

AN INVESTIGATION INTO THE EFFICACY OF A TEST PRODUCT INTENDED TO REDUCE FACIAL REDNESS

AMA Ref. No.: MS11.INUSE.REP.M1148.SCBI

Date: September 12, 2011

Sponsor: Stem Cell Beauty Innovations

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1.0 Objective:

This study was conducted to evaluate the efficacy of a test product intended to reduce the appearance of facial redness. Image analysis software was employed to quantify color changes observed in the scientifically matched photographs (Reverse Photo Engineering).

2.0 Sample Description:

On July 21, 2011 test samples labeled SCBI Gold Serum, Lot #: 03115 were received from Stem Cell Beauty Innovations and assigned AMA Lab No.: M-1148.

3.0 Test Material Handling:

Upon arrival at AMA Laboratories, Inc., the test material 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.

Samples are retained for a period of three months beyond submission of final report unless otherwise specified by the sponsor or if sample is known to be in support of governmental applications, in which case retained samples are kept two years beyond final report submission.

Sample disposition is conducted in compliance with appropriate federal, state and local ordinances.

4.0 Panel Demographics:

Number of subject	s enrolled	
Number of subject	s completing study	5
Age Range		40 - 55
Sex	Female	5
Race	Caucasian	4
	Hispanic	

4.1 Standards For Inclusion In A Study:

- 1. Female subjects between the ages of 18 and 55 experiencing facial redness (erythema).
- 2. Individuals who will complete a preliminary medical history mandated by AMA Laboratories, Inc.
- 3. Individuals who will read, understand and sign an informed consent document as required by Reference 21 CFR Ch. 1 Part 50, Subpart B. Consent forms will be kept on file and will be available for examination on the premises of AMA Laboratories, Inc., only.
- 4. Individuals in good health and free of any dermatological or systemic disorder, which would interfere with the results, at the discretion of the Investigator.
- 5. Individuals, who will be able to cooperate with the Investigator and research staff, be willing to have the test materials applied according the protocol and complete the full course of study.
- 6. Individuals with no known abnormal response to cosmetic products and who are willing to cooperate with the study requirements.
- 7. Individuals demonstrating skin redness in the test site, such that differences due to product effectiveness can be measured.
- 8. Individuals who have abstained from tanning during the test period.
- 9. Individuals who have abstained from using any erythema suppressants or skin lightening products for a period of 72 hours prior to study commencement and during the test period.

4.2 Standards Of Exclusion From The Study:

- 1. Individuals who are under doctor's care.
- 2. Individuals taking medication which in the opinion of the Investigator would mask or interfere with the results.
- 3. Individuals with chronic skin allergies or skin conditions such as severe dermatitis, psoriasis, and/or eczema.
- 4. Individuals with uncontrolled diseases such as diabetes,

- hypertension, hyperthyroidism, or hypothyroidism.
- 5. Individuals with irritation or sensitivity to cosmetic products, soaps, shampoos or personal hygiene cleansing products.
- 6. Female volunteers who indicate that they are pregnant or lactating.
- 7. Individuals with blemishes, nevi, sunburn, suntan, scars, moles and active dermal lesions in the test sites.
- 8. Individuals participating in any clinical research study at another facility or with a doctor's office at the commencement and duration of the study.

4.3 Recruitment:

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

4.4 Informed Consent Document:

An 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 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 and screening form. These forms, along with the signed consent forms, are available for inspection on the premises of AMA Laboratories, Inc., only. Reference 21 CFR Ch.1 Parts 50, Subpart B.

4.5 Institutional Review Board:

Reference: CFR Title 21 Part 56, Subparts A, B, C and D. The IRB of AMA Laboratories, Inc. consists of five or more individuals, chosen from within the company for technical expertise and from the local community for lay interaction. The list of IRB members is kept on file at AMA Laboratories, Inc. and is available for inspection during the hours of operation.

5.0 Procedure:

Five healthy female subjects between the ages of 40 and 55 were included into this study. The subjects were pre-qualified for participation on the basis of the presence of skin redness (erythema) in the facial area. In order to pre-condition the test sites and keep all topical treatments constant for all test subjects, panelists were required to abstain from

using any erythema suppressants and skin lightening products for a period of 72 hours prior to study commencement and during the test period.

On the initial day of the study, participants were advised of the general nature and purpose of this study. On each evaluation day panelists reported with the test sites devoid of topical treatments and were allowed to equilibrate to the ambient environment for 30 minutes prior to measurement.

The study was conducted according to the sponsor requested design wherein all subjects were instructed to use the test material according to the following sponsor supplied use directions:

Wash face gently before application. Apply 3-4 pumps of gold serum and massage gently on the face. Use for 4 weeks straight in the morning before anything else is applied to the face and at night after everything is washed off face.

On the evaluation days (Baseline and Day 28), panelists reported to the test facility without any topical treatments on their face. Upon arrival, panelists were allowed to equilibrate to the ambient environment for 30 minutes prior to their pictures be taken.

The following distinct noninvasive method was employed to establish evaluation parameters:

Reverse Photo Engineering

Exclusively detailed, high resolution before and after digital photographs are taken, with fixed camera background, angles, settings, lighting, panelist positioning, color bars, white balance, standardized and digitally certified unretouched. Photographs are evaluated using image analysis software which allows the evaluation parameter to be captured and quantified. Image analysis software detects subtle changes in color by three dimensional profile of hue, value and chroma. These characteristics are then translated into color coordinates (a*, b* and L*) whose spacing is considered with the color changes perceived by the human eye. This software also allows redness to be captured and quantified. The size of the area of involvement differs for each test panelist, therefore percent difference is calculated individually and then averaged.

	a* Coordinate		
Increase	Reddening		
Decrease	Green		

6.0 Results:

Please see attached Table and Charts.

