



Technical Summary:

BioProtect™ Hand Sanitizer

The products in this range are based on silyl-quat nanoparticle technology. Our products have efficacy and longevity advantages over the competition and are highly effective for surfaces and hands. Third party laboratory testing has shown exceptional efficacy far beyond anything else available on the market today. Global BioProtect products use a unique antimicrobial technology that not only kills microorganisms on contact, but also has persistent activity designed to help prevent infections in a wide variety of venues from healthcare to food service and everywhere in between. The following is a brief summary of testing and qualifications.

Efficacy Testing:

a. Rapid Broad Spectrum Kill

Tests of hand sanitizer showed it was effective at killing more than 99.99% (>99.99%) of FDA (25 specified) test organisms in 15 seconds, using Quantitative Suspension Test methods. Testing has shown BioProtect™ Hand Sanitizer products to effectively kill a total of 45 different bacteria, fungi and viruses (for active ingredients the kill list is even longer).

Table 1. Time-Kill Testing Results:

BioProtect™ Hand Sanitizer Meets or Exceeds Efficacy Standards in Applicable Regulations.

Micro-organism (Strain #)	Time	BioProtect™ Hand Sanitizer
Gram Negative Bacteria		
1. <i>Acinetobacter baumannii</i> (ATCC #19606) ⁵	15 sec	>6.02 (99.9999%)
	30 sec	>6.02 (99.9999%)
	60 sec	>6.02 (99.9999%)
2. <i>Bacteroides fragilis</i> (ATCC# 25285) ⁵	15 sec	6.03 (99.9999%)
	30 sec	6.03 (99.9999%)
	60 sec	6.03 (99.9999%)
3. <i>Haemophilus influenzae</i> (ATCC #33930) ⁵	15 sec	>6.12 (99.9999%)
	30 sec	>6.12 (99.9999%)
	60 sec	>6.12 (99.9999%)
4. <i>Enterobacter aerogenes</i> (ATCC #13048) ⁵	15 sec	>6.02 (99.9999%)
	30 sec	>6.02 (99.9999%)
	60 sec	>6.02 (99.9999%)
5. <i>Escherichia coli</i> (ATCC #11229) ^{3, 5}	15 sec	>6.01 (99.9999%)
	30 sec	>6.01 (99.9999%)
	60 sec	>6.01 (99.9999%)
6. <i>Escherichia coli</i> (ATCC #10536) ⁵	15 sec	>6.58 (99.9999%)
	30 sec	>6.58 (99.9999%)
	60 sec	>6.58 (99.9999%)
7. <i>Escherichia coli</i> (ATCC #25922) ⁴	30 sec	>5.0 (99.999%)
	60 sec	>5.0 (99.999%)
8. <i>Klebsiella oxytoca</i> (ATCC #13182) ⁵	15 sec	>6.03 (99.9999%)
	30 sec	>6.03 (99.9999%)
	60 sec	>6.03 (99.9999%)

9. <i>Escherichia coli</i> (O157:H7) ¹	15 sec	>4.0 (>99.99%)
10. <i>Klebsiella pneumoniae</i> (ATCC #51504) ⁴	15 sec	>5.0 (99.999%)
	30 sec	>5.0 (99.999%)
	60 sec	>5.0 (99.999%)
11. <i>Klebsiella pneumoniae</i> (ATCC #4352) ⁵	15 sec	>6.04 (99.9999%)
	30 sec	>6.04 (99.9999%)
	60 sec	>6.04 (99.9999%)
12. <i>Pseudomonas aeruginosa</i> (ATCC #9027) ⁷	15 sec	>6.58 (99.9999%)
	30 sec	>6.58 (99.9999%)
	60 sec	>6.58 (99.9999%)
13. <i>Pseudomonas aeruginosa</i> (ATCC #27853) ⁵	15 sec	>6.23 (99.9999%)
	30 sec	>6.23 (99.9999%)
	60 sec	>6.23 (99.9999%)
14. <i>Pseudomonas aeruginosa</i> (ATCC #27853) ⁴	15 sec	>5.0 (99.999%)
	30 sec	>5.0 (99.999%)
	60 sec	>5.0 (99.999%)
15. <i>Pseudomonas aeruginosa</i> (ATCC #15442) ^{2, 3}	15 sec	>5.0 (99.999%)
	30 sec	>5.0 (99.999%)
	60 sec	>5.0 (99.999%)
16. <i>Proteus mirabilis</i> (ATCC #7002) ⁵	15 sec	>6.12 (99.9999%)
	30 sec	>6.12 (99.9999%)
	60 sec	>6.12 (99.9999%)
17. <i>Serratia marcescens</i> (ATCC #14756) ⁵	15 sec	>6.12 (99.9999%)
	30 sec	>6.12 (99.9999%)
	60 sec	>6.12 (99.9999%)
18. <i>Salmonella enterica</i> GFS (ATCC #10398) ³	60 sec	>5.0 (99.999%)
19. <i>Salmonella typhimurium</i> ¹	15 sec	>4.0 (99.99%)

