



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

FINAL REPORT

August 12, 2016

SPONSOR:

Dermaclara
7868 Silverton Avenue, Suite B
San Diego, CA 92126

TEST PRODUCT:

1) Clarafuse Pads, Chest-Smooth, Medical Grade
Silicone Dermapads
2) Clarafuse Pads, Face-Smooth, Medical Grade
Silicone Dermapads

STUDY NUMBER:

BCS 16-057

PROJECT NUMBER:

954960

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. Study Conclusions.....	4
II. Summary of Results.....	5
III. Study Objective.....	8
IV. Study Dates.....	8
V. Testing Facility.....	8
VI. Test Products.....	8
VII. Test Product Handling.....	8
VIII. Study Participation Recruitment.....	8
IX. Informed Consent, Photography Release and Medical History Forms.....	9
X. Inclusion Criteria.....	9
XI. Exclusion Criteria.....	10
XII. Experimental Techniques.....	10
XIII. Procedure.....	11
XIV. References.....	12
XV. Adverse Events.....	12
XVI. Study Results and Analysis	
A. Study Subjects.....	13
B. Fine Lines and Wrinkles by Vaestro Analysis.....	15
C. Fine Lines and Wrinkles of the Chest Area by Clinical Grading.....	16
Appendix.....	17

I. STUDY CONCLUSIONS

Under the conditions of the study the following claims were substantiated for Test Product: Clarafuse Pads, Chest-Smooth, Medical Grade Silicone Dermapads; Clarafuse Pads, Face-Smooth, Medical Grade Silicone Dermapads:

- 1) Improved appearance of fine lines and wrinkles of the forehead area
- 2) Improved appearance of fine lines and wrinkles of the mouth area (Nasolabial Folds)
- 3) Improved appearance of fine lines and wrinkles of the chest area

Test Product: Clarafuse Pads, Chest-Smooth, Medical Grade Silicone Dermapads; Clarafuse Pads, Face-Smooth, Medical Grade Silicone Dermapads provided the following statistically significant improvements immediately after a 60 minute application of the test product(s):

- **17.21% improvement** in appearance of fine lines and wrinkles of the forehead area
- **69.35%** of subjects demonstrated an improvement appearance of fine lines and wrinkles of the forehead area
- **6.17% improvement** in appearance of fine lines and wrinkles of the mouth area (Nasolabial Folds)
- **2.15% improvement** in appearance of fine lines and wrinkles of the chest area

II. SUMMARY OF RESULTS

Under conditions of the study a total of 62 healthy female subjects, 45-65 years of age, completed the clinical study evaluating the efficacy of Test Product: Clarafuse Pads, Chest-Smooth, Medical Grade Silicone Dermapads and Clarafuse Pads, Face-Smooth, Medical Grade Silicone Dermapads

A. Fine Lines and Wrinkles of the Forehead Area by Vaestro

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

Parameter	Immediate (Post 60-Minute Application)
Mean Percent Difference From Baseline	-17.21%
Percent of Subjects with Improvement	69.35%

BOLD values indicate statistical significance ($p \leq 0.05$)

Clinical Findings:

- There was statistically significant improvement in appearance of fine lines and wrinkles of the forehead area from baseline at the immediate (post 60-minute application) interval.
- A statistically significant number of subjects showed improvement in appearance of fine lines and wrinkles of the forehead area from baseline at the immediate (post 60-minute application) interval.

B. Fine Lines and Wrinkles of the Mouth Area (Nasolabial Folds) by Vaestro

Note: Negative difference indicates improvement in appearance of fine lines and wrinkles of the mouth area (Nasolabial Folds).

Parameter	Immediate (Post 60-Minute Application)
Mean Percent Difference From Baseline	-6.17%
Percent of Subjects with Improvement	<i>66.13%</i>

BOLD values indicate statistical significance ($p \leq 0.05$). *Italicized* values indicate directional significance ($p < 0.10$).

Clinical Findings:

- There was statistically significant improvement in appearance of fine lines and wrinkles of the mouth area (Nasolabial Folds) from baseline at the immediate (post 60-minute application) interval.

- A directional significant number of subjects showed improvement in appearance of fine lines and wrinkles of the mouth area (Nasolabial Folds) from baseline at the immediate (post-60-minute application) interval.

