



Standard Test Method for Evaluation of Antibacterial Washes by Cup Scrub Technique¹

This standard is issued under the fixed designation E 1874; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This test method is designed to demonstrate the effectiveness of an antibacterial wash product in reducing the resident microbial flora or a marker organism (representing transients) when used as recommended. Microbial activity can be compared with either a bland soap control or to a baseline organism count. Microbial samples can be collected either manually or by the mechanical Thran² spray gun sampler.

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

1.3 In this test method, metric units are used for all applications.

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 limitations prior to use.*

1.5 It is the responsibility of the investigator to determine if Good Laboratory Practice (GLP) and Good Clinical Practice (GCP) is required.

2. Referenced Documents

2.1 ASTM Standards:

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products³

E 1173 Test Method for Evaluation of a Pre-Operative Skin Preparation³

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *bland control soap, n*—a formulation that does not exhibit antimicrobial activity under the test parameters.

3.1.2 *marker organism, n*—an applied inoculum of an organism that has characteristics that allow it to be readily

identified or differentiated. Marker organisms are used to simulate transient microorganisms. It also is referred to as a simulant or bacterial contaminant.

3.1.3 *resident flora, n*—microorganisms that live and multiply on skin, forming a permanent population.

3.1.4 *transient organisms, n*—organisms from the environment that contaminate but do not normally permanently colonize skin.

4. Summary of Test Method

4.1 Resident Flora:

4.1.1 This test method is conducted on a group of volunteer subjects who have refrained from using oral and topical antimicrobials for at least one week and exhibit skin flora counts of at least $1 \times 10^3/\text{cm}^2$ on the target sites.

4.1.2 Activity of the antibacterial wash is measured by comparing bacterial counts obtained at a specified time interval after application of the test material to one test site with the activity of a bland soap control or with a baseline value. The sites used for comparison should be contralateral to the test site whenever possible.

4.2 Transient Organisms (Marker):

4.2.1 This test method is conducted on a group of volunteer subjects who have refrained from using oral and topical antimicrobials for at least one week.

4.2.2 Activity of the antibacterial wash is measured by comparing microbial counts of a marker organism applied to test sites after application of the test material with counts obtained after application of a bland soap control to a contralateral site.

5. Significance and Use

5.1 The procedure should be used to evaluate test materials containing antibacterial ingredients that are intended to reduce significantly the number of organisms on intact skin. It also may be used to provide an indication of residual antibacterial activity.

5.2 Performance of this procedure requires the knowledge of regulations pertaining to the protection of human subjects (see Practices E 1054 and Test Method E 1173).

6. Apparatus

6.1 *Colony Counter*—Any of several types may be used.

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

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² Thran spray gun bacterial sampler may be obtained through Dr. Volker Thran, Kommission der Europäischen Gemeinschaften, Rue de la Loi 200, B-1049 Brussels, Belgium.

³ *Annual Book of ASTM Standards*, Vol 11.05.