Gram Positive Bacteria

20. <i>Staphylococcus aureus</i> (ATCC #6538) ^{3, 7}	15 sec	>6.56 (99.9999%)
	30 sec	>6.56 (99.9999%)
	60 sec	>6.56 (99.9999%)
21. <i>Staphylococcus aureus</i> (ATCC #29213) ^{4, 5}	15 sec	>6.11 (99.9999%)
	30 sec	>6.11 (99.9999%)
	60 sec	>6.11 (99.9999%)

22. <i>Staphylococcus epidermidis</i> (ATCC #12228) ⁵	15 sec	>6.22 (99.9999%)
	30 sec	>6.22 (99.9999%)
	60 sec	>6.22 (99.9999%)
23. <i>Staphylococcus hominis</i> (ATCC #27844) ⁵	15 sec	>6.21 (99.9999%)
	30 sec	>6.21 (99.9999%)
	60 sec	>6.21 (99.9999%)
24. <i>Staphylococcus haemolyticus</i> (ATCC #43253) ⁴	15 sec	>5.0 (99.999%)
	30 sec	>5.0 (99.999%)
	60 sec	>5.0 (99.999%)
25. <i>Staphylococcus haemolyticus</i> (ATCC #29970) ⁵	15 sec	>6.12 (99.9999%)
	30 sec	>6.12 (99.9999%)
	60 sec	>6.12 (99.9999%)
26. <i>Staphylococcus saprophyticus</i> (ATCC #35552) ⁵	15 sec	>6.11 (99.9999%)
	30 sec	>6.11 (99.9999%)
	60 sec	>6.11 (99.9999%)
27. <i>Micrococcus luteus</i> (ATCC #7468) ⁵	15 sec	>6.22 (99.9999%)
	30 sec	>6.22 (99.9999%)
	60 sec	>6.22 (99.9999%)
28. <i>Streptococcus pyogenes</i> (ATCC #19615) ^{3,7}	15 sec	>6.03 (99.9999%)
	30 sec	>6.03 (99.9999%)
	60 sec	>6.03 (99.9999%)
29. <i>Enterococcus faecalis</i> (ATCC# 29212) ⁵	15 sec	>6.01 (99.9999%)
	30 sec	>6.01 (99.9999%)
	60 sec	>6.01 (99.9999%)
30. <i>Enterococcus hirae</i> (ATCC #6057) ⁷	15 sec	>6.56 (99.9999%)
	30 sec	>6.56 (99.9999%)
	60 sec	>6.56 (99.9999%)
31. <i>Streptococcus pneumoniae</i> (ATCC #8043) ⁵	15 sec	>6.06 (99.9999%)
	30 sec	>6.06 (99.9999%)
	60 sec	>6.06 (99.9999%)

Fungi (Yeast and Mold)

32. <i>Candida albicans</i> (ATCC# 10231) ⁶	15 sec	>5.22 (99.999%)
	30 sec	>5.22 (99.999%)
	60 sec	>5.22 (99.999%)
33. <i>Aspergillus niger</i> (ATCC# 16404) ⁶	15 sec	>5.04 (99.999%)
	30 sec	>5.04 (99.999%)
	60 sec	>5.04 (99.999%)

b. Healthcare Hand Rub Efficacy Testing (EN 1500)

The FDA requires hand sanitizers to be tested on actual hands to prove real world performance. EN 1500 testing was chosen, as it is the European standard method for qualifying hand rubs used in healthcare facilities employing 20 test subjects. To be EN 1500 compliant a test product must exceed the efficacy of a reference alcohol. BioProtect™ Hand Sanitizer has passed testing and exceeded the efficacy of reference alcohol, qualifying for use in healthcare institutions in Europe and Australia.