C. Fine Lines and Wrinkles of the Chest Area by Clinical Grading

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

Parameter	Immediate (Post 60-Minute Application)
Mean Percent Difference From Baseline	-2.15%
Percent of Subjects with Improvement	19.35%

BOLD values indicate statistical significance ($p \leq 0.05$)

Clinical Findings:

- There was statistically significant improvement in appearance of fine lines and wrinkles of the chest area from baseline at the immediate (post 60-minute application) interval.

D. Post-Treatment Questionnaire

Scale: Questions #1-15: 1= Strongly Disagree, 2= Disagree, 3= Agree, 4= Strongly Agree

Questions #16-17: 1= Strongly Disagree, 2= Disagree, 3= Somewhat Agree, 4= Agree, 5= Strongly Agree

Questions #18: 1= The appearance of fine lines and wrinkles has improved dramatically,

2= The appearance of fine lines and wrinkles has improved noticeably,

3= The appearance of fine lines and wrinkles has improved somewhat, 4=

The appearance of fine lines and wrinkles has not improved

Questions #19-20: 1= Yes, 2= No

Statement / Question	% of Subjects with Favorable Response
1. I like the way the product feels on my skin	91.94%
2. The product was easy to apply	96.77%
3. The product was comfortable to wear	90.32%
4. The product was easy to remove	82.26%
5. Fine lines and wrinkles around the eyes are visibly improved	83.87%

6. Fine lines and wrinkles around the mouth are visibly improved	77.42%
7. Fine lines and wrinkles around the forehead are visibly improved	85.48%
8. Fine lines and wrinkles around the chest are visibly improved	87.10%
9. My skin looks transformed	67.74%
10. My skin looks younger	70.97%
11. My skin looks smoother	87.10%
12. My skin feels smoother	90.32%
13. My skin feels softer	87.10%
14. My skin looks revitalized	77.42%
15. This product improves the way I feel about my skin	75.81%
16. I prefer to use this treatment method (non invasive) over any other anti-aging treatments like injections and surgery	90.32%
17. The treatment seemed very easy to use	93.55%
18. Which statement best describes your how your skin looks after using this product for this 1 hour test?	1= 8.06% 2= 48.39% 3= 32.26% 4= 11.29%
19. After this test, would you continue to use this product?	87.10%
20. After this test, would you recommend this product to a friend or family member	83.87%

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

III. STUDY OBJECTIVE

To evaluate the effectiveness of a skin care product to:

- Improve the appearance of fine lines and wrinkles in the eye area (Crow's Feet)
- Improve the appearance of fine lines and wrinkles in the forehead area
- Improve the appearance of fine lines and wrinkles in the mouth area (Nasolabial Folds)
- Improve the appearance of fine lines and wrinkles in the chest area

IV. STUDY DATES

The study began on July 22, 2016 and was completed on July 27, 2016.

V. TESTING FACILITY

BioScreen Clinical Services Division
BioScreen Testing Services, Inc.
3305 N. 2nd Street
Phoenix, AZ 85012

VI. TEST PRODUCTS

Product Name	Number of Samples	Date Received	Accession Number
Clarafuse Pads, Chest-Smooth, Medical Grade Silicone Dermapads	50	06/27/2016	954960
	22	06/28/2016	
Clarafuse Pads, Face-Smooth, Medical Grade Silicone Dermapads	50	06/27/2016	954961
	21	06/28/2016	

VII. TEST PRODUCT HANDLING

Test product that had been reviewed and approved for use by the Regulatory and Safety representatives of Dermaclara was tested.

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. Sample was retained for a period of 30 days beyond submission of final report. Sample disposition were conducted in compliance with appropriate federal, state and local ordinances.

VIII. STUDY PARTICIPATION RECRUITMENT

Panel selection was accomplished by advertisements in local periodicals, community bulletin boards, phone solicitation, electronic media or any combination thereof.

IX. INFORMED CONSENT, PHOTOGRAPHY RELEASE AND MEDICAL HISTORY FORMS

Informed consent was 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 signed and dated the informed consent document and a photography release form to indicate their authorization to proceed and acknowledge their understanding of the contents. Each subject was assigned a permanent identification number and completed an extensive medical history form. These forms along with the signed consent forms are available for inspection on the premises of BCS only.¹

