A 12-Week Clinical Study Evaluating the Efficacy and Tolerance of a Skin Lightening Regimen

Protocol Number:	4043FBS0616
Sponsor:	Flawless Beauty and Skin
Issued To:	Jack Gindi Flawless Beauty and Skin 1750 Brielle Avenue, Suite A4 Ocean Twp., NJ 07712 Phone: 917.831.5948 E-Mail: jack@flawlessbeautyandskin.com
	In Copy: Laurence Gindi E-Mail: laurence@flawlessbeautyandskin.com
Date of Issue:	February 2, 2017
Study Site:	International Research Services, Inc. 222 Grace Church Street Port Chester, NY 10573 Phone: 914.937.6500 Fax: 914.937.8067
	Stephen R. Schwartz IRSI President, CEO E-Mail: sschwartz@irsi.org
Principal Investigator:	Robert J. Frumento IRSI VP Clinical Operations E-Mail: rfrumento@irsi.org
Study Coordinator:	Anna Gafner, CCRC E-Mail: agafner@irsi.org
Institutional Review Board:	Allendale Institutional Review Board

			Group 1	Group 2
Study Schedule	Initiation	Screening	August 31, 2016	September 16, 2016
	Completion	Week 12	November 22, 2016	December 9, 2016

Products: Relumins regimen: Advanced Derm 1650mg Gluta Complex #RL-DERM1650, Advance White Vitamin C MAX Complex #RL-VITAMINCMAX-60, TA Stem Cell Intensive Repair Soap #RL-STMCLWHITESOAP, TA Stem Cell Intensive Repair Lotion #RL-STEMCLRPRLTN-30, TA Stem Cell Intensive Repair Serum #RL-INTENSIVEREPAIRSERUM, TA Stem Cell Intensive

Repair Solution # RL-INTENSIVEREPAIRSOLUTION, TA Stem Cell Intensive Repair Weightless Day Cream (SPF) # RL-WEIGHTLESSCRM

Study Summary			
Title	A 12-Week Clinical Study Evaluating the Efficacy and Tolerance of a Skin Lightening Regimen		
Protocol Number	4043FBS0616		
Sponsor	Flawless Beauty and Skin		
Methodology	Monadic		
Objective	To evaluate the efficacy and tolerance of a regimen of products designed to improve the appearance and condition of skin.		
Number of Subjects	30 to complete, *target enrollment 35*		
Target Population	Female and male subjects, age 30-65 years old		
Duration	12 Weeks (Baseline, Week 4, Week 8, Week 12)		
Claims	***Claim***	***Support***	
	Lightens and brightens skin	Clinical Grading, Chromameter Clarity™ Image Analysis Subjective Questionnaire	
	Deep skin lightening		
	Improves the appearance of dark spots, discolorations		
	Improves skin tone evenness, homogeneity		
	Helps achieve a healthy, even glow (radiance/luminosity)	Clinical Grading, Subjective Questionnaire	
	Improves overall youthful appearance		
	Hydrates skin	Corneometer Subjective Questionnaire	
	Decreases melanin content	SIAScope	
	Exfoliates	D-Squame	
	Minimizes pore appearance	Clinical Grading, Clarity™ Image Analysis Subjective Questionnaire	
	Provides anti-aging benefits (lines/wrinkles, skin texture/smoothness, firmness and elasticity)	Clinical Grading, Cutometer (firmness/elasticity) Subjective Questionnaire	
Study Product	***Name***	***Formula/Product Number***	
	Relumins: Advanced Derm 1650mg Gluta Complex Advance White Vitamin C MAX Complex TA Stem Cell Intensive Repair Soap TA Stem Cell Intensive Repair Lotion TA Stem Cell Intensive Repair Serum TA Stem Cell Intensive Repair Solution TA Stem Cell Intensive Repair Weightless Day Cream (SPF)	 RL-DERM1650 RL-VITAMINCMAX-60 RL-STMCLWHITESOAP RL-STEMCLRPRLTN-30 RL-INTENSIVEREPAIRSERUM RL-INTENSIVEREPAIRSOLUTION RL-WEIGHTLESSCRM	
Statistical Methodology	Descriptive statistics reported, monadic analysis using paired t-test to compare immediate results to baseline. Response frequency tables and percent positive responses will be reported for questionnaire data. All final statistical analyses will be performed on the PP population, significance set at $p \leq 0.05$.		
Study Schedule		**Group 1**	**Group 1**
	Initiation Baseline	August 31, 2016	September 16, 2016
	Interim Week 4	September 28, 2016	October 14, 2016
	Interim Week 8	October 26, 2016	November 11, 2016
	Completion Week 12	November 22, 2016	December 9, 2016

Summary	This was a 12-week, monadic evaluation of one product regimen's effects on facial skin appearance and condition, and to assess product tolerance in the subject population. A total of 35 subjects were enrolled in the study and 30 completed participation. Under the conditions of this study, use of the product regimen including **Relumins regimen: Advanced Derm 1650mg Gluta Complex #RL-DERM1650, Advance White Vitamin C MAX Complex #RL-VITAMINCMAX-60, TA Stem Cell Intensive Repair Soap #RL-STMCLWHITESOAP, TA Stem Cell Intensive Repair Lotion #RL-STEMCLRPRLTN-30, TA Stem Cell Intensive Repair Serum #RL-INTENSIVEREPAIRSERUM, TA Stem Cell Intensive Repair Solution # RL-INTENSIVEREPAIRSOLUTION, TA Stem Cell Intensive Repair Weightless Day Cream (SPF) # RL-WEIGHTLESSCRM** provided significant improvements in skin condition and appearance. All test products were well-tolerated in the subject population and consumer questionnaire results revealed significantly positive perception of product effects. See Sections 19.2, Discussion, and 20.0, Conclusion, for further detail.

Quality Assurance Statement

This report accurately reflects the data derived from the procedures and materials tested in this study. The conclusions are based on an interpretation of the data and have been reviewed by the Principal Investigator(s) and by personnel from International Research Services, Inc. responsible for assuring its accuracy.

Quality Assurance:	Kimberly A. Hammon Director of Quality Assurance E-mail: khammon@irsi.org	Signature and Date:
Principal Investigator:	Robert J. Frumento IRSI VP Clinical and Corporate Operations E-Mail: rfrumento@irsi.org	Signature and Date:
IRSI President, CEO:	Stephen R. Schwartz IRSI President, CEO E-Mail: sschwartz@irsi.org	Signature and Date:

Table of Contents

Appendices

List of Abbreviations

AE	Adverse Event
BL	Baseline
cm	centimeters
CRFs	Case Report Forms
e.g.	for example
etc.	etcetera
FDA	Federal Drug Administration
hr	hour
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IRSI	International Research Services, Inc.
mm	millimeters
PI	Principal Investigator
PP	Per protocol
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SPF	Sun Protective Factor
Sponsor	Flawless Beauty and Skin
VAS	Visual Analog Scales
Wx	Weeks after study Baseline, where "x" refers to a number

1.0 Introduction

This document is a report for a human research study. This study was conducted according to International Research Services, Inc. research policies and Standard Operating Procedures, U.S. and international standards of Good Clinical Practice (FDA and ICH guidelines) and applicable government regulations.

2.0 Objectives

2.1Primary Objective

To evaluate the effects of a regimen of seven products on skin condition and appearance.

3.0 Study Design

This was a 12-week, monadic evaluation of the performance of a regimen with regard to its effects on skin condition and appearance. The test regimen was used repeatedly by each subject per Sponsor instructions for 12 weeks. Product effects were determined from analysis of results from clinical visual grading, instrumental assessment, photographic image analysis and subjective questionnaires. Product tolerance was determined from analysis of results from objective and subjective grading of key indicators. Thirty (30) subjects completed study participation.

