

STUDY TITLE

Evaluation of Antimicrobial Activity of Odorox Device

**Test Organism:**

*Salmonella enterica* serotype - *typhimurium* (ATCC 23564)

PRODUCT IDENTITY

Mobile Disinfection Unit M.D.U.

AUTHOR

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STUDY COMPLETION DATE

April 10, 2013

PERFORMING LABORATORY

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SPONSOR

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Boynton Beach, FL 33426

PROJECT NUMBER

A14805

## STUDY REPORT

### GENERAL STUDY INFORMATION

**Study Title:** Evaluation of Antimicrobial Activity of Odorox Device  
**Project Number:** A14805  
**TRF Number:** HGI01021813.CUST

### TEST SUBSTANCE IDENTITY

**Test Substance Name:** Mobile Disinfection Unit M.D.U.

### STUDY DATES

**Date Sample Received:** March 14, 2013  
**Study Initiation Date:** March 25, 2013  
**Experimental Start Date:** March 28, 2013  
**Experimental End Date:** April 1, 2013  
**Study Completion Date:** April 10, 2013

Test Organism	ATCC #	Culture Medium	Incubation Parameters
<i>Salmonella enterica</i> serotype - typhimurium	23564	Synthetic Broth	35-37°C, aerobic

The microorganism used in this study was obtained from the American Type Culture Collection (ATCC), Manassas, Virginia.

**Test Exposure:** 1 hour, 3 hours and 5 hours  
**Exposure Temperature:** Room temperature (25.00-30.10°C).  
**Number of Carriers Tested/lot:** Duplicate carriers per exposure time utilizing two carrier types (1" x 1" stainless steel and 1" x 1" cotton fabric)  
**Soil Load Description:** No organic soil load required  
**Neutralizing Subculture Medium:** Lethen Broth + 0.07% Lecithin + 0.5% Tween 80  
**Agar Plate Medium:** Tryptic Soy Agar with 5% Sheep Blood (BAP)

### EXPERIMENTAL DESIGN

An incubator (approximately 35" x 26" x 76.5") was prepared for testing by turning off all applicable fans and heat sources allowing the incubator to equilibrate to room temperature. The Mobile Disinfection Unit M.D.U. was placed into the incubator; the unit was powered on and was allowed to run for 68 minutes prior to placing the carriers in the incubator. Duplicate test carriers, per carrier type, per exposure time point were inoculated with a dried film of test culture and were placed within the incubator. Fabric carriers were allowed to hang freely, while stainless steel carriers were exposed within Petri dishes with the dish lids fully ajar. Following 1 hour, 3 hour and 5 hour exposure times, the carriers were neutralized, mixed and assayed for survivors. Duplicate control carriers were neutralized immediately after drying (time zero). Additionally, duplicate control carriers were exposed for 1 hour, 3 hours and 5 hours, as in the test, under ambient conditions. Appropriate purity, carrier sterility, neutralization confirmation and neutralizing subculture medium sterility controls were performed. Percent and log<sub>10</sub> reductions were determined for the test carriers as compared to the quantitation control carriers at the same exposure time.

**TABLE 1: CONTROL RESULTS**

Type of Control		Results
		<i>Salmonella enterica</i> serotype - <i>typhimurium</i> (ATCC 23564)
Purity Control		Pure
Neutralizing Subculture Medium Sterility Control		No Growth
Carrier Sterility Control	Stainless Steel	No Growth
	Cotton Fabric	No Growth

**TABLE 2: NEUTRALIZATION CONFIRMATION CONTROL RESULTS**

Test Substance: Mobile Disinfection Unit M.D.U					
Test Organism	Carrier Type	Neutralization Confirmation (CFU)		Log <sub>10</sub> Difference	Pass/Fail (±1 log <sub>10</sub> )
		Numbers Control	Results		
<i>Salmonella enterica</i> serotype - <i>typhimurium</i> (ATCC 23564)	Stainless Steel	88,76	144,130	-0.23	Pass
	Cotton Fabric		91,85	-0.03	Pass

