

Bioscience, an independent testing house, used the In-Vitro Kinetic Time-Kill Method to evaluate the antimicrobial properties of one test product (0.05% Chlorhexidine Gluconate) when challenged with several different microorganism species. All testing was performed in accordance with Good Laboratory Practices, as specified in the FDA 21 CFR Part 58.



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Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log <sub>10</sub> Reduction	Percent Reduction
<i>Achromobacter xylosoxidans</i> (ATCC# 27061) Report# 1605248-201	5.40 x 10 <sup>8</sup>	1 minute	3.490 x 10 <sup>7</sup>	1.1896	93.5370%
		5 minutes	3.00 x 10 <sup>5</sup>	3.2553	99.9444%
		30 minutes	1.0250 x 10 <sup>3</sup>	5.7217	99.9998%
<i>Acinetobacter baumannii</i> (ATCC# 19606) Report# 130377-201	1.5950 x 10 <sup>9</sup>	1 minute	1.3550 x 10 <sup>7</sup>	2.0709	99.1505%
		5 minutes	3.350 x 10 <sup>5</sup>	3.6778	99.9790%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.2028	99.9999%
<i>Acinetobacter baumannii</i> (BSLI# 092216Asp1) Report# 1705193-201	2.4604 x 10 <sup>7</sup>	1 minute	2.7433 x 10 <sup>6</sup>	0.9658	88.8501%
		5 minutes	1.5817 x 10 <sup>4</sup>	3.1935	99.9357%
		30 minutes	<5.9233 x 10 <sup>3</sup>	5.3079	99.9759%
<i>Acinetobacter baumannii</i> MDR (ATCC# BAA-1605) Report #130377-201	4.250 x 10 <sup>9</sup>	1 minute	1.1950 x 10 <sup>8</sup>	1.5510	97.1882%
		5 minutes	8.50 x 10 <sup>3</sup>	5.6990	99.9998%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.6284	99.9999%
<i>Enterobacter cloacae</i> MDR <sup>1</sup> (ATCC# BAA-2468) Report# 130377-201	3.80 x 10 <sup>9</sup>	1 minute	4.550 x 10 <sup>5</sup>	3.9218	99.9880%
		5 minutes	< 1.00 x 10 <sup>3</sup>	6.5798	99.9999%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.5798	99.9999%
<i>Enterococcus faecalis</i> (BSLI# 092216Efs7) Report# 1708328-201	6.6832 x 10 <sup>7</sup>	1 minute	> 2.9917 x 10 <sup>7</sup>	0.3495	55.2360%
		5 minutes	9.10 x 10 <sup>6</sup>	0.8697	86.3838%
		30 minutes	1.8833 x 10 <sup>4</sup>	3.7130	99.9718%
<i>Enterococcus faecium</i> VRE (BSLI #060613VRE9) Report #1705193-201	3.6139 x 10 <sup>7</sup>	1 minute	3.0350 x 10 <sup>7</sup>	0.0764	16.0187%
		5 minutes	1.9517 x 10 <sup>7</sup>	0.2696	45.9956%
		30 minutes	1.6471 x 10 <sup>5</sup>	3.1650	99.5443%
<i>Enterococcus faecium</i> VSE (BSLI #112613VSEfm10) Report #1705193-201	4.7525 x 10 <sup>7</sup>	1 minute	3.8933 x 10 <sup>7</sup>	0.0870	18.0782%
		5 minutes	1.3201 x 10 <sup>7</sup>	0.9881	72.2234%
		30 minutes	7.3167 x 10 <sup>3</sup>	3.8598	99.9846%
<i>Escherichia coli</i> (ATCC #BAA-2469) <sup>1,2,3,4</sup> Report #1605248-201	2.950 x 10 <sup>7</sup>	1 minute	2.0550 x 10 <sup>4</sup>	3.1570	99.9303%
		5 minutes	2.50 x 10 <sup>2</sup>	5.0719	99.9992%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.4698	99.9999%

\* Reference Sections 14 of Study Protocols for the calculations of reductions from the challenge suspensions

1-New Delhi metallo-beta-lactamase (NDM-1) positive

2-*blaKPC* negative by PCR

3-*blaNDM* positive by PCR

4-Carbapenem-resistant (Imipenem and Ertapenem)

