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Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus*[1]

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INTRODUCTION

Workers, primarily those in the healthcare profession involved in treating and caring for individuals injured or sick, as well as the patient, can be exposed to biological aerosols capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential of airborne exposure through the use of medical face masks.

1. Scope

1.1 This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials.

1.2 This test method is a quantitative method that allows filtration efficiency for medical face mask materials to be determined. The maximum filtration efficiency that can be determined by this method is 99.9 %.

1.3 This test method does not apply to all forms or conditions of biological aerosol exposure. Users of the test method should review modes for worker exposure and assess the appropriateness of the method for their specific applications.

1.4 This test method evaluates medical face mask materials as an item of protective clothing but does not evaluate materials for regulatory approval as respirators. If respiratory protection for the wearer is needed, a NIOSH-certified respirator should be used. Relatively high bacterial filtration efficiency measurements for a particular medical face mask material ~~does~~do not ensure that the wearer will be protected from biological aerosols, since this test method primarily evaluates the performance of the composite materials used in the construction of the medical face mask and not its design, fit, or facial-sealing properties.

1.5 *Units*—The values stated in SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance of the standard.

1.6 This test method does not address breathability of the medical face mask materials or any other properties affecting the ease of breathing through the medical face mask material.

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[1] This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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1.7 This test method may also be used to measure the bacterial filtration efficiency (BFE) of other porous medical products such as surgical gowns, surgical drapes, and sterile barrier systems.

1.8 *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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]
E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging
F1494 Terminology Relating to Protective Clothing
2.2 *ANSI/ASQ Standard:*[3]
ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection by Attributes
2.3 *ISO Standard:*[4]
ISO 2859-1 Sampling Plans for Inspection by Attributes
2.4 *Military Standard:*[5]
MIL-STD 36954C (1973) Military Specification: Mask, Surgical, Disposable

3. Terminology

3.1 *Definitions:*

3.1.1 *aerosol, n*—a suspension of solid or liquid particles in a gas.

3.1.2 *agar, n*—a semi-solid culture medium used to support the growth of bacteria and other microorganisms.

3.1.3 *airborne exposure pathways, n*—inhalation routes of exposure to the medical face mask wearer.

3.1.4 *bacterial filtration efficiency (BFE), n*—the effectiveness of a medical face mask material in preventing the passage of aerosolized ~~bacteria;~~bacteria, expressed in the percentage of a known quantity that does not pass the medical face mask material at a given aerosol flow rate.

3.1.5 *biological aerosol, n*—a suspension of particles containing biological agents which have been dispersed in a gas.

3.1.6 *blood-borne pathogen, n*—an infectious bacterium or virus, or other disease-inducing microbe carried in blood or other potentially infectious body fluids.

3.1.7 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.1.8 *medical face mask, n*—an item of protective clothing designed to protect portions of the wearer's face, including the mucous membrane areas of the wearer's nose and mouth, from contact with blood and other body fluids during medical procedures.

3.1.8.1 *Discussion*—
Medical face masks also function to partly limit the spread of biological contamination from the mask wearer (health care provider) to the patient.

3.1.9 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

[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.
[3] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.
[4] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[5] Available from Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

3.2 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F1494.

4. Summary of Test Method

4.1 The medical face mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of *Staphylococcus aureus*. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material. Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts.

4.2 The agar plates from the cascade impactor are incubated for 48 h and counted to determine the number of viable particles collected. The ratio of the upstream counts to the downstream counts collected for the test specimen are calculated and reported as a percent bacterial filtration efficiency.

5. Significance and Use

5.1 This test method offers a procedure for evaluation of medical face mask materials for bacterial filtration efficiency. This test method does not define acceptable levels of bacterial filtration efficiency. Therefore, when using this test method it is necessary to describe the specific condition under which testing is conducted.

5.2 This test method has been specifically designed for measuring bacterial filtration efficiency of medical face masks, using *Staphylococcus aureus* as the challenge organism. The use of *S. aureus* is based on its clinical relevance as a leading cause of nosocomial infections.

5.3 This test method has been designed to introduce a bacterial aerosol challenge to the test specimens at a flow rate of 28.3 ~~L/mm.~~L/mm (1 ft^3/min). This flow rate is within the range of normal respiration and within the limitations of the cascade impactor.

5.4 Unless otherwise specified, the testing shall be performed with the inside of the medical face mask in contact with the bacterial challenge. Testing may be performed with the aerosol challenge directed through either the face side or liner side of the test specimen, ~~thereby,~~thereby allowing evaluation of filtration efficiencies which relate to both patient-generated aerosols and wearer-generated aerosols.

5.5 Degradation by physical, chemical, and thermal stresses could negatively impact the performance of the medical face mask material. The integrity of the material can also be compromised during use by such effects as flexing and abrasion, or by wetting with contaminants such as alcohol and perspiration. Testing without these stresses could lead to a false sense of security. If these conditions are of concern, evaluate the performance of the medical face mask material for bacterial filtration efficiency following an appropriate pretreatment technique representative of the expected conditions of use. Consider preconditioning to assess the impact of storage conditions and shelf life for disposable products, and the effects of laundering and sterilization for reusable products.

