



Standard Test Method for Evaluation of Surgical Hand Scrub Formulations¹

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1. Scope

1.1 This test method is designed to measure the reduction of microbial flora on the skin. It is intended for determining both immediate and persistent microbial reductions, after single or repetitive treatments, or both. It may also be used to measure cumulative antimicrobial activity after repetitive treatments.

1.2 A knowledge of microbiological techniques is required for these procedures.

1.3 In this method, metric units are used for all applications, except for distance, in which case inches are used and metric units follow in parentheses.

1.4 Performance of this procedure requires the knowledge of regulations pertaining to the protection of human subjects.²

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 ASTM Standards:

D 1193 Specification for Reagent Water³

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products⁴

2.2 Other Documents:

21 CFR Parts 50 and 56⁵

AATCC Test Method 147 1993 Antibacterial Assessment of Textile Materials: Parallel Streak Method⁶

Horowitz, W. (Ed.), 2000, Official Methods of Analysis of AOAC International 17th Ed., Ch 17, p. 4, Sec. 17.2.01 (m). Assoc. of Off. Anal. Chemist, Washington, D.C.

United States Pharmacopeia, 25, 2001, United States Phar-

macopeial Convention, Inc., Rockville, MD. Chapter 61 “Microbial Limits Test”

3. Terminology

3.1 Definitions:

3.1.1 *active ingredient*—a substance added to a formulation specifically for the inhibition or inactivation of microorganisms.

3.1.2 *cleansing wash*—a non-antimicrobial wash intended to remove gross soil or residues from the hands of the subjects prior to collecting baseline samples.

3.1.3 *cleansing wash formulation*⁷—a liquid castile soap or other liquid soap with neutral pH which does not contain an antimicrobial.

3.1.4 *cumulative effect*—a progressive decrease in the number of microorganisms recovered following repeated applications.

3.1.5 *internal reference formulation*—a formulation with demonstrated performance characteristics within the laboratory.

3.1.6 *neutralization*—a process that results in quenching or inactivation of the antimicrobial activity of a formulation. This may be achieved through dilution of the formulation or through the use of chemical agents called neutralizers.

3.1.7 *persistence*—prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after treatment.

3.1.8 *sampling fluid*—a buffered solution that aids in recovery of microorganisms from the skin and neutralization of the active ingredient in test and internal reference formulations.

3.1.9 *test formulation*—a formulation containing an active ingredient(s).

4. Summary of Test Method

4.1 This test method is conducted on subjects selected from a group of volunteers who have refrained from using any antimicrobials for at least two weeks prior to initiation of the test. Subjects are selected from this group on the basis of high initial bacterial count, $\geq 1 \times 10^5$ CFU/per hand as determined by baseline measurements of the bacteria on their hands using the recovery techniques in this method.

4.2 The selected subjects perform a simulated surgical scrub

¹ This test method is under the jurisdiction of ASTM Committee E35 on Pesticides and is the direct responsibility of Subcommittee E35.15 on Antimicrobial Agents.

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² 21 CFR Ch. 1, Parts 50 and 56.

³ *Annual Book of ASTM Standards*, Vol 11.01.

⁴ *Annual Book of ASTM Standards*, Vol 11.05.

⁵ *United States Code of Federal Regulations*.

⁶ Technical Manual of the American Association of Textile Chemists and Colorists, P.O. Box 12215, Research Triangle Park, NC 27709.

⁷ Johnson's Baby Wash Head-to-Toe[®] Johnson's and Johnson's Inc., Skillman, NJ 08558–9418.