

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

May 28, 2013

PERFORMING LABORATORY

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PROJECT NUMBER

A14989

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antimicrobial Activity of Odorox Device
Project Number: A14989
TRF Number: HGI01042513.CUST

TEST SUBSTANCE IDENTITY

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

STUDY DATES

Date Sample Received: March 14, 2013
Study Initiation Date: May 8, 2013
Experimental Start Date: May 15, 2013
Experimental End Date: May 17, 2013
Study Completion Date: May 28, 2013

Test Organism	ATCC #	Culture Medium	Incubation Parameters
<i>Salmonella enterica</i> serotype - <i>typhimurium</i>	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: 8 hours
Exposure Temperature: Room temperature (25.0-29.1°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 76 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 an 8 hour exposure time, 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 8 hours, as in the test. Appropriate purity, carrier sterility, neutralization confirmation and neutralizing subculture medium sterility controls were performed. Percent and log₁₀ 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 ₁₀ Difference	Pass/Fail (±1 log ₁₀)
		Numbers Control	Results		
<i>Salmonella enterica</i> serotype - <i>typhimurium</i> (ATCC 23564)	Stainless Steel	12,8	14,14	-0.15	Pass
	Cotton Fabric		15,10	-0.11	Pass

CFU = Colony Forming Units

TABLE 3: EVALUATION OF QUANTITATION CONTROL CARRIER DATA

Test Organism	Exposure Time	Carrier type	Carrier #	CFU/carrier	Log ₁₀	Geometric Mean (Average Log ₁₀)
<i>Salmonella enterica</i> serotype - <i>typhimurium</i> (ATCC 23564)	Time Zero	Stainless Steel	1	2.70 x 10 ⁵	5.43	2.24 x 10 ⁵ (5.35)
			2	1.86 x 10 ⁵	5.27	
		Cotton Fabric	1	7.6 x 10 ⁵	5.88	7.41 x 10 ⁵ (5.87)
			2	7.0 x 10 ⁵	5.85	
	8 hours	Stainless Steel	1	2.40 x 10 ⁴	4.38	2.57 x 10 ⁴ (4.41)
			2	2.72 x 10 ⁴	4.43	
		Cotton Fabric	1	<1 x 10 ²	<2.00	<1.00 x 10 ² (<2.00)
			2	<1 x 10 ²	<2.00	

CFU = Colony Forming Unit

TABLE 4: EVALUATION OF TEST CARRIER DATA

Test Substance: Mobile Disinfection Unit M.D.U						
Test Organism: <i>Salmonella enterica</i> serotype – <i>typhimurium</i> (ATCC 23564)						
Exposure Time	Carrier type	Carrier #	CFU/carrier	Log ₁₀	Geometric Mean (Average Log ₁₀)	Percent Reduction (Log ₁₀)
8 hours	Stainless Steel	1	<1	<0.00	<1.00 (<0.00)	>99.99% (>4.41)*
		2	<1	<0.00		
	Cotton Fabric	1	<1	<0.00	<1.00 (<0.00)	>99.999% (>5.87)**
		2	<1	<0.00		

CFU = Colony Forming Unit

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

** As compared to the Quantitation Control Carrier results at Time Zero.

ANALYSIS

Mobile Disinfection Unit M.D.U., demonstrated a >99.99% (>4.41 log₁₀) reduction of *Salmonella enterica* serotype - *typhimurium* (ATCC 23564) on stainless steel carriers, as compared to the 8 hour stainless steel control carriers, when tested at room temperature (25.0-29.1°C).

Mobile Disinfection Unit M.D.U., demonstrated a >99.999% (>5.87 log₁₀) reduction of *Salmonella enterica* serotype - *typhimurium* (ATCC 23564) on cotton fabric carriers, as compared to the Time Zero fabric control carriers, when tested at room temperature (25.0-29.1°C).

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

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5.28.13
Date

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