



ATS實驗室最終報告-克雷博氏肺病菌

STUDY TITLE

Evaluation of Antimicrobial Activity of Odorox Device

**Test Organism:**

*Klebsiella pneumoniae* - NDM-1 positive (CDC 1000527)

PRODUCT IDENTITY

Mobile Disinfection Unit M.D.U.

AUTHOR

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STUDY COMPLETION DATE

September 19, 2013

PERFORMING LABORATORY

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PROJECT NUMBER

A15495

## STUDY REPORT

### GENERAL STUDY INFORMATION

**Study Title:** Evaluation of Antimicrobial Activity of Odorox Device  
**Project Number:** A15495  
**TRF Number:** HGI01081213.CUST

### TEST SUBSTANCE IDENTITY

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

### STUDY DATES

**Date Sample Received:** August 21, 2013  
**Study Initiation Date:** August 23, 2013  
**Experimental Start Date:** September 5, 2013  
**Experimental End Date:** September 9, 2013  
**Study Completion Date:** September 19, 2013

Test Organism	Designation #	Culture Medium	Incubation Parameters
<i>Klebsiella pneumoniae</i> - NDM-1 positive*	CDC 1000527*	Nutrient Broth	35-37°C, aerobic

The microorganism used in this study was obtained from the Centers for Disease Control and Prevention (CDC) Atlanta, Georgia.

\*This organism is a member of the CRE family of organisms associated with carbapenem resistance.

**Test Exposure:** 4 hours, 8 hours and 24 hours  
**Exposure Temperature:** Room temperature (23.41°C-38.54°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 36" x 26" x 60") 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 ≥30 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 each 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 each exposure time, as in the test. 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>Klebsiella pneumoniae</i> - NDM-1 positive (CDC 1000527)
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>Klebsiella pneumoniae</i> - NDM-1 positive (CDC 1000527)	Stainless Steel	27,28	22,27	0.05	Pass
	Cotton Fabric		24,27	0.04	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>Klebsiella pneumoniae</i> - NDM-1 positive (CDC 1000527)	Time Zero	Stainless Steel	1	1.36 x 10 <sup>6</sup>	6.13	1.02 x 10 <sup>6</sup> (6.01)
			2	7.7 x 10 <sup>5</sup>	5.89	
		Cotton Fabric	1	1.12 x 10 <sup>6</sup>	6.05	1.17 x 10 <sup>6</sup> (6.07)
			2	1.21 x 10 <sup>6</sup>	6.08	
	4 hours	Stainless Steel	1	1.85 x 10 <sup>5</sup>	5.27	2.95 x 10 <sup>5</sup> (5.47)
			2	4.7 x 10 <sup>5</sup>	5.67	
		Cotton Fabric	1	6 x 10 <sup>3</sup>	3.78	7.41 x 10 <sup>3</sup> (3.87)
			2	9 x 10 <sup>3</sup>	3.95	
	8 hours	Stainless Steel	1	1.27 x 10 <sup>5</sup>	5.10	1.17 x 10 <sup>5</sup> (5.07)
			2	1.07 x 10 <sup>5</sup>	5.03	
		Cotton Fabric	1	1.1 x 10 <sup>4</sup>	4.04	1.62 x 10 <sup>4</sup> (4.21)
			2	2.4 x 10 <sup>4</sup>	4.38	
	24 hours	Stainless Steel	1	3.0 x 10 <sup>4</sup>	4.48	2.19 x 10 <sup>4</sup> (4.34)
			2	1.6 x 10 <sup>4</sup>	4.20	
		Cotton Fabric	1	1.6 x 10 <sup>4</sup>	4.20	1.55 x 10 <sup>4</sup> (4.19)
			2	1.5 x 10 <sup>4</sup>	4.18	

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>Klebsiella pneumoniae</i> - NDM-1 positive (CDC 1000527)</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>
4 hours	Stainless Steel	1	8.1 x 10 <sup>4</sup>	4.91	9.55 x 10 <sup>4</sup> (4.98)	67.6% (0.49)
		2	1.12 x 10 <sup>5</sup>	5.05		
	Cotton Fabric	1	2.1 x 10 <sup>1</sup>	1.32	4.57 x 10 <sup>1</sup> (1.66)	99.4% (2.21)
		2	1.0 x 10 <sup>2</sup>	2.00		
8 hours	Stainless Steel	1	3.0 x 10 <sup>4</sup>	4.48	3.55 x 10 <sup>4</sup> (4.55)	69.7% (0.52)
		2	4.1 x 10 <sup>4</sup>	4.61		
	Cotton Fabric	1	<1	<0.00	<5.62 x 10 <sup>0</sup> (<0.75)	>99.9% (>3.46)
		2	3.1 x 10 <sup>1</sup>	1.49		
24 hours	Stainless Steel	1	4.4 x 10 <sup>3</sup>	3.64	2.24 x 10 <sup>3</sup> (3.35)	89.8% (0.99)
		2	1.11 x 10 <sup>3</sup>	3.05		
	Cotton Fabric	1	<1	<0.00	<1.00 (<0.00)	>99.99% (>4.19)
		2	<1	<0.00		

CFU = Colony Forming Unit

\*As compared to the corresponding Carrier Population Control result at the same exposure time

## ANALYSIS

Mobile Disinfection Unit M.D.U., demonstrated a 67.6% (0.49 log<sub>10</sub>) and 99.4% (2.21 log<sub>10</sub>) reduction of *Klebsiella pneumoniae* - NDM-1 positive (CDC 1000527) on stainless steel and cotton fabric carriers, respectively, as compared to the corresponding 4 hour control carrier, when tested at room temperature (23.41°C-38.54°C).

Mobile Disinfection Unit M.D.U., demonstrated a 69.7% (0.52 log<sub>10</sub>) and a >99.9% (>3.46 log<sub>10</sub>) reduction of *Klebsiella pneumoniae* - NDM-1 positive (CDC 1000527) on stainless steel and cotton fabric carriers, respectively, as compared to the corresponding 8 hour control carrier, when tested at room temperature (23.41°C-38.54°C).

Mobile Disinfection Unit M.D.U., demonstrated a 89.8% (0.99 log<sub>10</sub>) and a >99.99% (>4.19 log<sub>10</sub>) reduction of *Klebsiella pneumoniae* - NDM-1 positive (CDC 1000527) on stainless steel and cotton fabric carriers, respectively, as compared to the corresponding 24 hour control carrier, when tested at room temperature (23.41°C-38.54°C).

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

### PREPARED BY:

  
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9.19.13  
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