Designation: E 1173 – 93

Standard Test Method for Evaluation of a Pre-Operative Skin Preparation[1]

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1. Scope

1.1 The test method is designed to determine the ability of a pre-operative skin preparation to reduce the resident microbial flora on the skin when used in a skin pre-operative preparation procedure.

1.2 In this test method, metric units are used for all applications except for distance, in which case inches are used and metric units follow in parentheses.

NOTE 1—A knowledge of microbiological techniques is required for these procedures.

1.3 *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:*

E 1054 Practices for Evaluating Inactivators of Antimicrobial Agents Used in Disinfectant, Sanitizer, Antiseptic, or Preserved Products[2]

3. Summary of Test Method

3.1 This test method is conducted on panelists selected from a group of volunteers who, after refraining from using topical and oral antimicrobials for at least two weeks, exhibit high skin flora counts on the abdomen and groin.

3.2 Activity of the pre-operative skin preparation is measured by comparing microbial counts obtained at various time intervals after application of the pre-operative treatment to skin sites located on the abdomen and in the groin to counts obtained from the same sites prior to treatment application.

NOTE 2—Microbial samples are collected a minimum of three times after treatment application. The first two collections are made 10 min and 30 min post treatment, and the third collection is made no less than 4 h post treatment but may be made later.

4. Significance and Use

4.1 The procedure should be used to test antimicrobial-containing preparations that are intended to be fast-acting and to significantly reduce the number of organisms on intact skin.

4.2 Performance of this procedure requires the knowledge of regulations pertaining to the protection of human subjects.[3]

5. Apparatus

5.1 *Colony Counter*—Any of several types may be used, for example, Quebec colony counter.

5.2 *Incubator*—Any incubator capable of maintaining a temperature of 30 ± 2°C may be used.

5.3 *Sterilizer*—Any suitable steam sterilizer capable of producing the conditions of sterilization.

5.4 *Timer* (stop-clock)—One that can be read for hours and minutes.

5.5 *Examining Table*—Any elevated surface such as a 3 by 6-ft table with mattress or similar padding to allow the subject to recline.

6. Reagents and Materials

6.1 *Bacteriological Pipette*—10.0 and 2.2-mL or 1.1-mL capacity.[4]

6.2 *Water Dilution Bottles*—Any sterilizable glass container having a 150 to 200-mL capacity and tight closure may be used.[5]

6.3 *Scrubbing Cups*—Sterile glass cylinders, height approximately 2.5 cm, inside diameter of convenient size to place on anatomical area to be sampled. Useful sizes range from approximately 1.5 to 4.0 cm.

6.4 *Rubber Policeman*—Can be fashioned in the laboratory or purchased from most laboratory supply houses.

6.5 *Test Formulation*—With directions for use.

6.6 *Sterile Drape or Dressing*[6]—Used to cover treated skin sites.

6.7 *Sampling Solution*—Dissolve 0.4 g KH_2PO_4, 10.1 g Na_2HPO_4 and 1.0 g isocytlphenoxypolyethoxyethanol[7] in 1 L of distilled water. Include in this formulation an inactivator specific for the antimicrobial in the test formulation. Adjust to

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[2] *Annual Book of ASTM Standards*, Vol 11.05.

[3] See *Federal Register*, Vol 46, No. 17, Jan. 27, 1981.

[4] Presterilized/disposable bacteriological pipettes are available from most laboratory supply houses.

[5] Milk dilution bottles of 160-mL capacity having a screw-cap closure are available from Corning Glass Co., Kimble Glass Co. or most local laboratory supply houses.

[6] A suitable covering is TELFA Non-Adherent Dressing, No. 3279, from the Kendall Co.; Hospital Products; Boston, MA 02101.

[7] Triton X-100, is available from Rohm and Haas Co., Philadelphia, PA.