



Standard Test Method for Determining the Residual Kill Activity of Hand Antiseptic Formulations¹

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1. Scope

1.1 This test method is designed to determine the residual killing activity of skin antiseptics against transient microbial skin flora on the hands.² It may be used to evaluate products that are used with the aid of water and rinsed off and those that are used without the aid of water and not rinsed off.

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.

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 8.1.

2. Referenced Documents

2.1 ASTM Standards:³

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

E2752 Guide for Evaluation of Residual Effectiveness of Antibacterial Personal Cleansing Products

E1882 Test Method for Evaluation of Antimicrobial Formulations by the Agar Patch Technique

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 Rutter J.D., Angiulo K., Macinga D.R., Measuring residual activity of topical antimicrobials: is the residual activity of chlorhexidine an artefact of laboratory methods? *J. Hosp. Infect.* 88:113-115, 2014

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.

E2197 Quantitative Disk Carrier Test Method for Determining Bactericidal, Virucidal, Fungicidal, Mycobactericidal, and Sporocidal Activities of Chemicals

E2756 Terminology Relating to Antimicrobial and Antiviral Agents

2.2 *Federal Standards*:⁴

21 CFR Part 50 Protection of Human Subjects

21 CFR Part 56 Institutional Review Boards

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 hand rub, 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, hand sanitizers, or hand antiseptics.

3.2.2 *healthcare personnel hand wash, n*—a cleanser requiring rinsing or a non-rinse agent intended to reduce transient microbial skin flora on the hands.

3.2.3 *room temperature, n*—temperature in the range of 20 to 25°C (68 to 77°F).

3.2.4 *test bacteria, n*—an applied suspension of bacteria having characteristics that permit ready identification of colonies. Test bacteria are used to simulate a transient topical microbial contaminant. These may also be referred to as test organisms, marker organisms, simulants, or contaminants.

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

4. Summary of Test Method

4.1 This test method uses adult subjects who have provided a written informed consent and whose hands have been determined to be free from any clinical evidence of skin disorders, dermatosis, cuts, lesions, or hangnails at the time of

⁴ Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, <http://www.access.gpo.gov>.