

OFFICIAL CLINICAL STUDY REPORT

Independent Scientific Clinical Study of Safety and Efficacy: POPWHITE® Mouthwash

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CLAIM TESTED: DERIVED FROM SCIENTIFIC MEASUREMENTS OF POPWHITE MOUTHWASH:

1. Whitens Teeth
2. Brightens teeth
3. Whitens after just one use
4. Whitens after 7 days of use
5. Whitens better than market leading whitening mouthwash
6. Brightens after just one use
7. Brightens after 7 days of use
8. Brightens better than market leading whitening mouthwash
9. Possible to see visible results after first use
10. Improves gum health after 7 days of use
11. Freshens breath
12. Freshens breath for up to 8 hours
13. Freshens breath as well as the market leading whitening mouthwash
14. Safe to use
15. Causes no side effects after 7 days of use
16. This whitens _____% better than market leading whitening mouthwash
17. This whitens _____% better than the “whitening” mouthwash that contains peroxide.

SUBJECTIVE CLAIMS: DERIVED FROM SURVEYS ABOUT POPWHITE MOUTHWASH:

1. Tastes pleasant
2. Believe to be convenient, easy, fast to use
3. Would recommend to friend
4. Prefer this method of whitening to using strips/trays
5. Visible results seen after 1 use
6. Visible results seen after 7 days
7. Would use again

MAJOR OBJECTIVES:

- 1) Determine safety of POPWHITE® Mouthwash
- 2) Determine whitening and brightening efficacy of POPWHITE® Mouthwash
- 3) Compare performance of POPWHITE® Mouthwash to market leader
- 4) Determine length of time that POPWHITE® Mouthwash freshens breath

STUDY METHODS: 20 Subjects in each of three (3) groups:
POPWHITE® Mouthwash (n=20); TEST GROUP
LISTERINE Whitening Mouthwash (n=20); CONTROL GROUP
WATER (n=20); PLACEBO GROUP

Experimental Plan Used:

Twenty subjects were assigned to each group. Before starting the study, oral hygiene instruction was given to subjects, including rinsing time and technique. Subjects were instructed to rinse their teeth twice daily, in the morning after breakfast and in the evening before sleeping. Subjects were not given any instructions about drinking and eating, and were allowed to follow their previous patterns for these activities.

As per the protocol established by the American Dental Association, two experienced, trained examiners, who have achieved a 90% agreement during a pre-study calibration, performed the oral soft tissue examinations and shade assessments at baseline. Shade assessments were made by comparing the shade tabs from a Vita shade guide, with the facial aspects of the upper and lower central incisor teeth and selecting the closest matching shade.

Teeth shades of subjects were evaluated, near one window, between 10:00 am and 12:00 am in natural light, so as to simulate real life perceptions of teeth lightness. The examinations took place at the following time intervals: Baseline, Immediately After Rinsing, 5 Minutes, 1 Hour, 3 Hours, 8 Hours and 7 Days.

Vita Shade Score and L* Colorimeter Data was collected on maxillary anterior tooth #8 before and after treatment. Vita Shade Score and L* Colorimeter Data were collected by experienced and calibrated examiners. The study followed a parallel, double-blind research protocol that complied with industry and ADA standards.

Statistical Methods Used:

All statistical analyses were conducted using standard statistical software using a level of significance of $p < .05$. Data collected at each examination interval was compared between groups using a two-group Student's t-test for independent samples.

SUMMARY FINDINGS:

DEMOGRAPHICS: All subjects were residents of south Florida and all major races were represented in the study groups. All subjects were healthy and had healthy, natural maxillary teeth that were judged to have a Vita shade of A3 or darker on tooth #8. There were twenty (20) subjects in each group and each group was balanced for mean age and gender. The mean age for the Placebo Group was 46.5 ± 14.9 ; Control Group was 45.2 ± 18.2 ; the mean age of POPWHITE® Test Group was 46.2 ± 18.9 . The male: female ratio of each group was kept as balanced as possible. See **Table 1** for a summary of the demographic data.

