

FOR THE MEDICAL INDUSTRY WORLDWIDE

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REPORT TO: Mr. Habib ElSabbagh

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TEST ARTICLE: Sunjoy Panel

P.O. NO.: Credit Card

DATE RECEIVED/INITIATED/COMPLETED: 07-09-2014/07-14-2014/08-08-2014

TEST PROCEDURE: Evaluation of Anti-Microbial Efficacy of "Sunjoy

Panel" far Infrared (IR) Heat Panel, over a

Standard Exposure Period

DESCRIPTION OF THE TEST:

The aim of this test was to determine the efficacy of the "Sunjoy" infra-red heat panel to kill bacterial and fungal cultures exposed for 1 hour from a distance of 10 cm.

CONSIDERATIONS FOR IR PANEL SETUP:

The reflective area of the heat panel that was provided measured approximately 34×21 inches. The panel was set up horizontally on a flat surface and marked into twelve (12) zones, each measuring approximately 4×4 sq. in. The panel was turned on and the temperature in each zone was monitored every 15 minutes for 150 minutes using thermocouples connected to a digital thermometer. An area around the center of the panel showed a median temperature of $58\,^{\circ}\text{C}$ ($\pm 3\,^{\circ}\text{C}$). This area was marked to expose the test cultures during the testing (Figure 1).

Zone	Zone	Zone	Zone
1	2	3	4
Zone	Zone (Zone	Zone
5		7	8
Zone	Zone	Zone	Zone
9	10	11	12

Figure 1: Temperature zones on the panel. The area selected for exposing the test cultures is shown as a shaded box.

INOCULATION SURFACE:

Sterile microscopic glass slides were used to simulate a test surface.

TEST CULTURES:

Seven (7) bacteria and one (1) mold listed below, were specified by the customer to be used as test organisms. The specific clones of each test culture were selected by the test site.

- 1) Escherichia coli (bacteria, ATCC 8739)
- 2) Staphylococcus aureus (bacteria, ATCC 6538)
- 3) Pseudonomas aeruginosa (bacteria, ATCC 9027)
- 4) Acinetobacter spp (bacteria, ATCC 10153)
- 5) Stenotrophomonas maltophilia (bacteria, ATCC 13737)
- 6) Serratia marcescens (bacteria, ATCC 14756)
- 7) Clostridium difficile (bacteria, ATCC 9689)
- 8) Aspergillus brasiliensis (mold, ATCC 16404)

PROCEDURE:

The surface of the panel and the test area were sterilized with Lysol disinfectant and 70% alcohol prior to the initiation of the testing. A thermocouple was taped within the test surface zone to monitor the temperature during the testing (Table 1). The panel was placed in a chamber that was kept covered to minimize the air flow during the test period. The panel was turned on and allowed to equilibrate for at least 60 minutes prior to the initiation of testing.

Duplicate slides were inoculated with approximately 5 x 10^6 colony forming units (CFU's) for each test organism in a 50 μ L aliquot. The cultures were spread evenly over the slide with a sterile inoculation loop and allowed to dry for about 20-30 minutes. One slide was placed in a sterile 100 mm petri dish and kept covered for 1 hour (control). One slide was placed under the panel using sterile forceps and exposed for 1 hour. A maximum of 4 slides were exposed at any given time.

At the end of the exposure period, the slides were removed with sterile forceps and placed in a sterile, 100 mm petri dish. 10 mL of sterile NaCl peptone was added to each slide and the cultures scraped off into the media using a sterile, cotton tipped applicator. The cultures were transferred to a sterile glass tube. The tip of the applicator was broken off and added to the same glass tube.