MDR = Multi-Drug Resistant

VRE = Vancomycin Resistant *Enterococcus*

VSE = Vancomycin Susceptible *Enterococcus*

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Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log <sub>10</sub> Reduction	Percent Reduction
<i>Escherichia coli</i> 0157:H7 (ATCC# 43888) Report# 130377-201	2.70 x 10 <sup>9</sup>	1 minute	2.350 x 10 <sup>4</sup>	5.0603	99.9991%
		5 minutes	< 1.00 x 10 <sup>3</sup>	6.4314	99.9999%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.4314	99.9999%
<i>Escherichia coli</i> (BSLI# 083116Ec2) Report# 1705193-201	1.3366 x 10 <sup>7</sup>	1 minute	<9.150 x 10 <sup>2</sup>	5.3142	99.9931%
		5 minutes	<5.8333 x 10 <sup>1</sup>	5.7292	99.9995%
		30 minutes	<9.00 x 10 <sup>1</sup>	5.6600	99.9993%
<i>Klebsiella pneumoniae</i> (BSLI# 030116Kpn2) Report# 1705193-201	1.0891 x 10 <sup>7</sup>	1 minute	1.4667 x 10 <sup>2</sup>	4.9133	99.9987%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.0371	99.9999%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.0371	99.9999%
<i>Klebsiella pneumoniae pneumoniae</i> (ATCC# BAA-2146) <sup>1,2,3,4</sup> Report# 1605248-201	3.60 x 10 <sup>7</sup>	1 minute	1.10 x 10 <sup>2</sup>	5.5149	99.9997%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.5563	99.9999%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.5563	99.9999%
<i>Pseudomonas aeruginosa</i> (BSLI# 083116Pa18) Report# 1708328-201	9.7525 x 10 <sup>6</sup>	1 minute	<1.00 x 10 <sup>1</sup>	5.9891	99.9999%
		5 minutes	<1.00 x 10 <sup>1</sup>	5.9891	99.9999%
		30 minutes	<1.00 x 10 <sup>1</sup>	5.9891	99.9999%
<i>Staphylococcus aureus</i> MRSA <sup>CI</sup> (BSLI# 042511MRSA) Report# 130417-201	1.8850 x 10 <sup>9</sup>	1 minute	1.0250 x 10 <sup>8</sup>	1.2646	94.5623%
		3 minutes	5.80 x 10 <sup>6</sup>	2.5119	99.6923%
		15 minutes	1.1650 x 10 <sup>5</sup>	4.2090	99.9938%
<i>Staphylococcus aureus</i> MRSA <sup>CI</sup> (BSLI# 092211SaMRSA1) Report# 130417-201	2.0050 x 10 <sup>9</sup>	1 minute	5.80 x 10 <sup>8</sup>	0.5387	71.0723%
		3 minutes	6.40 x 10 <sup>7</sup>	1.4959	96.8080%
		15 minutes	3.80 x 10 <sup>4</sup>	4.7223	99.9981%
<i>Staphylococcus epidermidis</i> (BSLI# 080916Se1) Report# 1705193-201	2.2723 x 10 <sup>7</sup>	1 minute	1.5650 x 10 <sup>3</sup>	4.1861	99.9931%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.3565	99.9999%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.3565	99.9999%

\* Reference Sections 14 of Study Protocols for the calculations of reductions from the challenge suspensions

1-New Delhi metallo-beta-lactamase (NDM-1) positive

2-*blaKPC* negative by PCR

3-*blaNDM* positive by PCR

4-Carbapenem-resistant (Imipenem and Ertapenem)

CI- Clinical Isolate

MRSA = Methicillin Resistant *Staphylococcus aureus*

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<b>Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)</b>					
<b>Bacteria</b>	<b>Challenge Suspension* (CFU/ml)</b>	<b>Exposure Time</b>	<b>Post-Exposure Population (CFU/ml)</b>	<b>Log<sub>10</sub> Reduction</b>	<b>Percent Reduction</b>
<i>Staphylococcus epidermidis</i> (BSLI# 092216Se1) Report# 1705193-201	2.0594 x 10 <sup>7</sup>	1 minute	2.6833 x 10 <sup>2</sup>	4.8855	99.9987%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.3137	99.9999%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.3137	99.9999%
<i>Streptococcus pyogenes</i> (BSLI# 092216Spy1) Report# 1705193-201	2.9257 x 10 <sup>6</sup>	1 minute	8.20 x 10 <sup>5</sup>	0.5539	71.9725%
		5 minutes	7.7667 x 10 <sup>3</sup>	2.5936	99.7345%
		30 minutes	3.250 x 10 <sup>2</sup>	4.0327	99.9889%