5.6 If this procedure is used for quality control, perform proper statistical design and analysis of larger data sets. This type of analysis includes, but is not limited to, the number of individual specimens tested, the average percent bacterial filtration efficiency, and standard deviation. Data reported in this way help to establish confidence limits concerning product performance. Examples of acceptable sampling plans are found in references such as ANSI/ASQ Z1.4 and ISO 2859-1.

6. Apparatus and Materials

6.1 *Apparatus:*

6.1.1 *Autoclave,* capable of maintaining 121 to 123 °C.

6.1.2 *Incubator,* capable of maintaining 37 ± 2 °C.

6.1.3 *Analytical Balance,* capable of weighing 0.001 g.

6.1.4 *Vortex Mixer,* capable of mixing the contents of 16 mm by 150 mm test tubes.

6.1.5 *Orbital Shaker,* capable of achieving 100 to 250 rpm.

6.1.6 *Refrigerator,* capable of maintaining 2 to 8 °C.

6.1.7 *Six-Stage Viable Particle Cascade Impactor.*

6.1.8 *Vacuum Pump,* capable of 57 L/m (2 ft^3/mm).

6.1.9 *Air Pump/Compressor,* capable of 15 psig minimum.

6.1.10 *Peristaltic Pump,* capable of delivering 0.01 mL/min.

6.1.11 *Nebulizer,* capable of delivering a mean particle size of 3.0 µm ± 0.3 µm and a challenge level of 1700 to 3000 viable particles per test, as determined according to 12.3.

6.1.12 *Glass Aerosol Chamber,* 60 cm by 8 cm diameter tube.

6.1.13 *Colony Counter,* manual or automatic, capable of counting up to 400 colonies/plate.

6.1.14 *Timers,* capable of 0.1 s accuracy.

6.1.15 *Automatic Pipetor,* capable of delivering 1.0 mL ± 0.05 mL.

6.1.16 *Flow Meters,* capable of 28.3 L/min.

6.1.17 *Aerosol Condenser.*

6.1.18 *Pressure Gauge,* capable of 35 kPa ± 1 kPa accuracy.

6.1.19 *Air Regulator.*

6.2 *Materials:*

6.2.1 *Flasks,* 250 to 500 mL Erlenmeyer.

6.2.2 *Petri Dishes,* sterile, 15 by 100 mm.

6.2.3 *Pipettes,* 1 mL, 5 mL, and 10 mL.

6.2.4 *Test Tube Rack,* stainless.

6.2.5 *Bottles,* sterile, glass, 100 to 500 mL capacity.

6.2.6 *Inoculating Loop.*

6.2.7 *Stoppers/Closures,* of appropriate size to fit test tubes.

6.2.8 *Test Tubes,* 16 mm by 150 mm.

7. Reagents

7.1 *Tryptic Soy Agar (TSA).*[6]

7.2 *Tryptic Soy Broth (TSB).*[6]

7.3 *Peptone Water.*[6]

7.4 *Staphylococcus aureus,* ATCC #6538.

8. Hazards

8.1 Sterilize all apparatus and supplies which come into contact with the bacterial challenge ~~suspension,~~suspension by autoclaving at 121 to 123 °C for a minimum of 15 min. Extreme care must be taken to avoid contamination of the laboratory spaces by complete sterilization or high-level disinfection of all apparatus and supplies. This will reduce the possibility of laboratory contamination.

8.2 *Staphylococcus aureus* is common to the normal flora of the body, however, it is a leading cause of nosocomial infections and is a human pathogen. Technicians conducting the testing must have proper microbiological training. Gloves and other protective clothing equipment should be worn during testing to prevent contamination.

8.3 All aerosols must be contained to prevent exposure and reduce laboratory contamination.

9. Media Preparation

9.1 Prepare media using standard microbiological techniques.

9.2 Prepare agar plates for cascade impactor as specified by the manufacturer of the cascade impactor.

10. Test Specimen

10.1 Test specimens shall be taken from manufactured medical face masks, with all layers arranged in proper order.

11. Conditioning

11.1 Condition each specimen for a minimum of 4 h by exposure to a temperature of 21 ± 5 °C (70 ± 10 °F) and relative humidity of 85 ± 5 % as described in Practice E171/E171M using a controlled temperature and humidity chamber or space.

12. Preparation of the Bacterial Challenge

12.1 Inoculate an appropriate volume of tryptic soy broth and incubate with mild shaking at 37 ± 2 °C for 24 ± 2 h.

12.2 Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.

12.3 The challenge delivery rate will be maintained at 1700 to 3000 viable particles per test. The challenge delivery rate is determined each day of testing and is based on the results of the positive control plates when the aerosol is collected in a six-stage viable particle cascade impactor, with no test specimen clamped into the test system. The dilution of the challenge suspension will need to be adjusted to deliver the proper challenge level during testing.

13. Test Procedure

13.1 The aerosol challenge apparatus is outlined in Fig. 1.

[6] The sole source of supply of the apparatus known to the committee at this time is Difco, Detroit, MI 48232. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.