Designation: F1608 – 00(Reapproved 2009)

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

This standard is issued under the fixed designation F1608; 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 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 E691) should be conducted before this test method would be condsidered 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 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

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.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Terminology

3.1 *Definitions:*

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

[1] This test method is under the jurisdiction of ASTM Committee F02 on Flexible Barrier Packaging and is the direct responsibility of Subcommittee F02.15 on Chemical/Safety Properties.

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[2] 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.

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 units (CFU)/sample port.

5. Significance and Use

5.1 The exposure-chamber method is a quantitative procedure for determining the microbial-barrier properties of porous materials under the conditions specified by the test. Data obtained from this test are useful in assessing the relative potential of a particular porous material to contribute to the loss of sterility to the contents of the package versus another porous material. This test method is not intended to predict the performance of a given material in a specific sterile-packaging application. The maintenance of sterility in a particular packaging application will depend on a number of factors, including, but not limited to the following:

5.1.1 The bacterial challenge (number and kinds of microorganisms) that the package will encounter in its distribution and use. This may be influenced by factors such as shipping methods, expected shelf life, geographic location, and storage conditions.

5.1.2 The package design, including factors such as adhesion between materials, the presence or absence of secondary and tertiary packaging, and the nature of the device within the package.

5.1.3 The rate and volume exchange of air that the porous package encounters during its distribution and shelf life. This can be influenced by factors including the free-air volume within the package and pressure changes occurring as a result of transportation, manipulation, weather, or mechanical influences (such as room door closures and HVAC systems).

5.1.4 The microstructure of a porous material which influences the relative ability to adsorb or entrap microorganisms, or both, under different air-flow conditions.

6. Apparatus

6.1 This procedure should be conducted in a microbiological laboratory by trained personnel. As a result, it is assumed that basic microbiological equipment and supplies for conducting routine microbiological manipulations (that is, standard plate counts, sterilization with an autoclave, and so forth) will be available.

6.2 *Exposure Chamber,* constructed primarily from acrylic sheeting and consists of two major sections, as illustrated in Fig. 1. The bottom section contains a six-place manifold connected to six flowmeters, one per port, containing hoses attached to six filtering units. The port to the manifold is attached to a vacuum source. A vacuum gage is mounted between the manifold and the vacuum source. The upper chamber contains a fan for dispersion of the bacterial aerosol, a port for attachment of the nebulizer, a port for exhausting the

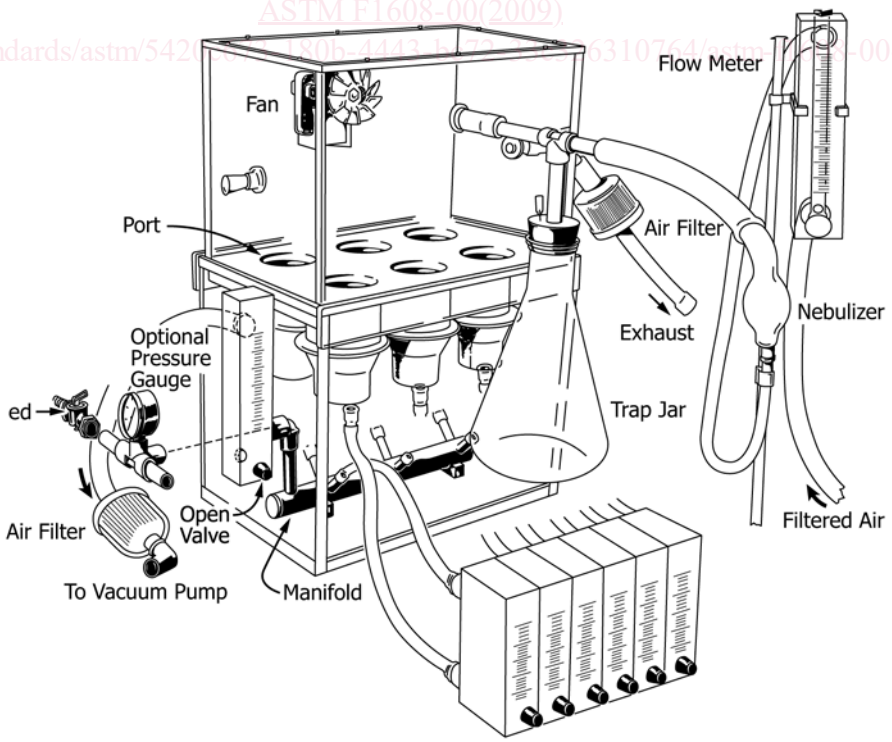

FIG. 1 Exposure Chamber