Evaluation points occurred pre-use (Baseline or BL), and at Weeks 4, 8 and 12 (W4, W8, W12). A detailed outline of study visits appears in Section 7.6 of the protocol. (Appendix I)

3.1 Claims:

Data were collected and analyzed with specific regard to the following proposed product claims:

1. **Lightens and brightens skin**, as assessed by clinical visual grading, Chroma Meter assessments, Clarity™ image analysis and subjective questionnaire results.
2. **Deep skin lightening**, as assessed by Clarity™ image analysis of sub-surface pigmentation.
3. **Improves the appearance of dark spots, discolorations**, as assessed by clinical visual grading, Chroma Meter assessments, Clarity™ image analysis and subjective questionnaire results.
4. **Improves skin tone evenness, homogeneity**, as assessed by clinical visual grading, Chroma Meter assessments, Clarity™ image analysis and subjective questionnaire results.
5. **Helps achieve a healthy even glow (radiance/ luminosity)**, as assessed by clinical visual grading and subjective questionnaire results.
6. **Improves overall youthful appearance**, as assessed by clinical visual grading and subjective questionnaire results.
7. **Hydrates the skin**, as assessed by Corneometer assessments and subjective questionnaire results.
8. **Decreases melanin content**, as assessed by SIAScope results.
9. **Exfoliates**, as assessed by D-Squame results.
10. **Minimizes pore appearance**, as assessed by clinical visual grading, Clarity™ image analysis and subjective questionnaire results.
11. **Provides anti-aging benefits (lines and wrinkles, skin smoothness/texture, firmness/elasticity)**, as assessed by clinical visual grading, Cutometer (firmness/elasticity) and subjective questionnaire results.

4.0 Product

All products were provided by the Sponsor and were labeled with appropriate codes and proper use instructions. Upon receipt, product was logged in and stored in a secure area. Within one month of issuance of the final signed report, unless otherwise instructed in writing, all test products, used and unused, will be destroyed and disposed of in accordance with IRSI's SOP.

4.1Product Descriptions

Name	Designation	Product/Formula Number	Date Received	Quantity Received
Study Product				
Relumins: Advanced Derm 1650mg Gluta Complex	Capsule A	RL-DERM1650	8/10/2016	42
			10/10/2016	75
Advance White Vitamin C MAX Complex	Capsule B	RL-VITAMINCMAX-60	8/10/2016	35
TA Stem Cell Intensive Repair Soap	Cleanser	RL-STMCLWHITESOAP	8/10/2016	70
TA Stem Cell Intensive Repair Lotion	Lotion	RL-STEMCLRPRLTN-30	8/10/2016	70
TA Stem Cell Intensive Repair Serum	Serum	RL-INTENSIVEREPAIRSERUM	8/10/2016	70
TA Stem Cell Intensive Repair Solution	Solution	RL-INTENSIVEREPAIRSOLUTION	8/10/2016	70
TA Stem Cell Intensive Repair Weightless Day Cream (SPF)	SPF Cream	RL-WEIGHTLESSCRM	8/10/2016	35
			10/10/2016	35

4.2Product Use Instructions

Sponsor-provided use instructions were explained to subjects and provided to subjects in writing. All subjects were assigned all seven test regimen products.

Test Regimen Directions:

Morning:
1. Take 1 Relumins Derm 1650mg capsule before breakfast
2. Take 2 Relumins Vitamin C Capsules before breakfast
3. Cleanse face & body with Repair Soap
4. Apply Repair Solution to face
5. Apply Weightless Day Cream to face
6. Apply Intensive Repair Lotion to body

Evening:
1. Take 2 Derm 1650mg capsule before dinner
2. Cleanse face & body with Repair Soap
3. Apply Repair Solution to face
4. Apply Repair Serum to face
5. Apply Repair Lotion to body

INDIVIDUAL INSTRUCTIONS:

1. **Relumins Advanced Derm 1650mg Gluta Complex** – take 3 capsules per day, preferably before breakfast and dinner.
2. **Relumins Advance White Vitamin C MAX Complex** – take 2 capsules per day, before breakfast
3. **Relumins TA Stem Cell Intensive Repair Soap** - Lather soap and apply to treatment areas. Leave the soap on for no longer than 30 seconds. Rinse first with warm water followed by a cold water rinse to tighten pores. Apply once per day and increase to twice a day if well tolerated (after week 1). Can increase to 1-2 minutes per treatment time according to toleration.
4. **Relumins TA Stem Cell Intensive Repair Lotion** - Apply liberally all over the body, ideally after shower or bath on damp skin for best skin softening and sealing in moisture.
5. **Relumins TA Stem Cell Intensive Repair Serum** - Apply serum, first dabbing extra serum on hyperpigmented areas or dark spots, then applying the rest over the face/neck with gentle upward circular motions.
6. **Relumins TA Stem Cell Intensive Repair Solution** - Apply directly on face, moving outward up and under chin and neck. Use AM and PM.
7. **Relumins TA Stem Cell Intensive Repair Weightless Day Cream** (SPF)- Apply cream, first dabbing extra cream on hyperpigmented areas or dark spots, then applying the rest over the face/neck with gentle upward circular motions.

5.0 Population

5.1Sample Size

The sample size of n=30 was requested by the Sponsor.
A total of 35 subjects were enrolled in the study and 30 subjects completed participation.

5.2Inclusion Criteria

1. Females and Males in good general health, and between ages of 30 and 65 years old, inclusive at enrollment
2. Uneven skin tone, dark spots, visible pores, and lines/wrinkles as determined by expert grader at Baseline
   a. Score of ≥2 on 10 cm VAS for skin tone/evenness
   b. Score of ≥2 on 5 point ordinal scale for dark spots
   c. Score of ≥2 on 10 cm VAS for pore appearance
   d. Score of ≥2 and ≤7 on 10 cm VAS for lines/wrinkles (crow's feet)
3. Able to read, understand and sign an informed consent form (includes HIPAA and State requirements)
4. Willing to be photographed and sign photograph (model) release form
5. Willing and able to follow all study directions, attend study visits as scheduled and must be willing to accept the restrictions of the study, including but not limited to:
   a. Arrive at each visit with clean facial skin, having cleansed within one hour of the study visit and having applied no topical products.

b. Refrain from using self-tanning products on the face and body for the duration of the study.
c. Refrain from excessive sun exposure for the purpose of tanning the duration of the study.

5.3Exclusion Criteria

1. Subjects with sunburn or deep tan on the face or body.

General exclusion criteria:

2. Subjects participating in any other clinical studies
3. Subjects having an acute or chronic disease or medical condition, including dermatological problems, which could put her at risk in the opinion of the Principal Investigator or compromise study outcomes. Typical uncontrolled chronic or serious diseases and conditions which would prevent participation in any clinical trial are cancer, AIDS, diabetes, morbid obesity, renal impairment, mental illness, drug/alcohol addiction.
4. Subjects who are unreliable or unlikely to be available for the duration of the study
5. History of allergic reactions, skin sensitization and/or known allergies to cosmetic ingredients, toiletries, sunscreens, etc.
6. Immunocompromised subjects
7. Woman who started Hormone Replacement Therapy within the last three months preceding the screening visit
8. Woman using oral contraception for less than three months before the screening visit or who has changed her contraceptive method within the three months before the Baseline visit or planning to modify her contraception treatment within the duration of the study
9. Woman known to be pregnant, lactating or planning to become pregnant within six months. Subjects who become pregnant during the study must inform the Principal Investigator immediately
10. Individuals unable to communicate or cooperate with the Principal Investigator due to language problems, poor mental development, or impaired cerebral function
11. Employees of IRSI or other testing firms/ laboratories, cosmetic or raw goods manufacturers or suppliers

6.0 Methods

This study was performed in accordance to IRSI final signed clinical study protocol number 4043FBS0616 version 2.1 dated July 19, 2016. A detailed description of study methods is outlined in the attached clinical study protocol (*See* Appendix I).

