



ATS實驗室最終報告-艱難梭狀芽孢杆菌

STUDY TITLE

Evaluation of Antimicrobial Activity of UV Illumination /
Hydroxyl Generator

Test Organism:

Clostridium difficile (ATCC 700792)

PRODUCT IDENTITY

Odorox Mobile Disinfection Unit Hydroxyl Generator

AUTHOR

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STUDY COMPLETION DATE

April 14, 2009

PERFORMING LABORATORY

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SPONSOR

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PROJECT NUMBER

A07538

STUDY REPORT

GENERAL STUDY INFORMATION

Study Title: Evaluation of Antimicrobial Activity of UV Illumination / Hydroxyl Generator
Project Number: A07538
TRF Number: HGI01012909.CUST

TEST SUBSTANCE IDENTITY

Test Substance Name: Odorox Mobile Disinfection Unit Hydroxyl Generator

STUDY DATES

Date Sample Received: September 30, 2008
Study Initiation Date: March 16, 2009
Experimental Start Date: March 30, 2009
Experimental End Date: April 6, 2009
Study Completion Date: April 14, 2009

Test Organism	ATCC #	Culture Medium	Subculture Plate Medium
<i>Clostridium difficile</i>	700792	Brain Heart Infusion (BHI)	Brucella Agar

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

Test Exposure: 48 hours, 72 hours, and 96 hours
Exposure Temperature: Room temperature (26.55-29.83°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 with 0.07% Lecithin and 0.5% Tween 80

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 Odorox Mobile Disinfection Unit Hydroxyl Generator was placed into the incubator; the unit was powered on and was allowed to run for 71 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 a 48 hour, 72 hour and 96 hour exposure, the carriers were neutralized, mixed and assayed for survivors. Side by side fabric and stainless steel quantitation control carriers were inoculated and dried as in the test. A single control carrier was neutralized immediately after drying (time zero). Additionally, duplicate control carriers were exposed for 48 hour, 72 hour and 96 hours, as in the test, under ambient conditions. Appropriate purity, carrier sterility, 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.

TABLE 1: CONTROL RESULTS

Type of Control		Results
		<i>Clostridium difficile</i> (ATCC 700792)
Purity Control		Pure
Neutralizing Subculture Medium Sterility Control		No Growth
Carrier Sterility Control	Stainless Steel	No Growth
	Cotton Fabric	No Growth

**TABLE 2: EVALUATION OF QUANTITATION CONTROL CARRIER DATA
(TIME ZERO)**

Test Organism	Carrier type	CFU/carrier	Log ₁₀
<i>Clostridium difficile</i> (ATCC 700792)	Stainless Steel	1.2 x 10 ⁵	5.08
	Cotton Fabric	1.1 x 10 ⁴	4.04

CFU = Colony Forming Unit

**TABLE 3: EVALUATION OF QUANTITATION CONTROL CARRIER DATA
 (FOLLOWING EXPOSURE)**

Test Organism	Exposure Time	Carrier type	Average CFU/carrier	Average Log ₁₀
<i>Clostridium difficile</i> (ATCC 700792)	48 hours	Stainless Steel	5 x 10 ⁴	4.0
		Cotton Fabric	2 x 10 ³	3.2
	72 hours	Stainless Steel	< 2 x 10 ²	<2.3
		Cotton Fabric	2 x 10 ³	3.2
	96 hours	Stainless Steel	8 x 10 ²	2.9
		Cotton Fabric	1 x 10 ³	3.1

CFU = Colony Forming Unit

TABLE 4: EVALUATION OF TEST CARRIER DATA

Test Substance	Test Organism	Exposure Time	Carrier type	Average CFU/carrier	Average Log ₁₀
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Clostridium difficile</i> (ATCC 700792)	48 hours	Stainless Steel	< 2 x 10 ²	<2.3
			Cotton Fabric	< 2 x 10 ²	<2.3
		72 hours	Stainless Steel	< 2 x 10 ²	<2.3
			Cotton Fabric	< 2 x 10 ²	<2.3
		96 hours	Stainless Steel	< 2 x 10 ²	<2.3
			Cotton Fabric	< 2 x 10 ²	<2.3

CFU = Colony Forming Unit

TABLE 5: RELATIVE ORGANISM REDUCTION AS COMPARED TO SIDE BY SIDE QUANTITATION CONTROL CARRIERS

Test Substance	Test Organism	Exposure Time	Carrier type	Percent Reduction	Log ₁₀ Reduction
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Clostridium difficile</i> (ATCC 700792)	48 hours	Stainless Steel	>99.6%	>1.7
			Cotton Fabric	>90.0%	>0.9
		72 hours	Stainless Steel	No relative reduction	No relative reduction
			Cotton Fabric	>90.0%	>0.9
		96 hours	Stainless Steel	>75.0%	>0.6
			Cotton Fabric	>80.0%	>0.8

TABLE 6: OVERALL ORGANISM REDUCTION AS COMPARED TO TIME ZERO QUANTITATION CONTROL CARRIERS

Test Substance	Test Organism	Exposure Time	Carrier type	Percent Reduction	Log ₁₀ Reduction
Odorox Mobile Disinfection Unit Hydroxyl Generator	<i>Clostridium difficile</i> (ATCC 700792)	48 hours	Stainless Steel	>99.8%	>2.8
			Cotton Fabric	>98.2%	>1.7
		72 hours	Stainless Steel	>99.8%	>2.8
			Cotton Fabric	>98.2%	>1.7
		96 hours	Stainless Steel	>99.8%	>2.8
			Cotton Fabric	>98.2%	>1.7

ANALYSIS

Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.6% (>1.7 log₁₀) relative reduction on stainless steel and greater than a 90.0% (>0.9 log₁₀) relative reduction on cotton fabric for *Clostridium difficile* (ATCC 700792) following a 48 hour exposure period, no relative reduction on stainless steel and greater than a 90.0% (>0.9 log₁₀) relative reduction on cotton fabric for *Clostridium difficile* (ATCC 700792) following a 72 hour exposure period, and greater than a 75.0% (>0.6 log₁₀) relative reduction on stainless steel and greater than an 80.0% (>0.8 log₁₀) relative reduction on cotton fabric for *Clostridium difficile* (ATCC 700792) following a 96 hour exposure period, as compared to side by side quantitation control carriers, when tested at room temperature (26.55-29.83°C).


Odorox Mobile Disinfection Unit Hydroxyl Generator, demonstrated greater than a 99.8% (>2.8 log₁₀) overall reduction on stainless steel and greater than a 98.2% (>1.7 log₁₀) overall reduction on cotton fabric for *Clostridium difficile* (ATCC 700792) following 48 hour, 72 hour and 96 hour exposure periods as compared to the time zero quantitation control carriers, when tested at room temperature (26.55-29.83°C).

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

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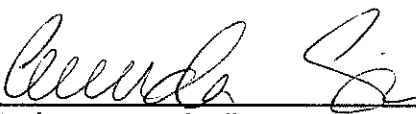


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4-14-09

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4/14/09

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