

# *Efficacy and Tolerance Study of a Shampoo/Conditioner System to increase hair growth rate*

## *Study N°10S-0802 Final Report*

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***This report is composed of 23 pages including appendices (10 pages).***

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## **OBJECTIVE**

The main objective of this study is to determine the efficacy of a Shampoo/Conditioner System to increase the rate of hair growth by a non-invasive method, in this case by hair coloring and measurements of the roots every 42 days (6 weeks). The study involved 20 healthy female volunteers and was conducted over three periods of 42 days for a total of 18 weeks. The first period was the reference during which the volunteers followed their regular hair cleansing routine. During the other two periods, the volunteers had to apply the test treatment once a day. Rates of hair growth determined at different time points were compared to each other. The volunteers also evaluated the effects of the treatment on the rate of hair growth by completing a self-assessment questionnaire.

The secondary objective of the study was to evaluate consumer acceptance and tolerance to the test products according to normal conditions of use.

## **PROTOCOL**

### **1. Ethics committee**

This procedure and associated documents were reviewed and approved by an Ethics Committee on May 26<sup>th</sup>, 2010 prior to the commencement of the study. The Ethics Committee is an independent organisation whose members' responsibility is to ensure the protection of the rights, security and well being of the volunteers participating in the study.

### **2. Investigation Site**

Evalulab Inc. located at 5475 rue Paré, Suite 206 Mont-Royal, Québec, Canada.

### **3. Personnel**

The study was realized by Evalulab Inc., conducted by Pamela Garcia, B.Sc. - Laboratory Assistant and Marie-Laure Oula, M.Sc. - Investigator, R&D Director, in collaboration with a professional hairdresser (Salon Vogue) sponsored by Evalulab.

### **4. Quality Assurance**

This study was conducted in accordance with Good Clinical Practices (GCP). GCP are defined by the totality of the pronouncements put in place for ensuring the quality and authenticity of the trials and the obtained data on one hand and the respect for the ethics on the other.

The data obtained for each volunteer is recorded in individual Case Report Forms. The data entry is made in black ink. In case of errors or omissions, the initial entry is crossed out and initialled by the investigator.

All recorded data is validated by the investigator, who assumes responsibility for the quality of the work presented and verifies that all gathered data is in agreement with the protocol.

The records obtained during the study will be kept by Evalulab Inc. for a period of 2 years.

### **5. Design of the Study**

#### **• Type of Study**

The study was conducted using a mono-centric and open-ended design, meaning the evaluator, the volunteers and the sponsor alike, were aware of the nature of the test material.

The treatment was composed of two products, labelled as FAST Shampoo and FAST Conditioner by the sponsor, which were the subjects of the study.

#### **• Duration**

The study took place from August 2<sup>nd</sup> to December 6<sup>th</sup>, 2010.

- **Test products**

Upon reception, the samples were registered in the "Receptions Book" and assigned a code followed by storage at ambient humidity and temperature in their original containers (as received) in an area allocated for this purpose.

All products were provided in homogeneously labelled containers in sufficient quantities and detailed as follows:

**Product names:** Fortified.Amino.Scalp.Therapy (FAST) Shampoo 360 mL  
Fortified.Amino.Scalp.Therapy (FAST) Conditioner 360 mL  
**Category:** Liquid Shampoo/Liquid Conditioner  
**Client lot #:** Shampoo # 072610 and 092310/ Conditioner # 062110 and 092310  
**Evalulab lot #:** Shampoo # 101015.CN.01/ Conditioner #101015.CN.02

- **Volunteers**

Recruitment of volunteers:

A total of 20 healthy volunteers were recruited. A profile of the volunteers is presented in Table I in the Appendices. Mean age for all volunteers is 33.8 (ranging from 21 to 54 years of age).

Informed Consent Forms:

Each volunteer was informed verbally and in writing of the nature of the test and of the potential risks involved. All volunteers were required to read, sign and date the Informed Consent Form explaining the conditions of the test, the risks involved and briefly describing the products to be tested.

Confidentiality:

Volunteer participation in this study is confidential. The information gathered during the course of the study was recorded in Case Report Forms that are numerically coded and that do not contain the names of the volunteers. Only the employees of Evalulab, the affiliated dermatologist, auditors of the sponsor and regulatory bodies (FDA, Health Canada & the Ethics Committee) may have access to the confidential information.

Inclusion Criteria:

1. Female volunteers, in good health, between 18 and 60 years of age,
2. Who declare having healthy hair without any hair loss,
3. Who agree to color their hair at least two (2) shades different from their natural hair color,
4. Women with dark hair provided their natural hair color can be lightened or darkened at least two (2) shades,
5. Cooperating and accepting the hairdresser's suggestions in exceptional circumstances (the volunteer's choice may not interfere with the purpose of the study, ...),
6. Who are cooperating individuals who can be followed at every visits, aware of duration and importance of the tests, thus allowing for complete adherence to the established protocol,
7. Who agree to sign the two Informed Consent Forms for the study with full knowledge of the details and the risks involved,
8. Who use a method of contraception (contraceptive pill, condoms, spermicidal creams, an intra-uterine device (IUD), abstinence ...).

Exclusion Criteria:

1. Women who refuse to use only the test products in their daily routine with the exception of their regular hair styling products,
2. Who have a history of skin irritation or allergies to the type of products to be tested (shampoo, conditioner, hair color, hair lotion...) or in general, with allergies to certain foods, certain chemical products, glues, latex (rubber gloves), jewellery...,
3. Who have a history of severe acne, eczema, topical dermatitis, psoriasis or significant skin anomalies on the areas to be tested that may bias the results of the study,
4. Who suffer from a serious illness or health problem, or a critical or progressive disease (asthma, diabetes, cancer, immunological deficiency, removed organ ...),
5. Who have taken prescription or over the counter medication (at a frequency equal to or more than 3 doses per week) that could affect skin characteristics or could bias the study (i.e. antibiotics, steroids, antihistamines, anti-inflammatories,...) within 7 days prior to the beginning of the study,
6. Who abuse of alcohol, drugs and/or tobacco,
7. Who are pregnant, lactating or expecting to become pregnant during the study,
8. Who have participated in a similar study less than a month before beginning this study.

## 6. Evaluation

- **Schedule**

The investigation was carried out according to the schedule summarized below in Figure 1.