7.0 Procedure

This four-visit clinical study included one visit for consenting, screening and qualification procedures and Baseline assessments, plus visits at Weeks 4, 8 and 12. A detailed description of procedures is outlined in the attached clinical study protocol (*See* Appendix I).

7.1Procedure Summary Table

Procedures		Baseline	Week 4	Week 8	Week 12
Study Initiation and Qualification	Informed Consent and Medical History	X			
	Inclusion/Exclusion Criteria reviewed	X			
Dispense / collect products D/C		D			C
Tolerance Grading	Objective (erythema, edema, dryness) Subjective (stinging, tingling, itching, burning)	X	X	X	X
Clinical Grading	- brightening/ lightening - intensity dark spots (discolorations) - skin tone (evenness) -radiance/luminosity - pore appearance - lines/wrinkles - skin texture/ smoothness *(tactile)* - firmness - elasticity (tactile) -overall youthful appearance	X	X	X	X
Instrumentation	-Corneometer *(hydration)* -Cutometer *(firmness, elasticity)* -D-Squame -Chromameter *(pigmented and non-pigmented spot)*	X	X	X	X
	-SIAScope *(Melanin)*	X		X	X
Photography	Clarity 2D Research Ti *(R, L, C view, standard, cross polarized, blue light) – N= 10*	X	X	X	X
Image Analysis	- Dark Spots, sub-surface spots - Skin Color (L*a*b*), homogeneity -Pores - Lines and Wrinkles *(Crow's feet)*	X	X	X	X
Consumer Perception	Subjective Questionnaire		X	X	X
Laboratory	Blood Draw, Glutathione n=20	X			X

8.0 Concomitant Medications and Products

The use of any topical skin treatment products on the face, other than those assigned for study purposes, was prohibited during the washout and study periods. This included, but was not limited to serums, moisturizers, cleansers and medicated creams.

9.0 Adverse Events

One adverse event was reported during the conduct of this study.

Subject #24 reported moderate intermittent headaches which lasted approximately eight hours daily. The subject reported on September 9, 2016 that headaches began on September 1, coinciding with the first dose of study product, and lasted until study product dosing was interrupted on September 9. Subject discontinued the study on September 13. Relationship of this AE to study product was deemed "Possible" by the PI.

10.0 Institutional Review Board

This study was overseen by an independent Institutional Review Board (IRB) to ensure the protection of the rights, safety and well-being of subjects. Prior to study initiation, the IRB reviewed and approved the study protocol (and subsequent amendments); methods and materials used in obtaining and documenting informed consent of the subjects. IRB approval letter appears in Appendix V.

IRB Information:
Name: Allendale Institutional Review Board
Address: 30 Neck Road, Old Lyme, CT 06371
Phone: 800.434.5892
E-Mail: Rta1ali@aol.com

11.0 Informed Consent

The informed consent process was completed prior to an individual's involvement in any study related activity. The process was documented using a written informed consent form (ICF) conforming to FDA 21 CFR 50.25 (See Appendix I Protocol, Section 11.0 and Appendix IV).

After review, two copies of the ICF were signed and dated by the individual and the Principal Investigator or his designee administering the consent. One original copy was retained by IRSI and the other was given to the individual.

12.0 Discontinuation of Study

The study was completed on schedule as per the clinical study protocol.

13.0 Changes to the Protocol

13.1 Protocol Amendments

One amendment was made to the signed protocol. See Appendix II for signed amendment forms.

1. An additional enrollment group was added in order to meet the required study population quota.

13.2 Protocol Deviations

Four protocol deviations were noted during the study. See Appendix III for signed deviation forms.

1. Minor: Subject #30 did not have Baseline burning assessed and is not included in the analysis for this subjective tolerance parameter.
2. Minor: Subject #5 did not have clarity at the Week 12 visit due to facial bruising
3. Minor: Subject #23 did not have Cutometer assessments at Week 4.
4. Minor: A total of 18 subjects had completed in the blood draw subgroup.

14.0 Monitoring

The Sponsor did not monitor any portion of this study.

15.0 Recording of Data

All data and information, except electronically recorded data where applicable, was recorded on specific paper case report forms (CRFs) as described in the clinical study protocol (*See* Appendix I Protocol, Appendix III).

16.0 Quality Control and Quality Assurance

This clinical study has been audited by the IRSI Quality Assurance / Quality Control auditor. The auditor verified study for accuracy, consistency and proper documentation in accordance to IRSI SOPs and practices. Additionally, accuracy of results reported in the body of this report with respect to the results reported in the data listings and statistical report (See Appendix II).

The data listings and database used for statistical analysis was verified against the CRFs. The data listings were verified against the CRFs for 100% of the data, in a randomly selected set of the subjects (25% of the total number of subjects). The statistical report was validated for accuracy and completeness, as well as verifying the correctness of all subject numbers (n) and the analyses performed according to the Statistical Analysis Plan as described in Section 18 of the clinical study protocol.

17.0 Ethics

The study was conducted in accordance with FDA GCP regulations and ICH guidelines in as much as they apply to cosmetic research with the following noted: This was not an IND / NDA clinical trial. IRSI does not assume any Sponsor obligations as stipulated in FDA GCP and ICH documents. This study is not intended for submission to the FDA.

18.0 Statistical Methods

The planned statistical analysis was performed as outlined in the study protocol for each type of data to be acquired (*See* Protocol, Section 18.0).

The per-protocol (PP) population is defined as the subset of subjects that who complied with the protocol sufficiently to ensure that their data will be likely to exhibit the effects of the treatment. To be considered a PP subject a subject could not miss the Baseline or W12 visit or be found to be non-compliant with the study protocol at the discretion of the Principal Investigator (PI).

The PP population was used for statistical analysis at each time point. Statistical significance was set at $p \leq 0.05$.

Data Type	Statistical Method	Data Reported
Demographics	Descriptive Statistics	Mean and standard deviation Min and Max Frequency (number and percent)
Tolerance Grading	Descriptive Statistics Paired T-test (monadic)	Mean and standard deviation Frequency (number and percent) P-value vs. Baseline (significance $p \leq 0.05$)
Clinical Grading, Instrumental Assessments, Image Analysis	Descriptive Statistics Paired T-test (monadic)	Mean and standard deviation Mean percent improvement from Baseline Percent of subjects improving P-value vs. Baseline (significance $p \leq 0.05$)
Subjective Questionnaire	Descriptive Statistics	Frequency (n,%) will be provided for each response Percent of positive response will be provided

19.0 Results

19.1 Tables

Enrollment and demographic information is reported below in Tables 1.0-2.1. Tolerance evaluation results are in Tables 3.0-3.1, expert clinical grading results are included in Table 4.0, Clarity™ image analysis results are included in Table 5.0, instrumental assessment results are in Tables 6.0-6.4, laboratory results are in Table 7.0, D-Squame results are in Table 8.0 and subjective questionnaire results are found in Table 9.0.

