A clinical study to evaluate the efficacy and tolerance of a scalp mask over a 12-week period

Product # Silver Rose Scalp Mask

TESTING FACILITY STUDY NUMBER: 6417-062-64-003

DRAFT REPORT DATE: 7/17/2017

SPONSOR: Blooming Rose Cosmetics

SPONSOR'S REPRESENTATIVE: Ruzanna Kirakosyan

INVESTIGATOR: John Ademola, Ph.D.

DERMATOLOGIST : James D. Jacobitz, MD

STARTING DATE: April 3, 2017

DATE OF COMPLETION: June 28, 2017

APPROVALS:

Investigator:

John Ademola, Ph.D.
Date: 8/10/17

Dermatologist :

James D. Jacobitz, MD
Date: 8/10/2017

Quality Assurance Statement

This study was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in CFR 21, part 50 (Protection of Human Subjects Informed Consent) and part 56 (Institutional Review Boards).

For the Purpose of this clinical study:

- [x] Informed Consent was obtained:
- [ ] Informed Consent was not obtained:
- [x] An IRB review was not required:
- [ ] An IRB review was conducted and approval to conduct the proposed clinical research was granted:

This study report has been reviewed to assure that it correctly describes the methods of testing and that the reported results accurately reflect the data obtained during the clinical study. Quality Assurance personnel signing below attest that the study was conducted in accordance with Good Clinical Practices / International Conference on Harmonization E6 Guidelines as well as the study protocol and Biometrix Inc. Standard Operating Procedures.

(Testing Facility Study Number: 6417-062-64-003)

Kelly Lockwood

Quality Assurance Auditor

8/10/2017

Date

Safety Tolerance and Efficacy Evaluation

Silver Rose Scalp Mask

1.0 Objective

To evaluate the efficacy and safety tolerance of a scalp mask in a human panel.

1.1 Testing Facility

BIOMETRIX, 2419 Ocean Avenue, San Francisco, CA 94127

1.2 Investigators

Principal Investigator: John Ademola, Ph.D.

Sub-Investigator: James D. Jacobitz, MD

2.0 Test Material

On March 13, 2017, 40 test samples labeled **Silver Rose Scalp Mask** were received from Blooming Rose Cosmetics Inc.and were assigned Biometrix Entry No: 6417-062-64-003.

2.1 Test Material Handling

Test products that had been reviewed and approved for use by the Regulatory and Safety representatives of Blooming Rose Cosmetics Inc. were tested.

Upon arrival at the Testing Facility, the test products were assigned a unique laboratory code number and entered into a log identifying the sample number, sample description, sponsor, date received and tests requested.

All unused samples will be returned to the Sponsor within 2 months after study completion, at the expense of the Sponsor. Used samples will be retained for a period of 30 days beyond submission of final report.

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

3.0 Panel Design

A total of 37 subjects were selected for study participation (Subject Demographics – Appendix I). They are aged between 26 and 60 years with an average age of 47.81 years. The study population included 16 (43.24%) women and 21 (56.76%) men, with ethnicities / race of Asia (12, 32.34%), Caucasian (21, 56.76%), and Hispanic (4, 10.81%). In the study, 23 (61.16%) participants exhibited mild intensity of hair loss, and 14 (37.84%) had moderate intensity of hair loss.

Subjects who met all of the inclusion criteria and none of the exclusion criteria listed in the study protocol were enrolled. Summary of demographic details appear below (Tables 1 to 5).

Table 1 -Ethnicity		
	Frequency	***Percent***
Asian	**12**	**32.43**
Caucasian	**21**	**56.76**
Hispanic	**4**	**10.81**

Table 2- Sex		
	Frequency	***Percent***
Female	**16**	**43.24**
Male	**21**	**56.76**

Table 3 - Intensity of hair loss		
	Frequency	***Percent***
Mild	**23**	**62.16**
Moderate	**14**	**37.84**

Table 4 -Grading scale		
	Frequency	Percent
Ludwig I	10	27.03
Ludwig II	1	2.7
Norwood I	3	8.11
Norwood I Temporal	1	2.7
Norwood II	5	13.51
Norwood III	1	2.7
Norwood III vertex	5	13.51
Norwood IV	5	13.51
Norwood V	4	10.81
Norwood VI	2	5.41

Table 5- Scalp region		
	Frequency	Percent
Frontal	12	32.43
Frontal ,Occipital	4	10.81
Frontal ,Temporal	1	2.7
Frontal, Vertex	3	8.11
Occipital	3	8.11
Temporal	1	2.7
Vertex	4	10.81
Vertex, Frontal	2	5.41
Vertex, Frontal, Temporal	2	5.41
Vertex, Frontal, Temporal, Occipital	1	2.7
Vertex, Frontal, Temporal, Parietlal, Occipital	1	2.7
Vertex, Frontal .Occipital	2	5.41
Vertex, Temporal	1	2.7

3.1 Standard for Inclusion in the Study

1) Male and female, mixed ethnicity subjects, age 20 - 60 years old
2) Mild to moderate hair loss as diagnosed by a dermatologist
3) Fitzpatrick skin type I to IV
4) Who have concerns and/or signs of premature hair aging including, but not limited to hair thinning, hair loss, dryness or brittleness, scalp oiliness, scalp redness, lack of shine
5) Completion of a Medical History form and the understanding and signing of the Informed Consent Document
6) Considered reliable and capable of following directions
7) Clinically-determined general good health as determined by responses to the initial study assessment
8) Willingness to maintain their normal hair shampooing frequency
9) Willingness to not substantially change their current diet, medications, or exercise routines for the duration of the study. If a subject receives physician guidance during the study to change diet, medications, or exercise routine, the subject will need to notify the clinic as soon as possible
10) Willingness to undergo a brief physical exam and a scalp exam. Both exam will occur at baseline
11) Willingness to have hair at selected site (0.8*0.8 cm square) being trimmed down to minimal length
12) Willingness to have digital photography of the target area and scalp for hair counts
13) Willingness to maintain a consistent haircut and hair color throughout the 3-month study period

3.2 Standard for Exclusion from the Study

1) Females who are nursing, pregnant, planning to become pregnant during the study
2) Individual who exhibits significant to extreme hair baldness
3) Individual who has used of medications that are intended to treat hair loss or promote hair growth such as minoxidil (Rogaine) or finasteride (Propecia) or any other hair growth and loss prevention products and treatments in the past 6 months;
4) Individual suffering from specific hair loss patterns, such as alopecia areata, traction alopecia, scarring focal loss, scarring alopecia, and telogen effluvium as determined on initial study assessment by the Investigator.
5) Individual with self-reported uncontrolled diseases (i.e. diabetes, hypertension, hyperthyroidism, hypothyroidism, etc.). Medical conditions that are under control with or without treatment will be considered on an individual basis by the Investigators
6) Individual with self-reported active hepatitis, immune deficiency, HIV or autoimmune disease
7) Individual having a known active dermatologic condition which, in the opinion of the examining Investigators, might place the subject at a greater risk or interfere with clinical evaluations (e.g., seborrheic dermatitis, psoriasis, atopic dermatitis, advanced skin cancer, etc.)
8) A history of adverse reactions to hair care products, cosmetics or other personal care products.
9) Individuals who are employees of the Testing Facility

3.3 Informed Consent, Photography Release, and Medical History Forms

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

4.0 Procedure

4.1 Visit 1: Screening Visit

Subjects reported to the facility a minimum of 3 days before the study for the screening visit. Prior to beginning all study related activities, subjects completed an informed consent form, photography release form, HIPAA form and a medical history form. Subjects who arrived for the screening visit were instructed to have their hair washed within 24 hours prior to visit. Subjects were enrolled upon screening per the inclusion/exclusion criteria.

