

An Evaluation of Avant Original™ 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 choleraesuis*, serotype Typhi and *Trichophyton mentagrophytes*. Each of the challenge species was exposed to the test product for a single contact time- fifteen seconds, thirty seconds, or one minute- depending upon the challenge strain (reference Table I). The Percent and Log₁₀ 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 Original™ Instant Hand Sanitizer

Lot Number: 9664

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), and *Streptococcus pneumoniae* (ATCC #49619) 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. Percent reductions of note include 99.999% effectiveness against *Clostridium difficile* (ATCC #9689), *Enterococcus faecium*; MDR (ATCC #51559), *Enterococcus faecalis*; VRE (BSLI #061700Efs12), and *Staphylococcus aureus* MMRSA (BSLI #032301MMRSA3).

RESULTS: Table I presents the Log₁₀ and percent reductions observed for Test Product (Avant Original™ Instant Hand Sanitizer [Lot Number 9664]) versus each of fifty-three (53) microorganisms tested.

TABLE I: Avant Original™ Instant Hand Sanitizer Lot Number 9664					
No.	Microorganism Species	(ATCC or Clinical Isolate*)	Exposure Time	Log ₁₀ Reduction	Percent Reduction
1	<i>Acinetobacter baumannii</i>	ATCC #19003	15 Seconds	5.9777	99.9999%
2*	<i>Acinetobacter baumannii</i>	BSLI #061700Ab16	15 Seconds	5.8692	99.9999%
3	<i>Bacteroides fragilis</i>	ATCC #43858	15 Seconds	7.6284	99.9999%
4*	<i>Bacteroides fragilis</i>	BSLI #090800Bf	15 Seconds	7.6175	99.9999%
5	<i>Candida albicans</i>	ATCC #10231	30 Seconds	6.2227	99.9999%
6*	<i>Candida albicans</i>	BSLI #040400Ca16	30 Seconds	6.3010	99.9999%
7	<i>Candida tropicalis</i>	ATCC #750	30 Seconds	6.2867	99.9999%
8*	<i>Candida tropicalis</i>	BSLI #121799Ct	30 Seconds	6.3054	99.9999%
9	<i>Clostridium difficile</i>	ATCC #9689	15 Seconds	5.4749	99.9997%
10	<i>Enterobacter aerogenes</i>	ATCC #29007	15 Seconds	6.1717	99.9999%
11*	<i>Enterobacter cloacae</i>	BSLI #070700Ec11	15 Seconds	6.3579	99.9999%
12	<i>Enterococcus faecalis</i>	ATCC #29212	15 Seconds	6.4793	99.9999%
13*	<i>Enterococcus faecalis</i> ; VRE	BSLI #061700Efs12	15 Seconds	6.4346	99.9999%
14	<i>Enterococcus faecium</i> ; MDR	ATCC # 51559	15 Seconds	6.2355	99.9999%
15*	<i>Enterococcus faecium</i> ; VRE	BSLI #061700Efm15	15 Seconds	6.0354	99.9999%
16	<i>Escherichia coli</i>	ATCC #11229	15 Seconds	6.1945	99.9999%
17*	<i>Escherichia coli</i>	BSLI #060199Ec	15 Seconds	6.1367	99.9999%
18	<i>Escherichia coli</i>	ATCC #25922	15 Seconds	6.1492	99.9999%
19*	<i>Escherichia coli</i>	BSLI #070399Ec	15 Seconds	6.4074	99.9999%
20	<i>Haemophilus influenzae</i>	ATCC #8149	15 Seconds	6.5911	99.9999%