Table 1.0 Enrollment

Status	n	
Enrolled	35	
Discontinued	5	Subject #'s 11, 15, 20, 24, and 29 discontinued at Week 4.
Completed Baseline Time Point	30	
Completed Week 4 Time Point	30	
Completed Week 8 Time Point	29	Subject #21 missed the Week 8 visit.
Completed Week 8 Time Point	30	

Table 2.0 Demographics

Variable	n	Mean ± SD	Min	Max
Age (years)	30	54.70 ± 8.19	34	65
Height (inches)	30	64.68 ± 3.12	59	73
Weight (pounds)	30	167.86 ± 42.64	108	268
			n	**Percent**
Sex	30	Female	27	90.0%
		Male	3	10.0%
			n	**Percent**
Ethnicity	30	Hispanic or Latino	2	6.7%
		Not Hispanic or Latino	28	93.3%
			n	**Percent**
Race	30	Asian	1	3.3%
		Black or African American	7	23.3%
		White	21	70.0%
		No Response *See Hispanic or Latino above*	1	3.3%
			n	**Percent**
Fitzpatrick Skin Type	30	Skin Type II	4	13.3%
		Skin Type III	15	50.0%
		Skin Type IV	6	20.0%
		Skin Type V	3	10.0%
		Skin Type VI	2	6.7%
			n	**Percent**
Facial Skin Type	30	Combination	14	46.7%
		Dry	4	13.3%
		Normal	12	40.0%
			n	**Percent**
Body Skin Type	30	Dry	8	26.7%

		Normal	21	70.0%
		Very Dry	1	3.3%

Table 3.0 Tolerance Evaluation – Monadic, comparison to Baseline

Assessment	Time Point	n	Mean ± SD	P-Value *TX vs. BL*
OBJECTIVE TOLERANCE				
Dryness	Baseline	30	0.23 ± 0.43	
	Week 4	30	0.23 ± 0.50	1.000
	Week 8	29	0.27 ± 0.52	0.663
	Week 12	30	0.20 ± 0.48	0.712
Erythema	Baseline	30	0.16 ± 0.37	
	Week 4	30	0.23 ± 0.43	0.423
	Week 8	29	0.13 ± 0.35	0.573
	Week 12	30	0.13 ± 0.34	0.326
Edema	Baseline	30	0.00 ± 0.00	
	Week 4	30	0.00 ± 0.00	NA
	Week 8	29	0.00 ± 0.00	NA
	Week 12	30	0.00 ± 0.00	NA
SUBJECTIVE TOLERANCE				
Stinging	Baseline	30	0.00 ± 0.00	
	Week 4	30	0.00 ± 0.00	NA
	Week 8	29	0.00 ± 0.00	NA
	Week 12	30	0.00 ± 0.00	NA
Tingling	Baseline	30	0.00 ± 0.00	
	Week 4	30	0.00 ± 0.00	NA
	Week 8	29	0.00 ± 0.00	NA
	Week 12	30	0.00 ± 0.00	NA
Itching	Baseline	30	0.00 ± 0.00	
	Week 4	30	0.00 ± 0.00	NA
	Week 8	29	0.00 ± 0.00	NA
	Week 12	30	0.00 ± 0.00	NA
Burning	Baseline	29^	0.00 ± 0.00	
	Week 4	29^	0.00 ± 0.00	NA
	Week 8	28^	0.10 ± 0.56	0.326
	Week 12	29^	0.13 ± 0.58	0.212

NA = No variance, no p-value calculated

^One subject (#30) did not have burning data at baseline, and was not included in the analysis (29 subjects analyzed).

Table 3.1 Tolerance Evaluation – Frequency Table

Assessment	Time Point	n	Frequency of Score n (%)				
			0	1	2	3	
OBJECTIVE TOLERANCE							
Dryness	Baseline	30	23 (76.7%)	7 (23.3%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	24 (80.0%)	5 (16.7%)	1 (3.3%)	0 (0.0%)	
	Week 8	29	22 (75.9%)	6 (20.7%)	1 (3.4%)	0 (0.0%)	
	Week 12	30	25 (83.3%)	4 (13.3%)	1 (3.3%)	0 (0.0%)	
Erythema	Baseline	30	25 (83.3%)	5 (16.7%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	23 (76.7%)	7 (23.3%)	0 (0.0%)	0 (0.0%)	
	Week 8	29	25 (86.2%)	4 (13.8%)	0 (0.0%)	0 (0.0%)	
	Week 12	30	26 (86.7%)	4 (13.3%)	0 (0.0%)	0 (0.0%)	
Edema	Baseline	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 8	29	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 12	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
SUBJECTIVE TOLERANCE							
Stinging	Baseline	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 8	29	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 12	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Tingling	Baseline	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 8	29	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 12	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Itching	Baseline	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 4	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 8	29	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 12	30	30 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Burning	Baseline	29^	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 4	29^	29 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	
	Week 8	28^	27 (96.4%)	0 (0.0%)	0 (0.0%)	1 (3.6%)	
	Week 12	29^	27 (93.1%)	1 (3.4%)	0 (0.0%)	1 (3.4%)	

^One subject (#30) did not have burning data at baseline, and was not included in the analysis (29 subjects analyzed).

Table 4.0 Expert Clinical Grader Evaluation – Monadic, Comparison to Baseline

Assessment	Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Lines/Wrinkles (Crow's Feet)	Baseline	30	4.44 ± 1.32			
	Week 4	30	4.04 ± 1.23	7.67%	66.7%	**0.007***
	Week 8	29	3.91 ± 1.14	8.71%	72.4%	**0.004***
	Week 12	30	3.79 ± 1.14	12.76%	83.3%	**<0.001***
Brightening/Lightening	Baseline	30	5.15 ± 1.23			
	Week 4	30	4.55 ± 1.10	10.09%	83.3%	**<0.001***
	Week 8	29	4.21 ± 1.07	16.32%	93.1%	**<0.001***
	Week 12	30	4.06 ± 1.00	19.52%	90.0%	**<0.001***
Skin Tone/Evenness	Baseline	30	5.60 ± 0.78			
	Week 4	30	5.10 ± 0.88	9.07%	90.0%	**<0.001***
	Week 8	29	4.61 ± 0.86	17.90%	100%	**<0.001***
	Week 12	30	4.47 ± 0.79	19.75%	96.7%	**<0.001***
Radiance/Luminosity	Baseline	30	4.97 ± 1.09			
	Week 4	30	4.48 ± 0.92	8.79%	90.0%	**<0.001***
	Week 8	29	4.24 ± 0.80	12.43%	82.8%	**<0.001***
	Week 12	30	4.08 ± 0.82	16.55%	86.7%	**<0.001***
Pores	Baseline	30	4.91 ± 1.22			
	Week 4	30	4.73 ± 1.31	3.15%	53.3%	0.151
	Week 8	29	4.30 ± 1.15	12.94%	86.2%	**<0.001***
	Week 12	30	4.04 ± 1.14	17.21%	86.7%	**<0.001***
Texture/Smoothness (Tactile)	Baseline	30	4.44 ± 1.28			
	Week 4	30	3.91 ± 1.28	11.10%	73.3%	**0.001***
	Week 8	29	3.45 ± 1.14	21.67%	89.7%	**<0.001***
	Week 12	30	3.07 ± 1.00	28.88%	96.7%	**<0.001***
Firmness	Baseline	30	4.58 ± 1.32			
	Week 4	30	4.35 ± 1.16	3.57%	63.3%	**0.023***
	Week 8	29	4.06 ± 1.02	8.81%	79.3%	**<0.001***
	Week 12	30	3.74 ± 0.93	15.51%	76.7%	**<0.001***
Elasticity (Tactile)	Baseline	30	4.40 ± 0.87			
	Week 4	30	4.07 ± 0.81	6.80%	80.0%	**0.002***
	Week 8	29	3.81 ± 0.83	11.47%	79.3%	**0.001***
	Week 12	30	3.54 ± 0.91	18.42%	86.7%	**<0.001***
Overall Youthful Appearance	Baseline	30	5.19 ± 1.10			
	Week 4	30	4.54 ± 1.08	11.99%	86.7%	**<0.001***
	Week 8	29	4.18 ± 0.95	18.61%	96.6%	**<0.001***
	Week 12	30	3.95 ± 0.84	22.86%	93.3%	**<0.001***
Intensity of Dark Spots	Baseline	30	2.91 ± 0.64			
	Week 4	30	2.71 ± 0.63	6.53%	33.3%	**0.001***
	Week 8	29	2.41 ± 0.53	15.94%	69.0%	**<0.001***
	Week 12	30	2.25 ± 0.58	22.20%	80.0%	**<0.001***

*Indicates a statistically significant improvement compared to baseline, $p \leq 0.05$