TABLE 1 - DEMOGRAPHICS				
DEMOGRAPHICS OF STUDY SUBJECTS ENROLLED IN PROPHY PASTE STUDY				
STUDY GROUP	MEAN AGE	STANDARD DEVIATION	RACE	M:F RATIO
PLACEBO (n=20)	46.5	14.9	13 W 3 B 2 H 2 A	10:10
CONTROL (n=20)	45.2	18.2	13 W 3 B 2 H 2 A	10:10
TEST (n=20)	46.2	18.9	13 W 3 B 2 H 2 A	10:10
<i>Note: There was no statistical difference in age, sex or race (p < 0.05) ALL THE GROUPS WERE STATISTICALLY SIMILAR</i>				

SUMMARY FINDINGS: **WHITENING EFFICACY RESULTS:** We judged the whitening efficacy of the POPWHITE® Mouthwash against Placebo and the Market Leading LISTERINE Whitening Mouthwash (containing 2% Hydrogen Peroxide) using Vita Shade Score analysis according to ADA Guidelines and industry standards. POPWHITE® Mouthwash contains no peroxide and uses its own unique VIOGIN™ technology.

Table 2 below shows the mean Vita Shade Score for all subject groups. **Table 3** below shows the mean change in Vita Shades after treatment. As can clearly be seen, all POPWHITE® test subjects had statistically significant whiter teeth after the first use of the product. The mean improvement for the POPWHITE group was 3.20 ± 0.4 shades. After one week, POPWHITE subjects exhibited an improvement of 4.00 ± 0.5 shades. Both the PLACEBO and CONTROL subjects teeth did not show any significant improvement over the same examination intervals. The difference in efficacy is likely attributed to the different mechanisms of action. The market leader relies on peroxide bleaching (slow) and the POPWHITE relies on its own, faster acting VIOGIN™ Technology.

TABLE 2

MEAN VITA SHADE SCORES AT EACH EXAMINATION INTERVAL

STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS	7 DAYS
PLACEBO (n=20)	9.85	9.70	9.70	9.75	9.75	9.75	9.80
MARKET LEADER (n=20)	9.85	9.20	9.30	9.30	9.30	9.35	9.30
POPWHITE (n=20)	9.85	6.65	6.55	6.85	7.50	8.20	5.85

NOTES:

POPWHITE works statistically better than MARKET LEADER after first use ($p < 0.05$) and at 7 days ($p < 0.05$)
 There is no statistical difference between MARKET LEADER and PLACEBO after one week