4.2 Visit 2: Baseline Visit (D0)

Subjects were instructed to wash their hair at morning time prior to visit. General photography, Clinical Grading of Efficacy, Dermatologist evaluation for the extent of hair thinning (Appendix I), hair trimming and tattooing at selected sites and Questionnaire procedures were performed. Subjects then received the pre-weighed test product and product usage instructions per the Sponsor for at home use for 12 weeks. Subjects were provided with a calendar of study visits, study instructions, and a daily diary. They were instructed to continue to only use their routine shampoo and conditioner approved by the Testing Facility for the duration of the study. It was emphasized not to a change any of these products for the duration of the study. Subjects were also instructed not to wash their hair for 48 hours.

4.3 Visit 3: Day 2 Visit (D2)

A clinician recorded concomitant medications and asked subjects if they had experienced any changes in their health since the previous visit. If an adverse event (AE) was reported, then the Investigator would have been informed, and an AE form would have been completed. No adverse events were reported during the study.

Phototrichogram was taken.

4.4 Visit 4: Week 6 Visit (D42)

A clinician recorded concomitant medications and asked subjects if they had experienced any changes in their health since the previous visit. If an adverse event (AE) was reported, then the Investigator would have ben informed, and an AE form would have been completed. Daily diaries were reviewed for compliance. Subjects that were non-compliant were counseled that if they continued to be non-compliant, they would be dropped from the study. Test product weights and a verbal confirmation were obtained for usage compliance and were documented in the case report files. Any suspected non-compliance with the treatment (i.e., missing applications, not following usage instructions, etc.) was addressed by the Investigator or designee. The Investigator made a determination if a subject's non-compliance would have an effect the outcome of the study and if the subject should be dropped from the study and/or data should be excluded from statistical analyses. Subjects were instructed to wash their hair at morning time prior to the visit. General photograph,

Clinical Grading of Efficacy, Dermatologist evaluation, and Questionnaire procedures were performed.

4.5 Visit 5: Week 12 Visit (D84)

A clinician recorded concomitant medications and asked subjects if they had experienced any changes in their health since the previous visit. If an adverse event (AE) was reported, then the Investigator would be informed, and an AE form would have been completed. Daily diaries were reviewed for compliance. Subjects that were non-compliant were counseled that if they continued to be non-compliant, they would be dropped from the study. Test product weights and a verbal confirmation were obtained for usage compliance and were documented in the case report files. Any suspected non-compliance with the treatment (i.e., missing applications, not following usage instructions, etc.) was addressed by the Investigator or designee. The Investigator made a determination if a subject's non-compliance would have an effect the outcome of the study and if the subject should be dropped from the study and/or data should be excluded from statistical analyses. Subjects were instructed to wash their hair at morning time prior to visit. General photograph, Clinical Grading of Efficacy, Dermatologist evaluation, Hair trimming and tattooing at selected sites and Questionnaire procedures were performed.

4.6 Visit 6: Day 86 Visit (D86)

Following Phototrichogram measurements, subjects returned any remaining product and then were dismissed from the study.

4.7 Product Usage

Subjects were provided with the following instructions to follow during the study and directed to apply the test product twice per week:

1) Use the applicator to get product out of the jar

2) Section the hair and apply a thin layer of product into the scalp

3) Once you have completed the product application, gently massage it evenly into scalp with finger tips.

4) Wait for 30 minutes

5) Rinse and follow with daily shampoo and conditioner

Product instruction sheet will be included in a take home pack.

1) Use the applicator to get product out of the jar

2) Section the hair and apply a thin layer of the product into the scalp.

3) Once you have completed the application of Silver Rose, gently massage Silver Rose evenly into scalp with fingertips.

4) Wait for 30 minutes.

5) Rinse and follow with daily shampoo and conditioner.

Recommended use: Twice a week.
Apply Silver Rose on wet or dry hair/scalp.
Silver Rose is for men and women
18 years of age and over.

5.0 Instrumentation

5.1 Phototrichogram

The phototrichogram is a non-invasive technique that allows for measurement of the proportion and the density of hair in the different phases of the hair growth cycle. The hairs at selected site (0.8×0.8 cm square) were trimmed down to minimal length by means of special portable trimmer. All hairs were shaved down to approximately identical lengths. The shaved area was disinfected with antiseptic solution, By means of a tattoo apparatus and a tattoo or permanent make-up paint, a dot tattoo, essentially invisible to the bare eye, was deposited in the center of the trimmed site. This allowed for site location at subsequent study visits. In order to obtain an accurate measurement of hair length and number, a transparent glass slide was pressed to the skin surface. The resulting images were recorded on a TrichoSciencePro © computer program and analyzed. After identifying the same hairs in the images taken at 0 h and 48 h following clipping, the length of each hair was measured, and the number of hairs in a given unit area was counted from the captured image. Then, the following parameters were calculated: hair shaft diameter, anagen/telogen ratio, hair density, and follicular units.

6.0 Clinical Grading for Efficacy

The efficacy of the test material was assessed by expert grading performed by a trained professional grader. The expert grader performed clinical evaluation on the hair parameters pre- and post-treatment using a 10-point analog scale.

The subjects were instructed to come to the testing center without any conditioning or styling products on the hair and had washed their hair in the morning of the visit prior to evaluation. The hair was assessed by the expert grader at baseline, week 6 and week 12 time points.

The 10-point analog scale is demonstrated below:

Hair Volume

0_____10

No volume Extreme volume

Hair Shine

0_____10

No shine Extreme shine

Hair Softness

0_____10

Not soft Very soft

Hair Manageability

0_____10

Difficult to style Easy to style

Hair Vitality

0_____10

No vitality Extreme vitality

Scalp Dryness

0_____10

Very dry Not dry

Scalp Redness

0_____10

Very red Not red

Note: Clinical grading of efficacy was performed by the same clinical grader at each test interval.

7.0 Self-Assessment

Panelists answered self-assessment questionnaires at weeks 6 and 12 at the testing facility.

		Greatly Decreased	Moderately Decreased	Slightly Decreased	Neither Increased/ Decreased	Slightly Increased	Moderately Increased	Greatly Increased
1	Overall hair volume	1	2	3	4	5	6	7
2	Scalp coverage	1	2	3	4	5	6	7
3	Thickness of hair body	1	2	3	4	5	6	7
4	Softness of hair body	1	2	3	4	5	6	7
5	Hair shine	1	2	3	4	5	6	7
6	Hair shedding on average day	1	2	3	4	5	6	7
7	Hair regrowth	1	2	3	4	5	6	7
8	Scalp itchiness	1	2	3	4	5	6	7

8.0 Standard Photography

Images of the target areas (scalp and hair) were taken for each subject at weeks 0, 6 and 12 at the test site using standard digit camera.

9.0 Dermatologist Evaluation

Subject's scalp and hair conditions were visually assessed by a dermatologist, and the results were recorded at baseline, week 6 and week 12 time points.

10.0 Adverse Events

One (1) adverse event was reported during the study.

11.0 Methods of analysis

Data analysis was performed by the Testing Facility according to the protocol, and digital photographs and tabulated data were sent to the sponsor.

Descriptive statistics were determined for all efficacy grading parameters, phototrichogram analysis data (with baseline response data). The descriptive statistical summary includes the number of observations (N), mean, median, standard deviation (SD), minimum (MIN) and maximum (MAX) of scores/values at all applicable time points.

The mean of the change from baseline (defined as post-baseline value minus baseline value) was determined for each post-baseline time point. The null hypothesis, that the mean change from baseline was zero, was tested using methods described in the Statistical Analysis Plan table.

11.1 Statistical Analysis Plan

Evaluation	Change from baseline	Notes/Interpretation
Clinical Grading of Efficacy Parameters	Wilcoxon signed –rank test	An increase in scores indicates an improvement for the indicated parameter
Self-perceptive questionnaire	Top-box analysis	

All statistical tests were 2-sided at significance level alpha=0.05, with P-values reported to 3 decimal places (0.000). No multiple testing corrections were considered in the study. Statistical analyses were performed using SAS software version 9.30 series or later (SAS Statistical Institute). The statistical results will be sent to the Sponsor along the raw data in a Microsoft Excel document.

11.2 Data Processing

Photographs in jpeg format will be forwarded to the Sponsor using a USB flash drive in accordance with Biometrix SOPs.