X. INCLUSION CRITERIA

1. Sex: Female
2. Age: 45-65
3. Race: Unrestricted
4. Individuals who were in good general health.
5. Individuals who, at baseline, were free of any dermatological or systemic disorder, which would interfere with the results, at the discretion of the Investigator.
6. Individuals who completed a preliminary medical history.
7. Individuals who were able to read, understand and sign an informed consent document.
8. Individuals who were able to cooperate with the Investigator and research staff, have each test product applied according to the protocol and complete the full course of the study.
9. Individuals who had not participated in any study involving the same test site (face/chest) for 14 days prior to study start.
10. Individuals who had healthy skin on the test site, with no evidence of irritation, tattoos, scars, non-removable piercings or any other condition that would interfere with study evaluations.
11. Individuals who agreed to refrain from using all personal care products (e.g., soaps, lotions, creams) on the test site (face/chest) 5 days prior to study start and for the entire study duration except for those products provided by BCS.
12. Individuals who agreed to continue usage of their current cosmetics (e.g., foundation, blush) if applicable, so long as products contained no anti-aging properties and the subjects had a safe usage history for the duration of the study. Subjects were instructed not to wear any form of cosmetics on the study visit days.
13. Individuals who were willing to bring their cosmetic products to the facility for inspection by a BCS staff member and agreed to discontinue use of products containing anti-aging ingredients.
14. Individuals who had visible fine lines and wrinkles in the eye area (Crow's feet).
15. Individuals who had visible fine lines and wrinkles in the forehead area.
16. Individuals who had visible fine lines and wrinkles in the mouth area (Nasolabial Folds).
17. Individuals who had visible fine lines and wrinkles in the chest area.
18. Individuals who agreed not to sunbathe/tan and agreed to avoid sun exposure as much as possible for the duration of the study.

XI. EXCLUSION CRITERIA

1. Individuals who had a history of any acute or chronic disease that would interfere with or increase the risk on study participation.
2. Individuals who had active (flaring) disease or chronic skin allergies (atopic dermatitis/eczema), or had recently treated skin cancer (within the last 12 months).
3. Individuals who had damaged skin in close proximity to test sites (e.g., sunburn, scars, tattoos, scars or other skin disfigurements).
4. Individuals who had any history, which, in the Investigator's opinion, indicated the potential for harm to the subject or placed the validity of the study in jeopardy.
5. Individuals who indicated that they were pregnant, planning a pregnancy or nursing.
6. Individuals who used injectable insulin to control their diabetes.
7. Individuals who 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).
8. Individuals who were currently using or during the last 3 months had used, Retin A, or other Rx/OTC Retinyl A, hydroquinone (skin lightening) or other astringent derived products or alpha hydroxyl acid treatments for photo-aging and fine lines/wrinkles.
9. Individuals who had a known history of hypersensitivity or allergies to any cosmetics, personal care products, fragrances and/or adhesives.
10. Individuals who were employees of BioScreen.

XII. EXPERIMENTAL TECHNIQUES

Clinical photography for Vaestro Analysis of Fine Lines and Wrinkles in the Eye Area, Forehead Area, and Mouth Area²⁻⁴

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 modalities.

Photographs obtained were evaluated for the appearance of fine lines and wrinkles in the eye area, forehead area, and mouth area utilizing the VAESTRO Image Analysis Toolkit.

Digital Photography for Clinical Grading Of Appearance of Fine Lines and Wrinkles in the Chest Area²⁻⁴

Consistency of photographic results will be achieved by eliminating all variables except the color and luminosity of the skin. Light source to subject distance will be constant for all photos. The flash units will be set so the light output is the same for every picture. The camera will be set to manual and the aperture will be determined using a light meter. The aperture and shutter speed will be held constant throughout the study. The images will not be digitally enhanced.

Digital photographs of subjects' chest (frontal) were taken. Photographs were analyzed for the appearance of fine lines and wrinkles on the following scale (half point increments were used):

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

Self-Assessment Questionnaire

Each subject was instructed to complete a self-assessment questionnaire provided by the Sponsor at the 1 Hour post-treatment interval.