**Figure 1: Study schedule**

Description	D0	D42	D84	D126
	Without treatment	With treatment		
Volunteer Selection according to inclusion and exclusion criteria	X			
Signing of the Informed Consent Form	X			
Completion of Medical History Questionnaire by the volunteer	X			
Distribution of the Questionnaire		X		
Distribution of the Follow-up form (log of daily application)		X	X	
Distribution of Samples		X	X	
Hair coloring by a professional hairdresser sponsored by Evalulab	X	X	X	
Digital Photographs using a Canon PowerShot 12.1 MP Digital camera	X	X	X	X
Measurement of hair regrowth		X	X	X
Return of completed follow-up form (log of daily application)			X	X
Return of completed self-evaluation questionnaire				X

- **Protocol**

On the first day (D0), the volunteers came to the hairdressing salon (Vogue, 1192 Rue Crescent, Montréal, Québec, Canada H3G 2A9) for verification of the inclusion/exclusion criteria by the investigator, followed by the signing of the Informed Consent Forms and the explanation of details concerning the conduct of the study.

The professional hairdresser, sponsored by Evalulab Inc., helped the volunteers choose a permanent hair color to be applied on the entire head, starting from the roots. The hairdresser then performed the coloring taking necessary care to cover the hair uniformly.

Then, the qualified Evalulab technician separated the volunteers' hair by making a line in the centre of the head and took a photograph to illustrate the appearance of hair immediately after coloring at D0 (baseline image).

The volunteers were instructed to follow their regular hair cleansing routine (same brand of shampoo & conditioner). Changes regarding the brand of their regular hair styling product were not permitted during the week prior to the commencement of the study or during the entire length of the study. The use of other products intended to increase the rate of hair growth (revitalizer, hair growth lotion...) was not allowed. Additionally, the volunteers were instructed not to wash their hair during the 24 hours following the coloring.

At D42, the volunteers returned to the hairdressing salon (Vogue). The qualified Evalulab technician took a photograph of the hair under the same conditions as D0 to illustrate the appearance of hair growth after 42 days. An example is presented in the Appendices-Table II. Then, the technician identified 4 regions of the scalp (Vertex, Frontal, Parietal and Occipital) using a template pierced cap (one cap per volunteer). Hairs exposed from the pierced areas (around 6cm<sup>2</sup>) were measured twice by the technician using a flexible ruler, allowing to determine the baseline hair growth rate (without treatment). The professional hairdresser then performed hair coloring following the same procedure used on D0.

Additionally, the volunteers were given the test products, a follow-up sheet to be completed after every application and a self-evaluation questionnaire to be completed after 84 days (12 weeks) of treatment use.

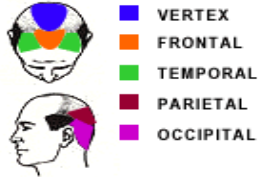
Volunteers were instructed to wet their hair once a day prior to applying the shampoo and working it into a rich lather. They were asked to scrub their entire scalp thoroughly, to rinse with warm water and to repeat the process. Following the shampoo, the volunteers had to apply the moisturizing conditioner, to massage their scalp thoroughly and to allow it to settle for 1-2 minutes before rinsing with hot water. They were asked to style their hair as usual, with their regular styling products.

The same procedure used on D42 was conducted on D84 to determine hair growth rate after 6 weeks of treatment.

On the last day, D126, the volunteers had to return to the laboratory, bringing with them their test product containers and their completed surveys (self-evaluation questionnaires) and daily logs.

The qualified Evalulab technician took a photograph of the hair under the same conditions as D0. Then, the technician identified the same regions of the scalp as on D0 (Vertex, Frontal, Parietal and Occipital) using the template pierced cap. Hairs exposed from the pierced areas were measured twice by the technician in order to determine hair growth rate after 12 weeks of treatment.

#### **REGIONS OF THE SCALP**



- **Test Methods**

Treatment Acceptance:

Treatment acceptance is defined by the overall participation of the volunteers in the study and the level of tolerance to the treatment in question. Tolerance to the treatment is based on the observed reactions if any, their degree of severity and reproducibility from one volunteer to another. These parameters are also evaluated by a questionnaire survey at the completion of the study.

Standardized length measurements:

Using a flexible ruler, the technician measures the length of hair roots twice in 4 regions of the volunteers' scalp, in a standardized fashion. These measurements allow determining hair growth rate by region, but also global hair growth rate when measurements are pooled into an average single value. The global hair growth rate is calculated from eight (8) independent measurements, allowing to increase the accuracy of the value.

Hair growth rates determined at D84 and D126 (respectively 6 and 12 weeks after treatment) are compared to one another as well as to the baseline hair growth rate obtained at D42 (before treatment).

Qualitative Survey:

A qualitative assessment of the treatment efficacy was conducted by a survey. A section of the self-evaluation questionnaire was designed to gauge the volunteers' perception of each test products' sensory attributes and overall performance. Also, the volunteers were encouraged to express their opinion by entering personal comments at the end of the questionnaire.

Digital Photographs using a Canon PowerShot 12.1 MP digital camera:

Digital photographs of hair using a Canon PowerShot 12.1 MP digital camera were taken for illustration of hair roots appearance before coloring at D0, and after hair regrowth at D42, D84 and D126. As it has been difficult to reproduce the photographs under standardized conditions (light, shooting angle, position...), only the most representative and most successful photographs are included in the DVD-ROM support.

### **7. Statistical Method**

Statistical analysis is conducted on the 2 following parameters for the evaluation of product efficacy:

- **Standardized length measurements**

The results will be reported in tables showing the average hair growth rates at different measurement time points. Statistical analysis will be conducted on all pertinent parameters. Results obtained at D84 and D126 (after treatment) are compared to one another as well as to the values obtained at D42 (baseline-before treatment) using the Student's t test.

- **Subjective self evaluation questionnaire**

Average of volunteer self-evaluation scores for each test product will be calculated and presented in tables.

## **8. Adverse Events or Serious Adverse Events**

The volunteers were instructed to immediately communicate any reactions to Evalulab.

An "Adverse Event" is defined as any noxious and unintended response observed in a volunteer testing a product that does not necessarily have a causal relation with the test product or the treatment in question.

The risks for adverse events associated with this test, both cutaneous and ocular may vary amongst the volunteers. Volunteers may be subject to ocular discomfort, rash (intense redness), cracking, exfoliation effect, dryness, or even pain if the test product is strongly irritant or if the volunteer is particularly sensitive to the product. Volunteers may also develop an allergic sensitisation to the test product or to its components.

The term "Serious Adverse Event" refers to any untoward medical occurrence, related or not to the test product that may lead to death, persistent or significant disability, that requires hospitalization or prolongation of a hospitalization period or that provokes invalidity, significant or permanent incapacity, or that translates to congenital anomaly or malformation.

## **9. Amendments to Protocol**

No amendments were made to the protocol.

## RESULTS

### 1. Treatment Acceptance

- **Participation**

Twenty (20) volunteers were recruited for this study. One volunteer (01-0802-020) left the study without explanation after D84. At this time of the study, she could not be replaced.

The nineteen (19) remaining volunteers completed the study without incidence. Considering each volunteer's hair length and volume, we can conclude that compliance was observed for all the participants. However, at the visit on D84, six (6) volunteers who were thought not to be using a sufficient quantity of the 2 test products (in comparison to the group and relative to their type of hair) were encouraged to use the products more generously. This recommendation was followed by most of them.

