

Interval	Parameter	Skin Barrier Differences from Baseline
Week 4	Mean	-1.02
	SD	1.27
	% Change	-17.29%
	<i>p</i>	≤0.001
	%Improvers	83.87%
	<i>p</i>	0.005
Week 8	Mean	-1.80
	SD	1.15
	% Change	-30.53%
	<i>p</i>	≤0.001
	%Improvers	93.55%
	<i>p</i>	≤0.001

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

C. Skin Redness (a*) - Chromameter

Table 4. Mean skin redness values.

Interval	Mean ± SD
Baseline	13.44 ± 1.63
Week 4	12.54 ± 1.51
Week 8	12.36 ± 1.74

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

Note: Negative difference indicates improvement in skin redness.

Interval	Parameter	Skin Redness Differences from Baseline
Week 4	Mean	-0.90
	SD	1.01
	% Change	-6.72%
	<i>p</i>	≤0.001
	%Improvers	83.87%
	<i>p</i>	0.005
Week 8	Mean	-1.08
	SD	1.26
	% Change	-8.01%
	<i>p</i>	≤0.001
	%Improvers	80.65%
	<i>p</i>	0.011

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

D. Skin Complexion – Clinical Grading

Table 6. Mean skin complexion values.

Interval	Mean ± SD
Baseline	6.48 ± 1.08
Week 4	6.35 ± 1.17
Week 8	6.23 ± 1.13

Table 7. Descriptive statistics of appearance of skin complexion differences from baseline.

Note: Negative difference indicates improvement in appearance of skin complexion.

Interval	Parameter	Skin Complexion Differences from Baseline
Week 4	Mean	-0.13
	SD	0.39
	% Change	-1.99%
	<i>p</i>	NS
	%Improvers	32.26%
	<i>p</i>	NS
Week 8	Mean	-0.26
	SD	0.48
	% Change	-3.98%
	<i>p</i>	0.009
	%Improvers	48.39%
	<i>p</i>	NS

Bold values indicate statistical significance ($p \leq 0.05$). NS= Not Significant.

APPENDIX A

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

Study Number: BCS 20-046

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.
2300 W. 205th St.
Torrance, CA 90501
PH: 602-277-1154

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 function
- Improve appearance of uneven skin complexion
- Improve appearance of skin redness
- Consumer perception

II. TESTING FACILITY

BioScreen Clinical Services Division
BioScreen Testing Services, Inc.
2300 W. 205th St.
Torrance, CA 90501

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 Olive Serum

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 30 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

Each morning, apply 5 to 6 drops of Supreme Olive Serum to a dry face, neck and décolleté using circular motion. Follow by applying SPF 30 Broad Spectrum sunscreen provided to face, neck and décolleté.

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. I, 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 30 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 agree to continue using approved cosmetics for the washout period and duration of the study so long as they do not contain anti-aging ingredients. BCS

- staff will review cosmetics for approval.
- i. Individuals who agree not to sunbathe/tan and agree to avoid sun (UV) exposure as much as possible for the duration of the study.
 - j. Individuals with mild/moderate/severe skin redness.
 - k. 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.
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 disfigurements).
 - 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 Redness

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 a* values provided to the Sponsor. One measurement will be taken from the designated treatment sites at each measurement interval.

Bioinstrumental Method to Measure Skin Barrier Function ^{5,6}

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.

Clinical Photography for Expert Grading for Appearance of Skin Complexion ²⁻⁴

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 skin complexion using the following scale (half point increments will be allowed):

Scale: 0= None (Even skin complexion), 1-3= Mild, 4-6= Moderate, 7-9= Severe (Uneven/mottled skin complexion)

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 of all cosmetics (e.g. foundation, blush, eye makeup) 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), 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:

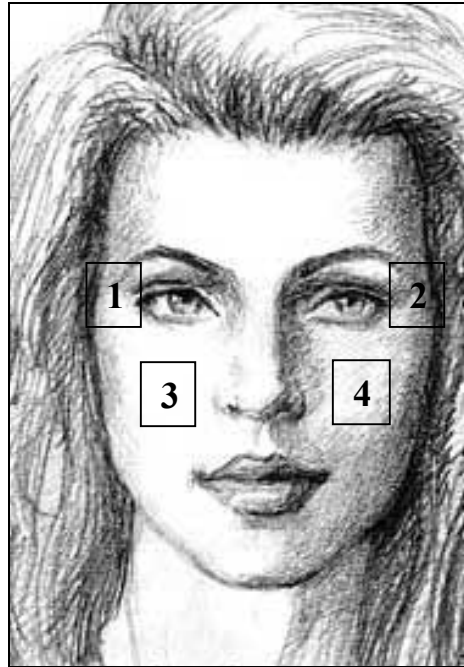
Baseline (pre-treatment)

- a. Clinical photography (frontal, left lateral, right lateral)
 - b. Skin barrier function measurement at sites 1 and 2
 - c. Skin redness measurement at sites 3 and 4
- See Figure 1 for schematic representation of test sites
13. 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.
 14. Subjects will be instructed to clean their face with a neutral cleanser and pat dry.
 15. 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.
 16. Following equilibration, subjects will have the below procedures/ measurements performed by trained BCS staff:

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

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

Graphs will be included in the final report for the efficacy data only.

XIV. STUDY REPORT

Final report will be issued to the sponsor by September 11, 2020.

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. Arch. Dermatol., 128: 347-351, 1992.
3. Br. J. Dermatol., 130: 167-173, 1994.
4. Skin Pharmacol. Appl. Skin Physiol., 16: 100-107, 2003
5. Information and instruction manual for the DermaLab Series SkinLab Combo.
6. Leveque JL, Garson JC, de Rigal J. Transepidermal Water Loss from Dry and Normal Skin. *J Soc Cosmet Chem* 1979, 30: 333-343.

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
483	8.8	6.8	8.9	7.1	5.0	5.9
3445	6.7	6.2	5.9	6	4.4	5.7
4591	6.4	6.7	6.1	4.9	6.4	3.0
5848	5.4	5.9	4.3	4.7	4.8	2.8
7326	10.7	7.1	5.7	5.6	6.7	5.2
7716	3.7	8.7	4.7	5.0	3.9	6.2
7840	8.0	8.9	6.3	6.9	5.5	6.9
7945	10.4	9.1	8.7	10.5	6.3	8.9
10230	4.8	5.8	3.5	5.2	1.7	2.4
10353	5.8	5.6	6.0	3.3	6.3	5.0

10359	6.0	8.0	5.7	7.5	5.5	3.8
14830	3.3	5	2.5	3.1	2.8	3.5
14977	3.0	2.9	1.5	4.8	3.8	2.2
15309	8.1	5.3	5.9	5.4	5.4	4.1
17733	6.1	6.4	5.3	5.7	5.4	3.4
19606	4.1	5.6	4.4	5.0	4.0	2.8
19775	4.8	2.9	3.7	2.4	1.8	2.4
21938	4.3	10.5	2.8	3.6	3.0	3.5
22971	3.6	3.9	3.3	3.1	2.4	3.3
23743	7.8	6.9	7.8	6.9	7.3	2.8
25312	6.7	5.7	6.2	5.9	5.1	3.6
27611	4.4	6.1	4.5	5.8	3.3	2.6
27758	4.4	4.5	3.8	2.3	3.0	2.4
31867	3.2	3.6	2.2	1.4	1.9	2.4
33613	13.2	4.8	4.1	4.3	3.1	3.6
33769	4.5	5.2	2.6	4.4	2.7	3.7
34698	3.4	2.8	3.9	4.5	2.4	3.8
34729	9.2	7.1	8.3	7.6	8.6	5.5
35018	3.7	3.7	2.5	3.1	2.2	3.0
36270	3.8	4.1	3.1	5.6	3.3	2.9
36841	6.1	5.4	3.5	3.1	5.7	3.0

