A Contract Testing Laboratory

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Cleaning Efficiency of The MicronSolo[™] Wipe Cleaning System

Sponsor: Vileda Professional

Study Director: Leo Gubenko, Global Technical Manager

Product Description: MicronSoloTM Wipe

PDA GLP Testing

Protocol: PDAP-210-02, 2017-08-21-01-R5 (PDA Labs. – Quote)

Date Received: 10/03/2017

Date On: 12/21/2017 Date Off: 02/05/2018

Testing Facility: **PDA Laboratories, Inc.**

Study Director: Artur Lewandowski, MS` Quality Assurance: Silmarie Guzman.

Product Information:

- 1. New bulk of 25 wrapped MicronSolo[™] Wipe.
- 2. Two new bottles of PERISEPT 62 Sporicidal Disinfectant Cleaner, Manufactured by SSS Triple S, Navigator Dilution Control System, Product # 48027, Batch Code: 725202 090517 0800.
- 3. One new Disinfectant dispenser (grey dispensing gun) manufactured by SSS Triple S.
- 4. One new Vileda Professional 6 liter grey plastic bucket.
- 5. EPA Registration Number: 10324-214-12120.

INTRODUCTION:

Various wiper systems and disinfectant chemistries have emerged over the last several years to combat Healthcare Associated Infections (HAI's). Historically, frequently used disinfectants have been one of the two following types: bleach or quaternary ammonium compounds (Quats). In the recent years, new, innovative disinfectants comprised of hydrogen peroxide and peracetic acid have emerged. Hydrogen peroxide and peracetic acid based disinfectants have broader kill claims that include Norovirus and c Diff and require a shorter surface contact time on surfaces, some as low as 2 minutes. It's important to note that not all single use wipers and mops are compatible with Hydrogen peroxide and peracetic acid based products. In this study, the compatibility MicronSolo™ Wipe will be evaluated when used in conjunction with SSS Perisept Sporicidal Disinfectant Cleaner #62.

PURPOSE:

To determine the cleaning effectiveness of the MicronSolo[™] Wipe when used in conjunction with SSS Perisept Sporicidal Disinfectant Cleaner #62. This study will validate the compatibility of MicronSolo[™] Wipe when saturated with Perisept Sporicidal Disinfectant Cleaner #62. SSS Perisept Sporicidal Disinfectant Cleaner #62 is effective in combating 45 different pathogens including c. Diff, VRE, and MRSA. By comparing the log reductions achieved over the course of a 24 hour period, results will support the compatibility of the single use item and disinfectant as a viable system for HAI control and reduction on hard non-porous surfaces typical in the healthcare arena.

EQUIPMENT AND MEDIA

Incubator (30 to 35C) PDA #	A004					
Laminar Flow Hood PDA #	A030					
Bio-Safety Cabinet PDA #	A028					
Sterile Trypticase Soy broth Broth (T	TSB) Lot # <u>M002938 Exp. 04/08/2018</u>					
Sterile Trypticase Soy Agar (TSA) I	Lot # M002953 Exp. 02/06/2018					
Saline 0.85% 9 Normal lot #	M002962 Exp. 10/27/2018					
RODAC Plates – TSA w/Lec. + P80 <u>M002961 Exp. 04/26/2018</u>						
Timer PDA # S/N130648924	1					
BD Culture Swabs Lot # 171673	Exp. 10/31/2022					
Reagent Water						

Vortex, Sterile Petri Dishes, Sterile Glass Containers, Sterile Spray Bottles.

Armstrong Commercial Vinyl Floor Tiles

Everbilt Stainless Steel 304 Metal Sheet.

PROCEDURE

- 1. Preparation of Organisms and Testing Surfaces.
 - 1.1. Preparation of testing surface.

Two types of surfaces will be prepared for the test for $MicronSolo^{TM}$ Wipe: Stainless Steel and PVC Surface.

The surface will be sterilized using Spor-Klenz[®] disinfectant. The surface was sterilized using 3 applications of Spor-Klenz[®] prepared as per manufacturer label recommendation for sterilization purposes (1 part of Spor-Klenz[®] into 99 parts of Reagent Water). After disinfectant application, surface was left for 10 minutes and the following two additional applications were performed. The final cleaning was performed using sterile reagent water.

1.2 Preparation of Testing Organism.

Clostridium difficile (received from Microbiologics) – forty (40) TSA plates were inoculated with *Clostridium difficile* and incubated anaerobically at 30-35C for up to 7 days.