XIII. PROCEDURE

1. Subjects reported to the facility a minimum of five (5) days prior to the start of the study.
2. Prior to beginning any study related activities, subjects were given an informed consent form, HIPAA form and photography release form to read.
3. Once subject had completed reading they were interviewed, in private, by BioScreen to ensure their understanding of the aforementioned forms and were given the opportunity to ask any study related questions.
4. Subjects who agreed to sign the informed consent, HIPAA and photography release forms were asked to complete a medical history form. Subjects declining to sign the informed consent, HIPAA, or photography release form were dismissed from the study.
5. Subjects were enrolled on the basis of the subject selection criteria. Subjects failing to meet criteria were dismissed from the study.
6. Enrolled subjects began the washout period. Subjects received a neutral soap (Neutrogena) to use exclusively on their face and chest during the washout period and study duration.
7. Enrolled subjects were given specific instructions prohibiting use of all personal care products (e.g., soaps, lotions, creams) on the test sites (face and chest) for the entire washout and study duration except for those products provided by BCS.
8. Subjects were instructed to bring their current cosmetics for inspection by a BCS staff member. Cosmetics were inspected for anti-aging properties and safe usage history. Subject were instructed to stop usage of any non-approved products. If subject declined, subject was dismissed from study. Subjects were instructed not to use any cosmetics on day of visits.
9. Following the 5 day washout period, subjects returned to the testing facility.
10. Subjects were instructed to cleanse their face and chest with a neutral soap and gently pat dry with a paper towel.
11. Thereafter, subjects equilibrated 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 were recorded during subject testing.
12. Following equilibration, subjects had the below procedures/ measurements performed by

trained BCS staff:

Baseline (pre-treatment)

- a. Close-up facial photography
- b. Digital photography of chest

13. Subjects were instructed to use the test product as directed by the Sponsor.
14. Subjects remained in the exam room.
15. At 1 hour (± 10 minutes), Step 12 was repeated.
16. Subjects were also instructed to complete a post-treatment questionnaire.
17. Upon completion of the post-treatment questionnaire, subjects were dismissed from the study and asked to participate* in a photography/videography session provided by the Sponsor.

*Subjects were only permitted to participate in the Q&A session with the Sponsor once they had completed the study requirements as outlined in the above procedure. Participation by the subject in the photography/videography session was completely voluntary.

XIV. 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.

XV. ADVERSE EVENTS

There were no test product related adverse events during the course of the study.

XVI. STUDY RESULTS AND ANALYSIS

A. Study Subjects

A total of 62 healthy female subjects consented, enrolled and completed the clinical study.

Table 1. Subject Demographics.

No.	Subject ID	Subject Initials	Age	Race
1	464	KDT	56	NA
2	495	MRP	56	NA
3	633	S-B	63	H
4	864	DAH	63	C
5	1298	L-C	62	C
6	3153	MMG	57	AA
7	3445	JLR	55	C
8	4027	MAA	65	C
9	4127	M-D	52	H
10	5773	SAW	56	C
11	5774	RJF	56	C
12	7116	SAF	59	C
13	7379	ALC	61	AA
14	7857	MLM	49	C
15	7957	MAV	56	C
16	8160	GRV	54	C
17	8225	JAP	58	C
18	8425	GAB	60	C
19	8426	ATG	56	H
20	8601	DAC	49	H
21	8657	LMP	63	C
22	8821	SML	50	C
23	8831	CLL	55	C
24	8963	JKG	64	H
25	9049	S-E	51	C
26	10896	SFD	59	AA
27	12887	BEP	50	C
28	13860	MMK	51	C
29	15308	LKM	45	C
30	15435	RSS	52	C
31	15684	MLA	47	C

No.	Subject ID	Subject Initials	Age	Race
32	16118	G-L	54	C
33	16472	EMW	51	C
34	17107	L-T	49	H
35	17733	SAS	59	C
36	17989	MLE	48	H
37	18891	R-G	46	H
38	19756	ABA	53	C
39	19789	JVK	65	C
40	20183	LMK	45	C
41	20383	L-C	46	H
42	20918	DEW	46	C
43	21375	PAC	61	C
44	21437	ACS	59	C
45	21515	MER	46	H
46	21938	MJD	55	C
47	21958	LSC	51	H
48	22259	P-D	63	C
49	22375	LAS	60	C
50	22806	LLK	54	C
51	22864	DKG	62	C
52	22867	TRK	50	NA
53	22878	P-S	59	H
54	23346	G-T	63	AA
55	23356	V-A	59	C
56	23516	GRB	57	AA
57	23520	KLD	47	C
58	23528	LJJ	63	AA
59	23727	TLH	48	AA
60	23853	MAL	54	C
61	24034	TKP	49	C
62	24075	JOR	59	C

AA = African American, C = Caucasian, H = Hispanic, NA = Native American

B. Fine Lines and Wrinkles by Vaestro Analysis

Table 2. Mean appearance of fine lines and wrinkles values.