The tubes were pulse vortexed for 10-20 seconds and serial dilutions prepared in NaCl peptone (for *E. coli, S. aureus, S. marcescens and Acinetobacter,* 10^{-4} and 10^{-5} dilutions were prepared. For *S. maltophilia, P. aeruginosa, C. difficile* and *A. brasiliensis,* 10^{-3} and 10^{-4} dilutions were prepared). From each dilution 0.1 was plated in duplicate plates. Plates were incubated till colonies were visible. Plate counts in duplicates were averaged to obtain the Total Plate Count.

The total count for each test culture was converted to \log_{10} value. The % reduction in Total Plate Counts and \log_{10} reduction in test slides, compared to control were calculated (Table 2). When the plate count was 0, the total plate count is shown as less than the lowest dilution plated.

For media sterility control, 0.1 mL of NaCl peptone was directly spread on the agar plates. For slide sterility control, 10 mL of NaCl peptone was added to an uninoculated, sterile slide in a petri dish. The slide was scrubbed with a sterile cotton tipped applicator. 0.1 mL from this stock was spread on the agar plate without any further dilution and incubated.

RESULTS:

Table 1: A representative example of temperature measured in the exposure zone over 60 minutes.

Time	0 Min.	15 Min.	30 Min.	45 Min.	60 Min.	Average	SD
Temperature	71.3	72.9	73.3	74.2	73.9	73.12	1.01

Table 2: Effect of exposure of the indicated microbial cultures to the heat panel for 60 minutes.

	E. coli (control)	E. coli (post exposure)		
Total Plate Count	1.04 x 10 ⁷	2.5 x 10 ⁴		
% Reduction, Total Count		97.6%		
Log ₁₀ of Total Count	7.010	2.350		
Log ₁₀ Reduction		4.670		
	S. aureus (control)	S. aureus (post exposure)		
Total Plate Count	1.58 x 10 ⁷	4 x 10 ⁵		
% Reduction, Total Count		97.5%		
Log ₁₀ of Total Count	7.200	2.950		
Log ₁₀ Reduction	4.250			
	P. aeruginosa (control)	P. aeruginosa (post exposure)		
Total Plate Count	1.35 x 10 ⁶	<103		
% Reduction, Total Count		99.9%		
Log ₁₀ of Total Count	6.130	0.000		
Log ₁₀ Reduction		6.130		
	S. marcescens (control)	S. marcescens (post exposure)		
Total Plate Count	1.15 x 10 ⁷	5 x 10 ³		
% Reduction, Total Count		99.9%		
Log ₁₀ of Total Count	7.060	0.000		
Log ₁₀ Reduction		6.320		

Table 2: Effect of exposure of the indicated microbial cultures to the heat panel for 60 minutes.

	Acinetobacter (control)	Acinetobacter (post exposure)		
Total Plate Count	2.1 x 10 ⁶	<104		
% Reduction, Total Count		99.9%		
Log ₁₀ of Total Count	6.320	0.000		
Log ₁₀ Reduction		6.320		
	S. maltophilia (control)	S. maltophilia (post exposure)		
Total Plate Count	1.62 x 10 ⁶	<10³		
% Reduction, Total Count		99.9%		
Log ₁₀ of Total Count	6.210	0.000		
Log ₁₀ Reduction		6.210		
	C. difficile (control)	C. difficile (post exposure)		
Total Plate Count	3.8 x 10 ⁵	2.5 x 10 ³		
% Reduction, Total Count		99.3%		
Log ₁₀ of Total Count	5.580	0.000		
Log ₁₀ Reduction		6.210		
	A. brasiliensis (control)	A. brasiliensis (post exposure)		
Total Plate Count	7.8 x 10 ⁵	<103		
% Reduction, Total Count		99.9%		
Log ₁₀ of Total Count	5.889	0.000		
Log ₁₀ Reduction		5.889		
Slide Sterility Control	No Growth			
Media Sterility Control	No Growth			

ANALYST: DATE: 08 18 2014.

ACCEPTED BY: StaumAnush
Technical Reviewer

Q.A. SIGNATURE: Robin L Bugner DATE: 08/26/2014