Spore suspension. After incubation, using twenty (20) inoculated TSA plates the suspension was prepared and heat shock was performed to eliminate the vegetative cultures. The suspension was tested using standard operation procedure for population verification. The final concentration 10E8/1ml was achieved. (See table #1)_

1.3 The Inoculum Preparation of Microorganisms.

Clostridium difficile spore form - 10 ml of 10E8 suspension was diluted 10 times using sterile Saline to achieve final concentration of 10E6- 10E7/1 ml. (see Table #2)

TABLE #1 – Individual *Clostridium difficile* Suspensions, Initial Concentration

		Final Concentration		
Organism	ID#	Plate 1 (10E-7)	Plate 2(10E-7)	Cfu/ml
Clostridium difficile	ATCC 9689	52	44	4.8×10^8
(spore form)				
Analyst/Date	01/05/2018 AL			

TABLE #2 – Individual Organisms Suspensions, Final Concentration used to inoculate surfaces.

Organism	ID#	Final Concentration				
		Plate 1 (10E-6)	Plate 2(10E-6)	Cfu/ml		
Clostridium difficile (spore form)	ATCC 9689	45	39	4.2 x 10 ⁷		
Analyst/Date	e	01/05/2018 AL				

- 2. Contamination of the Testing Surfaces using freshly prepared microorganisms suspensions.
 - 2.1 Floor PVC floor. The contamination of the floor was accomplished by spraying the surface individually and separately with prepared microorganism suspension until the floor surface was visually wet. After inoculation step, the surface was left for drying. The right, top area of the surface was used for positive control. The left, top area was not inoculated and was used as a negative control.
 - 2.2 Stainless steel. Contamination of stainless steel surface was accomplished by spraying the surface individually and separately with prepared microorganism suspension until stainless surface was visually wet. After inoculation step, the stainless steel surface was left for drying. The right, top area of the stainless steel surface was used for positive control. The left, top area was not inoculated and was used as a negative control.

3. Manual cleaning

Preparation of the cleaning solution: the plastic dispenser was placed on the disinfectant bottle and attached to the water source. The dispenser controlled the dilution factor between the water source and disinfectant. The bucket was filled with disinfectant solution and used to moist separately the bulk wipes (500ml solution was used to moist 25 wipes) The wipes were allowed to saturate in solution for 24 hour and tested.

For each surface, manual cleaning by applying hand force was performed. By gentle pressing the moist wipe on the stainless steel surface and PVC Surface separately and individually, the cleaning process was performed for contaminated areas.

- 4. Organism Recovery from the test samples (Quantitated and Qualitated).
 - 4.1 Surface Type Stainless Steel (cleaning with MicronSolo [™] Wipe).

After initial inoculation of the stainless steel surface with microorganism, individually and separately, manual cleaning, using the MicronSoloTM Wipe saturated with disinfectant for 24 hour was performed per operating procedure. The cleaning efficacy of the MicronSoloTM Wipe saturated in disinfectant was determined by using quantitated and qualitated test methods and the extraction of the microorganisms from the wipe using sterile water for injections and plating method. The testing results are presented in the tables below.

Quantitated Method – by using swabs, testing area approximately 25 sq.cm/swab (each swab will be taken from the area of 5cm x 5cm using vertical and horizontal swabbing directions)

Qualitated Method – by using Rodac[™] plates, testing area approximately 25 sq.cm/plate.

Date: 01/30/2016 Technician: AL

TABLE #3. $MicronSolo^{TM}$ Wipe - Dwell time 24 hour.

Clostridium difficile (spore form) and Stainless Steel surface.

Sample	Quantitated Testing	Qualitated Testing Method					
	10E-5 (A)	Average cfu/ml	Log	Wipe	Cfu/plate	Purity	Gram
	10E-0 (B)	/NC		Extraction		Test	Stain
	Plate Count cfu/ml			Cfu/ml			
1	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
2	B < 1, < 1	< 1 +	N/A	<1	< 1	N/A	N/A
3	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
4	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
5	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
6	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
+C	A 175, 163	1.7×10^7	7.23		> 200	Pure	GPB
+C	A 182, 206	1.9×10^7	7.28	N/A	> 200	Pure	GPB
-C	B < 1, < 1	N/A	N/A		< 1	N/A	N/A

Table Terminology

CFU = Colonies Forming Unit

+C = Positive Control -C = Negative Control

NC = Neutralization Challenge, performed on all negative count plates to exclude any inhibitory activities of the microbial growth. Each plate was challenge with <100 cfu of tested group of microorganisms.

+ = Positive results for NC

N/A = Not Applicable

GPB = Gram Positive Bacillus

4.2 Surface Type – PVC surface (cleaning with MicronSolo[™] Wipe).

After initial inoculation of the PVC surface with microorganism, individually and separately, manual cleaning, using the MicronSoloTM Wipe saturated with disinfectant for 24 was performed per operating procedure. The cleaning efficacy of the MicronSoloTM Wipe saturated in disinfectant was determined by using quantitated and qualitated test methods and the extraction of the microorganisms from the wipe using sterile water for injections and plating method. The testing results are presented in the tables below.