12 Attrition / Adverse Events

A total of 30 subjects completed the clinical study evaluating the safety tolerance and efficacy of Test Product: **Silver Rose Scalp Mask**. Three (3) subjects withdrew from the study for reasons unrelated to the study. Four (4) subjects were dropped from the study due to poor compliance. No adverse events were reported.

13.1 Clinical Grading Results

Clinical Grading was performed at three different times over the 12-week treatment period (i.e. Day 0, Weeks 6 and 12) and were analyzed for statistically significant differences from baseline (Day 0) value. The Wilcoxon Signed Rank Test was used to test for significance between the post-treatment time period and baseline.

A summary of the clinician scores is presented in Figure 1.

Statistically significant improvements in Hair Volume, Hair Shine, Hair Softness, Hair Manageability, Hair Vitality, Scalp Dryness, Scalp Redness were assessed at each of the post-treatment study visits (6 and 12 weeks).

The proportion of the subjects who showed improvement in all the clinical parameters over the baseline Day 0 was from 83.33% to 90.00% after 6 weeks and in the range of 86.67% to 90% after 12 weeks.

Figure 1. Clinical grading scores at different time points.

Data are expressed as Mean±SD, *** $p<0.001$ versus Baseline.

6417-062-64-003

Attributes	Time	Mean BL	Mean V	Mean (V-BL)	Med BL	Med V	% Change	%Subjects showed Improvement	P-value
Hair Volume	W6	4.07	4.93	0.87	4	5	22.44%	83.33%	P<0.001
Hair Shine	W6	4.07	5	0.93	4	5	24.11%	90.00%	P<0.001
Hair Softness	W6	4.07	5	0.93	4	5	24.11%	90.00%	P<0.001
Hair Manageability	W6	4.07	5.03	0.97	4	5	24.94%	90.00%	P<0.001
Hair Vitality	W6	4.07	5.03	0.97	4	5	24.94%	90.00%	P<0.001
Scalp Dryness	W6	4.07	4.97	0.90	4	5	23.44%	86.67%	P<0.001
Scalp Redness	W6	4.07	4.97	0.90	4	5	23.44%	86.67%	P<0.001
Hair Volume	W12	4.07	4.97	0.90	4	5	23.28%	86.67%	P<0.001
Hair Shine	W12	4.07	5.03	0.97	4	5	25.22%	90.00%	P<0.001
Hair softness	W12	4.07	5	0.93	4	5	24.11%	90.00%	P<0.001
Hair Manageability	W12	4.07	5.03	0.97	4	5	24.94%	90.00%	P<0.001
Hair Vitality	W12	4.07	5.07	1.00	4	5	26.06%	90.00%	P<0.001
Scalp Dryness	W12	4.07	5	0.93	4	5	24.11%	90.00%	P<0.001
Scalp Redness	W12	4.07	5	0.93	4	5	24.11%	90.00%	P<0.001

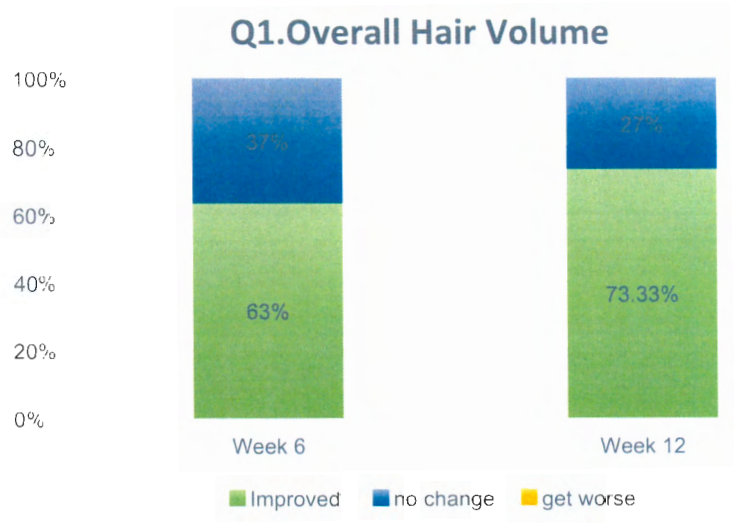
P-value	
	Comparable to baseline
	Better than baseline
	Worse than baseline

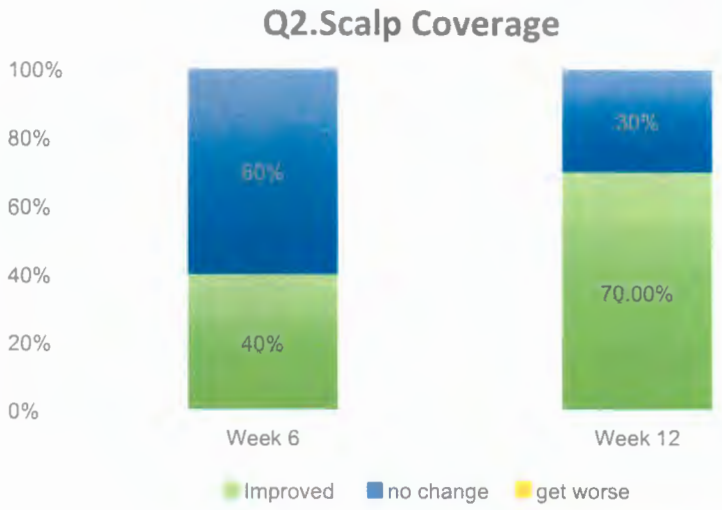
13.2 Self-Assessment

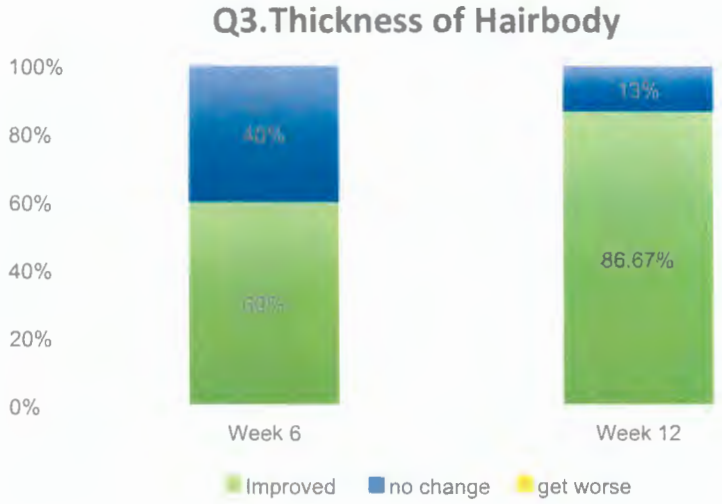
Self-assessment questionnaire were collected on Week 6 and 12. Top-box analysis was used to test for significance between the post-treatment time period and baseline.

The Silver Rose Scalp Mask was effective in improving the hair evaluation parameters at each of the post-treatment study visits (6 and 12 weeks). Under these study conditions, the product Silver Rose Scalp Mask was concluded as a good efficacy and tolerance scalp mask.

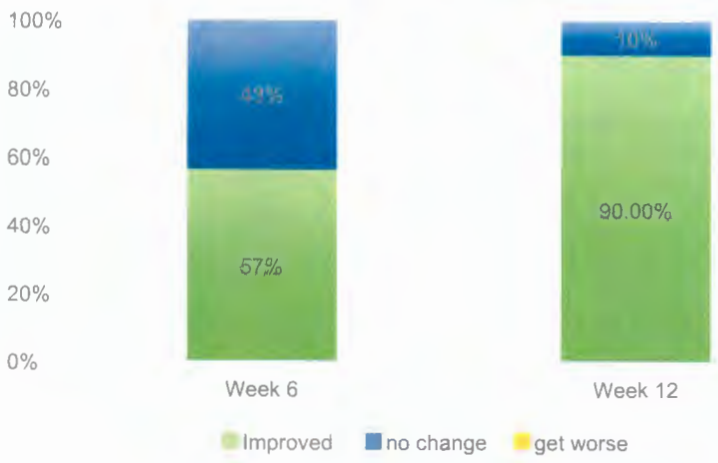
The top three positive response selections, indicating either a strong affect of improvement or satisfaction with test material qualities and the proportion of subjects reporting no change or a worsening are summarized in the charts that follow.