Healthcare Hand Rub Testing ⁸	Reference Alcohol	BioProtect™ Hand Sanitizer
Pre Log ¹⁰ Inoculum Values (SD)	6.43 (0.69)	6.62 (0.73)
Post Treatment Log ¹⁰ Values (SD)	2.53 (0.35)	2.38 (0.23)
Log ¹⁰ Reduction Values	3.90	4.23

c. Long Term Sustained Activity

The World Health Organization (WHO) and the Centre for Disease Control (CDC) recommends "persistent" antiseptics for hand sanitizers. Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product.

d. Extended Protection >24 hours

In an *ex-vivo* test using a pigskin model (using ASTM E2897-12 & ASTM WK36911), BioProtect™ Hand Sanitizer was applied to the skin. After the specified amount of time, the skin samples were challenged with *S. aureus*. Testing was performed at 2 minutes with >99.9% kill and sustained kill of 99.9% was shown at 1 hour, 98.3% at 2 hours, 96.9% at 4 hours, 84.9 at 8 hours, 79.5% at 16 hours, and 54% at 24 hours.

Figure 1. Persistent activity against S aureus.

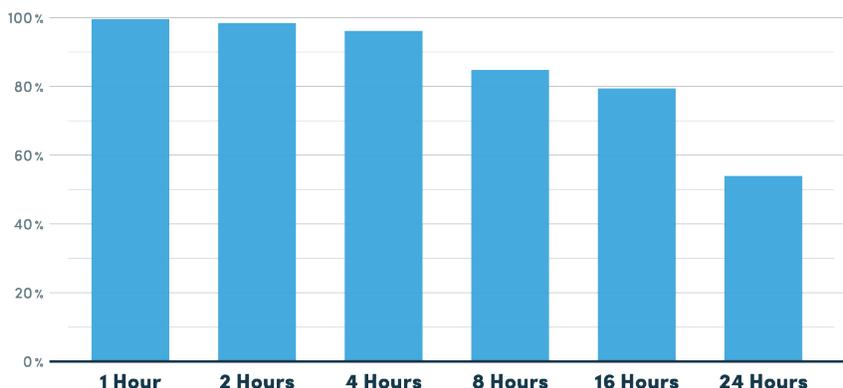


Table 2. Persistent Activity Against S. aureus for 24 hours.

37. <i>Staphylococcus aureus</i> (ATCC #12600) ⁹	2 Minutes	>99.9	(3.2)
	1 Hour	99.0	(2.0)
	2 Hours	98.3	(1.8)
	4 Hours	96.9	(1.5)
	8 Hours	84.9	(0.8)
	16 Hours	79.5	(0.7)
	24 Hours	54.1	(0.3)

Data presented in Figure 1 above

e. Extended Protection Against Antibiotic Resistant Strains

In using the same *ex-vivo* test method utilizing the pigskin model, persistent activity was shown against all three antibiotic resistant strains *MRSA*, *VRE* and *CRE* for up to 4 hours. Mean reduction between all 3 strains was over 99.9% at 2 minutes, 98.9% at 1 hour, 96.1% at 2 hours and 91.3% at 4 hours.

Table 3. Persistent Activity as Adjunct to Frequent Hand Hygiene.

	Time Post Hand Rub	% Reduction (Log ¹⁰ Reduction)	
34. Methicillin-Resistant <i>S. aureus</i> (MRSA; ATCC #33592) ¹⁰	2 Minutes	>99.9	(>3.0)
	1 Hour	99.2	(2.1)
	2 Hours	97.4	(1.6)
	4 Hours	95.2	(1.3)
35. Vancomycin-Resistant <i>Enterococcus</i> (VRE; ATCC #51575) ¹⁰	2 Minutes	>99.9	(>3.0)
	1 Hour	99.4	(2.2)
	2 Hours	98.1	(1.7)
	4 Hours	90.9	(1.0)
36. Carbapenem-Resistant <i>Enterobacteriaceae</i> (CRE/KPC) ATCC # BAA-1705 ¹⁰	2 Minutes	99.6	(2.4)
	1 Hour	98.3	(1.8)
	2 Hours	93.0	(1.2)
	4 Hours	87.9	(0.9)

f. Sustained Activity When Gloves are Utilized > 12 Hours

To assess persistent activity on hands when used in clinical settings ASTM Test method E1115-11 was used with 20 human volunteers. Immediate activity results demonstrated that bacterial reduction of hand flora after using the product was greater than a 5.8 Log₁₀ reduction factor. Persistent activity suppressing regrowth of skin bacteria was shown to be in the same order of magnitude (5.8 Log₁₀) at 3 hours, 6 hours and even at 12 hours after product application 99.99% (4.0 Log₁₀) with hands kept occluded within surgical gloves.

g. Challenge Testing as Further Proof of Wide Spectrum

Challenge testing of products regulated by FDA as over-the-counter antimicrobial drugs is the ultimate test of effectiveness of individual formulations. Instead of just killing germs on the hands or in suspension tests, multiple high-count inoculation and long term incubation are used. In a double 28 day challenge inoculated with over a million bacteria, BioProtect™ Hand Sanitizer killed off the following bacteria and fungi: *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Burkholderia cepacia*, *Bacillus subtilis*, *Candida albicans*, *Aspergillus niger* and *Penicillium luteum*.