<b>Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)</b>					
<b>Bacteria</b>	<b>Challenge Suspension* (CFU/ml)</b>	<b>Exposure Time</b>	<b>Mean Post-Numbers Control Population (CFU/ml) N=3</b>	<b>Mean Log<sub>10</sub> Reduction</b>	<b>Mean Percent Reduction</b>
<i>Propionibacterium acnes</i> ** (ATCC# 6919) Report# 140946-201	2.2250 X 10 <sup>9</sup>	1 minute	2.1033 x 10 <sup>7</sup>	1.5488	96.6236%
		3 minutes	2.090 x 10 <sup>7</sup>	2.2543	99.3945%
		30 minutes	2.1417 x 10 <sup>7</sup>	4.2984	99.9944%

\* Reference Sections 14 of Study Protocols for the calculations of reductions from the challenge suspensions

\*\*Testing was based upon ASTM E2783-11, using a numbers control per the method at each time point because of the fastidious nature of *P. acnes*. This avoids the possible attribution of the product efficacy to die-off of the organism due to the length of the exposure time to environmental conditions, allowing for a more accurate and actual assessment of the inoculum level.

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<b>Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)</b>					
<b>Fungi</b>	<b>Challenge Suspension* (CFU/ml)</b>	<b>Exposure Time</b>	<b>Post-Exposure Population (CFU/ml)</b>	<b>Log<sub>10</sub> Reduction</b>	<b>Percent Reduction</b>
<i>Aspergillus niger van Tiegham</i> (ATCC# 6275) Report# 130377-201	2.750 x 10 <sup>9</sup>	10 minutes	3.90 x 10 <sup>8</sup>	0.8482	85.8182%
		30 minutes	4.20 x 10 <sup>8</sup>	0.8161	84.7273%
		60 minutes	3.050 x 10 <sup>8</sup>	0.9550	88.9091%
<i>Candida albicans</i> (ATCC# 10231) Report# 130377-201	4.050 x 10 <sup>9</sup>	1 minute	7.30 x 10 <sup>5</sup>	3.7442	99.9820%
		5 minutes	1.650 x 10 <sup>4</sup>	5.3900	99.9996%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.6075	99.9999%
<i>Candida auris</i> (AR-BANK# 0381) Report# 1605248-201	3.80 x 10 <sup>7</sup>	1 minute	5.80 x 10 <sup>5</sup>	1.8164	98.4737%
		5 minutes	1.560 x 10 <sup>3</sup>	4.3867	99.9959%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.5798	99.9999%
<i>Candida auris</i> (AR-BANK# 0382) Report# 1605248-201	5.10 x 10 <sup>7</sup>	1 minute	3.30 x 10 <sup>6</sup>	1.1891	93.5294%
		5 minutes	1.2050 x 10 <sup>5</sup>	2.6266	99.7637%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.7076	99.9999%
<i>Candida auris</i> (AR-BANK# 0383) Report# 1605248-201	6.30 x 10 <sup>7</sup>	1 minute	1.8350 x 10 <sup>7</sup>	0.5357	70.8730%
		5 minutes	4.250 x 10 <sup>4</sup>	3.1709	99.9325%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.7993	99.9999%
<i>Candida glabrata</i> (ATCC# 2001) Report# 130377-201	1.1550 x 10 <sup>10</sup>	1 minute	4.030 x 10 <sup>9</sup>	0.4573	65.1082%
		5 minutes	6.40 x 10 <sup>7</sup>	2.2564	99.4459%
		30 minutes	< 1.00 x 10 <sup>3</sup>	7.0626	99.9999%

<b>Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)</b>				
<b>Virus</b>	<b>Exposure Time</b>	<b>TCID<sub>50</sub> (Log<sub>10</sub>) Post-Exposure Infectivity</b>	<b>Log<sub>10</sub> Reduction</b>	<b>Percent Reduction</b>
Hepatitis B Virus Surrogate: Duck Hepatitis B Virus (DHBV) Report# 130378-402	1 minute	5.00	1.00	90.00%
	5 minutes	4.75	1.25	94.38%
	30 minutes	4.00	2.00	99.00%
Hepatitis C Virus Surrogate: Bovine Viral Diarrhea Virus (BVDV) Report# 130378-402	1 minute	5.50	0.75	82.22%
	5 minutes	5.00	1.25	94.38%
	30 minutes	4.50	1.75	98.22%
Human Immunodeficiency Virus Type 1 (HIV-1) Report# 130378-402	1 minute	4.25	1.75	98.22%
	5 minutes	3.50	2.50	99.68%
	30 minutes	2.00	4.00	99.99%

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