

## FINAL REPORT

**CLIENT:** GoLove  
3701 Sacramento St. No. 107  
San Francisco, CA 94118

**ATTENTION:** John Renko

**TEST:** Repeated Insult Patch Test  
Protocol No.: CP-01.01S  
Protocol Date: 07/22/19

**TEST MATERIAL:** GL100 Lot: 091819-1

**STUDY NUMBER:** C19-7414.01

Reviewed by: *Richard R. Eisenberg*  
Richard R. Eisenberg, M.D.  
Medical Director  
Board Certified Dermatologist

Approved by: *Karen Rauen* 12/26/19  
Karen Rauen, Ph.D.  
Senior Director, Clinical Evaluations & Photobiology

Approved by: *Joy Frank* 12/26/19  
Joy Frank, R.N.  
Executive Vice President, Clinical Evaluations



FDA Registration# 1000151293  
DEA Registration# RC0199744 Schedule I-V  
US EPA/NJ DEP Registration# NJD982726648  
ISO/IEC 17025:2005 Accredited

Office: +1 (973) 808-7111 Fax: +1 (973) 808-7234 70 New Dutch Lane Fairfield, NJ 07004-2514

Clinical • Photobiology • Analytical Chemistry • Microbiology • In-Vitro Safety • Consulting

This report is submitted for the exclusive use of the person, partnership, or corporation to whom it is addressed, and neither the report nor the name of these Laboratories nor any member of its staff, may be used in connection with the advertising or sale of any product or process without authorization.

## QUALITY ASSURANCE UNIT STATEMENT

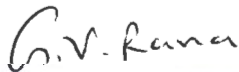
**Study Number:** C19-7414.01

The Consumer Product Testing Company, Incorporated (CPTC) Quality Assurance Unit (QAU) is responsible for auditing the conduct, content and reporting of all clinical trials that are conducted at CPTC.

This trial has been conducted in accordance with the Declaration of Helsinki, the ICH Guideline E6 for *Good Clinical Practice*, the requirements of 21 CFR Parts 50 and 56, other applicable laws and regulations, CPTC Standard Operating Procedures, and the approved protocol.

The CPTC QAU has reviewed all data, records, and documents relating to this trial and also this Final Report. The following QAU representative signature certifies that all data, records, and documents relating to this trial and also this Final Report have been reviewed and are deemed to be acceptable, and that the trial conforms to all of the requirements as indicated above.

All records and documents pertaining to the conduct of this trial shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QAU to obtain custody of trial records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, trial-related records shall be destroyed at the end of the CPTC archive period with no further notice in a manner that renders them useless.



Quality Assurance Representative

12/27/19

Date

**Objective:** To determine by repetitive epidermal contact the potential of a test material to induce primary or cumulative irritation and/or allergic contact sensitization.

**Participants:** Fifty-six (56) qualified subjects, male and female, ranging in age from 19 to 77 years, were selected for this evaluation. Fifty-three (53) subjects completed this study. The remaining subjects discontinued their participation for various reasons, none of which were related to the application of the test material.

**Inclusion Criteria:**

1. Subjects must have read, signed, and dated an Informed Consent Form that included a HIPAA statement;
2. Subjects were male or female, aged 16-79 years, inclusive;
3. Subjects were considered reliable and capable of understanding and following directions; and
4. Subjects aged 16 or 17 years must have read, signed, and dated an Adolescent Assent Form after their parent or legal guardian had read, signed, and dated an Informed Consent Form.

**Exclusion Criteria:**

1. Subjects who were in ill health, as determined by the Principal Investigator;
2. Subjects who were taking medication, other than birth control, that, in the opinion of the Investigator, could influence the purpose, integrity, or outcome of the trial;
3. Subjects who had used any prescribed or OTC anti-inflammatory, antihistamine, corticosteroid, immunosuppressant, or antibiotic drug within 7 days prior to initiation of the trial or during their participation on this trial;
4. Female subjects who were pregnant, planning to become pregnant, or lactating during the trial;
5. Subjects with any visible disease, sunburn, scars, excessive tattoos, etc., that might be confused with a skin reaction to the test material or, as determined by the Principal Investigator, might interfere with the evaluation;
6. Subjects who had a history of adverse reactions to cosmetics, adhesive tapes, OTC drugs, or other personal care products; or
7. Subjects who introduced the use of any new cosmetic, toiletry, or personal care products during the trial.

