

**Assessment of activity of a product on beard growth on  
a panel of volunteers**

**ETUDE 19E4398**

**D19-049-2**

**Assessment realized on:**

- ❖ 20 volunteers
- ❖ Product reference:  
**BEARD GROWTH SERUM  
IMBST19  
03/2021**
- ❖ Duration of the study: 3 months

**Study report submitted by BIO-EC, the 9<sup>th</sup> July 2019**

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<b>STUDY 19E4398</b>	
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## STUDY SUMMARY

### ▪ **TITLE:**

Assessment of activity of a product on beard growth on a panel of volunteers

### ▪ **AIM OF THE STUDY:**

The aim of the study was to evaluate effects of a cosmetic product on beard growth by topical application for 3 months (84 days) on a panel of male volunteers.

The effects will be evaluated by:

- Trichoscan (hair growth, count, density, thickness, anagen/telogen ratio);
- Questionnaire;
- Standardized photographs

The product will be tested on a panel of 20 male volunteers.

Duration of the study: 3 months (84 days).

Volunteers will come 8 times to the test facility for measurements.

### ▪ **PROGRESS OF THE STUDY :**

20 caucasian male volunteers age 18-50 years old with patchy beard, meeting the inclusion and non-inclusion criteria defined in the protocol participated in the study.

### ▪ **RESULTS AND CONCLUSION :**

**The purpose of this study was to evaluate the effects of a serum on beard growth by topical application for 3 months on a panel of 20 volunteers.**

**We can conclude that :**

#### ✓ **After 1 month of use of the Beard Growth Serum IMBST19:**

- **The beard hair growth is significantly improved (+87µm/day)**
- **The hair density is significantly improved (+14.1%)**
- **The quantity of hairs in anagen phase is significantly improved (+11.2%)**

#### ✓ **After 2 months of use of the Beard Growth Serum IMBST19:**

- **The beard hair growth is significantly improved (+118µm/day)**
- **The quantity of hairs in anagen phase is significantly improved (+8.0%)**

- ✓ **After 3 months of use of the Beard Growth Serum IMBST19:**
  - **The beard hair growth is significantly improved (+100µm/day)**
  - **The hair density is significantly improved (+24.7%)**
  - **The density of hairs having a diameter greater than 40 µm is significantly improved (18.9%)**
  - **The quantity of hairs in anagen phase is significantly improved (+11.2%)**

**These instrumental results are confirmed by the results of the volunteers' feeling on the questionnaire:**

- **75% of the volunteers found their beard denser**

**Furthermore,**

- **80% of the volunteers found that the product was pleasant or very pleasant**
- **85% of the volunteers found that the product takes care of their beard**
- **75% of the volunteers considered that the use of this product has improved the condition of their beard in an important, average or slightly way**

## 1 AIM OF THE STUDY

The aim of the study was to evaluate effects of a cosmetic product on beard growth by topical application for 3 months (84 days) on a panel of male volunteers.

The effects will be evaluated by:

- Trichoscan (hair growth, count, density, thickness, anagen/telogen ratio);
- Questionnaire;
- Standardized profile photographs by VISIA.

The product will be tested on a panel of 20 male volunteers.

Duration of the study: 3 months (84 days).

Volunteers will come 8 times to the test facility for measurements.

## 2 STUDY DESIGN

### 2.1 Study process

Activity of the serum was assessed on a panel of 20 men meeting the inclusion and non-inclusion criteria previously defined. Measurements were done in an air-conditioned room (21°C + 2°C), after at least 10 minutes of volunteer's acclimatization.

Biometric measurements and pictures were taken at the level of the beard.

Then, volunteers applied the product each day during 3 months on the beard zone.

Each volunteer had to inform BIO-EC laboratory for reporting any discomfort feelings or adverse events upon occurrence. They have not stopped or modified the frequency of application without inform us.

The measurements at T1month, T2month and T3month were carried out under conditions identical to T0.

