

Bioscience Labs Inc., (now part of Nelson Labs) 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.



BIO SCIENCE
LABORATORIES, INC.

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log ₁₀ Reduction	Percent Reduction
<i>Achromobacter xylosoxidans</i> (ATCC# 27061) Report# 1605248-201	5.40 x 10 ⁸	1 minute	3.49 x 10 ⁷	1.19	93.54%
		5 minutes	3.00 x 10 ⁵	3.26	99.94%
		30 minutes	1.03 x 10 ³	5.72	99.99%
<i>Acinetobacter baumannii</i> (ATCC# 19606) Report# 130377-201	1.60 x 10 ⁹	1 minute	1.36 x 10 ⁷	2.07	99.15%
		5 minutes	3.35 x 10 ⁵	3.68	99.98%
		30 minutes	< 1.00 x 10 ³	6.20	99.99%
<i>Acinetobacter baumannii</i> (BSLI# 092216Asp1) Report# 1705193-201	2.46 x 10 ⁷	1 minute	2.74 x 10 ⁶	0.97	88.85%
		5 minutes	1.58 x 10 ⁴	3.19	99.94%
		30 minutes	<5.92 x 10 ³	5.31	99.98%
<i>Acinetobacter baumannii</i> MDR (ATCC# BAA-1605) Report #130377-201	4.25 x 10 ⁹	1 minute	1.20 x 10 ⁸	1.55	97.19%
		5 minutes	8.50 x 10 ³	5.70	99.99%
		30 minutes	< 1.00 x 10 ³	6.63	99.99%

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

Bioscience Labs Inc., (now part of Nelson Labs) 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.



BIO SCIENCE
LABORATORIES, INC.

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log ₁₀ Reduction	Percent Reduction
<i>Enterobacter cloacae</i> MDR¹ (ATCC# BAA-2468) Report# 130377-201	3.80 x 10 ⁹	1 minute	4.55 x 10 ⁵	3.92	99.99%
		5 minutes	< 1.00 x 10 ³	6.58	99.99%
		30 minutes	< 1.00 x 10 ³	6.58	99.99%
<i>Enterococcus faecalis</i> (BSLI# 092216Efs7) Report# 1708328-201	6.68 x 10 ⁷	1 minute	> 2.99 x 10 ⁷	0.35	55.24%
		5 minutes	9.10 x 10 ⁶	0.87	86.38%
		30 minutes	1.88 x 10 ⁴	3.71	99.97%
<i>Enterococcus faecium</i> VRE (BSLI #060613VRE9) Report #1705193-201	3.61 x 10 ⁷	1 minute	3.04 x 10 ⁷	0.08	16.02%
		5 minutes	1.95 x 10 ⁷	0.27	46.00%
		30 minutes	1.65 x 10 ⁵	3.17	99.54%
<i>Enterococcus faecium</i> VSE (BSLI #112613VSEfm10) Report #1705193-201	4.75 x 10 ⁷	1 minute	3.89 x 10 ⁷	0.09	18.08%
		5 minutes	1.32 x 10 ⁷	0.99	72.22%
		30 minutes	7.32 x 10 ³	3.86	99.98%
<i>Escherichia coli</i> (ATCC #BAA-2469) ^{1,2,3,4} Report #1605248-201	2.95 x 10 ⁷	1 minute	2.06 x 10 ⁴	3.16	99.93%
		5 minutes	2.50 x 10 ²	5.07	99.99%
		30 minutes	<1.00 x 10 ¹	6.47	99.99%
<i>Escherichia coli</i> 0157:H7 (ATCC# 43888) Report# 130377-201	2.70 x 10 ⁹	1 minute	2.35 x 10 ⁴	5.06	99.99%
		5 minutes	< 1.00 x 10 ³	6.43	99.99%
		30 minutes	< 1.00 x 10 ³	6.43	99.99%
<i>Escherichia coli</i> (BSLI# 083116Ec2) Report# 1705193-201	1.34 x 10 ⁷	1 minute	<9.150 x 10 ²	5.31	99.99%
		5 minutes	<5.83 x 10 ¹	5.73	99.99%
		30 minutes	<9.00 x 10 ¹	5.66	99.99%
<i>Klebsiella pneumoniae</i> (BSLI# 030116Kpn2) Report# 1705193-201	1.09 x 10 ⁷	1 minute	1.47 x 10 ²	4.91	99.99%
		5 minutes	<1.00 x 10 ¹	6.04	99.99%
		30 minutes	<1.00 x 10 ¹	6.04	99.99%
<i>Klebsiella pneumoniae pneumoniae</i> (ATCC# BAA-2146) ^{1,2,3,4} Report# 1605248-201	3.60 x 10 ⁷	1 minute	1.10 x 10 ²	5.51	99.99%
		5 minutes	<1.00 x 10 ¹	6.56	99.99%
		30 minutes	<1.00 x 10 ¹	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*

Bioscience Labs Inc., (now part of Nelson Labs) 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.