Table 5.0 Clarity 2D – Monadic, Comparison to Baseline

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Lines/ Wrinkles Crow's Feet	Average Length (Pixels)	Baseline	12	117.63 ± 63.01			
		Week 4	12	115.66 ± 37.97	1.89%	75.0%	0.672
		Week 8	12	106.90 ± 29.77	8.58%	83.3%	**0.023**
		Week 12	11^	105.33 ± 30.46	11.90%	100%	**<0.001***
	Average Width (Pixels)	Baseline	12	24.22 ± 2.01			
		Week 4	12	23.91 ± 2.15	1.31%	66.7%	**0.046***
		Week 8	12	23.91 ± 1.97	1.21%	75.0%	0.231
		Week 12	11^	22.73 ± 2.05	5.20%	100%	**0.001***
	Average Wrinkles Severity	Baseline	12	4767.40 ± 1074.01			
		Week 4	12	4660.21 ± 999.89	1.95%	66.7%	**0.035***
		Week 8	12	4515.65 ± 1064.46	4.85%	75.0%	0.128
		Week 12	11^	4265.22 ± 965.78	8.8%	100%	**0.004**
	Total Wrinkle Count	Baseline	12	53.42 ± 16.24			
		Week 4	12	49.00 ± 14.73	8.20%	91.7%	**0.002***
		Week 8	12	47.42 ± 14.80	11.16%	91.7%	**0.001***
		Week 12	11^	42.73 ± 13.93	18.10%	100%	**<0.001***
	Fine Lines Count	Baseline	12	23.33 ± 12.69			
		Week 4	12	21.08 ± 13.28	11.59%	58.3%	0.062
		Week 8	12	21.25 ± 14.28	11.75%	75.0%	0.147
		Week 12	11^	18.64 ± 11.94	16.91%	81.8%	**0.008***
	Deep Lines Count	Baseline	12	4.58 ± 4.40			
		Week 4	12	4.17 ± 4.80	20.76%	33.3%	0.175
		Week 8	12	3.75 ± 4.39	29.39%	41.7%	**0.034***
		Week 12	11^	3.55 ± 4.08	31.82%	72.7%	**0.003***
	Emerging Lines Count	Baseline	12	25.50 ± 13.90			
		Week 4	12	23.25 ± 13.75	4.33%	66.7%	0.274
		Week 8	12	25.00 ± 12.22	NI	50.0%	0.855
		Week 12	11^	25.27 ± 14.16	NI	27.3%	0.804
Surface Spots	Surface Area Affected	Baseline	12	39547.01 ± 19973.00			
		Week 4	12	38506.86 ± 19443.37	0.51%	50.0%	0.898
		Week 8	12	37686.09 ± 19201.56	5.55%	81.8%	0.818
		Week 12	11^	37535.08 ± 21266.33	3.57%	80.0%	0.818
	Pigment Intensity	Baseline	12	91.73 ± 17.78			
		Week 4	12	86.63 ± 18.36	5.94%	100%	0.497
		Week 8	12	83.58 ± 18.26	9.25%	100%	0.280
		Week 12	11^	77.10 ± 19.16	17.36%	100%	0.073
	Spot Count	Baseline	12	76.59 ± 29.04			
		Week 4	12	72.49 ± 28.15	5.32%	100%	0.729
		Week 8	12	69.24 ± 26.12	8.48%	100%	0.521
		Week 12	11^	67.46 ± 28.13	11.08%	100%	0.452
	Homogeneity	Baseline	12	44.34 ± 1.57			
		Week 4	12	46.36 ± 1.49	4.58%	100%	**0.004***
		Week 8	12	45.66 ± 1.47	3.01%	100%	**0.044***

		Week 12	11^	64.73 ± 1.58	45.80%	100%	**<0.001***

NI=No Improvement
*Indicates a statistically significant improvement compared to baseline, p≤0.05
^One subject (#5) did not have Clarity data at Week 12 (11 subjects analyzed).

Table 5.0 Clarity 2D – Monadic, Comparison to Baseline (Continued)

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Sub-Surface Spots	Surface Area Affected (Pixels)	Baseline	12	64758.88 ± 33.130.23			
		Week 4	12	65453.69 ± 32072.40	NI	33.3%	0.693
		Week 8	12	63346.75 ± 32226.24	3.24%	58.3%	0.629
		Week 12	11^	58287.52 ± 28953.92	4.54%	72.7%	0.099
	Pigment Intensity	Baseline	12	91.15 ± 23.19			
		Week 4	12	91.83 ± 24.03	NI	33.3%	0.404
		Week 8	12	91.40 ± 25.43	0.45%	50.0%	0.844
		Week 12	11^	87.88 ± 24.07	5.22%	100%	**0.001***
	Spot Count	Baseline	12	160.25 ± 60.65			
		Week 4	12	154.08 ± 59.56	3.99%	83.3%	**0.020***
		Week 8	12	149.21 ± 59.50	7.89%	91.7%	**0.005***
		Week 12	11^	142.11 ± 59.25	10.13%	100%	**<0.001***
Skin Color	RGB	Baseline	12	114.45 ± 23.34			
		Week 4	12	115.63 ± 23.46	NI	33.3%	0.226
		Week 8	12	115.39 ± 25.74	NI	41.7%	0.605
		Week 12	11^	118.17 ± 27.15	NI	18.2%	0.114
Pores	Surface Area Affected (Pixels)	Baseline	12	25411.06 ± 10745.03			
		Week 4	12	22422.96 ± 10601.07	15.32%	91.7%	**<0.001***
		Week 8	12	22796.10 ± 10688.13	10.08%	75.0%	0.054
		Week 12	11^	21643.80 ± 9228.68	14.46%	90.9%	**0.014***
	Average Size	Baseline	12	61.77 ± 5.81			
		Week 4	12	59.67 ± 6.48	3.18%	58.3%	0.175
		Week 8	12	59.37 ± 7.12	3.83%	58.3%	0.103
		Week 12	11^	54.69 ± 4.73	11.93%	100%	**<0.001***
	Pore Count	Baseline	12	406.15 ± 159.79			
		Week 4	12	361.79 ± 163.15	14.29%	91.7%	**0.001***
		Week 8	12	357.52 ± 161.51	12.27%	83.3%	**0.007***
		Week 12	11^	324.55 ± 154.73	21.66%	90.9%	**<0.007***

NI=No Improvement
*Indicates a statistically significant improvement compared to baseline, p≤0.05
^One subject (#5) did not have Clarity data at Week 12 (11 subjects analyzed).

Table 6.0 Instrumental Evaluation – Monadic, Comparison to Baseline

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Corneometer		Baseline	30	51.14 ± 12.92			
		Week 4	30	59.90 ± 15.23	21.91%	76.7%	**0.003***
		Week 8	29	48.90 ± 15.46	NI	41.4%	0.355
		Week 12	30	52.42 ± 13.57	7.20%	56.7%	0.625
Cutometer	Firmness (R0 Uf)	Baseline	30	0.27 ± 0.08			
		Week 4	29^	0.22 ± 0.06	11.64%	75.9%	**0.005***
		Week 8	29	0.22 ± 0.07	12.36%	79.3%	**0.009***
		Week 12	30	0.21 ± 0.05	17.90%	83.3%	**<0.001***

	Elasticity (R5 Ur/Ue)	Baseline	30	0.44 ± 0.17			
		Week 4	29^	0.51 ± 0.12	45.76%	69.0%	**0.009***
		Week 8	29	0.60 ± 0.17	52.85%	82.8%	**<0.001***
		Week 12	30	0.56 ± 0.15	47.48%	80.0%	**<0.001***
SIAScope	Melanin	Baseline	30	302.35 ± 95.40			
		Week 8	29	299.77 ± 85.94	0.52%	51.7%	0.492
		Week 12	30	300.19 ± 92.89	0.46%	53.3%	0.690

*Indicates a statistically significant improvement compared to baseline, $p \leq 0.05$
^One subject (#23) did not have Week 4 Cutometer data (29 subjects analyzed).