The average amount of shampoo used during the first 42 days was recorded at 12g per day and at 13g per day during the last 42 days. The average amount of conditioner used during the whole study was recorded at 13g per day.

Product usage details are presented in the Appendices – Table III.

- **Tolerance**

One (1) "Adverse Event" was observed by the investigator in the case of volunteer 01-0802-006. It was determined that the reaction was not directly related to the test treatment. The volunteer had an allergic reaction to ammoniac contained in the professional dye. Thus, the use of the test products was interrupted for 3 days and replaced by a mild shampoo allowing the burning and itching sensations to reduce. On D84, no ammoniac dye was used.

All data for tolerance collected from the self-evaluation questionnaires completed by the volunteers are presented in Table IV in the Appendices. A summary of the individual sections is provided below, followed by a discussion.

As part of the questionnaire, the volunteers were to evaluate their tolerance to the treatments by selecting "None", "Slight", "Moderate", or "High" for each of the intolerance criteria. The list of the intolerance criteria and the responses expressed as the percentage of volunteers in each category after 12 weeks of treatment use are provided in Figure 2 below.

**Figure 2: Overall scores for skin tolerance to treatment at day 126**

Criteria	"None"	"Slight"	"Moderate" + "High"
Redness	100%	0%	0%
Burning sensation	100%	0%	0%
Itching sensation	89%	11%	0%
Peeling/Dandruff	68%	16%	16%

The summary of the results indicates that the Shampoo/Conditioner system was well tolerated by most of the participants. There were few reports of "Moderate" + "High" levels (16%) of dandruff. Additionally, there were some reports of "Slight" discomforts associated with an itching sensation (11%) and dandruff (16%).



## 2. Treatment Efficacy

The volunteers were asked to express their opinion on the treatment in regards to its cosmetic qualities (sensory attributes) and overall efficacy at D126, by completing a self-evaluation questionnaire providing scores for test treatment characteristics on a qualitative scale.

- **Sensory Attributes**

Highlights of the sensory scores are expressed as the combined percentage of volunteers who indicated either "Appreciated" or "Highly Appreciated" (Total Appreciated) for each sensory attribute.

All scores for sensory attributes collected from the self-evaluation questionnaires completed by the volunteers are presented in Tables V in the Appendices.

The results for the sensory attributes of the test products are summarized in Figure 3 below, followed by a discussion.

**Figure 3: Overall scores for the Shampoo/Conditioner system sensory attributes at day 126**

Criteria	Total Appreciated
Easy rinsing- Shampoo	95%
Easy rinsing- Conditioner	95%
Feeling after hair drying	89%
Fragrance- Shampoo	75%
Fragrance- Conditioner	74%

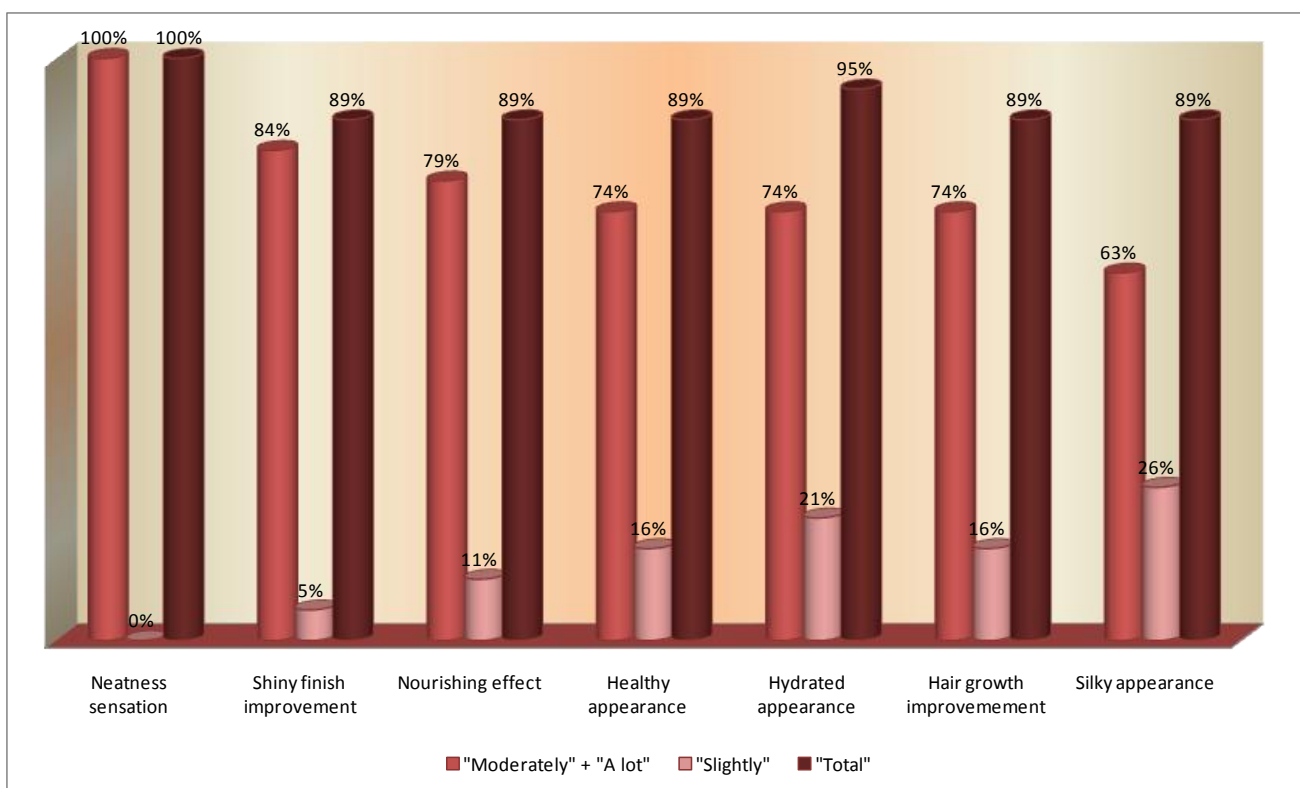
The overall level of appreciation in regards to the sensory attributes for the shampoo and conditioner was very good. Ninety-five percent (95%) greatly appreciated the test products ability to be rinsed off and eighty-nine percent (89%) were pleased with the feeling after hair drying. The least appreciated criterion was the fragrance, both for the shampoo and the conditioner. However, it is important to note that seventy-five percent (75%) of the volunteers really appreciated the fragrance of the shampoo versus seventy-four percent (74%) for the conditioner.