## 2.2 Study chronology for each volunteer

**Recruitment** (Week 10 and 11): Male volunteers age 18-50 years old with patchy beard;

- **First visit at M0** : (Week 12),

The person in charge of the study:

- Make stabilize volunteers in an air-conditioned room at least 10 minutes
- Check out of the criteria of inclusion and non-inclusion
- Check out of the well understanding of the study
- Signing of the agreement by the volunteers
- Shaves 1 cm<sup>2</sup> of beard
- Realizes a videotrichogramm of the shaved area
- Realizes face photographs
- Distribution of the product

- **Intermediary visit at M0+48h** : (Week 12),

The person in charge of the study:

- Make stabilize volunteers in an air-conditioned room at least 10 minutes
- Recording of the adverse events during the use of the product
- Realizes a videotrichogramm of the shaved area

**From M0 to M1**: Volunteers applied the product each day on the beard zone.

- **Intermediary visit at M1** (Week 16), **M2**: (Week 20) and **M3**: (Week 24),

The person in charge of the study:

- Make stabilize volunteers in an air-conditioned room at least 10 minutes
- Shaves 1 cm<sup>2</sup> of beard
- Realizes a videotrichogramm of the shaved area
- Realizes face photographs

- **Intermediary visit at M1+48h**: (Week 16) and **M2+48h**: (Week 20)

The person in charge of the study:

- Make stabilize volunteers in an air-conditioned room at least 10 minutes
- Realizes a videotrichogramm of the shaved area

**From M1 to M2**: Volunteers applied the product each day on the beard zone.

**From M2 to M3**: Volunteers applied the product each day on the beard zone.

- **Final visit at M3+48h**: (Week 24),

The person in charge of the study:

- Make stabilize volunteers in an air-conditioned room at least 10 minutes



- Realizes a videotrichogramm of the shaved area
- Gives their indemnity to the volunteers
- Recovers the questionnaire

### **3 VOLUNTEERS**

#### **3.1 Inclusion and non-inclusion criteria**

##### **3.1.1 Inclusion Criteria**

- Male volunteers age 18-50 years old with patchy beard
- Having signed the consent form;
- Volunteers complying with legal obligations for the biomedical research and social security scheme in accordance with French law.
- Use the product in conformity with the recommendation use, (in accordance with the customer)
- Not using any other product on the studied zone
- Subject accepting the shaving of an area of the beard, about 1 cm<sup>2</sup> to T0, T1M, T2M and T3M
- Subject accepting temporary coloring of this area of the beard at T0, T1M, T2M and T3M (only for subjects with white hair or too clear for analysis)

##### **3.1.2 Exclusion criteria**

- Individuals with dense beard;
- Having a chronic or acute disease which, with investigator opinion, could prejudice the volunteer as a result of its participation in the trial;
- Volunteer under finasteride, dutasteride or minoxidil treatment;
- Volunteers having progressive disease which could interfere with hair growth (systematic disease, unbalance endocrinal disease, neoplasia, malabsorption...).

### 3.2 Included volunteers

Overall, 20 men, meeting the inclusion and non-inclusion criteria define in the protocol, were included in the study. They were informed of the possible drawbacks linked to the product application. They were also informed of the practical conditions of study realization. They freely signed the consent form, written in accordance with Helsinki statement and the law of 20th December 1988.

#### 3.2.1 Demographic characteristics

The demographic characteristics of the panel (mean + SD) are presented below:

<b>Beard Growth</b>	N = 20 men
<b>Serum IMBST19</b>	Age : 36 + 10 years old

#### 3.2.2 Conduct of the study appointments

The volunteer 15 did not show up for the appointment of the T1month. The results obtained at T1month will therefore be on 19 volunteers.

#### 3.2.3 Concomitant treatments

No volunteer included in this study takes concomitant treatments which can induce a modification of cutaneous statement.

## 4 PRODUCTS

### 4.1 Tested product

The product is referenced: BEARD GROWTH SERUM IMBST19

It was a transparent liquid packed in glass vials with an application with a pipette on each vial. The tested product was packed by the promotor.