7.0 Observations:

No unexpected adverse reactions were observed on any of the subjects during the course of this study.

8.0 Statistical Source Data:

The source data consist of skin redness quantification (a* value measured from the same region) at Baseline and day 28. Data used in statistical analysis reflects changes in a* Value from Baseline (0% improvement) to Clear Skin (100% improvement) a* Value readings.

9.0 Archiving:

All original samples, raw data sheets, technician's notes, correspondence files, copies of final reports and remaining specimens are maintained on the premises of AMA Laboratories, Inc. in marked limited access storage files. A duplicate DVD copy of final reports is separately archived in a bank safe deposit vault.

10.0 Security Label Disclosure:

To prevent loss of and protect intellectual property, original, certified documents issued by AMA Laboratories Inc. can be identified by a proprietary, tamper evident security hologram affixed to all Conclusion/Signature pages on final reports. Any attempt to remove the hologram will irreversibly damage the label and leave an immediate trace, thus invalidating the document.

Only reports containing the AMA LABS, INC. hologram will be recognized by AMA Laboratories Inc. as a certified original.

11.0 Conclusions:

Within the limits imposed by the conduct and population size of the study described herein, it was demonstrated that the test product (AMA Lab No.: M-1148, Client No.: SCBI Gold Serum, Lot #: 03115) proved to be effective at reducing facial redness.

Data obtained through image analysis software demonstrated that after 28 days of twice daily use the test product reduced the appearance of facial redness by an average of 34.34%.

Rosacea Reduction - SUMMARY				
Baseline	Day 28			
0.00%	34.34%			

Further, this phenomenon was documented and confirmed by the photographic record made during the course of this study.

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Date



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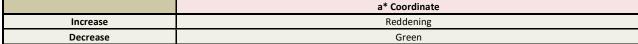
Reverse Photo Engineering - Redness Reduction Analysis						
AMA Lab No.:	M-1148					
Client No.:	SCBI Gold Serum, Lot #: 03115					
Panelist ID Nos.:	Redness Reduction Analysis					
	Baseline [px]	Baseline [px] Min.	Day 28 [px]	Individual % Difference:		
70 5391	41	24	37	23.53%		
50 3976	43	18	33	40.00%		
52 8160	41	20	34	33.33%		
58 1113	40	20	32	40.00%		
60 2360	43	27	38	31.25%		
Average:	41.60	21.80	34.80			
% Difference:	34.34%		34.34%			
р			0.003*			
t			6.369*			

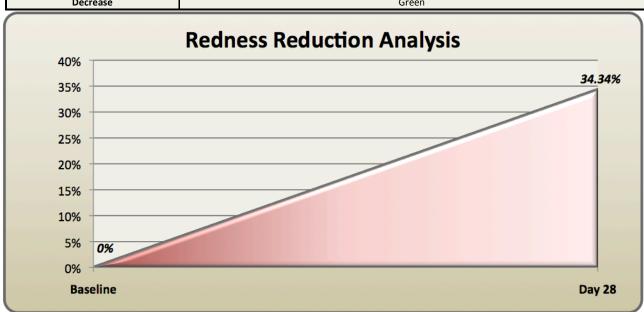
^{* -} Statistically Significant

Student's t-test was used in this investigation. This is the test of the null hypothesis that the difference between two responses measured on the same statistical unit has a mean value of zero. In this investigation the changes in skin color (coordinate a*corresponding to for skin redness) before and after a treatment were measured. If the treatment is effective, we expect a* value for many of the patients to be lower following the treatment. This is often referred to as the "paired" or "repeated measures" t-test. Dependent samples (or "paired") t-tests typically consist of a sample of matched pairs of similar units, or one group of units that has been tested twice (a "repeated measures" t-test). Once a t value is determined, a p-value can be found using a table of values from Student's t-distribution. If the calculated p-value is below the threshold chosen for statistical significance (0.05 (5%)), then the null hypothesis (Null Hypotesis p>0.05) is rejected in favor of the alternative hypothesis. Statistical analysis was computed using appropriate Excel statistical software functions, where one function returns the probability associated with a Student's t-Test and the other returns the t-value of the Student's t-distribution as a function of the probability and the degrees of freedom.

Reverse Photo Engineering

Exclusively detailed, high resolution before and after digital photography was taken, with fixed camera background, distances, angles, settings, lighting, panelist positioning, color bars, white balance, standardized and digitally certified unretouched. Each stage in the progression of the treatment regimen was photographically documented and the test area of involvement isolated. Photographs were evaluated using image analysis software which allows quantification observed in lips color to be quantified in the scientifically matched photographs. Image analysis software detects subtle changes in color by a three dimensional profile of hue, value and chroma. These characteristics are then translated into color coordinates (a*, b* and L*) whose spacing is considered to correlate with the color changes perceived by the human eye.Redness Reduction Analysis data reflects changes in skin color where baseline average a* value readings areconsidered 0% and the clearest (least red) skin color for each panelist is considered 100%.





12.0 Quality Assurance Statement:

This study was inspected in accordance with the Standard Operating Procedures of AMA Laboratories, Inc. To assure compliance with the study protocol, the Quality Assurance Unit completed an audit of the study records and report.

Report reviewed by:

Tasmiya Masud, B.A.

Quality Assurance Supervisor

Date