**Test Material:** GL100 Lot: 091819-1

<b>Study Schedule:</b>	<u>Panel #</u>	<u>Initiation Date</u>	<u>Completion Date</u>
	20190439	November 06, 2019	December 13, 2019

**Methodology:**

The upper back between the scapulae served as the treatment area. Approximately 0.2 g of the test material, or an amount sufficient to cover the contact surface, was applied to the 1 in<sup>2</sup> absorbent pad portion of a clear, adhesive dressing. This was then applied to the appropriate treatment site to form a semi-occlusive patch.

**Induction Phase:**

Patches were applied three (3) times per week (e.g., Monday, Wednesday, and Friday) for a total of nine (9) applications. The site was marked to ensure the continuity of patch application. Following supervised removal and scoring of the first Induction patch, participants were instructed to remove all subsequent Induction patches at home one day after application. The evaluation of this site was made again just prior to re-application. If a participant was unable to report for an assigned test day, one (1) makeup day was permitted. This day was added to the Induction period.

With the exception of the first supervised Induction Patch reading, if any test site exhibited a moderate (2-level) reaction during the Induction Phase, application was moved to an adjacent area. Applications were discontinued for the remainder of this test phase, if a moderate (2-level) reaction was observed on this new test site. Applications would also be discontinued if marked (3-level) or severe (4-level) reactivity was noted.

Rest periods consisted of one day following each Tuesday and Thursday removal, and two days following each Saturday removal.

**Challenge Phase:**

At least 10 days following the final Induction patch application, a Challenge patch was applied to a virgin test site adjacent to the original Induction patch site, following the same procedure described for Induction. The patch was removed and the site scored at the clinic Day 1 and Day 3 post-application.

**Methodology  
(continued):**

**Evaluation Criteria (Erythema and additional Dermal Sequelae):**

<b>0</b>	<b>=</b>	<b>No visible skin reaction</b>	<b>E</b>	<b>=</b>	<b>Edema</b>
<b>0.5</b>	<b>=</b>	<b>Barely perceptible</b>	<b>D</b>	<b>=</b>	<b>Dryness</b>
<b>1</b>	<b>=</b>	<b>Mild</b>	<b>S</b>	<b>=</b>	<b>Staining</b>
<b>2</b>	<b>=</b>	<b>Moderate</b>	<b>P</b>	<b>=</b>	<b>Papules</b>
<b>3</b>	<b>=</b>	<b>Marked</b>	<b>V</b>	<b>=</b>	<b>Vesicles</b>
<b>4</b>	<b>=</b>	<b>Severe</b>	<b>B</b>	<b>=</b>	<b>Bullae</b>
			<b>U</b>	<b>=</b>	<b>Ulceration</b>
			<b>Sp</b>	<b>=</b>	<b>Spreading</b>

Erythema was scored numerically according to this key. If present, additional Dermal Sequelae were indicated by the appropriate letter code and a numerical value for severity.

**Adverse Events:** There were no adverse events.

**Amendments:** There were no amendments.

**Deviations:** There were no deviations

**Results:** The results of each participant are appended (Table 1).

Observations remained negative throughout the test interval.

Subject demographics are presented in Table 2.

**Summary:** Under the conditions of this study, test material, GL100 Lot: 091819-1, indicated no potential for dermal irritation or allergic contact sensitization.

Table 1  
 Panel #20190439

Individual Results

GL100 Lot: 091819-1

Subject Number	Day1*	-----Induction Phase-----									Virgin Challenge Site		
		1	2	3	4	5	6	7	8	9	Day 1*	Day 3	
1	0	0	0	0	0	0	0	0	0	0	0	0	0
2	0	0	0	0	0	0	0	0	0	0	0	0	0
3	0	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	0	0	0	0	0	0	0	0	0	0	0
6	0	0	0	0	0	0	0	0	0	0	0	0	0
7	0	0	0	0	0	0	0	0	0	0	0	0	0
8	0	0	0	0	0	0	0	0	0	0	0	0	0
9	0	0	0	0	0	0	0	0	0	0	0	0	0
10	0	0	0	0	0	0	0	0	0	0	0	0	0
11	0	0	0	0	0	0	0	0	0	0	0	0	0
12	0	0	0	0	0	0	0	0	0	0	0	0	0
13	0	0	0	0	0	0	0	0	0	0	0	0	0
14	0	0	0	0	0	0	0	0	0	0	0	0	0
15	0	0	0	0	0	0	0	0	0	0	0	0	0
16	0	0	0	0	0	0	0	0	0	0	0	0	0
17	0	0	0	0	0	0	0	0	0	0	0	0	0
18	0	0	0	0	0	0	0	0	0	0	0	0	0
19	0	0	0	0	0	0	0	0	0	0	0	0	0
20	0	0	0	0	0	0	0	0	0	0	0	0	0
21	0	0	0	0	0	0	0	0	0	0	0	0	0
22	0	0	0	0	0	0	0	0	0	0	0	0	0
23	0	0	0	0	0	0	0	0	0	0	0	0	0
24	0	0	0	0	0	0	0	0	---WITHDREW CONSENT---		0	0	
25	0	0	0	0	0	0	0	0	0	0	0	0	0
26	0	0	0	0	0	0	0	0	0	0	0	0	0
27	0	0	0	0	0	0	0	0	0	0	0	0	0
28	0	0	0	0	0	0	0	0	0	0	0	0	0
29	0	0	0	0	0	0	0	0	0	0	0	0	0

