

Bioscience Labs Inc., an independent testing organization used the In-Vitro Kinetic Time-Kill Method to evaluate the properties of Irrisept solution containing 0.05% Chlorhexidine Gluconate when challenged with several different microorganism species. CHG acts as a preservative to inhibit microbial growth in the solution. All testing was performed in accordance with Good Laboratory Practices, as specified in 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
<b><i>Achromobacter xylosoxidans</i></b> (ATCC# 27061) Report# 1605248-201	5.40 x 10 <sup>8</sup>	1 minute	3.49 x 10 <sup>7</sup>	1.19	93.54%
		5 minutes	3.00 x 10 <sup>5</sup>	3.26	99.94%
		30 minutes	1.03 x 10 <sup>3</sup>	5.72	99.99%
<b><i>Acinetobacter baumannii</i></b> (ATCC# 19606) Report# 130377-201	1.60 x 10 <sup>9</sup>	1 minute	1.36 x 10 <sup>7</sup>	2.07	99.15%
		5 minutes	3.35 x 10 <sup>5</sup>	3.68	99.98%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.20	99.99%
<b><i>Acinetobacter baumannii</i></b> (BSLI# 092216Asp1) Report# 1705193-201	2.46 x 10 <sup>7</sup>	1 minute	2.74 x 10 <sup>6</sup>	0.97	88.85%
		5 minutes	1.58 x 10 <sup>4</sup>	3.19	99.94%
		30 minutes	<5.92 x 10 <sup>3</sup>	5.31	99.98%
<b><i>Acinetobacter baumannii</i> MDR</b> (ATCC# BAA-1605) Report #130377-201	4.25 x 10 <sup>9</sup>	1 minute	1.20 x 10 <sup>8</sup>	1.55	97.19%
		5 minutes	8.50 x 10 <sup>3</sup>	5.70	99.99%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.63	99.99%

Bacteria	Initial Population (CFU/ml)	Exposure Time	Mean Post-Exposure Population (CFU/ml)	Mean Log <sub>10</sub> Reduction	Mean Percent Reduction
<b><i>Bacteroides fragilis</i>**</b> (BSLI #080916Bf1) Report # 1710439-201.01	1.67 x 10 <sup>10</sup>	1 minute	2.43 x 10 <sup>4</sup>	3.31	99.95%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.68	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.68	99.99%
<b><i>Clostridium difficile</i>**</b> Spore suspension (ATCC #43598) Report # 1710439-201.01	2.33 x 10 <sup>9</sup>	1 minute	2.23 x 10 <sup>7</sup>	0.03	6.55%
		5 minutes	2.18 x 10 <sup>7</sup>	0.05	10.04%
		30 minutes	2.06 x 10 <sup>7</sup>	0.07	13.81%
<b><i>Clostridium difficile</i>**</b> Vegetative cells (ATCC #43598) Report # 1710439-201.01	6.05 x 10 <sup>7</sup>	1 minute	7.72 x 10 <sup>5</sup>	0.14	27.88%
		5 minutes	7.83 x 10 <sup>5</sup>	0.14	26.79%
		30 minutes	7.25 x 10 <sup>5</sup>	0.17	32.24%
<b><i>Cutibacterium acnes</i></b> (formerly <i>Propionibacterium acnes</i> ***) (ATCC# 6919) Report# 140946-201	2.23 X 10 <sup>9</sup>	1 minute	2.10 x 10 <sup>7</sup>	1.55	96.62%
		3 minutes	2.09 x 10 <sup>7</sup>	2.25	99.39%
		30 minutes	2.14 x 10 <sup>7</sup>	4.30	99.99%

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

\*\*Testing was based upon recommendations outlined in ASTM E2783-11 (2016).

\*\*\*Testing was based upon recommendations outlined in 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.

MDR = Multi-Drug Resistant.