TABLE 3

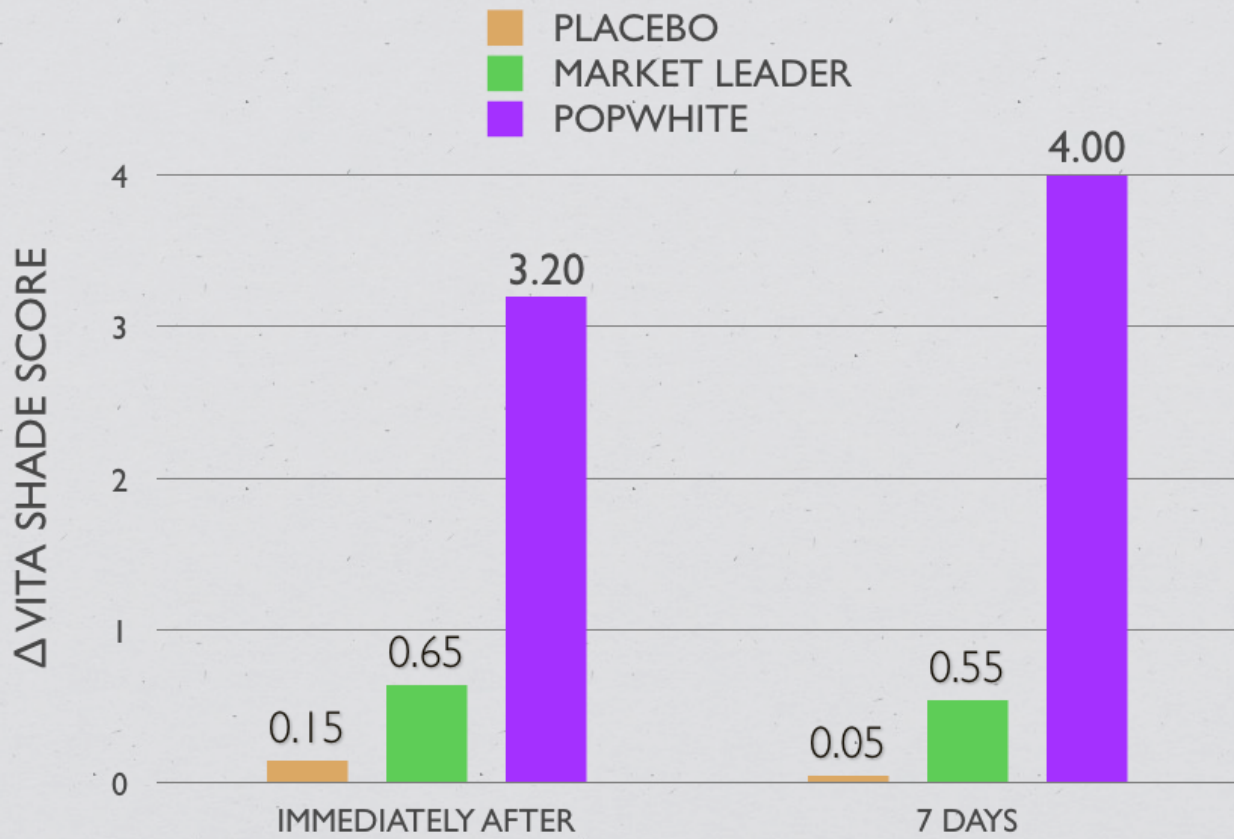
MEAN CHANGE IN VITA SHADE SCORES

STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS	7 DAYS
PLACEBO (n=20)	-	0.15	0.15	0.10	0.10	0.10	0.05
MARKET LEADER (n=20)	-	0.65	0.55	0.55	0.55	0.50	0.55
POPWHITE (n=20)	-	3.20	3.30	3.00	2.35	1.65	4.00
SIG DIFFERENCE?	-	YES	YES	YES	YES	YES	YES

NOTES:

POPWHITE works statistically better than Market Leader after first use ($p < 0.05$)
 POPWHITE works statistically better than Market Leader at all time intervals through all seven days ($p < 0.05$)
 PLACEBO has no statistical whitening effect

ABILITY TO WHITEN TEETH Mean Change in Vita Shade Score



POPWHITE WHITENS SIGNICANTLY BETTER & FASTER

SUMMARY FINDINGS:

BRIGHTENING EFFICACY RESULTS: We judged the stain removal efficacy of the POPWHITE® Mouthwash against Placebo and the Market Leading LISTERINE Whitening Mouthwash (containing 2% Hydrogen Peroxide) using Objective Minolta Colorimeter analysis (L*) according to ADA Guidelines and industry standards.

Table 4 below shows the mean change in Brightness after treatment. As can clearly be seen, the POPWHITE® test subjects had statistically significant brighter teeth after the first use of the product. The mean improvement for the POPWHITE group was 12.46 ± 0.93 L* units. After one week, POPWHITE subjects exhibited an improvement of 14.56 ± 0.99 L* units. Both the PLACEBO and CONTROL subjects teeth did not show any significant improvement over the same examination intervals. The difference in brightening efficacy is likely attributed to the different mechanisms of action. The market leader relies on peroxide bleaching (slow) and the POPWHITE relies on its own, faster acting VIOCIN™ Technology.

