



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

This standard is issued under the fixed designation E1173; 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 The test method is designed to measure the reduction of the microflora of the skin.

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

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

1.3.1 *Exception*—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 Performance of this procedure requires a knowledge of regulations pertaining to the protection of human subjects (1).²

1.5 *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.*

2. Referenced Documents

2.1 *ASTM Standards*:³

E1054 Test Methods for Evaluation of Inactivators of Antimicrobial Agents

E1874 Test Method for Recovery of Microorganisms From Skin using the Cup Scrub Technique

E2756 Terminology Relating to Antimicrobial and Antiviral 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 The boldface numbers in parentheses refer to the list of references at the end of this standard.

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.

3. Terminology

3.1 Terms used in this standard are defined in **E2756**, Standard Terminology Relating to Antimicrobial and Antiviral Agents. Others defined below are specific to their use in this document.

3.2 *Definitions of Terms Specific to This Standard*:

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

3.2.2 *inguen, n*—groin: the junctional region between the abdomen and thigh; pl. *inguina*.

3.2.3 *inguinal crease*—the discrete region of flexure between the abdomen and the thigh.

3.2.4 *sampling fluid*—a recovery fluid that contains a neutralizer demonstrated to inactivate or quench the active ingredient(s) in test and reference control formulations. See Test Method **E1054**.

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

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 preoperative, vascular 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, or the median cubital region of the arm for vascular precatheterization preparations, or both; 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 three (3) times