B. Skin Redness (a* value) - Chromameter

ID	Baseline		Week 4		Week 8	
	Right Cheek	Left Cheek	Right Cheek	Left Cheek	Right Cheek	Left Cheek
483	14.2	13.2	13.6	13.5	13.7	12.5
3445	14.6	15.3	15.2	14.7	16.0	16.5
4591	15.40	15.40	15.0	14.2	14.0	13.9
5848	13.1	12.7	10.8	10.9	10.8	12.1
7326	14.4	14.0	11.8	12.9	11.8	13.1
7716	13.7	10.9	10.4	11.2	8.3	10.3
7840	14.3	13.1	16.5	12.5	13.3	11.7
7945	16.0	16.0	15.3	13.5	13.0	12.9
10230	13.2	11.2	12.5	9.8	12.5	11.0
10353	12.8	12.8	12.7	12.8	12.3	11.3
10359	16.5	15.6	16.9	13.4	16.1	14.9

14830	12.8	10.4	11.2	9.9	12.8	10.8
14977	12.1	14.2	12.6	12.1	13.7	12.7
15309	11.8	11.4	11.2	10.7	11.1	10.7
17733	13.30	12.60	13.5	12.6	12.3	12.8
19606	13.4	13.8	12.5	13.5	11.0	11.9
19775	15.2	14.8	12.5	13.8	13.2	14.7
21938	10.5	10.2	11.5	11.3	9.0	9.9
22971	9.5	10.0	9.3	9.7	9.6	10.5
23743	15.3	13.5	14.5	13.8	14.1	13.8
25312	12.9	11.9	12.5	11.9	12.3	11.8
27611	16.0	14.7	13.7	12.7	10.1	10.3
27758	13.6	12.2	9.9	9.3	9.1	10.7
31867	14.1	12.9	12.7	12.3	12.3	13.5
33613	15.7	14.0	13.1	12.6	13.6	14.0
33769	14.2	13.3	12.6	12.1	12.5	15.5
34698	15.2	13.7	14.6	13.2	13.6	12.4
34729	14.8	14.3	14.1	12.7	14.7	14.4
35018	10.5	9.9	11.4	10.3	9.3	10.3
36270	12.2	13.8	12.1	12.6	11.8	11.7
36841	15.0	15.1	13.4	11.1	14.1	11.9

C. Skin Complexion – Clinical Grading

Scale: 0= None (Even skin complexion), 1-3= Mild, 4-6= Moderate, 7-9= Severe (Uneven/mottled skin complexion)

