



**BIO SCIENCE**  
LABORATORIES • INC

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Michael Bralkowski  
Science officer  
ESC BRANDS  
600 La Terrazzo Blvd.  
Escondido CA 92025

Mr. Bralkowski:

Testing for Study #1707288-204, entitled “A NON-GLP QUANTITATIVE HARD SURFACE DISINFECTION EVALUATION OF ONE TEST PRODUCT (HAND SANITIZER) VERSUS SPORES OF *Clostridium difficile*” has been completed. Results from the Test Procedures defined in Section 17.0 of The Study Protocol #1707288-204 are presented in Table 1 below. Results from the Quantitative HCl Resistance Evaluation defined in Section 16.0 of The Study Protocol #1707288-204 are presented below in Table 2. Table 3 presents the results from the Study Controls as defined by Section 18.0 of The Study Protocol.

**TABLE 1: CONTROL CARRIER RESULTS**

Control Solution: Phosphate Buffered Saline with 0.1% (v/v) Tween 80 (PBS-T)  
Contact Time: 10 minutes  
Test Strain: *Clostridium difficile* (ATCC #43598; Spore Suspension)

Initial Suspension Population (CFU/mL)	Carrier No.	CFU/carrier Post-Exposure	Log <sub>10</sub> CFU/Carrier	Mean Log <sub>10</sub> Density (M)
2.910 x 10 <sup>9</sup>	1	1.2778 x 10 <sup>7</sup>	7.1065	7.2247

**TABLE 1 (Continued): TEST RESULTS**

Test Formulation: Propriety OTC compliant formulation Lot number: 07K17  
Contact Time: 10 minutes  
Test Strain: *Clostridium difficile* (ATCC #43598; Spore Suspension)

Carrier No.	Mean Log <sub>10</sub> Density of Control Carriers (M): 7.2247			
	CFU/membrane Post-Exposure	Log <sub>10</sub> CFU/Carrier	Mean Log <sub>10</sub> Density (MT)	Mean Log <sub>10</sub> Reduction (M-MT)
1	> 200	> 2.3010	> 2.3010	<4.9237
2	> 200	> 2.3010		
3	> 200	> 2.3010		
4	> 200	> 2.3010		
5	> 200*	> 2.3010		

Note: This batch/lot of the test product did NOT meet the minimum 6-Log<sub>10</sub> reduction in viable spores acceptance criterion.

\*Presence of *Clostridium difficile* verified via gram stain.

**TABLE 1 (Continued): TEST RESULTS**

Test Formulation: Proprietary OTC compliant formulation Lot number: 07K17

Contact Time: 20 minutes

Test Strain: *Clostridium difficile* (ATCC #43598; Spore Suspension)

Carrier No.	Mean Log <sub>10</sub> Density of Control Carriers (M): 7.2247			
	CFU/membrane Post-Exposure	Log <sub>10</sub> CFU/Carrier	Mean Log <sub>10</sub> Density (MT)	Mean Log <sub>10</sub> Reduction (M-MT)
1	> 200	> 2.3010	> 2.3010	<4.9237
2	> 200	> 2.3010		
3	> 200	> 2.3010		
4	> 200	> 2.3010		
5	> 200*	> 2.3010		

Note: This batch/lot of the test product did NOT meet the minimum 6-Log<sub>10</sub> reduction in viable spores acceptance criterion.

\*Presence of *Clostridium difficile* verified vial gram stain.

**TABLE 2: HCl RESISTANCE EVALUATION RESULTS**

Test Formulation: 2.5 N Hydrochloric Acid

Test Strain (ATCC #)	Log <sub>10</sub> Average Recovery Control Solution	Log <sub>10</sub> Average Recovery 2.5 N HCl	Log <sub>10</sub> Reduction
<i>Clostridium difficile</i> (ATCC #43598; spore suspension)	7.5185	6.0719	1.4466

Note: The Quantitative HCl Resistance Evaluation acceptance criterion has been met.

**TABLE 3: NEUTRALIZATION RESULTS 10<sup>-5</sup> Dilution**

Test Formulation: Proprietary OTC compliant formulation Lot number: 07K17

Test Strain (ATCC #)	Test Description	Replicate	Log <sub>10</sub> Recovery	Acceptance Criterion Met? (Yes / No)
<i>Clostridium difficile</i> (ATCC #43598; spore suspension)	EFFECTIVENESS POPULATION	1	*	N/A
		2	1.5911	
	Log <sub>10</sub> Average TEST Population (n = 1)		1.5911	YES①
	TITER CONTROL POPULATION	1	2.2648	N/A
		2	>2.3010	
Log <sub>10</sub> Average TITER CONTROL Population (n = 2)		>2.2829	YES①	

① = The mean recovery from the Neutralizer Effectiveness test must be at least 50% of Neutralization Titer Control to demonstrate that the neutralizer (PBS-T/ST) is effective in neutralizing the test product. A mean recovery higher than the Neutralization Titer Control is also valid.

\* = Not used for calculations due to gram reaction result.

Please feel free to contact me if you have any questions regarding the data. I can be reached at [ddragotoiu@biosciencelabs.com](mailto:ddragotoiu@biosciencelabs.com), or by telephone at (406) 587-5735, ext. 128.

We appreciate your business and look forward to serving you in the near future with any of your testing needs. Please contact our Sales and Marketing Department at (877) 858-2754, toll free.

Sincerely,

A handwritten signature in blue ink, appearing to read "Dan M. Dragotoiu".

Dan M. Dragotoiu  
Study Director: In-Vitro Laboratory  
[ddragotoiu@biosciencelabs.com](mailto:ddragotoiu@biosciencelabs.com)  
(406) 587-5735 ext. 128  
FAX (406) 586-7930