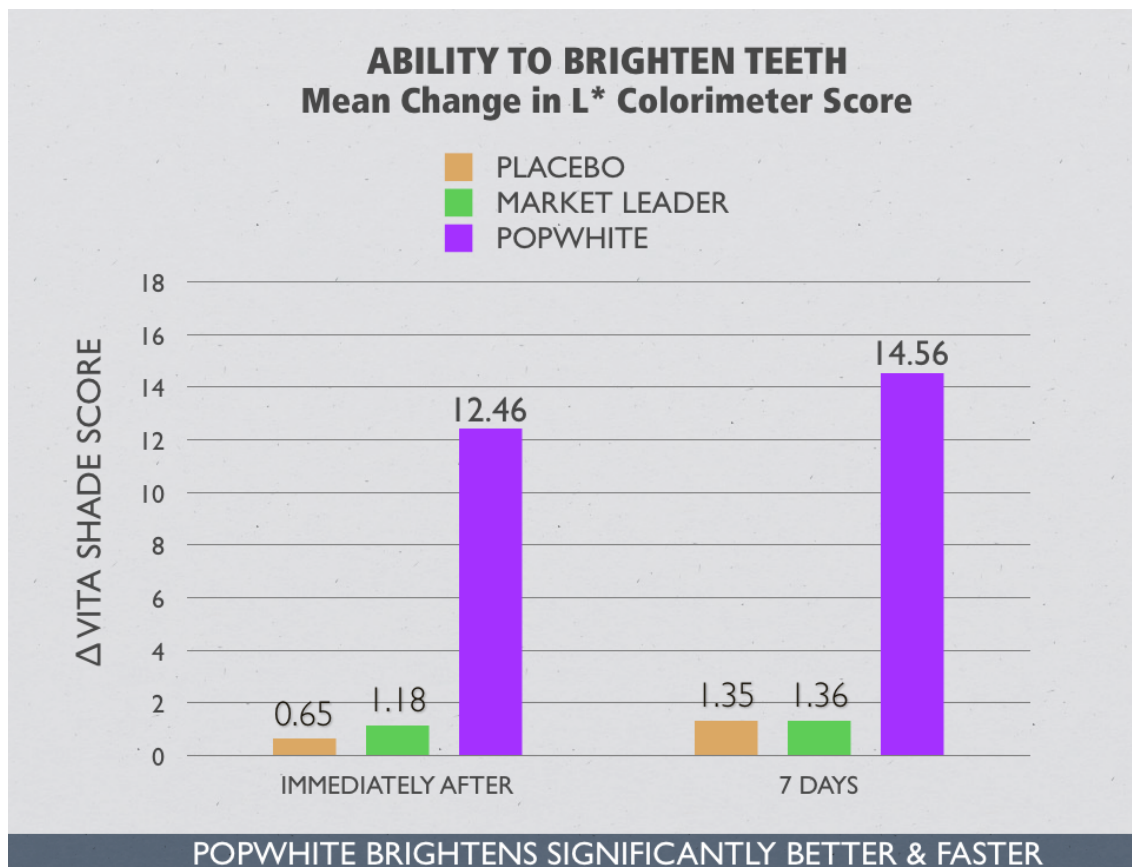
TABLE 4

MEAN CHANGE IN L* BRIGHTENING SCORES

STUDY GROUP	BASELINE	AFTER	7 DAYS
PLACEBO (n=20)	-	0.65	1.35
MARKET LEADER (n=20)	-	1.18	1.36
POPWHITE (n=20)	-	12.46	14.56

NOTES:

POPWHITE works statistically better than MARKET LEADER ($p < 0.05$)
 There is no statistical difference between MARKET LEADER and PLACEBO after one week



SUMMARY FINDINGS: We judged the ability of the products to freshen breath. The assessment included organoleptic assessment of whole-mouth air and measurement of VSCs by means of a calibrated Halimeters (Interscan Corporation, Chatsworth, CA, USA). Subjects were asked to rinse (not to gargle) with their assigned product under supervision for 1 minute. Additional organoleptic assessment will collected after 5 min and 1, 3 and 8 h while new evaluations of VSC levels were rendered after 1, 3 and 8 h. In general we found that Placebo had no effect, but Control and POPWHITE® products were judged to be very effective against oral malodor for up to 8 hours.

Oral Malodor Improvement

Table 5 shows that both the POPWHITE and MARKET LEADER significantly freshened breath for up to 8 hours. Immediately after rinsing, the subjects in the MARKET LEADER group improved by 41.35 ± 2.4 halimeter units. The POPHITE subjects had a statistically similar improvement, 36.35 ± 2.78 units. In fact there was no statistical difference between the Control and Test subjects at any examination interval. Bothe products were equally effective and both products significantly freshened breath for up to 8 hours. Organoleptic judges scored both the MARKET LEADER and the POPWHITE subjects equally at 8 hours (see **Table 6**)