21*	<i>Haemophilus influenzae</i>	BSLI #121699Hi3	15 Seconds	5.9614	99.9999%
22	<i>Klebsiella oxytoca</i>	ATCC #15764	15 Seconds	6.1399	99.9999%
23*	<i>Klebsiella oxytoca</i>	BSLI #060199Ko	15 Seconds	6.2707	99.9999%
24	<i>Klebsiella pneumoniae</i>	ATCC #29019	15 Seconds	6.1351	99.9999%
25*	<i>Klebsiella pneumoniae</i>	BSLI #040400Kpn2	15 Seconds	6.3128	99.9999%
26	<i>Micrococcus luteus</i>	ATCC #7468	15 Seconds	5.9708	99.9999%
27*	<i>Micrococcus luteus</i>	BSLI #061901M13	15 Seconds	6.4556	99.9999%
28	<i>Proteus mirabilis</i>	ATCC #7002	15 Seconds	5.9138	99.9999%
29*	<i>Proteus mirabilis</i>	BSLI #121699Pm2	15 Seconds	6.0531	99.9999%
30	<i>Pseudomonas aeruginosa</i>	ATCC #15442	15 Seconds	6.1717	99.9999%
31*	<i>Pseudomonas aeruginosa</i>	BSLI #070199Pa	15 Seconds	6.5563	99.9999%
32	<i>Pseudomonas aeruginosa</i>	ATCC #27853	15 Seconds	6.1255	99.9999%
33*	<i>Pseudomonas aeruginosa</i>	BSLI #040400Pa5	15 Seconds	6.5185	99.9999%
34	<i>Salmonella typhi</i>	ATCC #6539	15 Seconds	6.4764	99.9999%
35	<i>Serratia marcescens</i>	ATCC #14756	15 Seconds	6.5119	99.9999%
36*	<i>Serratia marcescens</i>	BSLI #081499Sm	15 Seconds	6.3729	99.9999%
37	<i>Staphylococcus aureus</i>	ATCC #6538	15 Seconds	6.4814	99.9999%
38*	<i>Staphylococcus aureus</i> MMRSA	BSLI #032301MMR5a3	15 Seconds	6.6180	99.9999%
39	<i>Staphylococcus aureus</i>	ATCC #29213	15 Seconds	6.6857	99.9999%
40*	<i>Staphylococcus aureus</i> MRSA	BSLI #040400Sa8	15 Seconds	6.3636	99.9999%
41	<i>Staphylococcus epidermidis</i>	ATCC #12228	15 Seconds	6.6580	99.9999%
42*	<i>Staphylococcus epidermidis</i>	BSLI #061700Se2	15 Seconds	6.1931	99.9999%
43	<i>Staphylococcus haemolyticus</i>	ATCC #29970	15 Seconds	6.0663	99.9999%
44*	<i>Staphylococcus haemolyticus</i>	BSLI #062900Sha	15 Seconds	6.4362	99.9999%
45	<i>Staphylococcus hominis</i>	ATCC #27844	15 Seconds	5.9754	99.9999%
46*	<i>Staphylococcus hominis</i>	BSLI #060700Sho4	15 Seconds	6.5966	99.9999%
47	<i>Staphylococcus saprophyticus</i>	ATCC #35552	15 Seconds	6.6812	99.9999%
48*	<i>Staphylococcus saprophyticus</i>	BSLI #062900Ss	15 Seconds	6.3953	99.9999%
49	<i>Streptococcus pneumoniae</i>	ATCC #49619	15 Seconds	5.9165	99.9999%
50*	<i>Streptococcus pneumoniae</i>	BSLI #061901Spn1	15 Seconds	7.2589	99.9999%
51	<i>Streptococcus pyogenes</i>	ATCC #19615	15 Seconds	5.8195	99.9998%
52*	<i>Streptococcus pyogenes</i>	BSLI #040400Spy4	15 Seconds	6.9542	99.9998%
53	<i>Trichophyton mentagrophytes</i>	ATCC #9533	1 Minute	5.3284	99.9995%

* = Clinical Isolate

VRE = Vancomycin-Resistant *Enterococcus*

MMRSA = Mupirocin-Resistant, Methicillin-Resistant *Staphylococcus aureus*

MDR = Multi-Drug Resistant

MRSA = Methicillin-Resistant *Staphylococcus aureus*