

# An Evaluation of Avant-EX™ Instant Hand Sanitizer for its Antimicrobial Properties when Challenged with Various Microorganism Strains Using an In-Vitro Time-Kill Method

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## **Purpose:**

This evaluation used an in-vitro time-kill method to assess the broad-spectrum antimicrobial efficacy of one (1) test product, an alcohol-based hand sanitizer, when challenged with fifty-three (53) microorganism strains. The test product was evaluated at a concentration of 99% (v/v).

## **SCOPE:**

An in-vitro time-kill evaluation was performed for one test product using challenge suspensions of fifty-three different microorganism strains. The microorganism strains evaluated included twenty-five American Type Culture Collection (ATCC) strains and twenty-five Clinical Isolates of those same species, as well as *Clostridium difficile*, *Salmonella enterica enterica* serovar Typhi and *Trichophyton mentagrophytes*. Each of the challenge species was exposed to the test product for a single contact time - fifteen seconds or thirty seconds, depending upon the challenge strain (reference Table I). The Percent and Log<sub>10</sub> reduction from the initial populations were determined for each challenge microorganism following the appropriate timed exposure to the test product. All agar-plating was performed in duplicate.

## **TEST MATERIAL:**

**Test Product:** Avant-EX Instant Hand Sanitizer

**Lot Number:** 9222

**All testing was performed in accordance with Good Laboratory Practices, as specified in 21 CFR part 58.**

## **GROWTH MEDIA AND DILUTING FLUIDS:**

The growth media used in this study were: Phosphate Buffered Saline (PBS) for Neutralization Assay; Tryptic Soy Agar with product neutralizers (TSA+); Tryptic Soy Agar for Neutralization Assay (TSA); and Tryptic Soy Broth (TSB) for Inoculum Preparation.

The neutralization/ diluting fluid used in this study was Butterfields' Phosphate Buffer Solution with Product Neutralizers (BBP++).

## **NEUTRALIZATION STUDY:**

Neutralization studies (SOP L-2007) were performed for the test product versus *Clostridium difficile* (ATCC #9689), *Escherichia coli* (ATCC #11229), *Staphylococcus aureus aureus* (ATCC #6538) and *Streptococcus pneumoniae* (ATCC #6303) to ensure that the neutralizing solution employed (BBP++) was effective in neutralizing the antimicrobial properties of the product. This neutralization procedure followed guidelines set forth in ASTM E-1054-02, Standard Test.

## **RESULTS:**

The results of the evaluation indicate broad spectrum antimicrobial effectiveness of greater than 99.999% for the fifty-three microorganisms tested in 30 seconds or less. Percent reductions of note include 99.999% effectiveness against *Clostridium difficile* (ATCC #9689), *Enterococcus faecium*; MDR, VRE (ATCC #51559), *Enterococcus faecalis*; VRE (BSLI #051707VREfs1), and *Staphylococcus aureus* MRSA (BSLI #051707MRSa1).

**RESULTS:** Table I presents the Log<sub>10</sub> and percent reductions observed for Test Product (Avant-EX™ Instant Hand Sanitizer [Lot Number 9222]) versus each of fifty-three (53) microorganisms tested.