### 4.2 Product use method

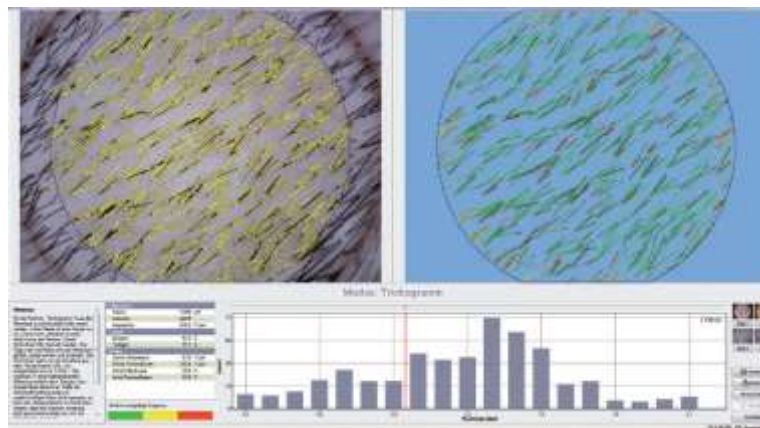
The product was distributed to volunteers at D0 and applied daily for 3 months on the beard.

## 5 METHODOLOGY

### 5.1 Assessment of the beard through TrichoScan

On day 0 (D0), a device developed in BIO-EC laboratory is used to define the area to be shaved using 4 points of reference on the beard zone. The defined area is shaved at the defined measurement time points (D0, D28, D56, D84).

48 hours after shaving, 1 photo is taken with TrichoScan®. Using Trichoscan® images, beard hair growth, density, thickness, count and cycle (anagen/telogen ratio) on the same area will be quantified.



### 5.2 Self assessment survey

A questionnaire will be developed to assess the feelings about the activity of the product. It will be established with the Study Promoter and completed by the volunteers at the end of the study.

The end-of-study questionnaire was filled via the Eval & GO software by the volunteers.

Eval & GO is a SaaS application for managing comments. It allows you to create surveys online, publish them by link or email, collect responses and analyze results in real time. Access to the service is via an Internet connection and a recent web browser (Internet Explorer 9+, Chrome, Safari, Firefox). It is based on subscriptions without installation on computers. Any use of the Eval & GO software or services is subject to the terms and conditions.

### 5.3 Standardized profile photographs

For each time point: D0, D28, D56 and D84, standardized photographs (light conditions, face angles) of a profile will be taken for each volunteer.

## 6 RESULTS

### 6.1 Weather conditions in Paris region

The higher and lower temperatures in Paris region during the study were:

- March 2019 (M0): 1.8°C to 14.7°C
- April 2019 (M1): 1°C to 27.2°C
- May 2019 (M2): 3.6°C to 25.9°C
- June 2019 (M3): 9.5°C to 33.2°C

### 6.2 Statistical methodology

The basic statistical parameters (mean, standard deviation) were calculated for each time and point of measurement.

1st step: Verification of the normality of the distributions by a test of Shapiro-Wilk.

2nd step: Verification of the significance:

- If the distribution follows a normal distribution:

The test used is Student's t-test (Via Prism v5.04 software by GraphPad) on matched data. The conditions of application are the randomness and simplicity of the samples and the normality of the population of the differences.

- If the distribution does not follow a normal distribution:

The test used is the Wilcoxon test. (Via the Prism v5.04 software by GraphPad).

Degree of significance:

# Significant  $p < 0.1$  \* Significant  $p < 0.05$  \*\* Significant  $p < 0.01$  \*\*\* Significant  $p < 0.001$

### 6.3 Protocol deviations

The volunteer 15 did not show up for the appointment of the T1month. The results obtained at T1month will therefore be on 19 volunteers.

### 6.4 Adverse events

No adverse event occurs during the study.

## 6.5 TrichoScan results

The means and standard deviations of the different parameters are summarized in the table below. The individual values for each volunteer are presented in appendices.

