



Standard Test Method for Evaluation of Preoperative, Precatheterization, or Preinjection Skin Preparations¹

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^{€1} NOTE—The title was editorially updated in March 2002.

1. Scope

1.1 The test method is designed to measure the reduction of the resident microbial flora of the skin.

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 except for linear measure, in which case inches are used, and metric units follow in parentheses.

1.4 *This standard does not purport to address all of the safety problems, 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 Performance of this procedure requires a knowledge of regulations pertaining to the protection of human subjects (1).²

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 1874 Test Method for Evaluation of Antibacterial Washes by Cup Scrub Technique³

3. Terminology

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

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

3.3 *internal reference formulation*—a formulation with demonstrated performance characteristics within a specific laboratory.

3.4 *sampling fluid*—a recovery fluid that may or may not contain a neutralizer to inactivate the active ingredient(s) in test and internal reference formulations.

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

3.6 *neutralization*—a process that results in quenching the antimicrobial activity of a formulation. This may be achieved through dilution of the formulation to reduce the antimicrobial activity, or through use of chemical agents, called neutralizers, to curtail antimicrobial activity.

4. Summary of Test Method

4.1 These test methods are conducted on human subjects selected randomly from a group of volunteers who, after refraining voluntarily from using topical and oral antimicrobials for at least two weeks (14 days), exhibit acceptably high normal flora counts on the skin sites to be used in testing (see Section 8).

4.2 The antimicrobial activity of the preoperative, precatheterization, or preinjection skin preparations is measured by comparing microbial counts, obtained at various time intervals after application of a test formulation to skin sites, to counts obtained from those same sites prior to application of the test formulation. Skin sites recommended for use in testing are: 1) the inguinal region and the abdomen for preoperative skin preparations; 2) the inguinal region, the subclavian (clavicular) region, and/or the median cubital region of the arm for precatheterization preparations; and 3) the median cubital region of the arm for preinjection skin preparations.

4.2.1 *Preoperative Skin Preparation*—Microbial samples are collected from the test sites a minimum of 3 times after treatment application on both moist and dry skin sites. The sample times are 10 min, 30 min, and 6 h (or other appropriate times) post-treatment.

4.2.2 *Precatheterization Preparation*—Microbial samples are collected from the test sites a minimum of 3 times after treatment application on both moist and dry skin sites. The sample times are “immediate,” 12 h, and 24 h post-treatment. The immediate sample may be 30 sec to 10 min, depending on

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

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