MICROCHEM LABORATORY

STUDY REPORT

Study Title

Antibacterial Activity and Sanitizing Efficacy of Aerus' Device

Test Method

ASTM International Method E1153 Modified for Devices
Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces

Study Identification Number

Study Sponsor

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Test Facility

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Testing performed by: Michaela Cash

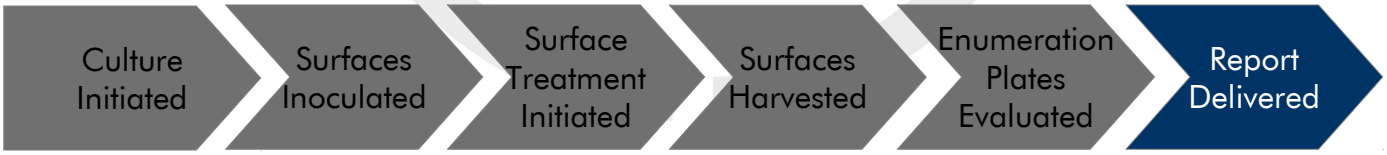
ASTM E1153: General Information

ASTM International, formerly the American Society for Testing and Materials (ASTM), is an internationally recognized organization that develops and publishes product and testing standards. ASTM E1153 is a quantitative test method designed to evaluate the antimicrobial efficacy of sanitizers on pre-cleaned inanimate, nonporous, non-food contact surfaces. The method is typically used with a maximum contact time of 5 minutes, during which the sanitizer reduces the concentration of viable test microorganisms. ASTM E1153 utilizes non-antimicrobial agents as controls to establish baselines for microbial reductions. The ASTM E1153 method is a benchmark method for non-food contact surface sanitizers and is recognized by several regulatory agencies as an approved method for claim substantiation. See study modifications for changes made to the study method to accommodate a device.

Laboratory Qualifications Specific to ASTM E1153

Microchem Laboratory began conducting the ASTM E1153 test method in 2007. Since then, the laboratory has performed hundreds of ASTM E1153 tests on a broad array of test substances, against a myriad of bacterial and fungal species. The laboratory is also experienced with regard to modifying the test method as needed in order to accommodate customer needs. Every ASTM E1153 test at Microchem Laboratory is performed in a manner appropriate for the test substances submitted by the Study Sponsor, while maintaining the integrity of the method.

Study Timeline



Culture Initiated	Surfaces Inoculated	Surface Treatment Initiated	Surfaces Harvested	Enumeration Plates Evaluated	Report Delivered
12 APR 2019	16 APR 2019	16 APR 2019	16 APR 2019 17 APR 2019	19 APR 2019 22 APR 2019	24 APR 2019

Test Device Information

The test device was received on 04 FEB 2019 and the following picture was taken:

Note: the photo above depicts the test device evaluated in this study

Test device received: Hydroxyl Blaster

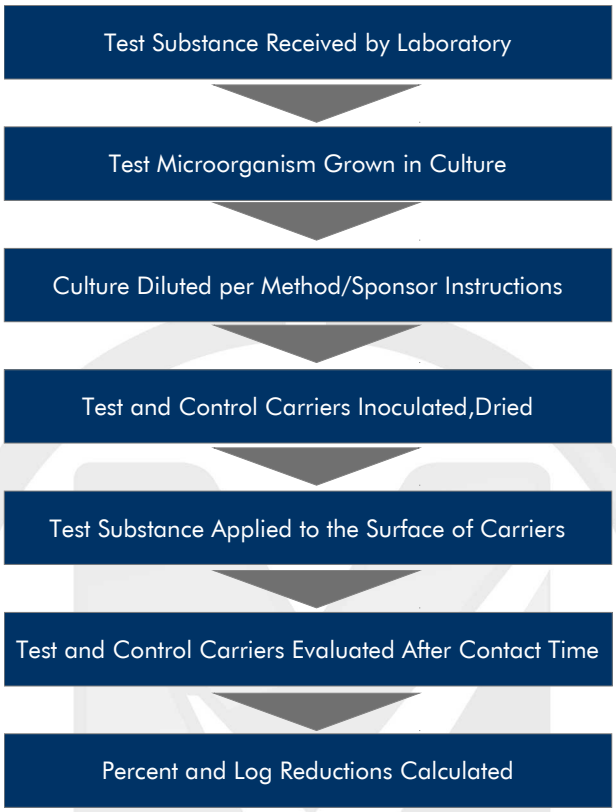
Test Microorganism Information

The test microorganism(s) selected for this test:

Candida auris AR Bank #0381

This fungi grows as a yeast and is ascomycetous. *C. auris* is an emerging pathogen and the epidemiology for transmission is still under investigation. Infections have most often occured in hospitalized patients and healthcare facilities. This yeast has developed resistance to commonly used antifungal drugs and specialized laboratory methods are needed to accurately identify *C. auris* infections. Because of this, *C. auris* infections are increasingly difficult to identify and treat.