Interval	Mean ± SD		
	Eye Area	Forehead Area	Mouth Area
Baseline	157.29 ± 76.78	311.35 ± 230.51	243.92 ± 92.46
Immediate (Post 60-Minute Application)	157.37 ± 77.10	257.76 ± 221.02	228.88 ± 88.33

Table 3. 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	Fine Lines and Wrinkles Differences from Baseline		
		Eye Area	Forehead Area	Mouth Area
Immediate (Post 60- Minute Application)	Mean	0.08	-53.60	-15.04
	SD	21.31	103.25	53.88
	% Change	0.05%	-17.21%	-6.17%
	<i>p</i>	NS	≤0.001	≤0.001
	%Improvers	51.61%	69.35%	<i>66.13%</i>
	<i>p</i>	NS	0.028	0.069

BOLD values indicate statistical significance ($p \leq 0.05$). *Italicized* values indicate directional significance ($p < 0.10$).
NS= Not Significant

C. Fine Lines and Wrinkles of the Chest Area by Clinical Grading

Table 5. Mean appearance of fine lines and wrinkles of the chest area scores.

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

Interval	Mean ± SD
Baseline	4.87 ± 0.97
Immediate (Post 60-Minute Application)	4.77 ± 0.92

Table 6. Descriptive statistics of appearance of fine lines and wrinkles of the chest area differences from baseline.

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

Interval	Parameter	Fine Lines and Wrinkles of the Chest Area Differences from Baseline
Immediate (Post 60-Minute Application)	Mean	-0.10
	SD	0.30
	% Change	-2.15%
	<i>p</i>	0.013
	%Improvers	19.35%
	<i>p</i>	NS

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

APPENDIX

A) Fine Lines and Wrinkles of the Eye Area by Vaestro

ID	Baseline		60 Minute	
	Left Eye Area	Right Eye Area	Left Eye Area	Right Eye Area
464	114.22	139.97	119.22	174.10
495	237.89	250.54	269.78	244.54
633	105.84	149.37	98.77	169.56
864	132.91	80.76	161.17	108.93
1298	89.30	53.91	72.48	66.01
3153	414.11	362.07	329.07	387.32
3445	203.81	266.54	217.13	246.02
4027	117.77	111.97	124.53	118.27
4127	187.38	192.45	169.86	175.89
5773	116.29	129.57	145.09	165.95
5774	123.98	86.23	140.50	111.00
7116	196.94	183.32	158.39	165.28
7379	294.84	205.77	357.45	178.08
7857	150.45	169.17	136.98	165.66
7957	145.16	77.44	146.86	72.82
8160	91.69	63.22	84.80	61.84
8225	86.83	115.28	67.28	127.74
8425	37.57	66.29	59.11	81.11
8426	155.67	135.53	189.39	125.87
8601	290.98	244.21	287.62	183.10
8657	116.03	99.87	125.73	126.63
8821	98.99	66.74	80.97	67.23
8831	162.23	114.70	163.48	107.42
8963	135.76	165.43	179.11	189.66
9049	88.17	105.78	84.47	98.97
10896	235.54	261.90	204.00	265.04
12887	102.83	113.79	92.52	79.07
13860	298.00	265.87	380.70	208.84
15308	108.49	138.59	70.31	99.60
15435	134.34	134.29	165.60	188.25
15684	131.43	156.68	105.53	125.22
16118	108.75	96.43	85.97	82.88
16472	105.18	102.33	108.61	93.34
17107	187.58	171.94	187.57	176.00
17733	99.59	143.16	79.92	123.91
17989	109.94	149.78	104.11	142.46
18891	217.75	291.74	252.71	285.50
19756	200.95	177.46	254.91	238.03
19789	204.54	177.08	204.95	173.22

20183	81.54	67.56	74.51	83.49
20383	64.79	60.39	75.91	68.48
20918	219.68	201.88	196.96	222.93
21375	73.01	121.40	52.41	88.97
21437	82.41	70.92	88.28	73.50
21515	104.43	137.36	103.15	139.45
21938	254.12	266.51	271.54	302.45
21958	169.85	118.52	172.19	106.13
22259	213.57	273.27	197.83	246.39
22375	83.55	134.31	98.46	139.60
22806	149.19	167.19	147.10	207.44
22864	131.41	183.34	127.93	163.73
22867	92.04	82.33	82.67	95.56
22878	155.11	156.41	198.80	131.79
23346	271.90	478.00	255.88	380.93
23356	163.94	131.17	166.54	128.94
23516	136.66	157.73	147.55	127.10
23520	84.65	83.23	64.19	56.62
23528	312.33	208.99	325.73	265.48
23727	369.10	318.60	367.95	367.16
23853	216.98	188.59	171.16	152.98
24034	73.26	108.83	70.83	108.37
24075	70.92	55.65	64.67	66.57