Table 6.1 Instrumental Evaluation – Chromameter - Monadic, Comparison to Baseline

Assessment		Time Point	n	Mean ± SD	Mean Percent Improvement *From BL mean*	Percent of Subjects Showing Improvement *From BL*	P-Value *TX vs. BL*
Non-Pigmented							
Chroma Meter	L*	Baseline	30	57.29 ± 8.10			
		Week 4	30	57.37 ± 8.51	0.06%	50.0%	0.801
		Week 8	29	57.14 ± 8.48	NI	51.7%	0.790
		Week 12	29^	57.77 ± 9.26	0.57%	62.1%	0.325
	a*	Baseline	30	12.09 ± 2.34			
		Week 4	30	11.70 ± 2.56	2.36%	56.7%	0.287
		Week 8	29	12.56 ± 2.51	NI	44.8%	**0.045****
		Week 12	29^	12.01 ± 2.61	NI	51.7%	0.809
	b*	Baseline	30	17.01 ± 2.40			
		Week 4	30	17.33 ± 2.36	NI	36.7%	0.265
		Week 8	29	16.73 ± 2.45	1.21%	62.1%	0.234
		Week 12	29^	16.93 ± 2.58	0.16%	55.2%	0.801
Pigmented							
Chroma Meter	L*	Baseline	30	55.91 ± 7.87			
		Week 4	30	56.16 ± 8.49	0.34%	53.3%	0.527
		Week 8	29	56.42 ± 8.52	1.12%	65.5%	0.164
		Week 12	29^	56.67 ± 8.29	1.40%	69.0%	**0.042***
	a*	Baseline	30	12.15 ± 2.14			
		Week 4	30	12.15 ± 2.14	NI	53.3%	0.981
		Week 8	29	12.06 ± 2.22	NI	55.2%	0.864
		Week 12	29^	12.45 ± 2.80	NI	37.9%	0.246
	b*	Baseline	30	17.12 ± 2.07			
		Week 4	30	17.33 ± 2.62	NI	30.0%	0.542
		Week 8	29	16.80 ± 2.44	1.29%	51.7%	0.427
		Week 12	29^	17.20 ± 2.25	NI	41.4%	0.661

NI= No improvement
*Indicates a statistically significant improvement compared to baseline, p≤0.05
**Indicates a statistically significant worsening compared to baseline, p≤0.05
^One subject (#5) did not have Chromameter Data at Week 12 (29 subjects analyzed).

Table 6.2 Instrumental Evaluation – Chromameter - Mean Comparison - Pigmented vs. Non-Pigmented

Assessment		Time Point	n	Non-Pigmented Mean ± SD	n	Pigmented Mean ± SD	P_T-Value *Pigmented vs. Non-Pigmented*
Chroma Meter	L*	Baseline	30	57.29 ± 8.10	30	55.91 ± 7.87	0.504
		Week 4	30	57.37 ± 8.51	30	56.16 ± 8.49	0.584
		Week 8	29	57.14 ± 8.48	29	56.42 ± 8.52	0.749
		Week 12	29^	57.77 ± 9.26	29^	56.67 ± 8.29	0.635
	a*	Baseline	30	12.09 ± 2.34	30	12.15 ± 2.14	0.907
		Week 4	30	11.70 ± 2.56	30	12.15 ± 2.14	0.499
		Week 8	29	12.56 ± 2.51	29	12.06 ± 2.22	0.429

		Week 12	29^	12.01 ± 2.61	29^	12.45 ± 2.80	0.542
	b*	Baseline	30	17.01 ± 2.40	30	17.12 ± 2.07	0.857
		Week 4	30	17.33 ± 2.36	30	17.33 ± 2.62	0.991
		Week 8	29	16.73 ± 2.45	29	16.80 ± 2.44	0.911
		Week 12	29^	16.93 ± 2.58	29^	17.20 ± 2.25	0.678

^One subject (#5) did not have Chromameter Data at Week 12 (29 subjects analyzed).

Table 6.3 Instrumental Evaluation – Chromameter - Mean Difference Comparison - Pigmented vs. Non-Pigmented

Assessment		Time Point	n	Non-Pigmented Mean Difference ± SD *From BL*	n	Pigmented Mean Difference ± SD *From BL*	P_T-Value *Pigmented vs. Non-Pigmented*
Chroma Meter	L*	Week 4	30	0.08 ± 1.73	30	0.25 ± 2.20	0.730
		Week 8	29	-0.09 ± 1.81	29	0.64 ± 2.42	0.198
		Week 12	29 ^	0.46 ± 2.48	29 ^	0.77 ± 1.95	0.598
	a*	Week 4	30	-0.39 ± 1.97	30	-0.00 ± 1.99	0.459
		Week 8	29	0.53 ± 1.37	29	-0.05 ± 1.75	0.159
		Week 12	29 ^	0.07 ± 1.56	29 ^	0.40 ± 1.82	0.463
	b*	Week 4	30	0.31 ± 1.51	30	0.21 ± 1.93	0.829
		Week 8	29	-0.25 ± 1.12	29	-0.29 ± 1.96	0.925
		Week 12	29 ^	-0.07 ± 1.49	29 ^	0.15 ± 1.85	0.615

^One subject (#5) did not have Chromameter Data at Week 12 (29 subjects analyzed).

Table 6.4 Instrumental Evaluation– Monadic – Chroma Meter, Delta E Homogeneity

Assessment		Time Point	n	Pigmented vs. Non- Pigmented Mean	P-Value *TX vs. BL*
Chroma Meter	ΔE Homogeneity	Baseline	30	3.02	
		Week 4	30	2.93	0.831
		Week 8	29	3.17	0.796
		Week 12	29 ^	3.39	0.436

^One subject (#5) did not have Chromameter Data at Week 12 (29 subjects analyzed).

Table 7.0 Laboratory Assessment – Monadic, Comparison to Baseline

Assessment	**Time Point**	**n**	**Mean ± SD***	**Mean Percent Change** *From BL mean*	**P-Value** *TX vs. BL*
Glutathione	Baseline	18	275.65 ± 47.68		
	Week 12	18	269.35 ± 43.42	-0.22	0.649

*Mean values are within normal range of 176 – 323 ug/ml

Table 8.0 D-Squame – Monadic, Comparison to Baseline

Assessment	**Time Point**	**n**	**Mean ± SD**	**Mean Percent Improvement** *From BL mean*	**Percent of Subjects Showing Improvement** *From BL*	**P-Value** *TX vs. BL*
D-Squame	Baseline	30	1.94 ± 1.09			
	Week 4	30	1.68 ± 0.70	0.48%	36.7%	0.058
	Week 8	29	1.40 ± 0.56	12.56%	44.8%	**0.004***
	Week 12	30	1.52 ± 0.51	3.01%	43.3%	**0.025***

*Indicates a statistically significant improvement compared to baseline, p≤0.05

Table 9.0 Subjective Questionnaire – Consumer Perception

Question	n	Week 4 Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
1. The test product regimen lightened skin.	30	1 (3.3%)	13 (43.3%)	13 (43.3%)	3 (10.0%)	0 (0.0%)	46.7%
2. The test product regimen brightened skin.	30	2 (6.7%)	12 (40.0%)	14 (46.7%)	2 (6.7%)	0 (0.0%)	46.7%
3. The test product regimen deeply lightened the skin.	30	1 (3.3%)	4 (13.3%)	19 (63.3%)	5 (16.7%)	1 (3.3%)	16.7%
4. The test product improved the appearance of dark spots/ discolorations.	30	3 (10.0%)	13 (43.3%)	10 (33.3%)	4 (13.3%)	0 (0.0%)	**53.3%**

Question	n	Response n (%)						Percent Responding Favorably
		0 Shades	1 Shade	2 Shades	3 Shades	4 Shades	5 Shades	
5. The test product regimen lightened my skin by this many shades:	30	7 (23.3%)	21 (70.0%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	