BIO SCIENCE
LABORATORIES, INC.

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Bacteria	Initial Population (CFU/ml)	Exposure Time	Mean Post-Exposure Population (CFU/ml)	Mean Log ₁₀ Reduction	Mean Percent Reduction
<i>Haemophilus influenzae</i> (ATCC #19418) Report# 2204217-201	3.00 x 10 ⁸	1 minute	<1.00 x 10 ²	4.45	99.99%
		5 minutes	<1.00 x 10 ²	4.45	99.99%
		10 minutes	<1.00 x 10 ²	4.45	99.99%
		15 minutes	<1.00 x 10 ²	4.45	99.99%
<i>Lactobacillus iners</i> (ATCC #55195) formerly known as <i>Gardnerella vaginalis</i> Report # 2204217-201	1.40 x 10 ⁷	1 minute	4.40 x 10 ³	1.53	97.03%
		5 minutes	1.35 x 10 ³	2.05	99.09%
		10 minutes	0.87 x 10 ³	2.25	99.41%
		15 minutes	2.83 x 10 ²	2.72	99.81%
<i>Moraxella catarrhalis</i> (ATCC #25240) Report# 2204217-201	3.95 x 10 ⁸	1 minute	2.18 x 10 ²	4.24	99.99%
		5 minutes	<1.00 x 10 ¹	5.57	99.99%
		10 minutes	<1.00 x 10 ¹	5.57	99.99%
		15 minutes	<1.00 x 10 ¹	5.57	99.99%
<i>Prevotella intermedia</i> (ATCC #25611) Report# 1710439-201.01	4.25 x 10 ⁸	1 minute	1.00 x 10 ⁴	2.51	99.42%
		5 minutes	1.35 x 10 ²	5.07	99.99%
		30 minutes	<1.00 x 10 ¹	5.39	99.99%
<i>Ralstonia pickettii</i> (ATCC #27512) Report# 1710439-201.01	1.19 x 10 ¹⁰	1 minute	>4.56 x 10 ⁷	<0.30	<49.58%
		5 minutes	>4.81 x 10 ⁷	<0.28	<46.85%
		30 minutes	>4.32 x 10 ⁷	<0.33	<52.23%
<i>Serratia marcescens</i> (ATCC #14756) Report# 2204217-201	3.75 x 10 ⁸	1 minute	7.13 x 10 ²	3.48	99.97%
		5 minutes	<1.16 x 10 ¹	5.26	99.99%
		10 minutes	<1.00 x 10 ¹	5.32	99.99%
		15 minutes	<1.00 x 10 ¹	5.32	99.99%
<i>Staphylococcus epidermidis</i> (ATCC #12228) <i>Coagulase-negative Staphylococcus</i> Report# 2204217-201	4.25 x 10 ⁸	1 minute	2.32 x 10 ²	4.28	99.99%
		5 minutes	<1.00 x 10 ¹	5.64	99.99%
		10 minutes	<1.00 x 10 ¹	5.64	99.99%
		15 minutes	<1.00 x 10 ¹	5.64	99.99%
<i>Streptococcus pneumoniae</i> (ATCC #49619) Report# 2204217-201	5.05 x 10 ⁷	1 minute	1.89 x 10 ⁵	0.34	53.34%
		5 minutes	1.62 x 10 ⁴	1.42	96.01%
		10 minutes	0.65 x 10 ³	2.96	99.84%
		15 minutes	<1.00 x 10 ²	3.61	99.98%

Bioscience Labs Inc., (now part of Nelson Labs) 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.



BIOSCIENCE
LABORATORIES, INC.