- **Perception of Treatment efficacy**

To assess the volunteers' perception of treatment efficacy at D126, they were asked to complete questions pertaining to the efficacy of the products at improving their rate of hair growth. They were also asked to indicate whether their hair appeared to be more fed and if there was an improvement in the hydration level and the shininess of their hair. The responses for each criterion expressed as "A lot", "Moderately", and "Slightly" have been combined and summarized as the total percentage of positive responses in Figure 4.

All scores for perception of treatment efficacy collected from the self-evaluation questionnaires completed by the volunteers are presented in Table VI in the Appendices.

**Figure 4: Overall scores for the perception of treatment efficacy at day 126**



Pooling all the positive answers (Total) together, all (100%) the volunteers thought the product as very effective, particularly for the provided neatness sensation. The results for the other criteria were also very remarkable. In fact, ninety-five percent (95%) of the participants associated a moisturising effect to the treatment. Then, eighty-nine percent (89%) of the volunteers were very satisfied with the nourishing effect of the test products, the shiny finish as well as the healthy and silky appearance of their hair. Finally, Eighty-nine percent (89%) of the participants considered the product was functional to increase the rate of hair growth.

**Other data not shown in the figure 4:**

The participants were also asked to indicate the time (in weeks) associated with a noticeable effectiveness of the treatment in regards to an increased rate of hair growth, when compare to their normal hair growth rate. Among the 89% of volunteers considering the test products increased their rate of hair growth; eleven percent (11%) noticed the effectiveness after only two weeks of use. After four (4) weeks of treatment, a significant number of volunteers (42%) experienced the treatments' efficacy. Finally, twenty-six percent (26%) of the participants noticed the test products' efficacy after six (6) weeks versus eleven percent (11%) after eight weeks of treatment use.

Additionally, the participants were asked to express their opinion on the feeling on their scalp immediately after treatment application and rinse off. Fifty-three percent (53%) answered they felt a neatness sensation while twenty-one percent (21%) experienced freshness. Twenty-one percent (21%) considered the treatment provided both neatness and freshness sensations. Finally, five percent (5%) of the volunteers thought the Shampoo/Conditioner system left the hair dry.

Finally, the treatment global performance was rated by combining the scores for "Excellent", "Very Good" and "Good". It is noted that eighty-four percent (84%) of the participants considered the test treatment as a performing hair growth treatment. Seventy-nine percent (79%) would recommend the treatment and eighty-four percent (84%) of the participants would purchase the test products (at a competitive price).

- **Comments**

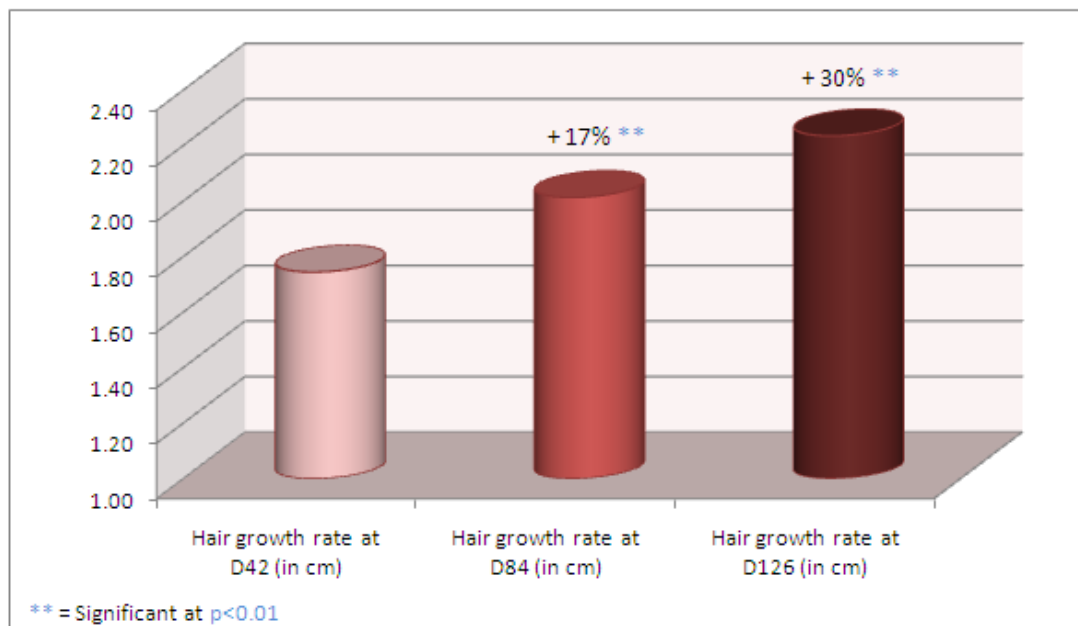
The complete list of all the comments expressed by the volunteers about the treatments is presented in Table VII in the Appendices including all details of negative and positive comments collected at D126. None of these comments need to be underscored or discussed at any length.

### 3. Hair Growth Rate

To assess hair growth rate, the qualified Evalulab technician measured the length of the hair roots twice in 4 regions of the volunteers' scalp, in a standardized fashion.

The measurement data expressed in centimetres are provided in the Appendices-Tables VIII and IX. A summary of the measurements expressed in a percentage of improvement in hair growth rate at D84 and D126 compared to D42 are provided in Figure 5 and discussed below.

**Figure 5: Percent Improvement in Hair Growth Rate at D84 and D126 compared to D42**



Statistical analysis showed no significant difference between the growth rates of the four (4) selected sites. Thus, we can pool the obtained values to infer the average growth rate per volunteer.

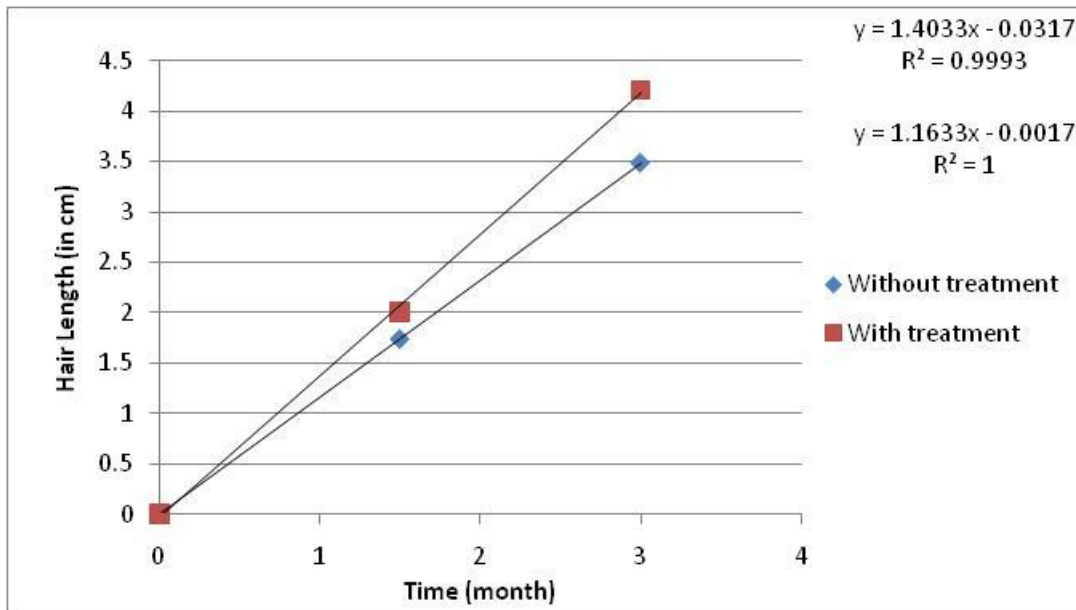
Statistical analysis of the data revealed that the treatment allowed an improvement of hair growth rate when applied daily. After only 42 days of treatment, a significant improvement in hair growth rate of 17% ( $p < 0.01$ ) with values reaching 52% (Vol. 01-0802-004) was observed. After 84 days of product use, the treatment efficacy is confirmed by an average effectiveness of 30% with an efficient starting value of 4% (Vol. 01-0802-019) up to an optimum value of 99% (Vol. 01-0802-013). When comparing the hair growth rates obtained at D84 and D126, statistical analysis revealed that the difference is significant ( $p < 0.01$ ), implying that the treatment becomes more effective with time.