Question	n	Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
6. The test product regimen improved skin tone evenness/homogeneity.	30	1 (3.3%)	17 (56.7%)	10 (33.3%)	2 (6.7%)	0 (0.0%)	**60.0%**
7. The test product regimen helped skin achieve a healthy, even glow.	30	2 (6.7%)	14 (46.7%)	12 (40.0%)	2 (6.7%)	0 (0.0%)	**53.3%**
8. The test product regimen improved skin's radiance.	30	3 (10.0%)	12 (40.0%)	13 (43.3%)	2 (6.7%)	0 (0.0%)	50.0%
9. The test product regimen improved skin's luminosity.	30	2 (6.7%)	11 (36.7%)	14 (46.7%)	3 (10.0%)	0 (0.0%)	43.3%
10. The test product regimen hydrated skin.	30	2 (6.7%)	18 (60.0%)	7 (23.3%)	2 (6.7%)	1 (3.3%)	**66.7%**
11. The test product regimen minimized the appearance of pores.	30	1 (3.3%)	17 (56.7%)	9 (30.0%)	2 (6.7%)	1 (3.3%)	**60.0%**
12. The test product regimen improved he appearance of lines/wrinkles in the crow's feet area.	30	2 (6.7%)	11 (36.7%)	12 (40.0%)	4 (13.3%)	1 (3.3%)	43.3%
13. The test product regimen improved the texture/smoothness of skin.	30	3 (10.0%)	15 (50.0%)	9 (30.0%)	3 (10.0%)	0 (0.0%)	**60.0%**
14. The test product regimen improved skin's overall texture/appearance.	30	2 (6.7%)	17 (56.7%)	9 (30.0%)	2 (6.7%)	0 (0.0%)	**63.3%**
15. The test product regimen improved the firmness of skin.	30	1 (3.3%)	17 (56.7%)	8 (26.7%)	3 (10.0%)	1 (3.3%)	**60.0%**
16. The test product regimen improved the elasticity of skin.	30	1 (3.3%)	13 (43.3%)	12 (40.0%)	4 (13.3%)	0 (0.0%)	46.7%
17. The test product regimen improved elasticity and firmness, providing my skin with a more youthful look.	30	1 (3.3%)	11 (36.7%)	13 (43.3%)	5 (16.7%)	0 (0.0%)	40.0%
18. The test product regimen improved the overall youthful appearance of skin.	30	3 (10.0%)	12 (40.0%)	9 (30.0%)	6 (20.0%)	0 (0.0%)	50.0%

Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 9.0 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Week 8 Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
1. The test product regimen lightened skin.	29	4 (13.8%)	12 (41.4%)	10 (34.5%)	3 (10.3%)	0 (0.0%)	**55.2%**
2. The test product regimen brightened skin.	29	2 (6.9%)	17 (58.6%)	8 (27.6%)	2 (6.9%)	0 (0.0%)	**65.5%**
3. The test product regimen deeply lightened the skin.	29	1 (3.4%)	7 (24.1%)	17 (58.6%)	4 (13.8%)	0 (0.0%)	27.6%
4. The test product improved the appearance of dark spots/ discolorations.	29	2 (6.9%)	15 (51.7%)	9 (31.0%)	3 (10.3%)	0 (0.0%)	**58.6%**

Question	n	Response n (%)						Percent Responding Favorably
		0 Shades	1 Shade	2 Shades	3 Shades	4 Shades	5 Shades	
5. The test product regimen lightened my skin by this many shades:	29	7 (24.1%)	14 (48.3%)	5 (17.2%)	1 (3.4%)	2 (6.9%)	0 (0.0%)	

Question	n	Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
6. The test product regimen improved skin tone evenness/homogeneity.	29	3 (10.3%)	10 (34.5%)	14 (48.3%)	2 (6.9%)	0 (0.0%)	44.8%
7. The test product regimen helped skin achieve a healthy, even glow.	29	3 (10.3%)	14 (48.3%)	10 (34.5%)	2 (6.9%)	0 (0.0%)	**58.6%**
8. The test product regimen improved skin's radiance.	29	4 (13.8%)	12 (41.4%)	12 (41.4%)	1 (3.4%)	0 (0.0%)	**55.2%**
9. The test product regimen improved skin's luminosity.	29	2 (6.9%)	8 (27.6%)	18 (62.1%)	1 (3.4%)	0 (0.0%)	34.5%
10. The test product regimen hydrated skin.	29	3 (10.3%)	13 (44.8%)	10 (34.5%)	3 (10.3%)	0 (0.0%)	**55.2%**
11. The test product regimen minimized the appearance of pores.	29	2 (6.9%)	16 (55.2%)	10 (34.5%)	1 (3.4%)	0 (0.0%)	**62.1%**
12. The test product regimen improved he appearance of lines/wrinkles in the crow's feet area.	29	2 (6.9%)	7 (24.1%)	17 (58.6%)	3 (10.3%)	0 (0.0%)	31.0%
13. The test product regimen improved the texture/smoothness of skin.	29	3 (10.3%)	15 (51.7%)	11 (37.9%)	0 (0.0%)	0 (0.0%)	**62.1%**
14. The test product regimen improved skin's overall texture/appearance.	29	3 (10.3%)	15 (51.7%)	11 (37.9%)	0 (0.0%)	0 (0.0%)	**62.1%**
15. The test product regimen improved the firmness of skin.	29	3 (10.3%)	14 (48.3%)	11 (37.9%)	1 (3.4%)	0 (0.0%)	**58.6%**
16. The test product regimen improved the elasticity of skin.	29	1 (3.4%)	11 (37.9%)	15 (51.7%)	2 (6.9%)	0 (0.0%)	41.4%
17. The test product regimen improved elasticity and firmness, providing my skin with a more youthful look.	29	0 (0.0%)	16 (55.2%)	11 (37.9%)	2 (6.9%)	0 (0.0%)	**55.2%**
18. The test product regimen improved the overall youthful appearance of skin.	29	2 (6.9%)	13 (44.8%)	11 (37.9%)	3 (10.3%)	0 (0.0%)	**51.7%**

Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 9.0 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Week 12 Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
1. The test product regimen lightened skin.	30	2 (6.7%)	14 (46.7%)	13 (43.3%)	1 (3.3%)	0 (0.0%)	**53.3%**
2. The test product regimen brightened skin.	30	2 (6.7%)	18 (60.0%)	8 (26.7%)	2 (6.7%)	0 (0.0%)	**66.7%**
3. The test product regimen deeply lightened the skin.	30	2 (6.7%)	6 (20.0%)	12 (40.0%)	10 (33.3%)	0 (0.0%)	26.7%
4. The test product improved the appearance of dark spots/ discolorations.	30	3 (10.0%)	16 (53.3%)	10 (33.3%)	1 (3.3%)	0 (0.0%)	**63.3%**

Question	n	Response n (%)						Percent Responding Favorably
		0 Shades	1 Shade	2 Shades	3 Shades	4 Shades	5 Shades	
5. The test product regimen lightened my skin by this many shades:	30	0 (0.0%)	6 (20.0%)	18 (60.0%)	5 (16.7%)	0 (0.0%)	1 (3.3%)	

