

SINGLE-CELL SAFETY AND EFFICACY EVALUATION OF TEETH WHITENING PRODUCT

Teeth Whitening Gel Formula #502-1014-A 35%cp

1.0 OBJECTIVE

The objective of this study was to determine if the use of a teeth whitening product whitened the teeth immediately following a single use in a panel of 35 male and female subjects, aged 18-45 years. The majority of subject were to be individuals with stained teeth who were smokers, wine drinkers and/or carbonated beverage drinkers.

3.0 CLINICALLY INVESTIGATORS

Study Director: Annemarie E. Hollenback, BA
Laboratory Manager

Principle Investigator:: Toni F. Miller, PhD, DABT, BCFE
Scientific Director

Medical Investigator: Stuart Isler, DMD

4.0 CLINICAL TESTING FACILITY

Essex Testing Clinic, Inc.
799 Bloomfield Avenue
Verona, NJ 07044

5.0 STUDY SATES

Group 1: 11/12/10
Group 2: 11/19/10

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6.0 ETHICS

6.1 Ethical Conduct of the Study

This was conducted in accordance with the intent and purpose of Good Clinical Practice regulations described in Title 21 of the U.S. Code of Federal Regulations (CFR), the Declaration of Helsinki and/or Essex Testing Clinic (ETC) Standard Operating Procedures (SOPs).

6.2 Subject Information and Consent

This study was conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed Consent was obtained from each subject in the study and documented in writing before participation in the study. A copy of the informed Consent was provided to each subject.

7.0 TEST ARTICLE

It was received on October 14, 2010 and identified as follows:

<u>ETC</u> <u>Enty No.</u>	<u>Qty</u> <u>Received</u>	<u>Test Article I.D.</u>
19076	45 kits	Teeth Whitening Gel Formula #502-1014-A 35%cp

Physical
Description

Each kit contained:
2 syringes, 1 mouth tray, 1 light
device and 4 aloe And vitamin E
swabs

8.0 TEST SUBJECTS

A sufficient number of male and female subjects ranging in age from 18 to 45 years were to be empanelled for the testing procedures so that approximately 35 subjects would complete the study.

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9.0 STUDY DESIGN (CONT'D)

9.2 Test Procedure

The study was designed as a 1-day, single-use study in which the test article was used by each of the test panelists according to Sponsor's use instructions.

Subjects reported to the Testing Facility for the baseline visit. The Medical Investigator examined the teeth and gums of each subject to determine if the subject did not have any-existing irritation or condition present which would have precluded use of the test article. Additionally, the Medical Investigator also assigned a Vita® shade grade to each of four selected teeth. The location of teeth that were selected and the Vita® shade grade assigned to each tooth was recorded on each subject data sheet. A trained technician took digital photographs of each subject.

Ordinal changes in shade values were calculated using the conversion defined in Table 1. The numerical equivalent of the Vita® shade guide evaluations were used for ordering sequence. By this scale, B1 (lightest) = 1 and C4 (darkest) = 16. Hence, the larger shade guide values are darker.

Table 1
Ordinal Designation of tooth Shades

Shade Number	Designation
1	B1
2	A1
3	B2
4	D2
5	A2
6	C1

Shade Number	Designation
7	C2
8	D4
9	A3
10	D3
11	B3
12	A3.5
13	B4
14	C3
15	A4
16	C4

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10.0 RESULT AND DISCUSSION

Thirty-five (35) subject, 6 males and 29 female between the age 18 and 46 years, were empanelled. A protocol deviation occurred when one (1) test subject was enrolled outside of the age ranged specified in the protocol. (Subject No. 11 was 46 years of age.) This deviation did not affect the integrity of the study. Subject demographics are presented in Appendix 1.

10.1 Vita® shade Grading

Prior to product application and following a single use of the test product, the study dentist examined the teeth of each subject and assigned a Vita® shade grade to each of four selected teeth. Ordinal changes in shade guide values were calculated using the conversion defined in the table found in Section 9.2. The numerical equivalent of the Vita® shade guide evaluation were for ordering sequence. By this scale, B1 (lightest) = 1 and C4 (darkest) = 16. Hence, the larger shade guide value are darker. Individual Vita® shade values and statistical analysis are presented in Appendix 2, Table 1-4.

The following table presented a summary of mean Vita® shade scores.