B) Fine Lines and Wrinkles of the Forehead Area by Vaestro

ID	Baseline	60 Minute
464	505.16	545.00
495	436.96	434.84
633	317.95	350.85
864	44.53	53.52
1298	89.10	97.37
3153	1194.00	1154.30
3445	385.99	395.70
4027	217.10	123.81
4127	433.68	397.99
5773	37.14	44.33
5774	83.44	115.18
7116	249.74	273.70
7379	803.26	603.42
7857	35.20	41.57
7957	175.87	107.81
8160	298.18	263.15
8225	164.31	96.36
8425	181.37	173.57
8426	204.32	270.37
8601	593.07	512.83
8657	295.28	299.54
8821	156.46	55.58
8831	239.74	118.68
8963	395.31	342.59
9049	371.90	226.47
10896	777.22	673.51
12887	203.14	151.58
13860	370.41	286.99
15308	198.56	117.46
15435	275.00	240.94
15684	314.48	110.83
16118	91.73	18.09
16472	304.44	87.58
17107	351.37	310.79
17733	61.56	44.90
17989	238.61	266.36
18891	592.35	592.39
19756	296.43	195.94
19789	135.85	126.25
20183	121.82	73.74
20383	22.72	23.73
20918	278.42	127.17

21375	145.57	128.65
21437	170.80	128.23
21515	331.88	180.74
21938	381.67	303.10
21958	290.90	210.72
22259	402.45	238.90
22375	31.20	56.80
22806	243.86	216.99
22864	218.45	147.15
22867	147.05	114.44
22878	573.09	427.78
23346	475.07	742.12
23356	756.58	172.78
23516	355.79	333.63
23520	157.21	172.56
23528	807.06	844.34
23727	750.28	575.66
23853	232.60	172.22
24034	262.85	234.67
24075	26.43	32.59

D) Fine Lines and Wrinkles of the Mouth Area by Vaestro

ID	Baseline	60 Minute
464	342.25	326.31
495	421.54	454.96
633	414.24	364.77
864	313.71	274.23
1298	342.74	83.04
3153	229.87	230.27
3445	177.71	167.11
4027	152.37	150.67
4127	315.81	250.13
5773	242.93	223.78
5774	252.74	221.25
7116	209.39	179.52
7379	290.11	303.26
7857	276.91	249.33
7957	127.67	154.28
8160	119.74	133.07
8225	200.30	160.61
8425	195.89	187.89
8426	253.80	225.14
8601	329.09	330.71
8657	373.00	350.63
8821	209.53	169.23
8831	270.22	225.43
8963	295.52	284.35
9049	141.62	120.66
10896	247.68	261.26
12887	212.18	236.76
13860	252.50	269.29
15308	165.33	137.80
15435	137.35	127.46
15684	198.36	168.70
16118	147.59	152.32
16472	174.52	157.27
17107	171.39	173.28
17733	210.29	188.12
17989	290.62	255.56
18891	259.09	278.03
19756	202.65	133.01
19789	190.34	182.19
20183	107.45	87.41
20383	67.89	325.27
20918	112.85	131.28

21375	399.40	330.65
21437	191.23	175.69
21515	403.68	343.61
21938	297.74	301.07
21958	327.01	317.33
22259	454.19	397.35
22375	164.50	171.83
22806	130.53	138.06
22864	373.91	418.61
22867	212.25	166.89
22878	305.64	241.56
23346	238.37	196.78
23356	216.97	189.87
23516	256.86	235.70
23520	84.75	103.68
23528	402.00	422.63
23727	392.99	357.88
23853	192.51	178.48
24034	245.86	230.32
24075	186.02	187.02

D) Fine Lines and Wrinkles of the Chest Area by Clinical Grading

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

ID	Baseline	60 Minute
464	6.0	5.0
495	5.5	5.5
633	6.0	6.0
864	4.0	4.0
1298	6.5	5.5
3153	4.0	4.0
3445	6.5	6.5
4027	5.0	5.0
4127	5.5	5.5
5773	5.5	5.5
5774	5.0	5.0
7116	5.5	5.5
7379	5.0	5.0
7857	5.0	5.0
7957	4.5	4.5
8160	3.0	3.0
8225	5.0	4.5
8425	6.0	6.0
8426	4.5	4.0
8601	5.0	5.0
8657	4.0	4.0
8821	5.0	5.0
8831	4.0	4.0
8963	5.5	5.5
9049	3.0	3.0
10896	5.5	5.5
12887	5.0	5.0
13860	6.0	5.0
15308	4.0	4.0
15435	4.5	4.5
15684	2.0	2.0
16118	3.0	3.0
16472	3.5	3.5
17107	4.0	4.0
17733	5.0	5.0
17989	5.5	5.5
18891	5.5	5.0
19756	5.0	5.0
19789	4.0	4.0
20183	5.5	5.0
20383	3.5	3.5