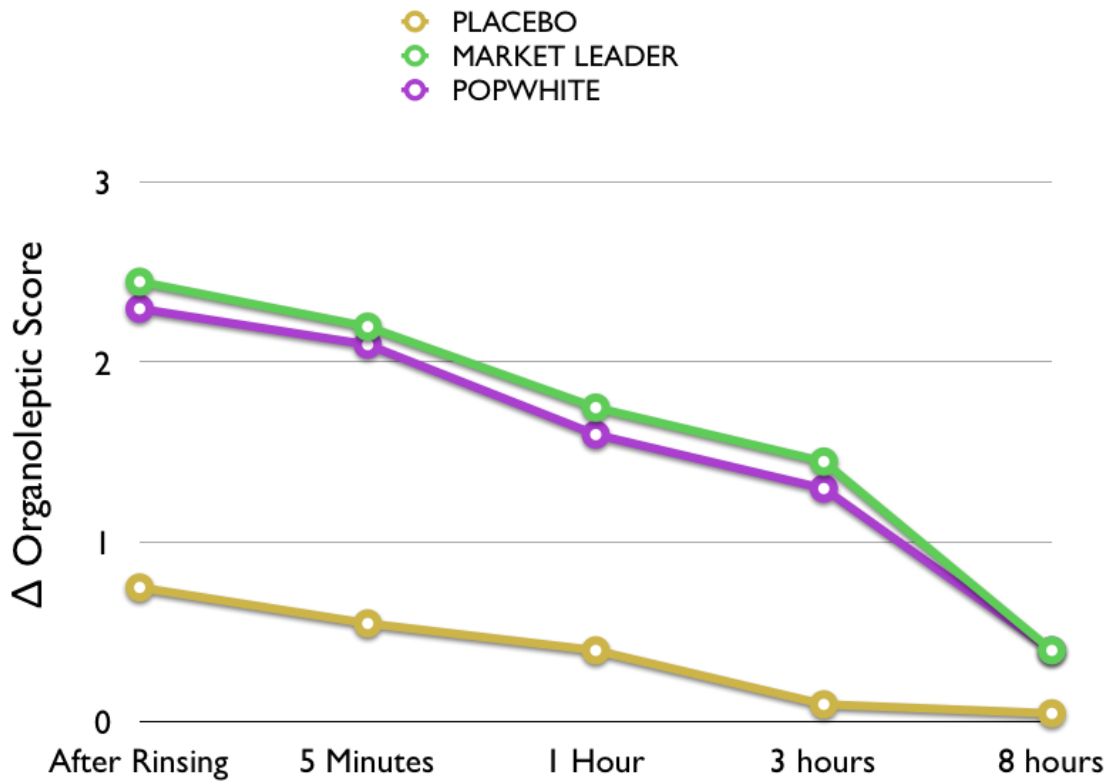
TABLE 5						
MEAN CHANGE IN HALIMETER SCORE AT EACH EXAMINATION INTERVAL						
STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS
PLACEBO (n=20)	-	19.25	7.50	1.75	1.50	1.30
MARKET LEADER (n=20)	-	41.35	39.30	36.95	34.40	14.65
POPWHITE (n=20)	-	36.35	34.30	31.95	29.40	9.50
SIG DIFFERENCE?	-	NO	NO	NO	NO	NO

NOTES:
POPWHITE AND MARKET LEADING MOUTHWASH help to improve bad breath for up to 8 hours
There is no statistical difference between MARKET LEADER and POPWHITE after 8 Hours

TABLE 6						
MEAN CHANGE IN ORGANOLEPTIC SCORE AT EACH EXAMINATION INTERVAL						
STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS
PLACEBO (n=20)	-	0.75	0.55	0.40	0.10	0.05
MARKET LEADER (n=20)	-	2.45	2.20	1.75	1.45	0.40
POPWHITE (n=20)	-	2.30	2.10	1.60	1.30	0.40
SIG DIFFERENCE?	-	NO	NO	NO	NO	NO

NOTES:
POPWHITE AND MARKET LEADING MOUTHWASH help to improve bad breath for up to 8 hours
There is no statistical difference between MARKET LEADER and POPWHITE after 8 Hours

ABILITY TO FRESHEN BREATH Mean Change in Organoleptic Score



POPWHITE AND MARKET LEADER SIGNIFICANTLY FRESHENS BREATH FOR UP TO 8 HOURS.
PLACEBO (WATER) WORKS TO A MUCH LESSER DEGREE FOR 1 HOUR ONLY

SUMMARY FINDINGS: We judged safety of the products based on the results of Loe and Silness Gingival Index scoring and through thorough monitoring the hard tissue / soft tissue oral health of the 40 subjects entered in the study. In general we found no adverse reaction or serious side effects in any of the subjects tested. Placebo, Control and POPWHITE® products were judged by us to be very safe. The instructions were easy to follow and the subjects found the product easy to apply. This also contributed to the safety profile of the products.