On the centimeter scale, we can see that without treatment ( $T=0$  week) the average hair growth rate is of 1.70 cm ( $\pm 0.20$  cm) after 6 weeks, value also confirmed by the literature. After 6 weeks of treatment, the average rate of hair growth is of 2.00 cm ( $\pm 0.19$  cm). Additionally, six (6) volunteers had a hair growth rate above 20%. Finally after 12 weeks of treatment, the average rate of hair growth reached 2.20 cm ( $\pm 0.27$  cm) with sixty-five (65%) percent of the volunteers or thirteen (13) volunteers having a global growth rate increased by over 20%.

In fact, in the case of volunteer #01-0802-013 who had an initial hair growth rate of 1.60 cm after 6 weeks, the rate of growth almost doubled to 3.20 cm after 12 weeks of treatment with the Shampoo/Conditioner system.

Statistical analysis of the data highlights the trend of the treatment to be more effective on short hair. Indeed, if the volunteers are split into three groups according to their initial hair length, there are 7 volunteers with short hair, 9 volunteers with medium hair and 3 with long hair. The participants with short hair obtained the highest results with an average rate improved by thirty-eight percent (38%) versus twenty-eight percent (28%) and fourteen percent (14%) for the participants with medium and long hair respectively, at D126. However, this observation requires confirmation with more data, especially for long hair.

**Figure 6: Improvement in Hair Growth Rate versus time**



When the length of hair is summed up over time, we can observe that without treatment a new hair would have grown to a length of 1.10 cm after one month and of 3.50 cm after 3 months.

With the test products, the same hair has a length of 1.34 cm after one month and 4.20 cm after three months of treatment. Thus, we can deduce that the treatment efficacy increases with time.

## CONCLUSION

This study evaluates the potential of a Shampoo/Conditioner System in increasing hair growth rate. A total of twenty (20) healthy female volunteers were recruited but nineteen (19) completed the study. Mean age for all the volunteers was 33.8 years of age.

Compliance with the established protocol was observed for all remaining 19 participants. The study was completed without any adverse events directly related to treatment use. Both test products were well tolerated by the majority of the volunteers. There were few reports of "Moderate" + "High" levels (16%) of dandruff. Additionally, there were some reports of "Slight" discomforts associated with an itching sensation (11%) and dandruff (16%).

Subjective data obtained from the volunteer self-evaluation questionnaires indicate that the sensory attributes and the performance of the Shampoo/Conditioner System were greatly appreciated by the participants. When pooling all the positive answers together, all (100%) of the volunteers considered the product as very effective particularly for the provided neatness sensation. The results for the other criteria were also very remarkable. In fact, ninety-five percent (95%) of the participants associated a moisturising effect to the treatment. Then, eighty-nine percent (89%) of the volunteers were very satisfied with the nourishing effect of the test products, the shiny finish as well as the healthy and silky appearance of their hair. Finally, Eighty-nine percent (89%) of the participants considered the product was functional to increase the rate of hair growth. Eleven percent (11%) of the participants reported an improvement in their rate of hair growth as soon as two (2) weeks after starting the treatment. Forty-two percent (42%) of the volunteers experienced the treatments' efficacy after four (4) weeks of product use.

Objective data obtained for the treatment confirmed subjective data and also revealed significant improvement in hair growth rate (at  $p < 0.01$ ). An average improvement of 17% was obtained after 6 weeks of treatment. Following 12 weeks of product use, the treatment efficacy is established at an average effectiveness of 30%, with an efficient starting value of 4% (Vol. 01-0802-019) up to an optimum value of 99% (Vol. 01-0802-013).

In conclusion, the treatment tested under the conditions described herein has a significant action on hair growth rate. Used on a daily basis, the Shampoo/Conditioner system allowed to increase the average rate of hair growth from 1.70 cm to 2.00 cm after 6 weeks and finally to 2.20 cm after 12 weeks. Additionally, statistical analysis revealed a linear relationship (at  $R=0.99$ ) between the period of treatment use and the improvement in hair growth rate. Thus, results become more noticeable with time.

I the undersigned, Marie-Laure Oula, M. Sc. declare that this study was conducted under my supervision, in accordance with the principles of "*Good Clinical Practices*". The recorded results show exactly and completely the raw data of the study.



Signature  
Marie-Laure Oula, M. Sc. – Investigator

Date: Mont-Royal, December 22<sup>th</sup>, 2010.

I the undersigned, Elisabeth Fiquet, declare that the information provided in this report reflects in a complete and exact manner the results obtained during the study.



Signature  
Elisabeth Fiquet, M. Sc.  
Quality Assurance Director, President

Date: Mont-Royal, December 22<sup>th</sup>, 2010.