Diagram of the Procedure



Summary of the Procedure

- The test microorganism is prepared, usually by growth in liquid culture medium or on an appropriate agar plate.
- The test culture may be supplemented with an artificial soil load, such as horse or fetal bovine serum, for one-step cleaner/sanitizer claims.
- Sterilized carriers are inoculated with a volume of the test culture. Inoculated slides are dried. Only completely dried carriers are used in the test.
- Test carriers are treated with the test device and incubated for the predetermined contact time.
- Control carriers are harvested at appropriate intervals to accurately represent any reduction during the contact time.
- At the conclusion of the contact time, test and control carriers are chemically neutralized.
- Dilutions of the neutralized test substance are evaluated using appropriate growth media to determine the surviving microorganisms at the respective contact time.
- The effect of the test substance is compared to the effect of the control substance in order to determine microbial reductions.

Criteria for Scientific Defensibility of an ASTM E1153 Study

For Microchem Laboratory to consider an ASTM E1153 study to be scientifically defensible, the following criteria must be met:

1. Ordinary consistency between replicates must be observed for the control carriers.
2. Positive/Growth controls must demonstrate growth of appropriate test microorganism.
3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

Due to the modified nature of testing, the study sponsor may determine success criteria.

Testing Parameters used in this Study

Carrier size and type	1" x 3" Glass Slides	Replicates	Single (1)
Culture growth media	Sabouraud Dextrose Agar	Incubation time	48-72 horus
Culture dilution media	0.85% Saline + 0.1% TX-100	Diluent supplement	0.1% Triton X-100
Target concentration	~1 x 10^6 CFU/Carrier	Inoculum volume	0.020ml
Contact time(s)	2, 4 and 6 hours	Contact temperature	Ambient
Carrier distances	~24 inches from exhaust	Neutralizer (Vol.)	Dey Engley Broth (20 ml)

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Control Results

Neutralization Method: Not Applicable
Media Sterility: Sterile – No Growth
Growth Confirmation: Confirmed – Target Microorganism

Calculations

$$\text{Percent Reduction} = \left(\frac{B - A}{B}\right) \times 100$$

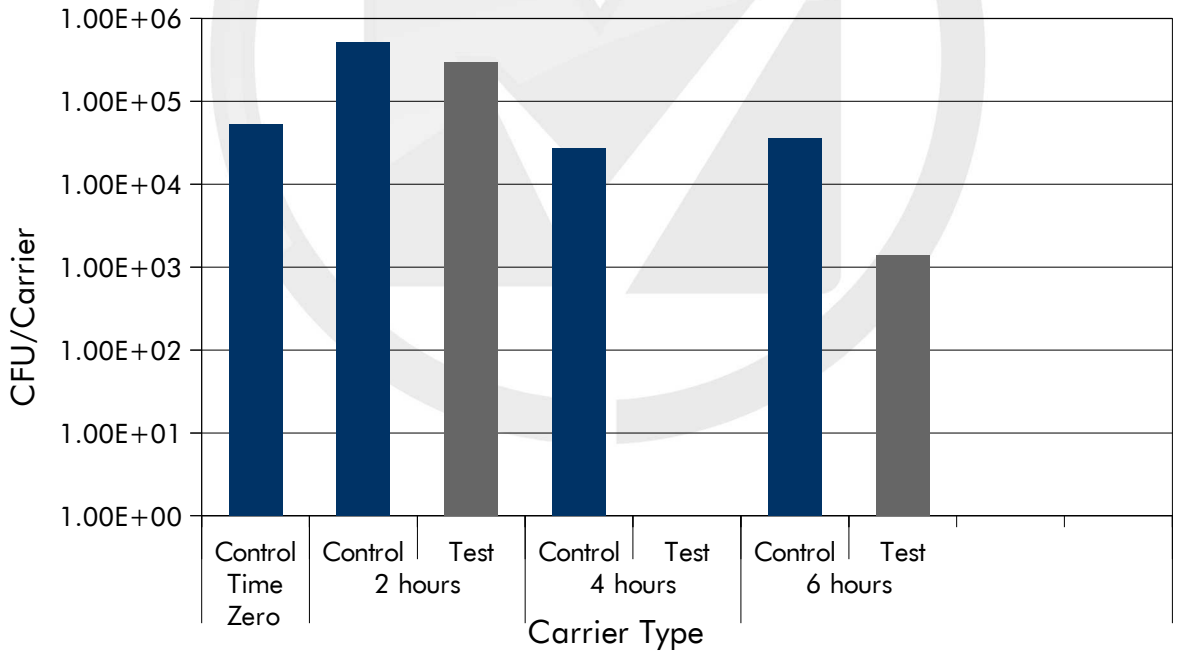
Where:
B = Number of viable test microorganisms on the control carriers after the contact time
A = Number of viable test microorganisms on the test carriers after the contact time

$$\text{Log}_{10}\text{Reduction} = \text{Log}\left(\frac{B}{A}\right)$$

Where:
B = Number of viable test microorganisms on the control carriers after the contact time
A = Number of viable test microorganisms on the test carriers after the contact time

Results of the Study

Test Microorganism	Contact Time	Carrier Type	CFU/Carrier	Percent Reduction Compared to Parallel Control	Log_{10} Reduction Compared to Parallel Control
C. auris CDC AR-Bank #0831	Time Zero	Control	5.30E+04	N/A	
	2 hours	Control	5.10E+05	N/A	
		Test	3.00E+05	41.18%	0.23
	4 hours	Control	2.70E+04	N/A	
		Test	4.40E+04		
	6 hours	Control	3.60E+04	N/A	
		Test	1.40E+03	96.11%	1.41



The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.