20918	5.5	5.5
21375	6.0	5.5
21437	6.5	6.0
21515	5.5	5.5
21938	4.5	4.5
21958	5.5	5.5
22259	5.0	5.0
22375	5.0	5.0
22806	5.5	5.5
22864	5.5	5.5
22867	6.0	5.5
22878	5.0	5.0
23346	5.0	6.0
23356	4.5	4.5
23516	4.5	4.5
23520	5.0	4.5
23528	5.5	5.5
23727	3.0	3.0
23853	3.5	3.0
24034	4.0	4.0
24075	5.5	5.5

E) Post-Treatment Questionnaire

Scale: Questions #1-15: 1= Strongly Disagree, 2= Disagree, 3= Agree, 4= Strongly Agree

Questions #16-17: 1= Strongly Disagree, 2= Disagree, 3= Somewhat Agree, 4= Agree, 5= Strongly Agree

Questions #18: 1= The appearance of fine lines and wrinkles has improved dramatically, 2= The appearance of fine lines and wrinkles has improved noticeably, 3= The appearance of fine lines and wrinkles has improved somewhat, 4= The appearance of fine lines and wrinkles has not improved

Questions #19-20: 1= Yes, 2= No

ID	1. I like the way the product feels on my skin	2. The product was easy to apply	3. the product was comfortable to wear	4. The product was easy to remove	5. Fine lines and wrinkles around the eyes are visibly improved	6. Fine lines and wrinkles around the mouth are visibly improved	7. Fine lines and wrinkles around the forehead are visibly improved	8. Fine lines and wrinkles around the chest are visibly improved	9. My skin looks transformed	10. My skin looks younger	11. My skin looks smoother	12. My skin feels smoother	13. My skin feels softer	14. My skin looks revitalized	15. This product improves the way I feel about my skin	16. I prefer to use this treatment method (noninvasive) over any other anti-aging treatments like injections and surgery	17. The treatment seemed very easy to use	18. Which statement best describes your how your skin looks after using this product for this 1 hour test?	19. After this test, would you continue to use this product?	20. After this test, would you recommend this product to a friend or family member
464	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	5	2	1	1	
495	3	3	3	4	3	3	3	3	3	3	3	3	3	3	5	4	2	1	1	
633	4	4	4	4	4	4	4	4	4	3	3	3	3	3	4	5	5	2	1	1
864	3	3	3	3	2	3	3	3	3	3	3	4	4	4	4	5	4	2	1	1
1298	4	3	4	3	3	3	3	3	3	3	3	4	3	3	3	5	5	2	1	1
3153	3	3	3	3	3	4	4	4	3	3	3	3	3	3	2	4	4	3	1	1
3445	3	4	3	3	3	4	4	4	4	4	4	4	4	4	4	4	5	2	1	1
4027	3	4	3	3	3	3	3	3	3	3	3	3	3	3	3	5	5	3	1	1