### 6.5.1 Analysis of the growth rate after 48 hours of shaving

	Median length hair after 48h (µm)	Sprouting speed (µm / day)	variation in shoot speed (µm / day)
<b>T0 (N=19)</b>	<b>1056 ± 169</b>	<b>89 ± 96</b>	<b>+87**</b>
<b>T1month (N=19)</b>	<b>1239 ± 98</b>	<b>176 ± 55</b>	
<b>T0 (N=20)</b>	<b>1057 ± 165</b>	<b>91 ± 94</b>	<b>+118***</b>
<b>T2 months (N=20)</b>	<b>1290 ± 163</b>	<b>209 ± 68</b>	
<b>T0 (N=20)</b>	<b>1057 ± 165</b>	<b>91 ± 94</b>	<b>+100**</b>
<b>T3 months (N=20)</b>	<b>1247 ± 183</b>	<b>191 ± 103</b>	

# Significatif p<0.1

\* Significatif p<0.05

\*\*Significatif p<0.01

\*\*\*Significatif p<0.001

We observe that the **speed of hair growth at 48h** is:

- Significantly **increased by 87µm/day** (Student test: p=0.0021, n=19) after **1 month** of treatment
- Significantly **increased by 118µm/day** (Student test: p=0.00003, n=20) after **2 months** of treatment
- Significantly increased by **100µm/day** (Student test: p=0.0052, n=20) after **3 months** of treatment

→ We can therefore conclude that, with the use of the Beard Growth Serum IMBST19 during 3 months, the speed of hair growth is significantly improved from 1 month and this improvement continues after 2 and 3 months.

### 6.5.2 Density analysis (Number of hairs / cm<sup>2</sup>)

	Nb of hair per cm <sup>2</sup>	% of variation in hair density
<b>T0 (N=19)</b>	<b>40.6 ± 18.2</b>	<b>14.1*</b>
<b>T1month (N=19)</b>	<b>46.4 ± 19.7</b>	
<b>T0 (N=20)</b>	<b>42.4 ± 19.4</b>	12.0
<b>T2 months (N=20)</b>	<b>47.5 ± 20.8</b>	
<b>T0 (N=20)</b>	<b>42.4 ± 19.4</b>	<b>24.7**</b>
<b>T3 months (N=20)</b>	<b>52.9 ± 22.8</b>	

# Significatif p<0.1

\* Significatif p<0.05

\*\*Significatif p<0.01

\*\*\*Significatif p<0.001

We observe that the **hair density** is:

- significantly **increased by 14.1%** (Student test: p = 0.0456, n = 19) after **1 month** of treatment
- not significantly increased by 12.0% (Student test: p = 0.1193, n = 20) after 2 months of treatment
- significantly **increased by 24.7%** (Student test: p = 0.0011, n = 20) after **3 months** of treatment

→ We can therefore conclude that, with the use of the Beard Growth Serum IMBST19 during 3 months, the density of hair is significantly improved from 1 month and this improvement continues after 3 months.

### 6.5.3 Analysis of the density of hairs with a diameter greater than 40µm

	Nb of hair per cm <sup>2</sup>	% of variation in hair density
<b>T0 (N=19)</b>	<b>29.51 ± 14.14</b>	10.5
<b>T1 month (N=19)</b>	<b>32.62 ± 14.40</b>	
<b>T0 (N=20)</b>	<b>30.93 ± 15.16</b>	9.9
<b>T2 months (N=20)</b>	<b>34.00 ± 14.08</b>	
<b>T0 (N=20)</b>	<b>30.93 ± 15.16</b>	<b>18.9*</b>
<b>T3 months (N=20)</b>	<b>36.78 ± 14.44</b>	

# Significatif p<0.1

\* Significatif p<0.05

\*\*Significatif p<0.01

\*\*\*Significatif p<0.001

We observe that the **density of hairs having a diameter greater than 40 µm** is:

- not significantly increased by 10.5% (Student test: p=0.1672, n=19) after **1 month** of treatment
- not significantly increased by 9.9% (Student test: p=0.2676, n=20) after **2 months** of treatment
- significantly **increased by 18.9%** (Student test: p=0.0134, n=20) after **3 months** of treatment

→ We can therefore conclude that, with the use of the Beard Growth Serum IMBST19 during 3 months, the density of hair with a diameter greater than 40µm is significantly improved after 3 months.