CFU = Colony Forming Units

**TABLE 3: EVALUATION OF QUANTITATION CONTROL CARRIER DATA**

Test Organism	Exposure Time	Carrier type	Carrier #	CFU/carrier	Log <sub>10</sub>	Geometric Mean (Average Log <sub>10</sub> )
<i>Salmonella enterica</i> serotype - <i>typhimurium</i> (ATCC 23564)	Time Zero	Stainless Steel	1	8.3 x 10 <sup>6</sup>	6.92	9.12 x 10 <sup>6</sup> (6.96)
			2	9.7 x 10 <sup>6</sup>	6.99	
		Cotton Fabric	1	9.1 x 10 <sup>6</sup>	6.96	7.94 x 10 <sup>6</sup> (6.90)
			2	6.7 x 10 <sup>6</sup>	6.83	
	1 hour	Stainless Steel	1	4.9 x 10 <sup>6</sup>	6.69	5.50 x 10 <sup>6</sup> (6.74)
			2	6.0 x 10 <sup>6</sup>	6.78	
		Cotton Fabric	1	3.2 x 10 <sup>5</sup>	5.51	3.55 x 10 <sup>5</sup> (5.55)
			2	3.9 x 10 <sup>5</sup>	5.59	
	3 hours	Stainless Steel	1	5.7 x 10 <sup>6</sup>	6.76	5.62 x 10 <sup>6</sup> (6.75)
			2	5.4 x 10 <sup>6</sup>	6.73	
		Cotton Fabric	1	3.2 x 10 <sup>5</sup>	5.51	3.63 x 10 <sup>5</sup> (5.56)
			2	4.0 x 10 <sup>5</sup>	5.60	
	5 hours	Stainless Steel	1	3.7 x 10 <sup>6</sup>	6.57	3.98 x 10 <sup>6</sup> (6.60)
			2	4.3 x 10 <sup>6</sup>	6.63	
		Cotton Fabric	1	3.0 x 10 <sup>5</sup>	5.48	3.98 x 10 <sup>5</sup> (5.60)
			2	5.1 x 10 <sup>5</sup>	5.71	

CFU = Colony Forming Unit

**TABLE 4: EVALUATION OF TEST CARRIER DATA**

<b>Test Substance: Mobile Disinfection Unit M.D.U</b>						
<b>Test Organism: <i>Salmonella enterica</i> serotype – <i>typhimurium</i> (ATCC 23564)</b>						
<b>Exposure Time</b>	<b>Carrier type</b>	<b>Carrier #</b>	<b>CFU/carrier</b>	<b>Log<sub>10</sub></b>	<b>Geometric Mean (Average Log<sub>10</sub>)</b>	<b>Percent Reduction* (Log<sub>10</sub>)</b>
1 hour	Stainless Steel	1	3.9 x 10 <sup>6</sup>	6.59	3.47 x 10 <sup>6</sup> (6.54)	36.9% (0.20)
		2	3.1 x 10 <sup>6</sup>	6.49		
	Cotton Fabric	1	5.3 x 10 <sup>4</sup>	4.72	7.59 x 10 <sup>4</sup> (4.88)	78.6% (0.67)
		2	1.08 x 10 <sup>5</sup>	5.03		
3 hours	Stainless Steel	1	6.0 x 10 <sup>5</sup>	5.78	6.46 x 10 <sup>5</sup> (5.81)	88.5% (0.94)
		2	6.8 x 10 <sup>5</sup>	5.83		
	Cotton Fabric	1	3.0 x 10 <sup>4</sup>	4.48	2.63 x 10 <sup>4</sup> (4.42)	92.8% (1.14)
		2	2.23 x 10 <sup>4</sup>	4.35		
5 hours	Stainless Steel	1	1.13 x 10 <sup>5</sup>	5.05	2.29 x 10 <sup>5</sup> (5.36)	94.2% (1.24)
		2	4.6 x 10 <sup>5</sup>	5.66		
	Cotton Fabric	1	1.46 x 10 <sup>4</sup>	4.16	1.58 x 10 <sup>4</sup> (4.20)	96.0% (1.40)
		2	1.75 x 10 <sup>4</sup>	4.24		

CFU = Colony Forming Unit

\*As compared to the Quantitation Control Carrier results at the same applicable exposure time.

## ANALYSIS

Mobile Disinfection Unit M.D.U., demonstrated a 36.9% (0.20 log<sub>10</sub>) reduction, 88.5% (0.94 log<sub>10</sub>) reduction and 94.2% (1.24 log<sub>10</sub>) reduction, respectively, of *Salmonella enterica* serotype - *typhimurium* (ATCC 23564) on stainless steel carriers when tested at room temperature (25.00-31.10°C).

Mobile Disinfection Unit M.D.U., demonstrated a 78.6% (0.67 log<sub>10</sub>) reduction, 92.8% (1.14 log<sub>10</sub>) reduction and 96.0% (1.40 log<sub>10</sub>) reduction, respectively, of *Salmonella enterica* serotype - *typhimurium* (ATCC 23564) on cotton fabric carriers when tested at room temperature (25.00-31.10°C).

This study was performed following ATS Labs' Standard Operating Procedures (SOPs) and internal quality systems.



**PROFESSIONAL PERSONNEL INVOLVED:**

- Scott R. Steinagel, B.S. - Director, Microbiology Operations
- Becky Lien, B.A. - Manager, Microbiology Operations
- Peter Toll, B.S. - Supervisor, Microbiology Laboratory Operations
- Anne Stemper, B.S. - Senior Microbiologist
- Joshua Luedtke, M.S. - Microbiologist
- Philip Lange, B.S. - Associate Microbiologist
- Kristen Niehaus, B.A. - Microbiologist
- Nicole Zroka, B.A. - Lead Laboratory Technician
- Elizabeth Schwandt, B.S. - Associate Microbiologist
- Shane Hager, A.A. - Associate Laboratory Technician

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