Q2.Scalp Coverage
100%
80%
60%
40%
20%
0%
60%
40%
30%
70.00%
Week 6
Week 12
Improved
no change
get worse


Q3.Thickness of Hairbody
100%
80%
60%
40%
20%
0%
40%
60%
13%
86.67%
Week 6
Week 12
Improved
no change
get worse

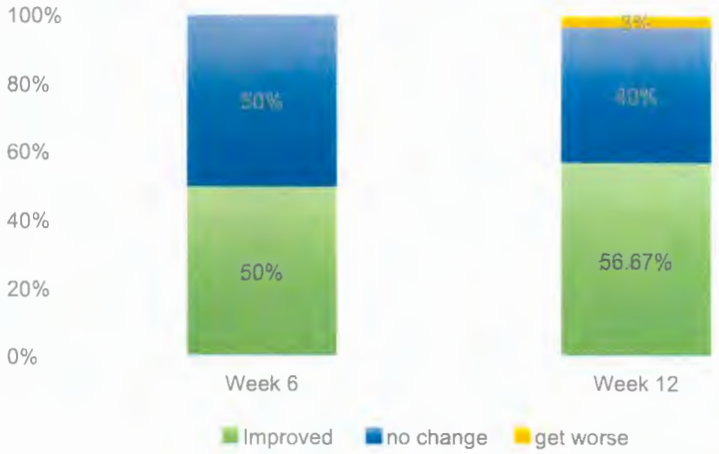
Q4.Softness of Hair



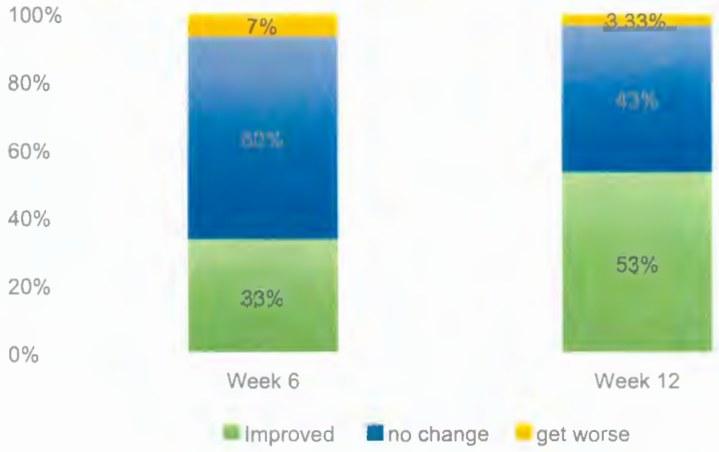
Q5.Hair Shine

Q6.Hair Shedding on Average Day

Q7.Hair Regrowth



Q8.Scalp Itchness



Q9.Scalp Oiliness

13.3 Hair Trichoscopy and Phototrichogram Data

There were no statistically significant changes in hair density of the number of follicular units at Week 12 relative to baseline.

For hair diameter and anagen to telogen ratio, 83.33% and 66.67%, respectively, showed improvement. Hair density improved in 43.33% of the total population, and 26.67% of subjects showed improvement in follicular units.

6417-062-64-003

Attributes	Time	Mean BL	Mean V	Mean (V-BL)	Med BL	Med V	% Change	%Subjects showed Improvement	P-value
Average Hair Diameter (μM)	W12	42.13	49.92	7.79	44.00	50.25	22.92%	83.33%	
Anagen to Telogen Ratio	W12	4.63	4.69	0.06	1.74	2.70	72.60%	66.67%	
Hair Density	W12	75.2	79.7	4.5	74.00	74.50	10.84%	43.33%	
Follicular Units	W12	55.8	59.5	3.7	54.4	58.1	6.62%	26.67%	0.223

P-value	
	Comparable to baseline
	Better than baseline
	Worse than baseline

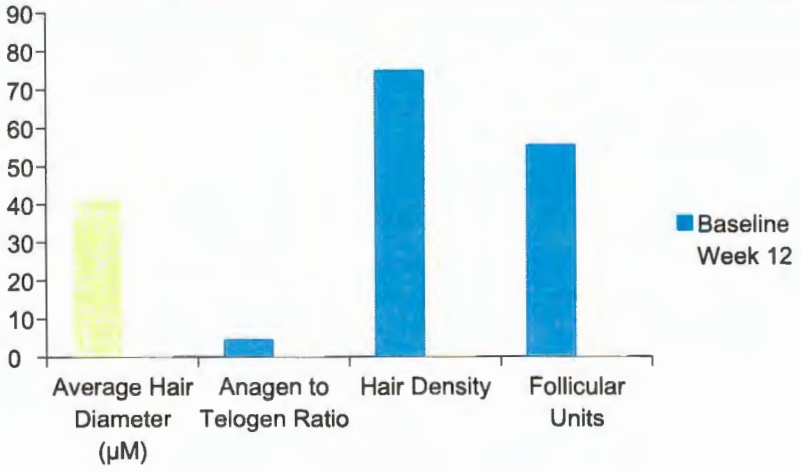


Figure 2. Hair Diameter (μM), Anagen to Telogen Ratio, Hair Density (total / cm^2), and Follicular Units at Baseline and Week 12.

14.0 Archiving

All original samples, raw datasheets, technician notebooks, correspondence files and copies of final reports and remaining specimens are maintained on premises of Biometrix,

Inc. in limited access storage files marked "Archive". These documents will be stored for a minimum of 2 years following the submission of the final report.

Appendix I

Subject Demographic

Panelist	Panelist Initials	AGE	ETHNICITY	Sex	Intensity of hair loss	Scalp region	Grading scale	Comment
1	JS	59	CAUCASIAN	M	Moderate	Vertex, Frontal	Norwood III Vertex	
2	AK	33	CAUCASIAN	F	Mild	Temporal	Norwood I Temporal	
3	HC	60	CAUCASIAN	M	moderate	Vertex, Frontal, Temporal, Occipital	Norwood VI	Dropped at W12
4	DW	46	CAUCASIAN	F	Mild	Frontal ,Temporal	Ludwig I	
5	TS	40	ASIAN JAPANESE	F	Mild	Frontal	Ludwig I	
6	RD	51	CAUCASIAN	M	Moderate	Frontal ,Occipital	Norwood V	Dropped at W12
7	CM	58	CAUCASIAN	F	Mild	Frontal	Norwood I	
8	JB	59	CAUCASIAN	M	Mild	Vertex	Norwood III Vertex	Dropped at W6
9	DS	46	CAUCASIAN	M	Mild	Frontal	Norwood II	
10	YZ	56	HISPANIC	F	Mild	Vertex	Ludwig I	
11	LF	56	CAUCASIAN	F	Mild	Frontal	Ludwig I	
12	JF	60	CAUCASIAN	F	Mild	Vertex	Ludwig I	
13	CR	45	HISPANIC	F	Mild	Vertex, Frontal	Norwood I	
14	ES	51	CAUCASIAN	M	Moderate	Frontal ,Occipital	Norwood IV	
15	JB	41	CAUCASIAN	F	Mild	Frontal	Norwood I	
16	JH	56	HISPANIC	M	Moderate	Vertex, Frontal, Temporal	Norwood IV	
17	LF	58	CAUCASIAN	M	Moderate	Vertex, Frontal, Temporal	Norwood IV	
18	MJ	45	CAUCASIAN	M	moderate	Vertex, Frontal, Temporal, Parietlal, Occipital	Norwood VI	Dropped at W12
19	RM	54	ASIAN CHINESE	F	Mild	Vertex, Temporal	Ludwig I	

