



Standard Guide for Testing Leave-On Products Using In-Situ Methods¹

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1. Scope

1.1 This guide covers test methods and sampling procedure options for leave-on products for consumer and hospital personnel. Leave-on products, such as alcohol hand rubs and lotions containing antimicrobial ingredients, are increasingly marketed and used by consumers and health care personnel. These products are distinguished from conventional washing and scrubbing preparations in that they do not rely on the rinsing, physical removal, and antimicrobial action in determining their effectiveness. Although agitation and friction may serve to release organisms from the skin and folds and crevices, organisms are then killed in situ and are not rinsed from the skin surface before sampling. Appropriate test methods for the hands have been published, while other sampling methods will be needed for testing body areas other than the hands.

1.1.1 Researchers have described techniques to identify the expanded flora we now know can be present on the skin. It is impractical, if not prohibitive to attempt to recover and identify these varieties of organisms with each test. At some point in the design of a test, a decision is necessary for defining the target organisms. Should the sampling be designed to recover as much of the microflora as possible or a particular portion of it? Consideration of transient and resident, superficial and deep, or aerobic and anaerobic flora must be included in defining the objective in testing products. The recovery methods selected for any testing must be based on the projected use of the product type being tested.

1.2 Methods of recovery after application of the contaminating organisms to a part of the body other than by the agitation/rubbing of the hands against a glass petri plate also need examination. Consideration should be given to contact plating, controlled swabbing with a template, and cup scrubbing (detergent/agitation used) since the target organisms for recovery are likely to be on the superficial layers of skin.

1.3 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

¹ This guide 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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1.4 *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 requirements prior to use.*

2. Referenced Documents

2.1 ASTM Standards:²

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

E1327 Test Method for Evaluation of Antimicrobial Handwash Formulations by Utilizing Fingernail Regions

E2755 Test Method for Determining the Bacteria-Eliminating Effectiveness of Hand Sanitizer Formulations Using Hands of Adults

2.2 European Standard:³

EN1500 Chemical Disinfectants and Antiseptics-Hygienic Handrub-Test Method Requirements (phase 2/step 2) approved by CEN (Comité Européen de Normalisation)

3. Summary of Guide

3.1 In this guide, choices of recovery techniques after the use of antimicrobial products will be considered. By the nature of the distribution of the skin flora, these sampling techniques estimate the flora remaining after antimicrobial use; some of it is superficial and some hidden. An appropriate sampling method can be selected depending on product use and the importance of superficial (transient) and hidden or deep (mostly resident) flora. Recent publications have revealed a greater variety of organisms that populate the skin and comprise the skin microbiome (1, 2).⁴ This information requires a larger selection of recovery media. For certain applications, such as acne studies or when recovery of the greatest diversity of organisms is desired, specific anaerobic/microaerophilic media should be used.

² 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.

³ Available from British Standards Institute (BSI), 389 Chiswick High Rd., London W4 4AL, U.K.

⁴ The boldface numbers in parentheses refer to the list of references at the end of this standard.