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Bacteria	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log ₁₀ Reduction	Percent Reduction
<i>Pseudomonas aeruginosa</i> (BSLI# 083116Pa18) Report# 1708328-201	9.75 x 10 ⁶	1 minute	<1.00 x 10 ¹	5.99	99.99%
		5 minutes	<1.00 x 10 ¹	5.99	99.99%
		30 minutes	<1.00 x 10 ¹	5.99	99.99%
<i>Staphylococcus aureus</i> MRSA^{CI} (BSLI# 042511MRSA) Report# 130417-201	1.89 x 10 ⁹	1 minute	1.03 x 10 ⁸	1.26	94.56%
		3 minutes	5.80 x 10 ⁶	2.51	99.69%
		15 minutes	1.17 x 10 ⁵	4.21	99.99%
<i>Staphylococcus aureus</i> MRSA^{CI} (BSLI# 092211SaMRSA1) Report# 130417-201	2.01 x 10 ⁹	1 minute	5.80 x 10 ⁸	0.54	71.07%
		3 minutes	6.40 x 10 ⁷	1.50	96.81%
		15 minutes	3.80 x 10 ⁴	4.72	99.99%
<i>Staphylococcus epidermidis</i> (BSLI# 080916Se1) Report# 1705193-201	2.27 x 10 ⁷	1 minute	1.57 x 10 ³	4.19	99.99%
		5 minutes	<1.00 x 10 ¹	6.36	99.99%
		30 minutes	<1.00 x 10 ¹	6.36	99.99%
<i>Staphylococcus epidermidis</i> (BSLI# 092216Se1) Report# 1705193-201	2.06 x 10 ⁷	1 minute	2.68 x 10 ²	4.89	99.99%
		5 minutes	<1.00 x 10 ¹	6.31	99.99%
		30 minutes	<1.00 x 10 ¹	6.31	99.99%
<i>Streptococcus pyogenes</i> (BSLI# 092216Spy1) Report# 1705193-201	2.93 x 10 ⁶	1 minute	8.20 x 10 ⁵	0.55	71.97%
		5 minutes	7.77 x 10 ³	2.59	99.73%
		30 minutes	3.25 x 10 ²	4.03	99.99%

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

CI- Clinical Isolate

MRSA = Methicillin Resistant *Staphylococcus aureus*

Bioscience Labs Inc., (now part of Nelson Labs) 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.



BIO SCIENCE
LABORATORIES, INC.

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)					
Fungi	Challenge Suspension* (CFU/ml)	Exposure Time	Post-Exposure Population (CFU/ml)	Log ₁₀ Reduction	Percent Reduction
<i>Aspergillus niger van Tiegham</i> (ATCC# 6275) Report# 130377-201	2.75 x 10 ⁹	10 minutes	3.90 x 10 ⁸	0.85	85.82%
		30 minutes	4.20 x 10 ⁸	0.82	84.73%
		60 minutes	3.05 x 10 ⁸	0.96	88.91%
<i>Candida albicans</i> (ATCC# 10231) Report# 130377-201	4.05 x 10 ⁹	1 minute	7.30 x 10 ⁵	3.74	99.98%
		5 minutes	1.65 x 10 ⁴	5.39	99.99%
		30 minutes	< 1.00 x 10 ³	6.61	99.99%
<i>Candida auris</i> (AR-BANK# 0381) Report# 1605248-201	3.80 x 10 ⁷	1 minute	5.80 x 10 ⁵	1.82	98.47%
		5 minutes	1.56 x 10 ³	4.39	99.99%
		30 minutes	<1.00 x 10 ¹	6.58	99.99%
<i>Candida auris</i> (AR-BANK# 0382) Report# 1605248-201	5.10 x 10 ⁷	1 minute	3.30 x 10 ⁶	1.19	93.53%
		5 minutes	1.21 x 10 ⁵	2.63	99.76%
		30 minutes	<1.00 x 10 ¹	6.71	99.99%
<i>Candida auris</i> (AR-BANK# 0383) Report# 1605248-201	6.30 x 10 ⁷	1 minute	1.84 x 10 ⁷	0.54	70.87%
		5 minutes	4.25 x 10 ⁴	3.17	99.93%
		30 minutes	<1.00 x 10 ¹	6.80	99.99%
<i>Candida glabrata</i> (ATCC# 2001) Report# 130377-201	1.16 x 10 ¹⁰	1 minute	4.03 x 10 ⁹	0.46	65.11%
		5 minutes	6.40 x 10 ⁷	2.26	99.45%
		30 minutes	< 1.00 x 10 ³	7.06	99.99%

Chlorhexidine Gluconate 0.05% in sterile water, USP (99.95%)				
Virus	Exposure Time	TCID ₅₀ (Log ₁₀) Post-Exposure Infectivity	Log ₁₀ Reduction	Percent Reduction
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%

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