Gum Health Improvement

We found that there were no ill effects caused by the use of any of the products in all subjects tested. In fact, the Loe and Silness Gingival Index showed that gum health improved three hours after treatment and continued during the weeklong study. **Table 7 and Table 8** below show the results.

TABLE 6

MEAN GI INDEX SCORE AT EACH EXAMINATION INTERVAL

STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS	7 DAYS
PLACEBO (n=20)	1.24	1.26	1.26	1.30	1.30	1.31	1.33
MARKET LEADER (n=20)	1.30	1.37	1.43	1.43	1.09	1.09	1.05
POPWHITE (n=20)	1.25	1.26	1.26	1.28	1.05	1.05	1.03

NOTES:

POPWHITE AND MARKET LEADING MOUTHWASH help to improve gingival health within 3 hours (p < 0.05)
There is no statistical difference between MARKET LEADER and POPWHITE after one week

TABLE 7

MEAN CHANGE IN GI INDEX SCORE

STUDY GROUP	BASELINE	AFTER	5 MINS	1 HOUR	3 HOURS	8 HOURS	7 DAYS
PLACEBO (n=20)	-	0.03	0.03	0.07	0.07	0.08	0.09
MARKET LEADER (n=20)	-	0.07	0.13	0.13	-0.21	-0.21	-0.25
POPWHITE (n=20)	-	0.01	0.01	0.02	-0.20	-0.20	-0.23
SIG DIFFERENCE?	-	NO	NO	NO	YES	YES	YES

NOTES:

POPWHITE AND MARKET LEADING MOUTHWASH help to improve gingival health within 3 hours (p < 0.05)
There is no statistical difference between MARKET LEADER and POPWHITE after one week

CONSUMER PERCEPTIONS:

We were asked to administer pre-use and post-use consumer surveys to all subjects. Below is a summary of some of the most important post-use responses given by the 20 subjects in the Double Action Whitening System test group:

TEST GROUP (POPWHITE MOUTHWASH)

- POPWHITE Mouthwash has a pleasant taste: **100% Agreed**
- POPWHITE Mouthwash is convenient, easy and fast to use: **100% Agreed**
- I saw visible results after a single application: **100% Agreed**
- I saw visible results after one week of use: **100% agreed**
- I prefer using POPWHITE Mouthwash over strips / trays for whitening my teeth: **100% agreed**
- Freshens my breath: **100% Agreed**

We conclude that consumers unanimously found that the POPWHITE Mouthwash:

1. Tastes pleasant
2. Is convenient, easy, fast to use
3. Would recommend to friend
4. More preferred than whitening to using strips/trays to whiten teeth
5. Gives clearly visible results seen after 1 use
6. Gives even greater clearly visible results after 7 days of use
7. Freshens breath

Moreover, consumers unanimously said that they would recommend POPWHITE Mouthwash to a friend, and they would all definitely use again.

SCIENTIFIC CONCLUSIONS:

1. POPWHITE Mouthwash significantly whitens teeth
2. POPWHITE Mouthwash significantly brightens teeth
3. POPWHITE Mouthwash whitens after just one use (3.2 Shades)
4. POPWHITE Mouthwash whitens after 7 days of use (4.0 Shades)
5. POPWHITE Mouthwash whitens better than market leading whitening mouthwash
6. POPWHITE Mouthwash whitens faster than market leading whitening mouthwash
7. POPWHITE Mouthwash brightens after just one use
8. POPWHITE Mouthwash brightens after 7 days of use
9. POPWHITE Mouthwash brightens better than market leading whitening mouthwash
10. POPWHITE Mouthwash improves gum health after 3 hours and 7 days of use
11. POPWHITE Mouthwash significantly freshens breath for up to 8 hours
12. POPWHITE Mouthwash significantly freshens breath as well as the market leader
13. POPWHITE Mouthwash is safe to use
14. POPWHITE Mouthwash causes no side effects after 7 days of use
15. POPWHITE Mouthwash whitens 5 times better than market leader after the first use
16. POPWHITE Mouthwash whitens 7 times better than market leader after 7 days
17. POPWHITE Mouthwash contains VIOGIN™ technology that whitens teeth fast without peroxide

TESTIMONIAL:

The claims that were requested to be tested by POPWHITE were “verified to be true” by our clinical scientists and we stand behind these findings under the testing conditions described above.

VERIFIED:

X 

Date: August 30, 2014

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Principal Investigator

NOTES