Table 4A. Efficacy Testing as per ASTM E640-12 a Double 28 day Challenge¹².

Micro-organism	ATCC Stain #	1 st Inoculum Counts (28 day duration)	2 nd Inoculum Counts (28 day duration)
5. <i>Escherichia coli</i>	11229	2 x 10 ⁶	3 x 10 ⁶
11. <i>Klebsiella pneumoniae</i>	4352	2 x 10 ⁶	5 x 10 ⁶
15. <i>Pseudomonas aeruginosa</i>	15442	2 x 10 ⁶	5 x 10 ⁶
20. <i>Staphylococcus aureus</i>	6538	2 x 10 ⁶	3 x 10 ⁶
32. <i>Candida albicans</i>	10231	2 x 10 ⁶	5 x 10 ⁶
38. <i>Burkholderia cepacia cepacia</i>	25416	2 x 10 ⁶	6 x 10 ⁶
39. <i>Bacillus subtilis</i>	6051	2 x 10 ⁶	5 x 10 ⁶
40. <i>Aspergillus niger</i>	1015	2 x 10 ⁶	5 x 10 ⁶
41. <i>Penicillium luteum</i>	10466	2 x 10 ⁶	1 x 10 ⁶

Table 4B. Antimicrobial Effectiveness Testing as per USP35-NF30 51 & EP7.0.

Micro-organism	ATCC Stain #	USP 35-NF3051	EP7.0-5.1.3
42. <i>Escherichia coli</i>	8739	x	
12. <i>Pseudomonas aeruginosa</i>	9027	x	x
20. <i>Staphylococcus aureus</i>	6538	x	x
32. <i>Candida albicans</i>	10231	x	x
40. <i>Aspergillus niger</i>	16404	x	x

Table 4A & 4B: BioProtect™ Hand Sanitizer possesses bactericidal and fungicidal reduction of microbial species in double challenge testing as well as testing to normal US and EU standards, thus satisfies all applicable test standards including ASTM E640-06(2012)¹².

h. Antiviral Activity

BioProtect™ Hand Sanitizer has been shown to have antiviral activity against Norovirus (*Murine Norovirus Type 1*), Rhinovirus cause of the common cold (ATCC VR-482), Influenza virus (*ATCC VR-1741*) and Enterovirus 71 (Hand, Foot & Mouth Disease Virus).

Mode of Action:

Global BioProtect products are PolyQuats (a mixtures of quaternary ammonium chloride compounds). They consist of a sophisticated polymer backbone formula employing multifaceted modes of activity. It is a 3-component system working synergistically to deliver a safe but powerful antimicrobial punch. By building onto the well-proven safety of the 3-TSP polymer a chemo-electro-mechanical mode of action can be demonstrated. This highly effective formulary goes beyond any other family of antimicrobial products available today.

Toxicology:

Global BioProtect has carried out extensive toxicology testing and completed the “six pack” of acute toxicology testing. All results indicate extremely low toxicity and exceptional safety to humans, yet deadly to pathogens:

- **OEDC 402 Acute Dermal Toxicity Study**
- **OEDC 403 Acute Inhalation Toxicity Study**
- **OEDC 404 Acute Dermal Irritation/Corrosion Study**
- **OEDC 405 Acute Eye Irritation/Corrosion Study**
- **OEDC 406 Skin Sensitization Study**
- **OEDC 425 Acute Oral Toxicity Study**

Intellectual Property:

Global BioProtect has patented the technology with the key claims being a product that has exceptionally high kill claims against both gram negative and gram positive bacteria and viruses, longevity in action and kills as fast as alcohol based products. Patent coverage has been applied for in the following countries;

- **Brazil**
- **China**
- **Mexico**
- **United States of America**
- **Japan**
- **New Zealand**
- **Australia**
- **India**
- **South Korea**
- **European Patent Convention** (38 countries)