TABLE I: Avant -EX™ Instant Hand Sanitizer Lot Number 9222					
No.	Microorganism Species	(ATCC or Clinical Isolate*)	Exposure Time	Log <sub>10</sub> Reduction	Percent Reduction
1	Acinetobacter baumannii	ATCC #19606	15 Seconds	6.4472	99.9999%
2*	Acinetobacter baumannii	BSLI #071906Ab1	15 Seconds	6.6284	99.9999%
3	Bacteroides fragilis	ATCC #25285	15 Seconds	4.7720	99.9983%
4*	Bacteroides fragilis	BSLI #013106Bfl	15 Seconds	4.3192	99.9952%
5	Candida albicans	ATCC #10231	15 Seconds	6.2135	99.9999%
6*	Candida albicans	BSLI #011706Ca26	15 Seconds	6.1629	99.9999%
7	Candida tropicalis	ATCC #750	15 Seconds	6.2553	99.9999%
8*	Candida tropicalis	BSLI #011706Ctl	15 Seconds	6.3646	99.9999%
9	Clostridium difficile	ATCC #9689	15 Seconds	6.6021	99.9997%
10	Enterobacter aerogenes	ATCC #13048	15 Seconds	6.7324	99.9999%
11*	Enterobacter aerogenes	BSLI #042905Ea	15 Seconds	6.5315	99.9999%
12	Enterococcus faecalis	ATCC #29212	15 Seconds	6.4548	99.9999%
13*	Enterococcus faecalis; VRE	BSLI #051707VREfs1	15 Seconds	6.4346	99.9999%
14	Enterococcus faecium; MDR, VRE	ATCC # 51559	15 Seconds	6.4065	99.9999%
15*	Enterococcus faecium; VRE	BSLI #0106006Efm1	15 Seconds	6.3945	99.9999%
16	Escherichia coli	ATCC #11229	15 Seconds	6.3738	99.9999%
17*	Escherichia coli	BSLI #111705Ecl	15 Seconds	6.5966	99.9999%
18	Escherichia coli	ATCC #25922	15 Seconds	6.4232	99.9999%
19*	Escherichia coli	BSLI #071906Ec4	15 Seconds	6.4216	99.9999%
20	Haemophilus influenzae; MDR	ATCC #33930	15 Seconds	6.6628	99.9999%
21*	Haemophilus influenzae	BSLI #071906Hi13	15 Seconds	6.6232	99.9999%
22	Klebsiella oxytoca	ATCC #43165	15 Seconds	7.0607	99.9999%
23*	Klebsiella oxytoca	BSLI #071906Ko1	15 Seconds	6.7745	99.9999%
24	Klebsiella pneumoniae	ATCC #10031	15 Seconds	6.3201	99.9999%
25*	Klebsiella pneumoniae	BSLI #071906Kpn3	15 Seconds	6.4354	99.9999%
26	Micrococcus luteus	ATCC #7468	15 Seconds	5.6232	99.9998%
27*	Micrococcus luteus	BSLI #071906M13	15 Seconds	6.4314	99.9999%
28	Proteus mirabilis	ATCC #7002	15 Seconds	6.4472	99.9999%
29*	Proteus mirabilis	BSLI #071906Pm3	15 Seconds	6.5502	99.9999%
30	Pseudomonas aeruginosa	ATCC #15442	15 Seconds	6.4624	99.9999%
31*	Pseudomonas aeruginosa	BSLI #071906Pa1	15 Seconds	6.4354	99.9999%
32	Pseudomonas aeruginosa	ATCC #27853	15 Seconds	6.3847	99.9999%
33*	Pseudomonas aeruginosa	BSLI #072605Pa	15 Seconds	6.5315	99.9999%
34	Salmonella enterica	ATCC #6539	15 Seconds	6.5966	99.9999%
35	Serratia marcescens	ATCC #14756	15 Seconds	6.3979	99.9999%
36*	Serratia marcescens	BSLI #071906Sm1	15 Seconds	6.6857	99.9999%
37	Staphylococcus aureus	ATCC #6538	15 Seconds	6.4601	99.9999%
38*	Staphylococcus aureus ; MRSA	BSLI #051707Mrsa1	15 Seconds	5.1430	99.9993%
39	Staphylococcus aureus	ATCC #29213	15 Seconds	6.5119	99.9999%
40*	Staphylococcus aureus	BSLI #071906Sa29	15 Seconds	7.5459	99.9999%
41	Staphylococcus epidermidis	ATCC #12228	15 Seconds	5.0158	99.9990%
42*	Staphylococcus epidermidis; MRSE	BSLI #051707MRSe1	15 Seconds	6.8325	99.9999%
43	Staphylococcus haemolyticus	ATCC #29970	15 Seconds	6.1903	99.9999%
44*	Staphylococcus haemolyticus	BSLI #122305Sha41	15 Seconds	6.1563	99.9999%
45	Staphylococcus hominis	ATCC #27844	15 Seconds	6.0000	99.9999%
46*	Staphylococcus hominis	BSLI #010606Sho30	15 Seconds	5.8603	99.9999%
47	Staphylococcus saprophyticus	ATCC #15305	15 Seconds	6.2405	99.9999%
48*	Staphylococcus saprophyticus	BSLI #122305Ss35	15 Seconds	6.3738	99.9999%
49	Streptococcus pneumoniae	ATCC #6303	15 Seconds	4.7818	99.9983%
50*	Streptococcus pneumoniae	BSLI #072605Spn1	15 Seconds	4.5119	99.9969%
51	Streptococcus pyogenes	ATCC #19615	15 Seconds	6.3010	99.9999%
52*	Streptococcus pyogenes	BSLI #071906Spy2	15 Seconds	7.3531	99.9999%
53	Trichophyton mentagrophytes	ATCC #9533	15 seconds	4.7404	99.9982%

\* = Clinical Isolate

VRE = Vancomycin-Resistant Enterococcus

MDR = Multi-Drug Resistant

MRSA = Methicillin-Resistant Staphylococcus aureus