## APPENDICES

**Table I: Volunteer profile**

Volunteer #			Initials	Age	Gender
01	-0802-	001	VC	30	F
01	-0802-	002	LD	33	F
01	-0802-	003	DM	34	F
01	-0802-	004	CB	36	F
01	-0802-	005	SG	29	F
01	-0802-	006	SG	35	F
01	-0802-	007	JL	39	F
01	-0802-	008	MR	29	F
01	-0802-	009	EM	30	F
01	-0802-	010	ML	25	F
01	-0802-	011	SS	43	F
01	-0802-	012	LC	54	F
01	-0802-	013	MD	25	F
01	-0802-	014	EP	40	F
01	-0802-	015	MM	37	F
01	-0802-	016	AG	35	F
01	-0802-	017	LM	26	F
01	-0802-	018	HC	21	F
01	-0802-	019	EA	43	F
01	-0802-	020	GH	31	F

**Table II: Images for illustration of hair after coloring and regrowth**



**Figure 1: Hair after coloring- Vol. #007**



**Figure 2: Hair 42 days after coloring-Vol. #007**

**Table III-a: Volunteer Compliance to the test product according to product weight (g) - Shampoo**

Volunteer #			Initials	Initial hair length	Weight at D0	Weight at D84	Difference at D84	Daily Use at D84	Weight at D126	Difference at D126	Daily Use at D126
01	-0802-	001	VC	short & fine	865	547	318	7.6	176	371	8.8
01	-0802-	002	LD	medium & fine	1300	916	384	9.1	314	602	14.3
01	-0802-	003	DM	long & thick	1734	965	769	18.3	196	769	18.3
01	-0802-	004	CB	medium	1295	895	400	9.5	419	476	11.3
01	-0802-	005	SG	medium & thick	1729	1007	722	17.2	349	658	15.7
01	-0802-	006	SG	medium & thick	1301	826	475	11.3	288	538	12.8
01	-0802-	007	JL	medium & thick	1298	819	479	11.4	355	464	11.0
01	-0802-	008	MR	mi-long	1295	733	562	13.4	234	499	11.9
01	-0802-	009	EM	long & fine	1296	675	621	14.8	246	429	10.2
01	-0802-	010	ML	short & thick	1295	767	528	12.6	254	513	12.2
01	-0802-	011	SS	medium & fine	1300	569	731	17.4	190	379	9.0
01	-0802-	012	LC	short & thick	1300	904	396	9.4	323	581	13.8
01	-0802-	013	MD	short & fine	1299	1010	289	6.9	484	526	12.5
01	-0802-	014	EP	medium & fine	1297	719	578	13.8	354	365	8.7
01	-0802-	015	MM	short & thick	1298	800	498	11.9	169	631	15.0
01	-0802-	016	AG	short & thick	1297	1021	276	6.6	319	702	16.7
01	-0802-	017	LM	short & fine	2161	1375	786	18.7	533	842	20.0
01	-0802-	018	HC	medium & fine	1300	906	394	9.4	290	616	14.7
01	-0802-	019	EA	long & thick	1297	665	632	15.0	286	379	9.0
<b>Average</b>					<b>1366</b>	<b>848</b>	<b>518</b>	<b>12</b>	<b>304</b>	<b>544</b>	<b>13</b>



**Table III-b: Volunteer Compliance to the test product according to product weight (g) – Conditioner**

Volunteer #			Initials	Initial hair length	Weight at D0	Weight at D84	Difference at D84	Daily Use at D84	Weight at D126	Difference at D126	Daily Use at D126
01	-0802-	001	VC	short & fine	847	565	282	6.7	137	428	10.2
01	-0802-	002	LD	medium & fine	1269	883	386	9.2	304	579	13.8
01	-0802-	003	DM	long & thick	1692	920	772	18.4	152	768	18.3
01	-0802-	004	CB	medium	1268	725	543	12.9	271	454	10.8
01	-0802-	005	SG	medium & thick	1691	955	736	17.5	285	670	16.0
01	-0802-	006	SG	medium & thick	1269	775	494	11.8	226	549	13.1
01	-0802-	007	JL	medium & thick	1271	750	521	12.4	313	437	10.4
01	-0802-	008	MR	mi-long	1268	617	651	15.5	197	420	10.0
01	-0802-	009	EM	long & fine	1689	921	768	18.3	152	769	18.3
01	-0802-	010	ML	short & thick	1273	717	556	13.2	248	469	11.2
01	-0802-	011	SS	medium & fine	1266	662	604	14.4	380	282	6.7
01	-0802-	012	LC	short & thick	844	633	211	5.0	108	525	12.5
01	-0802-	013	MD	short & fine	1265	1023	242	5.8	443	580	13.8
01	-0802-	014	EP	medium & fine	1268	616	652	15.5	321	295	7.0
01	-0802-	015	MM	short & thick	1266	773	493	11.7	149	624	14.9
01	-0802-	016	AG	short & thick	1274	952	322	7.7	236	716	17.0
01	-0802-	017	LM	short & fine	2110	1335	775	18.5	506	829	19.7
01	-0802-	018	HC	medium & fine	1689	1102	587	14.0	384	718	17.1
01	-0802-	019	EA	long & thick	1265	711	554	13.2	478	233	5.5
<b>Average</b>					1357	823	534	13	278	544	13

**Table IV: Scores for Tolerance at D126**

(0=No Sign 1=Slight, 2=Moderate and 3= High)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Redness	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Stinging/Itching sensation	0	0	0	0	0	0	0	0	0	0	1	0	0	1	0	0	0	0	0
Burning sensation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Peeling/Dandruff	0	1	3	0	0	1	0	0	0	0	0	2	0	2	0	0	1	0	0

**Table V: Scores for Sensory attributes at D126**

(3=Highly appreciated, 2=Appreciated, 1=Indifferent and 0=Did not appreciate)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Fragrance- Shampoo	2	0	2	2	2	2	2	3	2	3	0	3	0	2	1	3	3	3	3
Easy rinsing- Shampoo	3	2	2	2	2	2	2	3	2	3	2	3	2	2	2	3	3	1	3
Fragrance-Conditioner	2	0	2	2	2	2	2	3	2	3	1	3	1	2	1	3	3	1	3
Easy rinsing-Conditioner	3	2	2	2	2	2	2	3	2	2	1	3	2	2	2	3	3	2	3
Feeling after hair drying	3	0	1	2	2	2	2	3	2	2	2	3	3	2	2	3	2	2	2

**Table VI: Scores for Performance at D126**

F=Freshness, N=Neatness, FandN= Freshness and Neatness, Dryness

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Sensation on the scalp	N	Dryness	N	N	F	F	N	FandN	FandN	N	N	N	FandN	N	N	F	FandN	F	N

(3= A lot, 2= Moderately, 1= Slightly, 0= Not at all)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Neatness sensation	3	3	3	2	2	2	2	3	2	3	2	3	3	2	2	3	3	2	3
Nourishing effect	2	0	1	3	1	2	2	2	2	2	0	3	3	2	2	3	3	2	2
Healthy appearance	2	0	1	2	1	2	2	2	2	1	0	3	3	2	2	3	3	2	2
Glossy appearance	3	0	1	2	1	3	2	3	1	2	0	3	3	1	1	2	3	2	2
Hydrated appearance	3	0	1	2	1	3	2	3	2	2	1	3	3	1	2	2	3	2	3
Shiny/Luster finish improvement	2	0	1	2	2	2	2	3	2	2	0	3	3	2	2	3	3	2	3
Hair growth improvement	2	0	2	3	2	2	0	2	2	2	1	2	3	1	2	3	2	1	3

