



Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)¹

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1. Scope

1.1 This test method is used to determine the passage of airborne bacteria through porous materials intended for use in packaging sterile medical devices. This test method is designed to test materials under conditions that result in the detectable passage of bacterial spores through the test material.

1.1.1 A round-robin study was conducted with eleven laboratories participating. Each laboratory tested duplicate samples of six commercially available porous materials to determine the LRV. Materials tested under the standard conditions described in this test method returned average values that range from LRV 1.7 to 4.3.

1.1.2 Results of this round-robin study indicate that caution should be used when comparing test data and ranking materials, especially when a small number of sample replicates are used. In addition, further collaborative work (such as described in Practice E 691) should be conducted before this test method would be considered adequate for purposes of setting performance standards.

1.2 This test method requires manipulation of microorganisms and should be performed only by trained personnel. The U.S. Department of Health and Human Services publication *Biosafety in Microbiological and Biomedical Laboratories* (CDC/NIH-HHS Publication No. 84-8395) should be consulted for guidance.

1.3 *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.*

2. Referenced Documents

2.1 ASTM Standards:

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods²

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method²

¹ This test method is under the jurisdiction of ASTM Committee F-2 on Flexible Barrier Materials and is the direct responsibility of Subcommittee F02.60 on Medical Packaging.

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² *Annual Book of ASTM Standards*, Vol 14.02.

3. Terminology

3.1 Definition:

3.1.1 *porous packaging material, n*—a material used in medical packaging which is intended to provide an environmental and biological barrier, while allowing sufficient air flow to be used in gaseous sterilization methods (for example, EO, steam, gas plasma).

4. Summary of Test Method

4.1 Samples of porous materials are subjected to an aerosol of *Bacillus subtilis* var. *niger* spores within an exposure chamber. Spores which pass through the porous sample are collected on membrane filters and enumerated. The logarithm reduction value (LRV) is calculated by comparing the logarithm of the number of spores passing through the porous material with the logarithm of the microbial challenge.

4.2 *Standard Set of Conditions*—This test method specifies a standard set of conditions for conducting the exposure chamber test method. A standard set of conditions is required to enable evaluation of materials between laboratories. The conditions stated in this test method were chosen for several reasons. First, it is difficult to maintain an aerosol of spores over long periods of time. (Also, if the spore challenge time is long, the cost of the test increases). Second, to determine the differences between materials, it is necessary to test the materials under conditions which allow passage of bacterial spores. If a material does not allow any passage of spores, all that can be stated is that it has better resistance to penetration than the severity of the challenge conditions. Third, it is necessary to have a large spore challenge level to be able to detect the passage of spores through the entire range of commercially available porous packaging materials. The standard conditions stated in this test method are based upon these factors. (Additional information may be found in the References section). However, since many factors influence the determination of an appropriate porous material (outlined in 5.1.1-5.1.4), each user may modify these conditions (that is, bacterial challenge, time, flow rate) after first conducting studies at the specified standard conditions. The standard set of target parameters for conducting the test method are as follows:

4.2.1 *Flow Rate Through Sample*—2.8 L/min.

4.2.2 *Exposure Time*—15 min.

4.2.3 *Target Microbial Challenge*— 1×10^6 colony forming