Question	n	Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
6. The test product regimen improved skin tone evenness/homogeneity.	30	1 (3.3%)	21 (70.0%)	7 (23.3%)	1 (3.3%)	0 (0.0%)	**73.3%**
7. The test product regimen helped skin achieve a healthy, even glow.	30	2 (6.7%)	21 (70.0%)	6 (20.0%)	1 (3.3%)	0 (0.0%)	**76.7%**
8. The test product regimen improved skin's radiance.	30	2 (6.7%)	18 (60.0%)	9 (30.0%)	1 (3.3%)	0 (0.0%)	**66.7%**
9. The test product regimen improved skin's luminosity.	30	1 (3.3%)	16 (53.3%)	12 (40.0%)	1 (3.3%)	0 (0.0%)	**56.7%**
10. The test product regimen hydrated skin.	30	4 (13.3%)	17 (56.7%)	5 (16.7%)	2 (6.7%)	2 (6.7%)	**70.0%**
11. The test product regimen minimized the appearance of pores.	30	3 (10.0%)	16 (53.3%)	9 (30.0%)	2 (6.7%)	0 (0.0%)	**63.3%**
12. The test product regimen improved he appearance of lines/wrinkles in the crow's feet area.	30	2 (6.7%)	15 (50.0%)	10 (33.3%)	3 (10.0%)	0 (0.0%)	**56.7%**
13. The test product regimen improved the texture/smoothness of skin.	30	2 (6.7%)	22 (73.3%0	6 (20.0%)	0 (0.0%)	0 (0.0%)	**80.0%**
14. The test product regimen improved skin's overall texture/appearance.	30	1 (3.3%)	24 (80.0%)	5 (16.7%)	0 (0.0%)	0 (0.0%)	**83.3%**
15. The test product regimen improved the firmness of skin.	30	2 (6.7%)	16 (53.3%)	9 (30.0%)	3 (10.0%)	0 (0.0%)	**60.0%**
16. The test product regimen improved the elasticity of skin.	30	2 (6.7%)	12 (40.0%)	13 (43.3%)	3 (10.0%)	0 (0.0%)	46.7%
17. The test product regimen improved elasticity and firmness, providing my skin with a more youthful look.	30	2 (6.7%)	16 (53.3%)	9 (30.0%)	3 (10.0%)	0 (0.0%)	**60.0%**
18. The test product regimen improved the overall youthful appearance of skin.	30	1 (3.3%)	14 (46.7%)	12 (40.0%)	3 (10.0%)	0 (0.0%)	50.0%

Bold / Shaded = The majority of subjects responded favorably, >50%.

Table 9.0 Subjective Questionnaire – Consumer Perception (Continued)

Question	n	Week 12 (Continued) Response n (%)					Percent Responding Favorably
		Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	
19. I would make this regimen as part of my regular routine.	30	5 (16.7%)	17 (56.7%)	2 (6.7%)	6 (20.0%)	0 (0.0%)	**73.3%**
20. I would recommend this regimen to friends/family.	30	7 (23.3%)	14 (46.7%)	8 (26.7%)	1 (3.3%)	0 (0.0%)	**70.0%**

Bold / Shaded = The majority of subjects responded favorably, >50%.

19.2 Discussion

19.2.1 Enrollment and Demographics

A total of 30 female and male subjects between the ages of 30 and 65 years old were required to complete study participation. The study completed with a total of 30 subjects, 27 female subjects and 3 male. The population had an age range of 34-65 and an average age of 54.70 years old. The population reported their ethnicity as 93.3% Non-Hispanic or Latino and 6.7% Hispanic/Latino, and they reported their race as 70.0% White, 23.3% Black or African American, 3.3% Asian and 3.3% No response (Hispanic/Latino). Fitzpatrick Skin Types II-VI were represented as well as Combination, Dry and Normal facial skin types and Dry, Normal and Very Dry body skin types.

19.2.2 Tolerance Evaluations

Objective Assessments: No statistically significant changes from mean Baseline scores for the appearance of dryness, erythema or edema were observed at any timepoint.

Subjective Assessments: Mean Baseline scores of 0.00 remained unchanged throughout the study for the sensations of stinging, tingling and itching. Mean Baseline scores of 0.00 remained unchanged at Week 4 for burning and numerical, but not statistically significant, increases were observed at Weeks 8 and 12.

19.2.3 Expert Clinical Grading

Comparison of mean Baseline scores to those at subsequent time intervals revealed statistically significant improvements from Baseline in the appearance of lines/wrinkles (crow's feet), skin brightening/lightening, tone/evenness, radiance/luminosity, texture/smoothness (tactile), firmness, elasticity (tactile), overall youthful appearance and intensity of dark spots after four, eight and twelve weeks of test regimen use. Additional statistically significant improvements from Baseline were seen in mean results for the appearance of pores at Weeks 8 and 12.

19.2.4 Clarity™ 2D Image Analysis

Comparison of mean subjective scores from Baseline to subsequent visits revealed statistically significant improvements in the appearance of the following lines/wrinkles – crow's feet characteristics: average length at Weeks 8 and 12, average width at Weeks 4 and 12, average severity at Weeks 4 and 12, total wrinkle count at Weeks 4, 8 and 12, fine lines count at Week 12 and deep lines count at Weeks 8 and 12.

Comparison of mean subjective scores from Baseline to subsequent visits revealed statistically significant improvements in the appearance surface spots: homogeneity at Weeks 4, 8 and 12 and in the appearance of sub-surface spots: pigment intensity at Week 12 and spot count at Weeks 4, 8 and 12.

Comparison of mean subjective scores from Baseline to subsequent visits revealed statistically significant improvements in the appearance of pores: surface area at Weeks 4 and 12, average size at Week 12 and pore count at Weeks 4, 8 and 12.

19.2.5 Instrumental Assessments

Statistically significant improvement from Baseline was observed in Corneometer results for mean skin hydration results at Week 4.

Statistically significant improvement from Baseline was observed in Cutometer results for skin firmness and elasticity at Weeks 4, 8 and 12.

No statistically significant changes from Baseline were observed in mean SIAscope results for melanin at any time point.

Chroma meter assessments of non-pigmented facial skin revealed a significant difference from Baseline in mean score for a* at Week 8. Chroma meter assessments of pigmented facial skin revealed a significant difference from Baseline in mean score for L* at Week 12.

Comparative analysis of means and of mean-difference-from-Baseline scores for the pigmented and non-pigmented sites revealed no statistically significant differences.

The results from Delta E analysis for color homogeneity revealed that the difference between mean pigmented and mean non-pigmented sites were greater than 2.0, indicating that at least a minimal perceivable color difference existed after using the test regimen for four, eight and twelve weeks. None of the subsequent Delta E scores were significantly different from Baseline. Scores ranged from a low of 2.93 at Week 4 to a maximum of 3.39 at Week 12.

19.2.6 Laboratory Assessment

Mean blood glutathione concentration at Week 12 was not statistically significantly different from baseline concentration.

19.2.7 D-Squame

Mean D-squame scores at Weeks 8 and 12 were all significantly lower than at Baseline, indicating an improvement in exfoliation.

19.2.8 Subjective Questionnaire

The majority of subjects (>50%) responded favorably to more queried statements at each subsequent visit. At Week 4, eight out of 18 queried statements were answered favorably, ranging from a low of 53.3 to a high of 66.7 percent. At Week 8, 12 out of 18 queries were answered favorably, ranging from a low of 51.7 to a high of 65.5 percent. At Week 12, 16 out of 18 queries were answered favorably, ranging from a low of 53.3 to a high of 83.3 percent. Of note, greater than 80% of subjects indicated that the test product regimen **improved skin's overall texture/appearance** after 12 weeks of use.

20.0 Conclusion

In conclusion, under the conditions of this study, use of the product regimen including **Relumins regimen: Advanced Derm 1650mg Gluta Complex #RL-DERM1650, Advance White Vitamin C MAX Complex #RL-VITAMINCMAX-60, TA Stem Cell Intensive Repair Soap #RL-STMCLWHITESOAP, TA**

Stem Cell Intensive Repair Lotion #RL-STEMCLRPRLTN-30, TA Stem Cell Intensive Repair Serum #RL-INTENSIVEREPAIRSERUM, TA Stem Cell Intensive Repair Solution # RL-INTENSIVEREPAIRSOLUTION, TA Stem Cell Intensive Repair Weightless Day Cream (SPF) # RL-WEIGHTLESSCRM was able to provide significant improvements in skin condition and appearance. All test products were well-tolerated in the subject population and consumer questionnaire results revealed significantly positive perception of product effects after four, eight and twelve weeks of use. Product perception also became increasingly positive as a function of regimen use over time.

Appendix I

Protocol

Appendix II

Protocol Amendments

Appendix III

Protocol Deviations

Appendix IV

Adverse Events

Appendix V

Statistical Report and Data Listing