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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
<b><i>Enterobacter cloacae</i> MDR<sup>1</sup></b> (ATCC# BAA-2468) Report# 130377-201	3.80 x 10 <sup>9</sup>	1 minute	4.55 x 10 <sup>5</sup>	3.92	99.99%
		5 minutes	< 1.00 x 10 <sup>3</sup>	6.58	99.99%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.58	99.99%
<b><i>Enterococcus faecalis</i></b> (BSLI# 092216Efs7) Report# 1708328-201	6.68 x 10 <sup>7</sup>	1 minute	> 2.99 x 10 <sup>7</sup>	0.35	55.24%
		5 minutes	9.10 x 10 <sup>6</sup>	0.87	86.38%
		30 minutes	1.88 x 10 <sup>4</sup>	3.71	99.97%
<b><i>Enterococcus faecium</i> VRE</b> (BSLI #060613VRE9) Report #1705193-201	3.61 x 10 <sup>7</sup>	1 minute	3.04 x 10 <sup>7</sup>	0.08	16.02%
		5 minutes	1.95 x 10 <sup>7</sup>	0.27	46.00%
		30 minutes	1.65 x 10 <sup>5</sup>	3.17	99.54%
<b><i>Enterococcus faecium</i> VSE</b> (BSLI #112613VSEfm10) Report #1705193-201	4.75 x 10 <sup>7</sup>	1 minute	3.89 x 10 <sup>7</sup>	0.09	18.08%
		5 minutes	1.32 x 10 <sup>7</sup>	0.99	72.22%
		30 minutes	7.32 x 10 <sup>3</sup>	3.86	99.98%
<b><i>Escherichia coli</i></b> (ATCC #BAA-2469) <sup>1,2,3,4</sup> Report #1605248-201	2.95 x 10 <sup>7</sup>	1 minute	2.06 x 10 <sup>4</sup>	3.16	99.93%
		5 minutes	2.50 x 10 <sup>2</sup>	5.07	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.47	99.99%
<b><i>Escherichia coli</i> 0157:H7</b> (ATCC# 43888) Report# 130377-201	2.70 x 10 <sup>9</sup>	1 minute	2.35 x 10 <sup>4</sup>	5.06	99.99%
		5 minutes	< 1.00 x 10 <sup>3</sup>	6.43	99.99%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.43	99.99%
<b><i>Escherichia coli</i></b> (BSLI# 083116Ec2) Report# 1705193-201	1.34 x 10 <sup>7</sup>	1 minute	<9.150 x 10 <sup>2</sup>	5.31	99.99%
		5 minutes	<5.83 x 10 <sup>1</sup>	5.73	99.99%
		30 minutes	<9.00 x 10 <sup>1</sup>	5.66	99.99%
<b><i>Klebsiella pneumoniae</i></b> (BSLI# 030116Kpn2) Report# 1705193-201	1.09 x 10 <sup>7</sup>	1 minute	1.47 x 10 <sup>2</sup>	4.91	99.99%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.04	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.04	99.99%
<b><i>Klebsiella pneumoniae pneumoniae</i></b> (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>	5.51	99.99%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.56	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.56	99.99%

\*Reference Sections in 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	Initial Population (CFU/ml)	Exposure Time	Mean Post-Exposure Population (CFU/ml)	Mean Log <sub>10</sub> Reduction	Mean Percent Reduction
<b><i>Prevotella intermedia</i></b> (ATCC# 25611) Report# 1710439-201.01	4.25 x 10 <sup>8</sup>	1 minute	1.00 x 10 <sup>4</sup>	2.51	99.42%
		5 minutes	1.35 x 10 <sup>2</sup>	5.07	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	5.39	99.99%
<b><i>Ralstonia pickettii</i></b> (ATCC# 27512) Report# 1710439-201.01	1.19 x 10 <sup>10</sup>	1 minute	>4.56 x 10 <sup>7</sup>	<0.30	<49.58%
		5 minutes	>4.81 x 10 <sup>7</sup>	<0.28	<46.85%
		30 minutes	>4.32 x 10 <sup>7</sup>	<0.33	<52.23%

Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log <sub>10</sub> Reduction	Percent Reduction
<b><i>Pseudomonas aeruginosa</i></b> (BSLI# 083116Pa18) Report# 1708328-201	9.75 x 10 <sup>6</sup>	1 minute	<1.00 x 10 <sup>1</sup>	5.99	99.99%
		5 minutes	<1.00 x 10 <sup>1</sup>	5.99	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	5.99	99.99%
<b><i>Staphylococcus aureus</i> MRSA<sup>CI</sup></b> (BSLI# 042511MRSA) Report# 130417-201	1.89 x 10 <sup>9</sup>	1 minute	1.03 x 10 <sup>8</sup>	1.26	94.56%
		3 minutes	5.80 x 10 <sup>6</sup>	2.51	99.69%
		15 minutes	1.17 x 10 <sup>5</sup>	4.21	99.99%
<b><i>Staphylococcus aureus</i> MRSA<sup>CI</sup></b> (BSLI# 092211SaMRSA1) Report# 130417-201	2.01 x 10 <sup>9</sup>	1 minute	5.80 x 10 <sup>8</sup>	0.54	71.07%
		3 minutes	6.40 x 10 <sup>7</sup>	1.50	96.81%
		15 minutes	3.80 x 10 <sup>4</sup>	4.72	99.99%
<b><i>Staphylococcus epidermidis</i></b> (BSLI# 080916Se1) Report# 1705193-201	2.27 x 10 <sup>7</sup>	1 minute	1.57 x 10 <sup>3</sup>	4.19	99.99%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.36	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.36	99.99%
<b><i>Staphylococcus epidermidis</i></b> (BSLI# 092216Se1) Report# 1705193-201	2.06 x 10 <sup>7</sup>	1 minute	2.68 x 10 <sup>2</sup>	4.89	99.99%
		5 minutes	<1.00 x 10 <sup>1</sup>	6.31	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.31	99.99%
<b><i>Streptococcus pyogenes</i></b> (BSLI# 092216Spy1) Report# 1705193-201	2.93 x 10 <sup>6</sup>	1 minute	8.20 x 10 <sup>5</sup>	0.55	71.97%
		5 minutes	7.77 x 10 <sup>3</sup>	2.59	99.73%
		30 minutes	3.25 x 10 <sup>2</sup>	4.03	99.99%

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CI- Clinical Isolate

MRSA = Methicillin Resistant *Staphylococcus aureus*

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Fungi	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log <sub>10</sub> Reduction	Percent Reduction
<b><i>Aspergillus niger van Tiegham</i></b> (ATCC# 6275) Report# 130377-201	2.75 x 10 <sup>9</sup>	10 minutes	3.90 x 10 <sup>8</sup>	0.85	85.82%
		30 minutes	4.20 x 10 <sup>8</sup>	0.82	84.73%
		60 minutes	3.05 x 10 <sup>8</sup>	0.96	88.91%
<b><i>Candida albicans</i></b> (ATCC# 10231) Report# 130377-201	4.05 x 10 <sup>9</sup>	1 minute	7.30 x 10 <sup>5</sup>	3.74	99.98%
		5 minutes	1.65 x 10 <sup>4</sup>	5.39	99.99%
		30 minutes	< 1.00 x 10 <sup>3</sup>	6.61	99.99%
<b><i>Candida auris</i></b> (AR-BANK# 0381) Report# 1605248-201	3.80 x 10 <sup>7</sup>	1 minute	5.80 x 10 <sup>5</sup>	1.82	98.47%
		5 minutes	1.56 x 10 <sup>3</sup>	4.39	99.99%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.58	99.99%
<b><i>Candida auris</i></b> (AR-BANK# 0382) Report# 1605248-201	5.10 x 10 <sup>7</sup>	1 minute	3.30 x 10 <sup>6</sup>	1.19	93.53%
		5 minutes	1.21 x 10 <sup>5</sup>	2.63	99.76%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.71	99.99%
<b><i>Candida auris</i></b> (AR-BANK# 0383) Report# 1605248-201	6.30 x 10 <sup>7</sup>	1 minute	1.84 x 10 <sup>7</sup>	0.54	70.87%
		5 minutes	4.25 x 10 <sup>4</sup>	3.17	99.93%
		30 minutes	<1.00 x 10 <sup>1</sup>	6.80	99.99%
<b><i>Candida glabrata</i></b> (ATCC# 2001) Report# 130377-201	1.16 x 10 <sup>10</sup>	1 minute	4.03 x 10 <sup>9</sup>	0.46	65.11%
		5 minutes	6.40 x 10 <sup>7</sup>	2.26	99.45%
		30 minutes	< 1.00 x 10 <sup>3</sup>	7.06	99.99%

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)				
Virus	Exposure Time	TCID <sub>50</sub> (Log <sub>10</sub> ) Post-Exposure Infectivity	Log <sub>10</sub> Reduction	Percent Reduction
<b>Hepatitis B Virus Surrogate:</b> 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%
<b>Hepatitis C Virus Surrogate:</b> 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%
<b>Human Immunodeficiency Virus Type 1 (HIV-1)</b> 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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