20	HG	54	ASIAN CHINESE	M	Moderate	Vertex, Frontal .Occipital	Norwood V	
21	SM	60	ASIAN CHINESE	F	Mild	Frontal	Ludwig I	
22	TK	58	ASIAN CHINESE	F	Mild	Frontal, Vertex	Ludwig I	
23	JM	34	CAUCASIAN	M	Mild	Frontal ,Occipital	Norwood IV	
24	YY	59	ASIAN CHINESE	F	Mild	Frontal, Vertex	Ludwig I	
25	JC	45	ASIAN CHINESE	M	moderate	Frontal	Norwood III	
26	VF	47	ASIAN CHINESE	F	Moderate	Occipital	Norwood III vertex	Dropped at W12
27	PS	38	CAUCASIAN	M	moderate	Occipital	Norwood V	
28	LD	46	ASIAN CHINESE	M	Moderate	Frontal ,Occipital	Norwood III vertex	
29	PV	46	CAUCASIAN	M	Mild	Frontal	Norwood II	
30	MP	27	CAUCASIAN	M	Mild	Frontal, Vertex	Norwood III vertex	
31	AG	39	ASIAN INDIAN	M	Mild	Frontal	Norwood II	
32	JNL	57	ASIAN CHINESE	F	Mild	Frontal	Ludwig II	Dropped at W12
33	GG	26	HISPANIC	M	Mild	Frontal	Norwood II	
34	KH	36	ASIAN CHINESE	F	Mild	Vertex	Ludwig I	Dropped at W12
35	EA	28	CAUCASIAN	M	Mild	Frontal	Norwood II	
36	IC	47	CAUCASIAN	M	Moderate	Occipital	Norwood IV	
37	DD	48	CAUCASIAN	M	moderate	Vertex, Frontal .Occipital	Norwood V	

Clinical Grading

Subject	Hair Volume			Hair shine			Hair softness			Hair Manageability			Hair Vitality			Scalp Dryness			Scalp Redness		
	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12	Baseline	Week 6	Week 12
1	4	4	4	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
2	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6
3	Drop																				
4	4	4	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
6	Drop																				
7	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
8	Drop																				
9	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
10	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
11	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6	5	5	6	5	5	6
12	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
13	4	5	5	4	5	5	4	5	5	4	6	6	4	6	6	4	5	5	4	5	5
14	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
15	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
16	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
17	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
18	Drop																				
19	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
20	3	5	5	3	5	5	3	5	5	3	5	5	3	5	5	3	5	5	3	5	5
21	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
22	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
23	3	4	4	3	4	5	3	4	4	3	4	4	3	4	5	3	4	4	3	4	4
24	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
25	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4
26	Drop																				
27	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
28	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
29	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
30	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
31	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
32	Drop																				
33	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
34	Drop																				
35	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
36	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
37	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
Mean	4.0667	4.9333	4.9667	4.067	5	5.033	4.067	5	5	4.0667	5.033333	5.03333	4.0667	5.0333	5.0666 7	4.06667	4.96667	5	4.06667	4.96667	5
Median	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5	4	5	5
SD	0.5208	0.4498	0.4138	0.521	0.37139	0.32	0.521	0.37	0.37139	0.5208	0.413841	0.41384	0.5208	0.4138	0.36515	0.52083	0.31984	0.37139	0.52083	0.31984	0.37139

MIN	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4	3	4	4
MAX	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6	5	6	6
p value		<0.001	<0.001		<0.001	<0.001		<0.001	<0.001		<0.001	<0.001		<0.001	<0.001		<0.001	<0.001		<0.001	<0.001

Self-Assessment

Week 6									
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Subject	Overall hair volume	Scalp Coverage	Thickness of hair body	Softness of hair	hair shine	hair shedding on average day	Hair regrowth	scalp itchiness	scalp oiliness
1	4	4	4	4	4	4	4	4	4
2	5	4	5	6	5	3	4	1	2
3	Drop								
4	4	4	5	4	3	2	5	4	4
5	5	6	4	4	5	4	6	4	3
6	Drop								
7	6	4	6	5	4	3	4	4	4
8	Drop								
9	4	4	4	4	4	4	4	4	4
10	5	4	4	5	4	3	5	4	4
11	5	4	5	5	6	4	5	6	3
12	4	4	4	4	4	4	4	2	4
13	6	6	6	7	7	4	6	1	3
14	5	5	4	4	4	3	5	3	3
15	5	5	5	5	5	1	7	1	1
16	5	5	5	7	5	5	5	4	4
17	5	5	5	4	6	1	4	4	2
18	Drop								
19	5	5	4	4	4	4	5	4	4
20	5	5	5	4	4	5	4	4	4
21	6	6	6	6	6	1	6	1	2
22	5	5	5	6	6	3	5	4	4
23	5	4	4	5	5	4	4	4	6
24	4	4	4	5	4	4	5	5	4
25	4	4	4	4	4	4	4	4	4
26	Drop								
27	5	4	5	5	5	4	4	4	4
28	4	4	4	5	4	4	4	2	4
29	5	5	6	6	6	1	5	2	4
30	4	4	4	4	4	4	4	3	3
31	4	4	5	5	5	3	4	4	4
32	Drop								
33	4	5	5	4	4	4	5	4	4
34	Drop								

Week 12									
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Subject	Overall hair volume	Scalp Coverage	Thickness of hair body	Softness of hair	hair shine	hair shedding on average day	Hair regrowth	scalp itchiness	scalp oiliness
1	4	4	4	5	5	4	4	3	4
2	5	5	5	6	5	3	5	1	2
3	Drop								
4	4	5	5	5	3	2	5	4	4
5	5	6	5	4	5	4	6	5	3
6	Drop								
7	6	5	6	5	4	3	4	2	4
8	Drop								
9	5	5	5	5	5	3	3	3	3
10	5	5	6	5	6	2	5	4	4
11	5	4	5	5	6	3	5	4	3
12	6	6	7	7	6	3	7	1	4
13	6	6	6	7	7	3	6	1	3
14	5	5	5	5	6	3	5	2	2
15	7	6	7	6	6	1	7	1	1
16	5	5	5	7	5	3	5	4	1
17	5	5	5	5	6	2	4	2	2
18	Drop								
19	6	5	6	6	6	3	5	3	3
20	6	5	6	5	4	4	4	4	3
21	6	5	6	5	5	4	4	4	3
22	5	5	5	5	6	3	5	4	4
23	5	4	4	6	6	3	4	3	3
24	5	5	5	5	5	3	5	3	3
25	4	4	4	4	4	4	4	4	4
26	Drop								
27	5	5	5	5	6	3	5	4	4
28	4	4	5	5	4	4	4	2	2
29	5	6	6	6	6	1	6	3	4
30	4	4	4	4	4	4	4	3	3
31	4	4	5	5	6	3	4	4	4
32	Drop								
33	4	5	5	6	6	2	5	4	2
34	Drop								

35	5	4	5	5	5	4	4	4	4
36	4	4	5	4	5	4	4	1	4
37	5	4	5	5	5	4	5	4	3
Improved	19	12	18	17	16	11	15	10	10
	63%	40%	60%	57%	53%	37%	50%	33%	33%
No change	11	18	12	13	13	17	15	18	19
	37%	60%	40%	43%	43%	57%	50%	60%	63%
get worse	0	0	0	0	1	2	0	2	1
	0%	0%	0%	0%	3%	7%	0%	7%	3%

35	5	4	5	5	5	3	4	4	4
36	4	4	5	5	5	4	4	1	4
37	5	5	6	6	6	4	5	4	3
Improved	22	21	26	27	24	21	17	16	18
	73.33 %	70.00 %	86.67 %	90.00 %	80.00 %	70.00 %	56.67 %	53.33 %	60.00 %
No change	8	9	4	3	5	9	12	13	12
	27%	30%	13%	10%	17%	30%	40%	43%	40%
Get worse	0	0	0	0	1	0	1	1	0
	0%	0%	0%	0%	3%	0%	3%	3%	0%

Source Documents

Enrollment Log–Sliver Rose Scalp Mask

#	Subject No:	Subject Initials	Date of Screening	Date of Enrolment	Comment

Prepared By:_____ Date:____/___/____
DD MM YY

Reviewed By:_____ Date:____/___/____
DD MM YY

Sign-In Form

Subject #	Subject Initials:	Check-In time (hh:mm)	Signature	Date (mm/dd/yy)	Comment (if any)

BIOMETRIX INC.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY TO DETERIMINE EFFECTIVENESS and TOLERANCEOFASCALPMASK (6417-062-64-003)

The purpose of this study is to determine the effectiveness and tolerance of scalp mask.
I am being asked to volunteer for this study because I am a healthyindividual between the ages of20-60 with mild to moderate hair loss.