4127	4	4	4	3	3	3	2	4	2	4	4	4	4	3	3	5	5	3	1	1
5773	3	4	3	3	3	3	3	3	3	3	4	4	3	3	3	5	5	2	1	1
5774	3	4	3	3	4	4	4	4	4	4	4	3	4	4	3	5	5	2	1	1
7116	2	3	2	2	3	2	2	2	2	2	2	3	2	2	2	3	3	4	2	2
7379	3	4	4	3	3	3	3	3	3	3	3	3	3	3	3	4	4	1	2	1
7857	4	4	3	3	3	3	3	3	3	3	4	4	4	3	4	5	5	2	1	1
7957	3	3	2	3	3	3	2	3	3	3	3	3	3	3	3	5	5	2	1	1
8160	3	3	3	3	4	4	3	3	2	2	3	3	3	3	3	4	5	3	1	1
8225	4	4	3	3	4	4	4	4	3	3	4	4	3	3	3	5	4	2	1	1
8425	4	4	4	4	2	3	3	2	2	4	4	4	4	4	4	4	4	3	1	1
8426	3	4	4	4	3	3	3	3	3	3	3	3	3	3	3	4	5	3	1	1
8601	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	4	5	2	1	1
8657	4	4	4	3	3	3	3	3	3	4	4	4	4	4	3	5	5	2	1	1
8821	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	5	5	3	1	1
8831	4	4	4	4	4	3	4	3	3	3	4	4	4	3	3	5	5	2	1	1
8963	4	4	4	4	4	4	4	4	3	3	3	3	3	3	3	5	4	2	1	1
9049	3	4	4	2	2	2	3	3	2	2	3	3	3	3	2	5	5	3	1	1
10896	3	3	3	2	3	2	3	2	3	2	2	3	3	2	3	5	4	3	1	1
12887	3	3	3	3	3	2	3	3	2	2	3	3	3	3	3	5	5	3	1	2
13860	4	4	4	4	3	3	3	4	4	4	4	4	4	4	4	5	5	2	1	1
15308	3	3	3	3	3	3	3	3	3	3	3	3	4	4	3	4	4	2	1	1
15435	3	3	3	1	3	2	2	3	2	2	3	2	2	2	2	3	3	4	1	1
15684	3	3	3	2	4	4	4	4	3	4	4	4	4	3	3	5	4	2	1	1
16118	3	2	3	2	3	3	3	3	3	3	3	3	3	3	3	4	3	3	1	1
16472	4	4	4	4	3	3	3	3	3	3	4	4	4	4	4	5	5	2	1	1
17107	3	4	4	4	3	3	3	3	3	3	4	4	4	3	4	4	5	2	1	1
17733	3	3	3	2	1	2	2	2	2	2	2	2	2	2	2	3	4	4	2	2
17989	3	3	3	3	3	3	3	3	3	3	3	4	4	3	3	4	4	2	1	1
18891	2	2	2	2	2	2	2	2	2	2	3	2	2	2	2	4	3	4	2	2
19756	3	4	3	3	3	3	3	3	2	2	3	3	2	2	3	5	5	3	1	1
19789	4	3	4	3	4	4	4	4	4	3	4	4	4	3	4	5	5	1	1	1

20183	3	3	3	3	4	4	4	4	4	4	4	3	4	4	4	4	1	1	1	
20383	3	3	3	3	3	3	4	4	2	3	3	3	4	3	3	5	4	2	1	1
20918	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	4	4	2	1	1
21375	4	4	4	4	4	4	4	4	4	4	4	4	4	4	4	5	5	1	1	1
21437	2	3	2	3	2	2	2	2	2	2	2	2	2	2	2	2	4	4	1	2
21515	3	3	3	1	3	2	3	3	2	2	3	3	3	2	2	2	4	3	2	2
21938	3	3	3	1	2	2	3	2	2	2	2	3	3	2	2	5	5	4	1	2
21958	4	3	3	4	4	4	4	3	3	4	4	4	3	4	4	5	5	2	1	1
22259	4	4	4	3	3	3	3	4	3	3	3	3	3	3	3	5	5	2	1	1
22375	3	3	3	3	3	3	3	3	3	3	3	4	4	3	3	5	5	2	1	1
22806	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	2	1	1
22853	2	3	2	3	4	2	2	3	2	2	2	3	3	3	2	3	5	3	2	2
22864	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	5	4	3	1	1
22867	4	3	3	4	3	3	3	3	2	2	2	3	3	2	2	4	4	3	1	1
22878	4	4	4	4	2	2	3	3	3	2	2	2	2	2	2	4	5	4	1	1
23346	3	3	3	3	2	2	4	2	2	2	3	3	3	2	2	3	2	3	2	2
23356	4	4	4	4	3	3	3	4	3	3	3	3	3	3	3	5	5	2	1	1
23516	2	3	2	2	3	3	3	3	2	2	3	3	3	2	2	2	3	3	2	2
23520	3	4	4	4	4	4	4	3	4	3	4	4	4	4	3	4	5	1	1	1
23528	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	4	3	3	1	1
23727	3	3	3	3	4	4	4	4	3	3	4	4	4	4	4	4	4	2	1	1
24034	4	4	4	3	2	2	3	3	2	3	3	3	3	3	3	4	4	3	1	1
24075	3	3	3	3	3	3	3	3	2	3	3	2	2	2	2	4	4	2	1	1



Jordan DeSantis
Clinical Supervisor



Steve Park
QA Analyst II