#### 6.5.4 Analysis of hair in anagen phase

	% hair in anagen phase	% of variation of hair in anagen phase
<b>T0 (N=19)</b>	<b>70.9 ± 9.0</b>	<b>11.2***</b>
<b>T1 month (N=19)</b>	<b>78.9 ± 4.5</b>	
<b>T0 (N=20)</b>	<b>71.5 ± 9.1</b>	<b>8.0**</b>
<b>T2 months (N=20)</b>	<b>77.2 ± 8.2</b>	
<b>T0 (N=20)</b>	<b>71.5 ± 9.1</b>	<b>11.2**</b>
<b>T3 months (N=20)</b>	<b>79.5 ± 5.1</b>	

# Significatif p<0.1

\* Significatif p<0.05

\*\*Significatif p<0.01

\*\*\*Significatif p<0.001

We observe that the **quantity of hairs in anagen phase** is:

- significantly **increased by 11.2%** (Student test: p=0.0008, n=19) after **1 month** of treatment
- significantly **increased by 8.0%** (Student test: p=0.0061, n=20) after **2 months** of treatment
- significantly **increased by 11.2%** (Student test: p=0.0047, n=20) after **3 months** of treatment

→ We can therefore conclude that, with the use of the Beard Growth Serum IMBST19 during 3 months, the quantity of hair in anagen phase is significantly improved from 1 month and this improvement continues after 2 and 3 months.



## 6.6 Photography

### Volunteer 19 :



T0



T1 month



T2 months



T3 months

Volunteer 18 :



T0



T1 month



T2 months



T3 months

## 6.7 Questionnaire results (expressed as a percentage)

### 6.7.1 Appreciation of the organoleptic and sensorial qualities

#### 6.7.1.1 Global appreciation of the product

- What is your overall impression concerning the product?

Very pleasant	Pleasant	Neither pleasant, nor unpleasant	Unpleasant	Very unpleasant
20	<b>60</b>	20	0	0

- **80%** of the volunteers found that the product was pleasant or very pleasant

#### 6.7.1.2 General appearance of the product

- How would you evaluate the product at the level of?

	Very pleasant	Pleasant	Neither pleasant, nor unpleasant	Unpleasant	Very unpleasant
Appearance	30	<b>45</b>	25	0	0
Texture	<b>35</b>	30	35	0	0
Colour	20	<b>45</b>	30	5	0
Perfume	25	<b>50</b>	15	10	0

- **75%** of the volunteers found that the appearance and the perfume of the product were pleasant or very pleasant
- **65%** of the volunteers found that the texture and the colour of the product were pleasant or very pleasant

#### 6.7.1.3 Application of the product

- **95%** of the volunteers found that the product was easy to apply
- **90%** of the volunteers found that the product penetrates easily

- ❖ After application of the product, you find that your beard is:

Very pleasant	Pleasant	Neither pleasant, nor unpleasant	Unpleasant	Very unpleasant
15	<b>45</b>	40	0	0

- **60%** of the volunteers found that their beard pleasant or very pleasant after application of the product

- ❖ Feelings immediately after the application:

	Agree	Somewhat agree	Somewhat disagree	Totally disagree
Feeling of <u>comfort</u>	30	<b>40</b>	30	0
Feeling of <u>softness</u>	<b>40</b>	30	30	0
Feeling of <u>appeasement</u>	15	<b>45</b>	35	5
Feeling of <u>hydration</u>	20	<b>65</b>	15	0

### 6.7.2 Evaluation of the efficacy

- After 3 months of application :

Do you consider that the use of this product has improved the condition of your beard in such a way as:

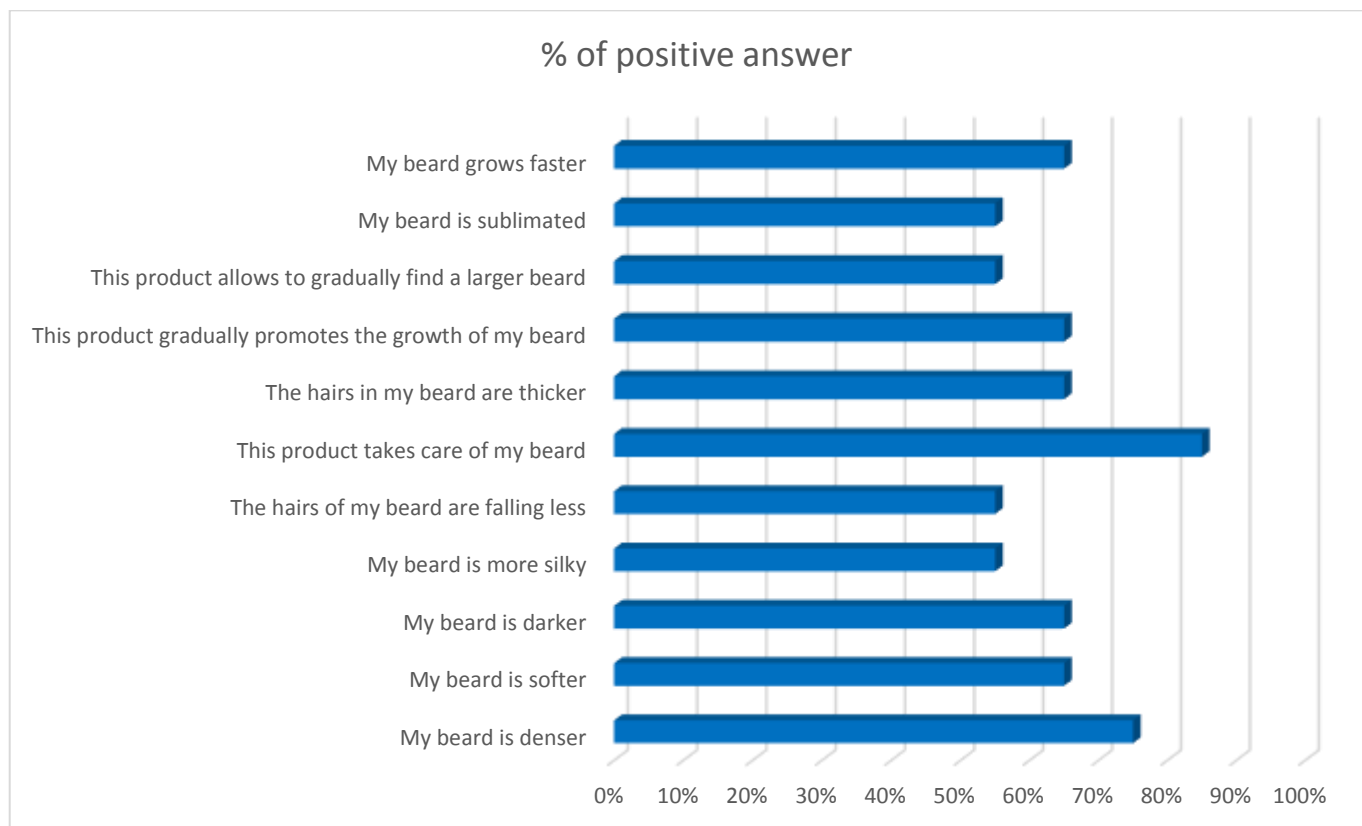
Important	Average	Slightly	Very slightly	No changes
20	<b>30</b>	25	10	15

- During the use of the product, have you got the feelings of:

Comfort	Discomfort	I do not know
<b>75</b>	15	10

	Agree	Somewhat agree	Somewhat disagree	Totally disagree
<b>My beard is denser</b>	20	<b>55</b>	20	5
<b>My beard is softer</b>	25	<b>40</b>	35	0
<b>My beard is darker</b>	20	<b>45</b>	20	15
<b>My beard is more silky</b>	10	<b>45</b>	35	10
<b>The hairs of my beard are falling less</b>	20	<b>35</b>	25	20
<b>This product takes care of my beard</b>	35	<b>50</b>	15	0
<b>The hairs of my beard are thicker</b>	25	<b>40</b>	35	0
<b>This product gradually promotes the growth of my beard</b>	<b>35</b>	30	25	10
<b>My beard grows faster</b>	25	<b>40</b>	25	10
<b>This product makes it possible to gradually find a larger beard</b>	<b>30</b>	25	30	15
<b>My beard is sublimated</b>	10	<b>45</b>	35	10

**Graphical representation of the positive answer :**



### 6.7.3 Evaluation of skin tolerance of the product

Serum
<u>After 3 months:</u> - 5% irritation - 20% tightness - 15% tingling - 0 % twinge - 15% redness - 5% itches - 55% cool effect

### 6.7.4 Conclusion

- After 3 months of application, the serum rated an average score of **7 /10**
- Regardless of its selling price, **55 %** of volunteers would buy the product.

## 7 GENERAL CONCLUSION

The purpose of this study was to evaluate the effects of a serum on beard growth by topical application for 3 months on a panel of 20 volunteers.

We can conclude that :

- ✓ after 1 month of use of the Beard Growth Serum IMBST19:
  - The beard hair growth is significantly improved (+87µm/day )
  - The hair density is significantly improved (+14.1%)
  - The quantity of hairs in anagen phase is significantly improved (+11.2%)
  
- ✓ after 2 months of use of the Beard Growth Serum IMBST19:
  - The beard hair growth is significantly improved (+118µm/day )
  - The quantity of hairs in anagen phase is significantly improved (+8.0%)
  
- ✓ after 3 months of use of the Beard Growth Serum IMBST19:
  - The beard hair growth is significantly improved (+100µm/day )
  - The hair density is significantly improved (+24.7%)
  - The density of hairs having a diameter greater than 40 µm is significantly improved (18.89%)
  - The quantity of hairs in anagen phase is significantly improved (+11.2%)

These instrumental results are confirmed by the results of the volunteers' feeling on the questionnaire:

- 75% of the volunteers found their beard denser

Furthermore,

- 80% of the volunteers found that the product was pleasant or very pleasant
- 85% of the volunteers found that the product takes care of their beard
- 75% of the volunteers considered that the use of this product has improved the condition of their beard in an important, average or slightly way



## 8 Study report archiving

### + Raw data filing

The raw data consists of:

- Image analysis results
- Assays results
- Biometrological results using devices

All the raw data is kept in a paper file and a backup is saved when it is possible (depending on the used device).

### + Products ; samples ; blocks and blades filing

The products entrusted to BIO-EC are preserved one year after using the tested product.

The blocs, the stained and immunostained slides revealed by alkaline phosphatase and peroxidase are kept at BIO-EC's for fifteen years.

The frozen blocs will stay in possession of BIO-EC for two years at minus 80°C. If the culture media are harvested during the study, they will be stored for two years at minus 80°C.

After that, and without any other instructions from the client, they will all be destroyed.

### + Final report filing

The paper file is archived and kept for 20 years

The study report (raw data, images, preliminary reports, final report) and all the computer data are saved thanks to a double internal backup (KERTEL BOX2CLOUD, RAID 1) and by an automated and daily external system, Backupia (KERTEL Group).

Our computer system is protected by the anti-viruses Microsoft Security Essential, F-Secure and McAfee Saas.



# Appendixes

### Characteristics of the volunteers

Volunteers	Age
1	50
2	36
3	29
4	42
5	25
6	50
7	27
8	29
9	41
10	32
11	47
12	20
13	35
14	38
15	26
16	48
17	48
18	22
19	38
20	37
Mean	36
SD	10