

**NAMSA**CONFIDENTIAL  
REPORT

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Test Facility  
9 Morgan  
Irvine, CA 92618  
949.951.3110**TEST ARTICLE NAME**"CAT3520-X X-Static" and "control  
CAT3520"**SPONSOR**Jose Portet  
Noble Biomaterials, Inc.  
300 Palm Street  
Scranton, PA 18505**TEST ARTICLE IDENTIFICATION**

Not Supplied

**TEST ARTICLE RECEIVED**

November 6, 2008

**STUDY TITLE**

Determining Antimicrobial Activity of Immobilized Antimicrobial Agents (ASTM E2149)

**RESULTS**

Sample Identification	Organism Count (CFU/ml)		Percent Reduction
	Zero Time	8 Hour	
CAT 3520-X X-Static - MRSA	$1.96 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - MRSA	$1.92 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - MRSA	$1.94 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Control CAT 3520 - MRSA	$1.73 \times 10^5$	$1.35 \times 10^5$	21.97
Replicate - MRSA	$1.93 \times 10^5$	$1.49 \times 10^5$	22.80
Replicate - MRSA	$1.75 \times 10^5$	$1.33 \times 10^5$	24.00
NAMSA Control - MRSA	$1.81 \times 10^5$	$1.93 \times 10^5$	No Reduction
CAT 3520-X X-Static - KP	$1.96 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - KP	$1.86 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - KP	$1.74 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Control CAT 3520 - KP	$1.74 \times 10^5$	$6.60 \times 10^4$	62.07
Replicate - KP	$1.61 \times 10^5$	$7.90 \times 10^4$	50.93
Replicate - KP	$1.60 \times 10^5$	$7.60 \times 10^4$	52.50
NAMSA Control - KP	$1.56 \times 10^5$	$3.40 \times 10^6$	No Reduction
CAT 3520-X X-Static - EC	$1.55 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - EC	$1.74 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - EC	$1.73 \times 10^5$	$< 1.00 \times 10^1$	> 99.99

Sample Identification	Organism Count (CFU/ml)		Percent Reduction
	Zero Time	8 Hour	
Control CAT 3520 - EC	$1.60 \times 10^5$	$6.80 \times 10^4$	57.50
Replicate - EC	$1.59 \times 10^5$	$8.10 \times 10^4$	49.06
Replicate - EC	$1.55 \times 10^5$	$8.90 \times 10^4$	42.58
NAMSA Control - EC	$1.59 \times 10^5$	$6.25 \times 10^6$	No Reduction
CAT 3520-X X-Static - PA	$1.74 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - PA	$1.90 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - PA	$2.03 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Control CAT 3520 - PA	$2.45 \times 10^5$	$1.36 \times 10^5$	44.49
Replicate - PA	$2.55 \times 10^5$	$1.38 \times 10^5$	45.88
Replicate - PA	$1.86 \times 10^5$	$1.25 \times 10^5$	32.80
NAMSA Control - PA	$2.44 \times 10^5$	$4.25 \times 10^6$	No Reduction
CAT 3520-X X-Static - VRE	$1.90 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - VRE	$1.75 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Replicate - VRE	$1.77 \times 10^5$	$< 1.00 \times 10^1$	> 99.99
Control CAT 3520 - VRE	$1.89 \times 10^5$	$9.20 \times 10^4$	51.32
Replicate - VRE	$1.98 \times 10^5$	$9.40 \times 10^4$	52.53
Replicate - VRE	$1.76 \times 10^5$	$1.00 \times 10^5$	43.18
NAMSA Control - VRE	$1.85 \times 10^5$	$2.80 \times 10^5$	No Reduction

Reduction, % (CFU/ml) =  $[(B-A)/B] * 100$

Where: A = CFU per ml (or mean  $\log_{10}$  density of bacteria) for the flask containing the treated substrate after the specified contact time.

B = "0" contact time CFU per ml (or mean  $\log_{10}$  density of bacteria) for the flask used to determine "A" before the addition of the treated substrate.



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**TEST INFORMATION**

Sample Size: 0.90 ± 0.01 g

Target Inoculum Level: (1.5 - 3.0) x 10<sup>5</sup> (CFU/mL)

Test Organism(s):

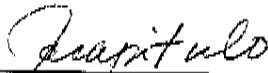
<i>Staphylococcus aureus</i> (MRSA)	ATCC 33591
<i>Klebsiella pneumoniae</i>	ATCC 4352
<i>Escherichia coli</i>	ATCC 8739
<i>Enterococcus faecalis</i> (VRE)	ATCC 51575
<i>Pseudomonas aeruginosa</i>	ATCC 9027

**REFERENCE**

American Society for Testing and Materials (ASTM) E 2149: Standard Test Method for Determining the Antimicrobial Activity of Immobilized Antimicrobial Agents Under Dynamic Contact Conditions (2001).

Results and conclusions apply only to the test article tested. Any extrapolation of these data to other samples is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices and certified to ISO 13485:2003.

**APPROVAL**

  
McInnis T. McKenzie, B.S.  
Manager, Microbiology

11-20-08  
Date

P.O. No.:  
P81303

Lab Number:  
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