(N= Never)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Visible effectiveness after (in weeks)	4	N	4	4	8	8	N	4	6	2	6	2	4	4	6	6	6	4	4

**EVALUATION** (4=Excellent, 3=Very good, 2=Good, 1=Acceptable, 0=Bad)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Global performance	4	0	2	3	1	2	2	3	2	3	0	4	4	2	2	4	4	2	3

**RECOMMENDATION** (3= Strongly agree, 2= Somewhat agree, 1= Somewhat disagree, 0= Fully disagree)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Recommendation	2	1	2	2	1	2	2	3	2	2	1	3	3	2	0	3	3	2	3

**PURCHASE** (2= Certainly, 1= Maybe, 0= Certainly not)

Criteria	001	002	003	004	005	006	007	008	009	010	011	012	013	014	015	016	017	018	019
Purchase at competitive price	1	0	2	2	1	1	2	2	1	2	0	2	2	1	0	2	2	1	1

**Table VII: Comment for test products at D126**

<b>Volunteer #</b>	<b>Negative comments</b>	<b>Positive comments</b>
01-0802-001		This treatment hydrate hair tips. My hair is healthy, soft, smooth and easy to comb.
01-0802-002	This treatment is not appropriate for my hair type as it has a drying effect...	
01-0802-003	...It is not recommended to wash hair every day.	Although I appreciated the effects of the test products,...
01-0802-009	The only thing I didn't like about this treatment is that my hair was more tangled than with my usual shampoo and conditioning system.	
01-0802-011	The treatment made my hair flat and dull. I didn't like the fragrance of the test products which is too strong and not natural enough for me. I also felt itching sensations almost every day.	
01-0802-012		I really appreciated this treatment, my hair grows faster, is more voluminous and curlier than ever before in my life! I like that it makes a lot of foam with a very small amount of product. I would certainly buy the treatment!
01-0802-013		I really liked this treatment, my hair has truly grown faster. My hair is also very shiny.
01-0802-015	... but towards the end of the day my hair became oily.	The treatment left my hair beautiful and silky...
01-0802-017		I have one word to say : I love it! This treatment really works!
01-0802-018	The treatment does not foam enough and it's not easy to rinse either. Despite its effectiveness, it makes hair 'heavy'.	
01-0802-019	The test products' fragrance is too strong.	

**Table VIII: Individual data –Roots measurements**

# Volunteer	Data at D42 (in cm)					Data at D84 (in cm)					Data at D126 (in cm)				
	Frontal	Vertex	Parietal	Occipital	Mean	Frontal	Vertex	Parietal	Occipital	Mean	Frontal	Vertex	Parietal	Occipital	Mean
01-0802-001	1.5	1.5	1.6	1.5	<b>1.5</b>	1.9	1.8	2.1	1.9	<b>2.0</b>	2.3	2.0	2.2	2.2	<b>2.2</b>
	1.5	1.6	1.3	1.6		2.0	1.8	2.1	2.0		2.2	2.1	2.2	2.2	
Average	1.5	1.6	1.5	1.6		2.0	1.8	2.1	2.0		2.3	2.1	2.2	2.2	
01-0802-002	2.0	1.8	1.7	2.0	<b>1.9</b>	1.9	1.9	2.0	1.9	<b>2.0</b>	2.1	2.1	2.2	2.1	<b>2.1</b>
	1.9	1.8	1.8	2.1		2.0	2.0	2.1	1.9		2.1	2.2	2.2	2.1	
Average	2.0	1.8	1.8	2.1		2.0	2.0	2.1	1.9		2.1	2.2	2.2	2.1	
01-0802-003	1.5	1.6	1.6	1.5	<b>1.6</b>	1.9	1.9	2.0	1.8	<b>2.0</b>	1.9	2.1	2.1	2.1	<b>2.1</b>
	1.5	1.5	1.6	1.6		2.0	2.0	2.1	1.9		2.0	2.2	2.1	2.2	
Average	1.5	1.6	1.6	1.6		2.0	2.0	2.1	1.9		2.0	2.2	2.1	2.2	
01-0802-004	1.2	1.5	1.2	1.2	<b>1.3</b>	2.0	1.9	1.9	2.0	<b>2.0</b>	2.0	2.1	2.3	2.0	<b>2.1</b>
	1.2	1.6	1.2	1.2		2.0	1.9	1.9	2.1		2.1	2.1	2.4	2.1	
Average	1.2	1.6	1.2	1.2		2.0	1.9	1.9	2.1		2.1	2.1	2.4	2.1	
01-0802-005	1.9	1.5	2.0	1.8	<b>1.8</b>	1.9	1.9	1.9	1.8	<b>1.9</b>	2.0	2.0	2.1	2.0	<b>2.1</b>
	1.9	1.7	1.9	1.8		1.8	2.0	1.9	1.9		2.1	2.0	2.2	2.0	
Average	1.9	1.6	2.0	1.8		1.9	2.0	1.9	1.9		2.1	2.0	2.2	2.0	
01-0802-006	1.7	1.6	1.7	1.5	<b>1.7</b>	2.0	1.8	2.1	2.1	<b>2.0</b>	2.2	2.1	2.3	2.1	<b>2.2</b>
	1.8	1.9	1.7	1.6		2.1	1.9	2.0	2.0		2.0	2.2	2.4	2.1	
Average	1.8	1.8	1.7	1.6		2.1	1.9	2.1	2.1		2.1	2.1	2.2	2.4	
01-0802-007	1.5	1.8	1.8	1.2	<b>1.6</b>	1.9	1.7	1.8	1.5	<b>1.8</b>	2.1	2.1	2.2	2.0	<b>2.1</b>
	1.5	1.8	1.8	1.2		1.8	1.8	1.9	1.8		2.1	2.2	2.1	2.1	
Average	1.5	1.8	1.8	1.2		1.9	1.8	1.9	1.7		2.1	2.2	2.2	2.1	
01-0802-008	1.8	1.5	1.7	1.7	<b>1.7</b>	2.1	1.8	2.1	1.9	<b>2.0</b>	2.2	2.1	2.2	2.3	<b>2.2</b>
	1.9	1.7	1.8	1.8		2.2	1.8	2.2	2.0		2.2	2.2	2.3	2.3	
Average	1.9	1.6	1.8	1.8		2.2	1.8	2.2	2.0		2.2	2.2	2.3	2.3	
01-0802-009	1.8	2.0	2.0	1.9	<b>1.9</b>	1.8	2.0	2.0	1.9	<b>1.9</b>	1.9	1.9	2.1	2.0	<b>2.0</b>
	1.9	1.9	2.1	1.9		1.9	1.9	2.1	1.9		2.0	2.1	2.1	2.1	
Average	1.9	2.0	2.1	1.9		1.9	2.0	2.1	1.9		2.0	2.0	2.1	2.1	
01-0802-010	1.8	1.6	1.8	1.7	<b>1.8</b>	2.0	1.8	3.5	2.1	<b>2.4</b>	2.1	2.1	2.3	2.5	<b>2.3</b>
	1.7	1.8	1.9	1.8		1.9	1.9	3.6	2.2		2.1	2.1	2.4	2.6	
Average	1.8	1.7	1.9	1.8		2.0	1.9	3.6	2.2		2.1	2.1	2.4	2.6	