Subject ID	Baseline	Week 4	Week 8
483	6.5	6.5	6.5
3445	8.0	8.5	8.0
4591	6.0	6.0	6.5
5848	7.0	7.0	7.0
7326	5.0	4.5	4.5
7716	8.5	8.5	8.0
7840	6.5	7.0	6.5
7945	6.5	6.0	6.0
10230	6.0	6.0	6.0
10353	6.5	6.5	6.5
10359	5.5	5.5	5.5
14830	6.5	6.0	6.0
14977	5.5	5.5	5.0
15309	5.5	4.5	4.5
17733	6.0	5.5	5.0
19606	7.5	7.0	6.5
19775	6.5	6.5	6.0
21938	8.0	8.5	8.0
22971	5.0	5.0	5.0
23743	6.0	6.0	6.0
25312	5.5	5.5	5.5
27611	6.5	5.5	5.0
27758	5.0	5.5	5.5
31867	6.5	6.0	7.0
33613	7.0	6.5	6.5
33769	8.5	8.5	8.0
34698	6.5	6.5	6.0
34729	6.5	6.5	7.0
35018	7.5	7.5	7.5
36270	4.5	4.5	4.0
36841	8.5	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.
483	4	4	4	4	4	4	3	4	4	4	4	4
3445	3	3	3	3	3	3	3	3	3	3	3	3
4591	4	4	4	4	4	4	4	3	3	3	3	4
5848	3	2	3	3	3	3	2	3	2	3	2	3
7326	3	3	3	3	2	3	3	3	3	3	2	3
7716	2	2	2	2	2	2	2	2	2	2	2	2
7840	3	2	3	3	2	2	2	2	2	2	2	2
7945	4	3	4	4	4	4	4	3	3	3	3	4
10230	3	3	3	3	3	3	3	3	3	3	3	3
10353	4	4	4	4	4	4	4	3	3	3	3	4
10359	4	4	4	3	4	3	3	3	3	3	3	4
14830	3	3	3	3	3	3	3	3	3	3	3	3
14977	2	1	3	3	3	3	2	2	2	2	2	3
15309	3	3	3	3	3	3	3	3	3	3	3	3
17733	3	3	3	4	4	4	3	3	3	3	3	4
19606	3	3	3	3	3	3	2	3	2	2	2	3
19775	3	3	4	4	4	4	3	3	3	3	3	3
21938	2	2	3	3	3	3	2	2	2	2	2	2
22971	3	3	3	3	3	3	3	3	3	3	3	3
23743	2	2	2	2	2	2	2	2	2	2	2	1
25312	3	3	3	3	3	3	3	3	3	3	2	2
27611	2	2	2	3	3	2	2	2	2	2	2	2
27758	3	3	3	3	3	3	3	3	3	3	3	3
31867	3	3	3	2	3	2	3	3	3	2	3	3
33613	3	4	4	4	4	4	4	3	3	4	4	4
33769	4	4	4	3	3	3	4	3	3	3	3	4
34698	3	3	3	3	3	3	3	3	3	3	3	3
34729	3	3	3	3	3	3	3	3	3	3	3	3
35018	4	3	3	4	4	3	3	3	2	3	3	3
36270	4	4	4	4	4	4	4	4	4	4	4	4
36841	4	4	4	4	4	4	4	4	4	4	4	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.
483	3	3	3	3	3	3	3	3	3	3	3	4
3445	3	3	3	3	3	3	3	3	3	3	2	3
4591	4	3	3	4	4	4	4	3	4	4	4	4
5848	3	2	3	3	3	3	3	3	3	3	3	3
7326	3	2	2	3	3	3	3	2	3	3	2	3
7716	2	2	2	2	2	2	2	2	2	2	2	2
7840	3	2	3	3	2	2	2	1	3	2	2	2
7945	4	3	4	4	4	4	3	4	4	4	3	4
10230	3	3	3	3	3	3	2	2	2	2	2	3
10353	3	3	3	3	3	4	3	3	3	3	3	4
10359	4	4	3	4	4	3	4	3	4	4	4	4
14830	4	4	4	4	4	4	4	4	4	4	4	4
14977	3	2	3	3	3	3	2	3	2	2	2	3
15309	3	3	3	3	3	3	3	3	3	3	3	3
17733	3	3	4	4	4	4	3	3	3	3	3	4
19606	3	3	3	3	3	3	3	3	4	3	4	3
19775	3	3	4	3	3	3	3	3	3	3	3	4
21938	3	3	3	3	3	2	2	2	2	2	2	3
22971	3	3	3	3	3	3	3	3	3	3	3	3
23743	2	2	2	2	2	2	2	2	2	2	2	1
25312	3	3	3	3	3	3	3	3	3	3	3	3
27611	2	2	2	2	2	2	2	2	2	2	2	2
27758	3	3	3	3	3	3	3	3	3	3	3	3
31867	3	2	4	3	3	3	3	3	2	3	2	3
33613	4	4	4	4	4	4	4	4	4	4	4	4
33769	3	3	4	3	3	3	3	3	3	3	3	4
34698	3	3	3	3	4	3	4	3	3	3	3	2
34729	3	3	3	3	3	3	3	3	3	1	3	3
35018	4	3	3	4	4	4	4	3	2	3	3	4
36270	4	4	4	4	4	4	4	4	4	4	4	4
36841	4	4	4	4	4	4	4	4	4	4	4	4



Jordan DeSantis
Clinical Manager



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Clinical QA Specialist