Day 1\* = Supervised removal

Table 1  
 (continued)  
 Panel #20190439

Individual Results

GL100 Lot: 091819-1

Subject Number	Day1*	-----Induction Phase-----									Virgin Challenge Site				
		1	2	3	4	5	6	7	8	9	Day 1*	Day 3			
30	0	0	0	0	0	0	0	0	0	0	0	0	0		
31	0	0	0	0	0	0	0	0	0	0	0	0	0		
32	0	0	0	0	0	0	0	0	0	0	0	0	0		
33	0	0	0	0	0	0	0	0	0	0	0	0	0		
34	0	0	0	0	0	0	0	0	0	0	0	0	0		
35	0	0	0	0	0	0	0	0	0	0	0	0	0		
36	0	0	0	0	0	0	0	0	0	0	0	0	0		
37	0	0	0	0	0	0	0	0	0	0	0	0	0		
38	0	0	0	0	0	0	0	0	0	0	0	0	0		
39	0	0	0	0	0	0	0	0	0	0	0	0	0		
40	0	0	0	0	0	0	0	0	0	0	0	0	0		
41	0	0	0	0	0	0	0	0	0	0	0	0	0		
42	0	0	0	0	0	0	0	0	0	0	0	0	0		
43	0	0	0	0	0	0	0	0	0	0	0	0	0		
44	0	0	0	0	0	0	0	0	0	0	0	0	0		
45	0	0	0	0	0	0	0	0	0	0	0	0	0		
46	0	0	0	0	0	0	0	0	0	0	0	0	0		
47	0	0	0	0	0	0	0	0	0	0 <sup>w</sup>	0	0	0		
48	0	0	0	0	-----WITHDREW CONSENT-----										
49	0	0	0	0	0	0	0	0	0	0	0	0	0		
50	0	0	0	0	0	0	0	0	0	0	0	0	0		
51	0	0	0	0	0	0	0	0	0	0	0	0	0		
52	0	0	0	0	0	0	0	0	0	0	0	0	0		
53	0	0	0	-----WITHDREW CONSENT-----											
54	0	0	0	0	0	0	0	0	0	0 <sup>w</sup>	0	0	0		
55	0	0	0	0	0	0	0	0	0	0	0	0	0		
56	0	0	0	0	0	0	0	0	0	0	0	0	0		

Day 1\* = Supervised removal  
 W = Inclement weather; subject unable to report as scheduled

Table 2  
Panel #20190439

Subject Demographics

---

Subject Number	ID#	Age	Gender
1	51534	54	F
2	51533	56	M
3	44709	46	F
4	72301	27	M
5	79420	68	F
6	29339	59	F
7	83698	19	M
8	85689	20	M
9	51938	66	F
10	44953	65	F
11	53140	77	F
12	61068	57	F
13	50004	68	F
14	86015	43	F
15	88102	35	F
16	87964	49	F
17	88535	43	F
18	57299	58	M
19	54964	41	F
20	88865	37	F
21	83147	60	F
22	49665	43	F
23	65657	55	F
24	67680	76	F
25	88987	65	F
26	25110	71	F
27	21806	39	F
28	89700	59	M
29	56808	60	F

---



Table 2  
(continued)  
Panel #20190439

Subject Demographics

Subject Number	ID#	Age	Gender
30	26899	54	F
31	60204	70	F
32	85073	58	F
33	38596	63	M
34	89602	46	F
35	85072	60	M
36	74716	57	F
37	10503	54	F
38	85722	36	F
39	66174	59	F
40	66170	58	M
41	88971	65	F
42	27829	48	M
43	4958	45	F
44	89404	53	M
45	76246	53	F
46	284	59	F
47	89958	47	F
48	89971	19	M
49	81433	30	F
50	36726	52	F
51	84264	29	M
52	78683	36	F
53	89960	26	F
54	46093	60	F
55	68839	53	F
56	89413	44	F