Only after carefully reading this consent form, signing it, and if I agree to participate, will the following happen:

First, a general screening to see if I am eligible:
To make sure I am in good physical health, and to make sure my hair type is suitable for this study my scalp and hair will be examined. This will be performed before the start of the study.

- To be eligible for this study, I will have to:
- Be between 20-60 years of age
- Possess mild to moderatehair loss
- Be in good physical health
- Must possess the premature hair aging signs including, but not limited to:
hair thinning, hair loss, dryness or brittleness, scalp oiliness, scalp redness, lack of shine
- Willing to cooperate with the investigator and comply with the study regimen
- Willing to not apply any hair products (i.e. conditioner,hair productor studyproduct) on day of visit to each scheduled clinic visit
- Willing to not use anyscalp treatment product for the duration of the study except the product provided for the duration of the study
- Willing to attend the clinic for Visit 1 (Screening), Visit 2(Baseline), Visit 3 (day 2), Visit 4 (Week 6),Visit 5 (week 12) and Visit 6 (day 86)
- Demonstrate the ability to understand what risks are associated with participation
- Demonstrate the ability to read and understand all items in the informed consent
document
- Willing to sign the informed consent document
-Willingness to maintain their normal hair shampooing frequency
-Willingness to not substantially change current diet, medications, or exercise routines for the duration of the study. If you receive physician guidance during the study to change diet, medications, or exercise routine, you will need to notify the clinic as soon as possible
-Willingness to undergo a brief physical exam and a scalp exam. Both exam will occur at baseline
-Willingness to have hair at selected site (0.8 x 0.8 cm square) being trimmed down to minimal length and a dot tattoo being perform in the target scalp
-Willingness to have digital photography of the target area and scalp for hair counts
-Willingness to maintain a consistent haircut and hair color throughout the 3-month study period

I will be excluded from the study if:
-I have significant to extreme hair baldness
-I have specific hair loss patterns, such as alopecia areata, traction alopecia, scarring focal loss, scarring alopecia, and telogen effluvium
- I have used medications that affect characteristics of the are intended to treat hair loss or promote hair growth such as minoxidil (Rogaine) or finasteride (Propecia) or any other hair growth and loss prevention products and treatments in the past 6 months.
-I have uncontrolled diseases (i.e. diabetes, hypertension, hyperthyroidism, hypothyroidism, etc.)
- I have participated in another study involving the hair in the past 2 months.
-Individual with self-reported active hepatitis, immune deficiency, HIV or

autoimmune disease.
-I have a history of adverse reactions to hair care products, cosmetics or other personal care products.
-I am pregnant, planning a pregnancy, or nursing.

If I am in the study, the following will happen
I will be provided Study Product (ScalpTreatment Mask) to be used as instructed.
The study will consist of 6 visits. Each visit session will last20-30 minutes.

On Visit 1, I will complete a sign in sheet, screener, consent document, medical history form, HIPPA, bill of rights and be instructed by study staff.
On Visit 2, I will come to the test site with freshly shampooed hair, then have my scalp and hair examined by study staff. My hair at staff-selected site (0.8 x 0.8 cm square) will be trimmed to minimal length, a dot will be tattooed on the target scalp, and pictures of my hair and scalp will be taken. I will also fill out a questionnaire. The product will be given to me to be used at home.
On Visit 3, I will report to the test site without washing my hair for 48 hours prior to arrival. I will then have my scalp and hair examined by study staff before having pictures taken.
On Visit 4, I will bring the study product and diary back to the test site and report with freshly shampooed hair.I will then have my scalp and hair examined by study staff and fill out a questionnaire.
On Visit 5, I will bring the study product and diary back to the test site and report with freshly shampooed hair.I will then have my scalp and hair examined by study staff.My hair at staff-selected site (0.8 x 0.8 cm square) will be trimmed to minimal length, a dot will be tattooed on the target scalp, and pictures of my hair and scalp will be taken. I will also fill out a questionnaire.
On Visit 6,I will report to the test site without washing my hair for 48 hours prior to arrival. I will then have my scalp and hair examined by study staff before having pictures taken.

Risks/Discomforts
The study product has been extensively tested in the past, thus significant side effects are unlikely to occur. The most common side effects may include (but are not limited to):burning, itching, stinging, tingling, etc.
If you should develop an adverse effect, then you will be discontinued from the study and treated (if necessary).
Cost to the Subject
All products for this study will be provided free of charge.
Potential Benefits to the Subject
There may not be any benefits besides compensation. Benefits to you may include skin improvement. You are participating with the understanding that your contribution to the study will help to determine the effectiveness of scalp mask.

Confidentiality
Records are maintained in confidentiality. The Sponsor and other Agencies are entitled to review the data, but the subjects' identities are not revealed (initials will be used). Anonymity will be maintained in any public reports or publications.
Consent Process and Documentation
The individual responsible for the conduct of this study is Dr. John Ademola. Before the commencement of this study, signed, written consent will be obtained from you by a delegated study staff member.
Benefits, Compensation, Questions
There are no direct benefits for participating in this study. The results of the study will enable the investigators to determine the performance of the test product. Compensation for full participation in this study (compliance with the study protocol, use of the product, visiting the study clinic at baseline,and recording the time you use the product on a diary) will be **$200**.Full payment will be fully compensated at the end of the study, and **$10** for screening fail. This study has been explained to me by Dr. Ademola or a by a study staff member. If I have further questions, I can call the study staffmembers at415-239-8006orDr.Ademola415-845-4638.
Consent
I have been given a copy of this consent form and photo release.
I have read the information about this study; I consent to participate in this study.
Participation in Research is Voluntary

I have the right to decline to participate and to withdraw at any point in this study.
If I wish to participate I should sign this form.

Subject's Name (Please Print)	Biometrix ID#
Subject Signature	Date
Signature of Person Obtaining Consent.	Date

BIOMETRIX INC.

Study # **6417-062-64-003** **Subject #:** _____

Subject Initials: _____

PHOTOGRAPHY RELEASE

For a consideration, mutually agreed upon, and received by me, I, _____, hereby grant BIOMETRIX INC. and its subsidiaries, affiliated companies, and assigns ("BIOMETRIX") permission to take photographs and video of me, and I also give BIOMETRIX INC. permission to use throughout the world the finished photographs and video for any commercial use BIOMETRIX INC. may deem proper. Further, I release and give to BIOMETRIX INC. all rights, titles and interests, including but not limited to copyright and rights of publicity, I may have in the pictures, negatives, reproductions, and video. The photographs and video may be reproduced and published in any and all media, including but not limited to newspapers, books, magazines, internet, and point of sale all without further payment or consideration to me. No further permission for any use of the photographs or video shall be required and the uses there under shall be permitted without limit as to time or geographic scope, and this agreement shall be deemed to be without term and irrevocable. I waive any right to inspect or approve any picture or likeness so used or the copy used in connection therewith, or the use to which it is applied. I release and discharge BIOMETRIX INC. and those acting pursuant to their permission or upon their authority from any liability resulting from the production, reproduction or use hereunder of my picture, or likeness, including any liability for any distortion, optical illusion, alteration or other circumstance that may occur or be produced in connection therewith.

_____ _____

Subject's Signature 2. Date

_____ _____

BIOMETRIX INC. Witness's Signature 4. Date

BIOMETRIX INC.