**Table VIII: Individual data –Roots measurements (cont'd & end)**

# Volunteer	Data at D42 (in cm)					Data at D84 (in cm)					Data at D126 (in cm)				
	Frontal	Vertex	Parietal	Occipital	Mean	Frontal	Vertex	Parietal	Occipital	Mean	Frontal	Vertex	Parietal	Occipital	Mean
01-0802-011	1.5	1.5	1.6	1.5	<b>1.6</b>	1.7	1.9	1.7	1.8	<b>1.8</b>	2.0	2.0	2.1	2.0	<b>2.0</b>
	1.5	1.5	1.7	1.6		1.7	1.9	1.7	1.9		2.0	1.9	2.0	2.0	
Average	1.5	1.5	1.7	1.6		1.7	1.9	1.7	1.9		2.0	2.0	2.1	2.0	
01-0802-012	2.0	2.0	2.0	2.0	<b>2.0</b>	2.3	2.4	2.2	2.3	<b>2.3</b>	2.4	2.5	2.4	2.6	<b>2.5</b>
	2.0	2.1	2.0	1.9		2.3	2.5	2.3	2.3		2.5	2.6	2.5	2.6	
Average	2.0	2.1	2.0	2.0		2.3	2.5	2.3	2.3		2.5	2.6	2.5	2.6	
01-0802-013	1.5	1.7	1.6	1.6	<b>1.6</b>	1.7	1.8	1.8	1.7	<b>1.8</b>	3.4	3.1	3.3	3.2	<b>3.2</b>
	1.4	1.7	1.6	1.8		1.8	1.8	1.9	1.8		3.3	3.1	3.2	3.1	
Average	1.5	1.7	1.6	1.7		1.8	1.8	1.9	1.8		3.4	3.1	3.3	3.2	
01-0802-014	1.8	2.0	2.0	1.9	<b>1.9</b>	2.1	2.0	2.1	2.0	<b>2.1</b>	2.1	2.1	2.2	2.1	<b>2.2</b>
	1.7	1.9	2.0	1.8		2.2	2.1	2.2	2.1		2.1	2.1	2.3	2.2	
Average	1.8	2.0	2.0	1.9		2.2	2.1	2.2	2.1		2.1	2.1	2.3	2.2	
01-0802-015	2.0	2.0	1.8	1.9	<b>2.0</b>	2.5	2.4	2.6	2.2	<b>2.4</b>	2.2	2.4	2.3	2.5	<b>2.3</b>
	2.0	2.0	2.0	1.9		2.5	2.4	2.6	2.3		2.3	2.2	2.3	2.5	
Average	2.0	2.0	1.9	1.9		2.5	2.4	2.6	2.3		2.3	2.3	2.3	2.5	
01-0802-016	1.9	1.9	2.0	2.0	<b>1.94</b>	1.9	2.0	2.4	2.1	<b>2.1</b>	2.3	2.2	2.4	2.3	<b>2.3</b>
	1.9	1.9	2.0	1.9		2.0	2.1	2.3	2.1		2.3	2.2	2.4	2.4	
Average	1.9	1.9	2.0	2.0		2.0	2.1	2.4	2.1		2.3	2.2	2.4	2.4	
01-0802-017	1.8	1.9	1.7	1.7	<b>1.8</b>	2.1	2.2	2.3	2.0	<b>2.2</b>	2.2	2.3	2.5	2.1	<b>2.3</b>
	1.9	2.0	1.8	1.8		2.2	2.2	2.5	2.1		2.3	2.4	2.6	2.2	
Average	1.9	2.0	1.8	1.8		2.2	2.2	2.4	2.1		2.3	2.4	2.6	2.2	
01-0802-018	1.5	1.7	1.6	1.7	<b>1.7</b>	2.0	1.9	2.0	1.9	<b>2.0</b>	2.1	2.1	2.2	2.2	<b>2.1</b>
	1.7	1.8	1.7	1.7		2.0	2.0	2.0	2.0		2.1	2.1	2.1	2.2	
Average	1.6	1.8	1.7	1.7		2.0	2.0	2.0	2.0		2.1	2.1	2.2	2.2	
01-0802-019	1.9	2.0	2.0	2.0	<b>2.0</b>	2.0	2.0	2.1	2.0	<b>2.0</b>	2.0	2.0	2.1	2.1	<b>2.1</b>
	2.0	2.1	2.0	2.0		2.0	2.0	2.1	2.0		2.0	2.1	2.1	2.2	
Average	2.0	2.1	2.0	2.0		2.0	2.0	2.1	2.0		2.0	2.1	2.1	2.2	

**Table IX: Table for Individual Results**

# Volunteer	Hair growth rate at D42 (in cm)	Hair growth rate at D84 (in cm)	Hair growth rate at D126 (in cm)	Improvement at D84 compared to D42	Improvement at D126 compared to D126
01-0802-001	1.5	2.0	2.2	29%	44%
01-0802-002	1.9	2.0	2.1	4%	13%
01-0802-003	1.6	2.0	2.1	26%	35%
01-0802-004	1.3	2.0	2.1	52%	66%
01-0802-005	1.8	1.9	2.1	4%	13%
01-0802-006	1.7	2.0	2.2	19%	29%
01-0802-007	1.6	1.8	2.1	13%	34%
01-0802-008	1.7	2.0	2.2	16%	28%
01-0802-009	1.9	1.9	2.0	0%	5%
01-0802-010	1.8	2.4	2.3	35%	29%
01-0802-011	1.6	1.8	2.0	15%	29%
01-0802-012	2.0	2.3	2.5	16%	26%
01-0802-013	1.6	1.8	3.2	11%	99%
01-0802-014	1.9	2.1	2.2	11%	14%
01-0802-015	2.0	2.4	2.3	25%	20%
01-0802-016	1.9	2.1	2.3	9%	19%
01-0802-017	1.8	2.2	2.3	21%	27%
01-0802-018	1.7	2.0	2.1	18%	28%
01-0802-019	2.0	2.0	2.1	1%	4%
<b>Mean</b>	<b>1.7</b>	<b>2.0</b>	<b>2.2</b>	<b>17%</b>	<b>30%</b>
	Standard Deviation			0.13	0.22
	t-Test			<0.01	<0.01
	Significance			S	S
			Min	0%	4%
			Max	52%	99%