Quantitated Method – by using swabs, testing area approximately 25 sq.cm/swab (each swab will be taken from the area of 5cm x 5cm using vertical and horizontal swabbing directions)

Qualitated Method – by using Rodac[™] plates, testing area approximately 25 sq.cm/plate.

Date: 01/30/2016 Technician: AL

TABLE #4. $MicronSolo^{TM}$ Wipe - Dwell time 24 hour.

Clostridium difficile (spore form) and PVC surface.

Sample	Quantitated Testing	Method	Qualitated Testing Method				
	10E-5 (A)	Average cfu/ml	Log	Wipe	Cfu/plate	Purity	Gram
	10E-0 (B)	/NC		Extraction		Test	Stain
	Plate Count cfu/ml			Cfu/ml			
1	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
2	B < 1, < 1	< 1 +	N/A	<1	< 1	N/A	N/A
3	B < 1, < 1	< 1 +	N/A	<1	< 1	N/A	N/A
4	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
5	B < 1, < 1	< 1 +	N/A	<1	< 1	N/A	N/A
6	B < 1, < 1	<1 +	N/A	<1	< 1	N/A	N/A
+C	A 193, 178	1.9×10^7	7.28		> 200	Pure	GPB
+C	A 162, 121	1.4×10^7	7.15	N/A	> 200	Pure	GPB
-C	B < 1, < 1	N/A	N/A		< 1	N/A	N/A

Table Terminology

CFU = Colonies Forming Unit

+C = Positive Control -C = Negative Control

NC = Neutralization Challenge, performed on all negative count plates to exclude any inhibitory activities of the microbial growth. Each plate was challenge with <100 cfu of tested group of microorganisms.

+ = Positive results for NC

N/A = Not Applicable

GPB = Gram Positive Bacillus

STUDY SUMMARY

TABLE #5 Summary Table MicronSolo™ Wipe On Stainless Steel surface. Dwell time 24 hour

Microorganism Group	Dwell Time	Inoculum	MicronSolo [™] Wipe		MicroSolo [™] Wipe – Extraction Results
			Survivors	Log Reduction (% Reduction)	Extraction from Wipe
Clostridium difficile Spore form	24 hour	Log = 7.23 Log = 7.28	<10cfu/swab <1cfu/ Rodac [™] plate	>6 (>99.9999%)	<1cfu/ml

TABLE #6 Summary Table MicronSolo™ Wipe On PVC surface. Dwell time 24hour

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	Microorganism			MicronSolo TM	Wipe	MicronSolo [™] Wipe –	
	Group	Dwell	Inoculum			Extraction Results	
		Time					
				Survivors	Log Reduction	Extraction from Wipe	
					(% Reduction)		
	Clostridium		1 7.30	<10cfu/swab			
	difficile	24 hour	Log = 7.28 $Log = 7.15$	<1cfu/ Rodac [™]	>6 (>99.9999%)	<1cfu/ml	
	Spore form		Log = 7.13	plate			

As per Summary Table #5, the microbiological cleaning performance after dwell time of 24 hour in disinfectant of the MicronSoloTM Wipe on the stainless Steel surface and microbial contaminant is clearly demonstrated. The system of the MicronSoloTM Wipe and PERISEPT 62 Sporicidal Disinfectant Cleaner demonstrate >99.9999% kill and removal of microbial contamination from the tested surface. There is no viable microbial present on the MicronSoloTM Wipe after extraction process.

As per Summary Table #6, the microbiological cleaning performance after dwell time of 24 hour in disinfectant of the MicronSolo[™] Wipe on the PVC surface and microbial contaminant is clearly demonstrated. The system of the MicronSolo[™] Wipe and PERISEPT 62 Sporicidal Disinfectant Cleaner demonstrate >99.999% kill and removal of microbial contamination from the tested surface. There is no viable microbial present on the MicronSolo[™] Wipe after extraction process.

FINAL CONCLUSION

The Micron Solo[™] Wipe saturated in SSS Perisept Sporicidal Disinfectant Cleaner #62 was tested at 24 hour interval for efficacy against *Clostridium difficile* (spore form) on Stainless Steel and PVC surfaces with effectiveness of >99.9999% (>6 log) reduction when compared to initial contamination levels. Based on this finding, it shows that no degradation occurred with regard to the single use Micron Solo[™] Wipe or the SSS Perisept Sporcidial Disinfectant Cleaner #62's efficacy or ability to achieve the same or better log reduction associated with the EPA master label for Perisept which has a 2 minute c. Diff claim at 99.9999% (>6 log).

Therefore, the MicronSolo[™] Wipe saturated with SSS Perisept Sporicidal Disinfectant, once combined, have a shelf life of 24 hours and are validated to effectively kill and remove *Clostridium difficile* from stainless steel and vinyl surfaces.