CCID# _____

Authorization for Release of Protected Health Information for Research Purposes

The attached Informed Consent Form requests your participation in a research study under the direction of John Ademola, PhDand hisresearch team. This Authorization for Release of Personal Health Information is a required supplement to the Informed Consent Form. The Authorization does not change any of the information or permissions described in the Informed Consent Form. The reason for a separate Authorization is new federal law, HIPAA, the Health Insurance Portability and Accountability Act. The HIPAA Privacy Rule protects the privacy of personal health information contained in your medical records. Biometrixhas to obtain this separate Authorization from you so it can use your personal health information for the medical research outlined in the Informed Consent Form.

This Authorization gives you information about:

- how your health information may be used as part of the research,
- how your health information may be disclosed to others as part of the research.
- who may disclose and receive your health information.

The purpose of this study is to evaluate the compatibility of a cosmetic product and to obtain your opinion of the product.

By signing this document, you will authorize to provide John Ademola, other members of the research team, the research sponsor or others with access to the following information about you:

Medical history/surgeries and current medications.

SPECIFIC AUTHORIZATIONS:

The following information will not be released unless you specifically authorize its disclosure by initialing the relevant line(s) below:

_NA_ I specifically authorize the release of information pertaining to drug and alcohol abuse diagnosis or treatment (42 C.F.R. §§2.34 and 2.35).

_NA_ I specifically authorize the release of information pertaining to mental health diagnosis or treatment (CA Welfare and Institutions Code §§5328, *et seq.*) as follows:

_____

_NA_ I specifically authorize the release of HIV/AIDS testing information (CA Health and Safety Code §120980(g)).

_NA_ I specifically authorize the release of genetic testing information (CA Health and Safety Code §124980(j)).

If you do not sign this authorization, you will not be part of the study.
This authorization has no expiration date.

You can revoke this authorization at any time. To revoke your authorization, you can write to John Ademola, or you can ask a member of the research team to give you a form to revoke the authorization. If you revoke this authorization, you will not be able to continue to participate in this study.

If you revoke this authorization, John Ademola and his research team can continue to use information about you that has been collected. No information will be collected after you revoke the authorization.

As part of this study, we may disclose your information to the sponsoring company for this research study. We will not share any information with the sponsor unless the sponsor agrees to keep the information confidential and use it only for purposes related to this study. Any information shared with the sponsor may no longer be protected under federal law.

Biometrix complies with the requirements of the Health Insurance Portability and Accountability Act of 1996 and its privacy regulations and all other applicable laws that protect your privacy. We will protect your information according to these laws. Despite these protections, there is a possibility that your information could be used or disclosed in a way that it will no longer be protected.

Possible Disclosures

Researchers can only use or disclose your health information as required by law or regulations and will continue to protect your personally identifiable health information as described in the attached Informed Consent Form. The information may be subject to re-disclosure and the HIPAA Privacy Rule may not apply in those circumstances. Biometrix complies with the requirements of the HIPAA Privacy Rule and its privacy regulations, and with all other applicable laws that protect the confidentiality of your health information.

I have read this authorization form and have been given the opportunity to ask questions. If I have questions later, I understand that I can contact Biometrix, Inc. at 415-239-8006. I will be given a signed copy of this authorization form for my records. I authorize use of my identifiable information as described in this form.

Signed:

_____ _____

Participant's Signature Date

_____

Participant's Printed Name

CCID#_____

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS THIS INFORMATION IS REQUIRED FOR SUBJECTS IN THE STATE OF CALIFORNIA

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS THIS INFORMATION IS REQUIRED FOR SUBJECTS IN THE STATE OF CALIFORNIA

Please read and keep this document for future reference. Although study personnel may be available to answer study related questions, those pertaining to subject rights listed below should be addressed to Biometrix Inc. at 415-239-8006

What are your rights as a research subject?

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AS REQUIRED BY CALIFORNIA STATE LAW, PLEASE SIGN AND DATE THIS DOCUMENT

_____
Printed Name of Adult Participant

_____ _____
Signature of Adult Participant Date

Participant Medical History Form

Subject No: _____ Initials: _____

Telephone No: _____ (Mobile) / (Home) / (Work)

Sex: Female / Male

Do you have a history of, or currently have, psoriasis, eczema or any other dermatological conditions?
Yes / No

If yes, explain _____

Do you have a history of, or currently have, any medical conditions for which you are under a Physician's care?
Yes / No

If yes, explain _____

Do you have sensitive skin or have sensitivity to new products or changing brands?
Yes /No

If yes, explain _____

FEMALES ONLY: Are you pregnant or nursing? Yes / No

If you are taking any medication please fill out the information below:

Name	Dose	How Often	Syndrome

To the best of my knowledge, the above information is true and I consider myself in general good health.

Signature _____ Date_____

DAILY DIARY
Subject Initials: ____ **Subject Number: _____**

Each day please record the time you use the product and make any comments you may have. Return this diary and the product to the Testing Center at every visit ant at the end of the study. Please use pen when filling out this form.

	Date	Morning	Evening	Comments
1	4/4/2017			
2	4/5/2017			
3	4/6/2017			
4	4/7/2017			
5	4/8/2017			
6	4/9/2017			
7	4/10/2017			
8	4/11/2017			
9	4/12/2017			
10	4/13/2017			
11	4/14/2017			
12	4/15/2017			
13	4/16/2017			
14	4/17/2017			
15	4/18/2017			
16	4/19/2017			
17	4/20/2017			
18	4/21/2017			
19	4/22/2017			
20	4/23/2017			
21	4/24/2017			
22	4/25/2017			
23	4/26/2017			
24	4/27/2017			
25	4/28/2017			
26	4/29/2017			
27	4/30/2017			
28	5/1/2017			

DAILY DIARY
Subject Initials: ____ **Subject Number: _____**

Each day please record the time you use the product and make any comments you may have. Return this diary and the product to the Testing Center at every visit ant at the end of the study. Please use pen when filling out this form.

	Date	Morning	Evening	Comments
29	5/2/2017			
30	5/3/2017			
31	5/4/2017			
32	5/5/2017			
33	5/6/2017			
34	5/7/2017			
35	5/8/2017			
36	5/9/2017			
37	5/10/2017			
38	5/11/2017			
39	5/12/2017			
40	5/13/2017			
41	5/14/2017			
42	5/15/2017			
43	5/16/2017			
44	5/17/2017			
45	5/18/2017			
46	5/19/2017			
47	5/20/2017			
48	5/21/2017			
49	5/22/2017			
50	5/23/2017			
51	5/24/2017			
52	5/25/2017			
53	5/26/2017			
54	5/27/2017			
55	5/28/2017			
56	5/29/2017			

DAILY DIARY
Subject Initials: ____ **Subject Number: _____**

Each day please record the time you use the product and make any comments you may have. Return this diary and the product to the Testing Center at every visit ant at the end of the study. Please use pen when filling out this form.

	Date	Morning	Evening	Comments
57	5/30/2017			
58	5/31/2017			
59	6/1/2017			
60	6/2/2017			
61	6/3/2017			
62	6/4/2017			
63	6/5/2017			
64	6/6/2017			
65	6/7/2017			
66	6/8/2017			
67	6/9/2017			
68	6/10/2017			
69	6/11/2017			
70	6/12/2017			
71	6/13/2017			
72	6/14/2017			
73	6/15/2017			
74	6/16/2017			
75	6/17/2017			
76	6/18/2017			
77	6/19/2017			
78	6/20/2017			
79	6/21/2017			
80	6/22/2017			
81	6/23/2017			
82	6/24/2017			
83	6/25/2017			
84	6/26/2017			
85	6/27/2017			

GRADING FORM

The 10-point analog scale is demonstrated below:

Hair Volume

0 _____ 10

No volume Extreme volume

Hair Shine

0 _____ 10

No shine Extreme shine

Hair Softness

0 _____ 10

Not soft Very soft

Hair Manageability

0 _____ 10

Difficult to style Easy to style

Hair Vitality

0 _____ 10

No vitality Extremevitality

Scalp Dryness

0 _____ 10

Very dry Not dry

Scalp Redness

0 _____ 10

Very red Not red

GRADING FORM

The 10-point analog scale is demonstrated below:

Hair Volume
0_____10
No volume Extreme volume

Hair Shine
0_____10
No shine Extreme shine

Hair Softness
0_____10
Not soft Very soft

Hair Manageability
0_____10
Difficult to style Easy to style

Hair Vitality
0_____ 10
No vitality Extremevitality

Scalp Dryness
0_____10
Very dry Not dry

Scalp Redness
0_____ 10
Very red Not red

Week 12
Subject Initials: _____ ***Subject Number: _____***

GRADING FORM

The 10-point analog scale is demonstrated below:

Hair Volume
0_____10
No volume Extreme volume

Hair Shine
0_____10
No shine Extreme shine

Hair Softness
0_____10
Not soft Very soft

Hair Manageability
0_____10
Difficult to style Easy to style

Hair Vitality
0_____ 10
No vitality Extremevitality

Scalp Dryness
0_____10
Very dry Not dry

Scalp Redness
0_____ 10
Very red Not red

Scalp Mask Study **Questionnaire (Baseline)**
Biometrix: 6417-062-64-003
Subject Initials or ID:_____ **Subject Number: _____**

In regard to your Hair loss, during the PAST week, how much have you felt…

	Not at all			Some		Extremely	
	1	2	3	4	5	6	7
Uncomfortable around others							
Self-conscious around others							
Like you want to avoid people							
Embarrassed							
Unattractive to others							
Stared at							
Afraid of encountering people							
Unhappy with your appearance							
Less self-confident							
Discouraged							
Humiliated							
Hopeless about my skin							
Ugly							
Like I can't be myself							
Angry							
Uneasy							
Sad or down							
Upset							
Frustrated							
Uncomfortable							
Mad							

During the past week, how would you rate the severity of your hair loss (circle one number):

Mild			Moderate			Severe		
1	2	3	4	5	6	7	8	9

Scalp Mask Study **Questionnaire (Week 6)**

Biometrix: 6417-062-64-003
Subject Initials or ID:_____ **Subject Number: _____**

Thinking about your hair now, please indicate how strongly you agree or disagree with the following statements.

		Greatly Decreased	Moderately Decreased	Slightly Decreased	Neither Increased/ Decreased	Slightly Increased	Moderately Increased	Greatly Increased
1	Overall hair volume	1	2	3	4	5	6	7
2	Scalp coverage	1	2	3	4	5	6	7
3	Thickness of hair body	1	2	3	4	5	6	7
4	Softness of hair body	1	2	3	4	5	6	7
5	Hair shine	1	2	3	4	5	6	7
6	Hair shedding on average day	1	2	3	4	5	6	7
7	Hair regrowth	1	2	3	4	5	6	7
8	Scalp itchiness	1	2	3	4	5	6	7
9	Scalp Oiliness	1	2	3	4	5	6	7

In regard to your Hair loss, during the PAST week, how much have you felt…

	Not at all			**Some**		**Extremely**	
	1	**2**	**3**	**4**	**5**	**6**	**7**
Uncomfortable around others							
Self-conscious around others							

Like you want to avoid people							
Embarrassed							
Unattractive to others							
Stared at							
Afraid of encountering people							
Unhappy with your appearance							
Less self-confident							
Discouraged							
Humiliated							
Hopeless about my skin							
Ugly							
Like I can't be myself							
Angry							
Uneasy							
Sad or down							
Upset							
Frustrated							
Uncomfortable							
Mad							

During the past week, how would you rate the severity of your hair loss (circle one number):

Mild			Moderate			Severe		
1	2	3	4	5	6	7	8	9

Scalp Mask Study **Questionnaire (Week 12)**

Biometrix: 6417-062-64-003
Subject Initials or ID:_____ **Subject Number: _____**

Thinking about your hair now, please indicate how strongly you agree or disagree with the following statements.

		Greatly Decreased	Moderately Decreased	Slightly Decreased	Neither Increased/ Decreased	Slightly Increased	Moderately Increased	Greatly Increased
1	Overall hair volume	1	2	3	4	5	6	7
2	Scalp coverage	1	2	3	4	5	6	7
3	Thickness of hair body	1	2	3	4	5	6	7
4	Softness of hair body	1	2	3	4	5	6	7
5	Hair shine	1	2	3	4	5	6	7
6	Hair shedding on average day	1	2	3	4	5	6	7
7	Hair regrowth	1	2	3	4	5	6	7
8	Scalp itchiness	1	2	3	4	5	6	7

In regard to your Hair loss, during the PAST week, how much have you felt…

	Not at all			**Some**		**Extremely**	
	1	**2**	**3**	**4**	**5**	**6**	**7**
Uncomfortable around others							
Self-conscious around others							
Like you want to avoid people							

Embarrassed							
Unattractive to others							
Stared at							
Afraid of encountering people							
Unhappy with your appearance							
Less self-confident							
Discouraged							
Humiliated							
Hopeless about my skin							
Ugly							
Like I can't be myself							
Angry							
Uneasy							
Sad or down							
Upset							
Frustrated							
Uncomfortable							
Mad							

During the past week, how would you rate the severity of your hair loss(circle one number):

Mild			Moderate			Severe		
1	2	3	4	5	6	7	8	9

Now that you have done the initial application,

1) how likely would you be to buy it if it were available at stores at a price you thought reasonable.....

Definitely would buy it .....□
Probably would buy it.....□
Might or might not buy it.....□
Probably would not buy it.....□
Definitely would not buy it.....□

2) What, if anything, did you like about the product?

_____

_____

3). What, if anything, did you dislike about the product?

_____

Product Return Record
Protocol No.: _____
Visit No.: _____ Investigator: _____

Subject Number	Subject Initials	Product ID	Qty Returned	Subject Signature	Date (mm/dd/yy)	Staff Initial	Date (mm/dd/yy)	Comments

Reviewed By:_____ Date (mm/dd/yy):_____

Product Weight form
6417-062-64-003
Sliver Rose Scalp Mask

subject #	Baseline	Week 6	Week12
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			

33			
34			
35			

AE form

Study Number:

Date:

ADVERSE EVENTS / UNCOMFORTABLE SENSATIONS

SUBJECT NUMBER _____ SUBJECT INITIALS _____ ETHNICITY _____ SKIN TYPE _____

Description of Symptom	Location of Symptom	Intensity	Onset Day	Onset Time after application	Duration of Symptom	Frequency	Consecutively	Relationship	Action Taken	Follow Up	Recorded By

Experienced Before? Y or N Explain: _____

If occurs with usual product this was: less than with their usual product the same as their usual product more than with their usual product

Usual Products: _____ _____

Comments: _____ (→)

Intensity (self-perceived)	Relationship To Test Product	Action Taken	Follow-Up
VSL= Very Slight Sli=Slight M=Moderate ST=Strong VST=Very Strong	1=None 2=Possible 3=Probable 4=Definite	1=None 2=Modify test product use 3=Medication/Seek Medical Attention 4=Discontinue	1=No follow-up necessary 2=Panelist will call if condition worsens 3=Panelist will see a doctor 4= Follow-up with panelist

Study Investigator Signature: _____

Outcome Assigned by Study Investigator (Circle below)
1=Resolved
2=Resolving
3: Not Resolved
4=Fatal

BIOMETRIX INC.

To be completed by a Study Staff Member.

Study #: 6417-062-64-003

First Name:_____ Initials:_____ CCID: _____ Subject #: _____

Patient Testing Records

Procedures	Screening	Baseline	Day 2	Week 6	Week 12	Day 86
Informed Consent Form, HIPPA, Bill of Rights, Medical History Form and Qualification/enrollment paperwork	X					
Clinical Grading of efficacy parameters		X		X	X	
Dermatologist Evaluation		X		X	X	
General Photographs		X		X	X	
Phototrichogram			X			X
Test Product, Diary and Usage Instructions Distribution		X				
Self-perceptive questionnaire		X		X	X	
Test Product Weights		X		X	X	
Test Products and dairy Collection						X
Recording reactions (AE, SAE)		X	X	X	X	X

Initial each station as it is performed during each visit.