



Standard Test Method for Determining the Bacteria-Eliminating Effectiveness of Healthcare Personnel Hand Rub Formulations Using Hands of Adults¹

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1. Scope

1.1 This test method is designed to determine the activity of healthcare personnel hand rubs, (also known as hand rubs, hygienic hand rubs, hand sanitizers, or hand antiseptics) against transient microbial skin flora on the hands after a single application and after repeated applications.

1.2 Performance of this procedure requires the knowledge of regulations pertaining to the protection of human subjects (see 21 CFR Parts 50 and 56).

1.3 This test method should be performed by persons with training in microbiology, in facilities designed and equipped for work with potentially infectious agents at biosafety level 2.²

1.4 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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.* For more specific precautionary statements, see 8.2.

2. Referenced Documents

2.1 ASTM Standards:³

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

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

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² CDC-NIH, *Biosafety in Microbiological and Biomedical Laboratories*, 5th ed., U.S. Department of Health and Human Services, U.S. Government Printing Office, Washington, DC, 2007.

³ For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

E1174 Test Method for Evaluation of the Effectiveness of Health Care Personnel Handwash Formulations

E2276 Test Method for Determining the Bacteria-Eliminating Effectiveness of Hygienic Handwash and Handrub Agents Using the Fingertips of Adults

E2756 Terminology Relating to Antimicrobial and Antiviral Agents

2.2 Other Standards:

AATCC Test Method 147 2004 Antibacterial Activity Assessment of Textile Materials: Parallel Streak Method⁴

21 CFR Parts 50 and 56 Protection of Human Subjects; Institutional Review Boards⁵

3. Terminology

3.1 *Definitions*: For definitions of terms used in this document, see Terminology **E2756**.

3.2 Definitions of Terms Specific to This Standard:

3.2.1 *healthcare personnel handrub, n*—an antimicrobial gel, foam, liquid, spray, or wipe, applied by rubbing to reduce the transient microbial skin flora on hands that are not visibly soiled, and which does not require a post-treatment water rinse. Such agents may also be referred to as hand rubs, hygienic hand rubs, or hand antiseptics.

3.2.2 *healthcare personnel handwash, n*—a cleanser or waterless agent intended to reduce transient microbial skin flora on the hands.

3.2.3 *test bacteria, n*—an applied inoculum of bacteria that has characteristics which allow it to be readily identified. Test bacteria are used to simulate a topical transient microbial contaminant. This may also be referred to as a test organism, marker organism, simulant, or contaminant.

3.2.4 *test material, n*—a product or formulation which incorporates an antimicrobial ingredient(s).

⁴ Available from American Association of Textile Chemists and Colorists (AATCC), P.O. Box 12215, Research Triangle Park, NC 27709, <http://www.aatcc.org>.

⁵ Available from U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, <http://www.access.gpo.gov>.