Mean Vita® shade Scores (± Standard Deviation [S.D.] and Mean % Improvement from Baseline

	Pre-Application Men Score	Post-Application Mean Score	P-Value	Mean % Improvement from Baseline
Tooth #1	4.1 ± 2.1	3.4* ± 2.1	0.001	18%
Tooth #2	3.8 ± 2.2	3.0* ± 1.8	0.008	14%
Tooth #3	3.8 ± 2.2	3.1* ± 1.7	0.006	10%
Tooth #4	4.1 ± 2.1	3.3 ± 2.1	0.006	14%

*statistically significant difference from baseline, $p \leq 0.05$

When Vita® shade grades assigned prior to product application were compared to grades assigned following a single use of the test product, there was:

- An 18% improvement in Vita® shade scores for tooth #1 following a single application of the test product;
- A 14% improvement in Vita® shade scores for tooth #2 following a single application of the test product;
- A 10% improvement in Vita® shade scores for tooth #3 following a single application of the test product; and
- A 14% improvement in Vita® shade scores for tooth #4 following a single application of the test product.

The improvement observed for each tooth were statistically significant ($p \leq 0.05$) when compared with baseline.

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10.0 RESULT AND DISCUSSION (CONT'D)

10.3 Irritation Evaluation

Prior to product application and following a single use of the test products, the study dentist examined the mouth, teeth and gums of each subject for irritation. Individual irritation scores are presented in Appendix 4.

There was no irritation observed on the mouth, teeth or gums of any subject prior to or following a single use of the test product.

11.0 CONCLUSIONS

A single-cell safety and efficacy study was conducted with 35 male and female subject to determine if Test Article: Teeth Whitening Gel Formula #502-1014A 35%cp whitened the teeth immediately following a single, 15-minutes use of the test product.

Vita® Shade Grade were significantly improved on four selected teeth following a single use of the test product, with up to a6 shade improvement observed.

Tooth Color was significantly lightened, based on image analysis, on both the upper right and left incisors, following a single use of the test product.

There was no irritation observed during the course of the study.

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ETC Panel No.: 10307

ETC Entry No.: 19076

**APPENDIX 1
SUBJECT DEMOGRAPHICS**

Test Article: Teeth Whitening Gel Formula #502-10140-A 35%cp

Subject No.	Initials	Age	Sex	Race
1	KLJ	38	F	BA
2	CET	19	F	BA
3	D-C	42	F	CA
4	KMD	30	F	CA
5	ASC	26	M	BA
6	SAP	21	F	CA
7	R-C	42	M	CA
8	B-C	44	F	CA
9	JMC	22	F	CA
10	L-M	42	F	CA
11	SCW	46	F	CA

Subject No.	Initials	Age	Sex	Race
12	JPK	20	F	CA
13	F-S	43	F	CA
14	A-H	28	F	BA
15	M-M	44	F	CA
16	Z-M	18	M	CA
17	L-D	44	F	CA
18	SOG	31	F	CA
19	LMS	42	F	CA
20	S-F	42	F	CA
21	A-J	44	F	HS
22	KIB	42	F	CA
23	CAZ	31	F	CA
24	J-Z	29	F	HS
25	JPD	22	M	CA
26	MET	41	M	CA
27	YKL	41	F	BA
28	TML	38	F	BA
29	MLT	30	F	BA
30	AHA	35	F	BA
31	JAS	19	F	CA
32	SAF	24	F	BA
33	A-G	27	F	BA
34	JKC	31	M	BA
35	JMC	25	F	CA

BA = Black

CA = White (Non-Hispanic)

HS = Hispanic

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**APPENDIX 4
IRRITATION EVALUATION**

Test Article: Teeth Whitening Gel Formula #502-1014A 35%cp

Subject No.	Are the subject's mouth, teeth and gums free of any condition that would prohibit use of the test product?	Is there any irritation preset in subject's mouth. Teeth and gums free of any conditions that you would attribute to use of the test product?
1	Yes	No
2	Yes	No
3	Yes	No
4	Yes	No
5	Yes	No
6	Yes	No
7	Yes	No
8	Yes	No
9	Yes	No
10	Yes	No
11	Yes	No
12	Yes	No
13	Yes	No
14	Yes	No

Subject No.	Are the subject's mouth, teeth and gums free of any condition that would prohibit use of the test product?	Is there any irritation present in subject's mouth. Teeth and gums free of any conditions that you would attribute to use of the test product?
15	Yes	No
16	Yes	No
17	Yes	No
18	Yes	No
19	Yes	No
20	Yes	No
21	Yes	No
22	Yes	No
23	Yes	No
24	Yes	No
25	Yes	No
26	Yes	No
27	Yes	No
28	Yes	No
29	Yes	No
30	Yes	No
31	Yes	No
32	Yes	No
33	Yes	No
34	Yes	No
35	Yes	No

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