**Designation: F2299/F2299M - 03 (Reapproved 2017)** 

# Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres<sup>1</sup>

This standard is issued under the fixed designation F2299/F2299M; 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 ( $\varepsilon$ ) indicates an editorial change since the last revision or reapproval.

#### 1. Scope

- 1.1 This test method establishes procedures for measuring the initial particle filtration efficiency of materials used in medical facemasks using monodispersed aerosols.
- 1.1.1 This test method utilizes light scattering particle counting in the size range of 0.1 to  $5.0~\mu m$  and airflow test velocities of 0.5 to 25~cm/s.
- 1.2 The test procedure measures filtration efficiency by comparing the particle count in the feed stream (upstream) to that in the filtrate (downstream).
- 1.3 The values stated in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.
- 1.4 The following precautionary caveat pertains only to the test methods portion, Section 10, of this specification. 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.
- 1.5 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:<sup>2</sup>

D1356 Terminology Relating to Sampling and Analysis of Atmospheres

D1777 Test Method for Thickness of Textile Materials
D2905 Practice for Statements on Number of Specimens for
Textiles (Withdrawn 2008)<sup>3</sup>

D3776/D3776M Test Methods for Mass Per Unit Area (Weight) of Fabric

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

F50 Practice for Continuous Sizing and Counting of Airborne Particles in Dust-Controlled Areas and Clean Rooms Using Instruments Capable of Detecting Single Sub-Micrometre and Larger Particles

F328 Practice for Calibration of an Airborne Particle Counter Using Monodisperse Spherical Particles (Withdrawn 2007)<sup>3</sup>

F778 Methods for Gas Flow Resistance Testing of Filtration Media

F1471 Test Method for Air Cleaning Performance of a High-Efficiency Particulate Air Filter System

F1494 Terminology Relating to Protective Clothing

F2053 Guide for Documenting the Results of Airborne Particle Penetration Testing of Protective Clothing Materials

#### 3. Terminology

- 3.1 Definitions:
- 3.1.1 *aerosol*, *n*—a suspension of a liquid or solid particles in a gas with the particles being in the colloidal size range.
- 3.1.1.1 *Discussion*—In this test method, aerosols include solid particles having a diameter of 0.1 to 5  $\mu$ m suspended or dispersed in an airflow at concentrations of less than 102 particles/cm<sup>3</sup>.
- 3.1.2 *isokinetic sampling*, *n*—a condition where the velocity of the airflow entering the sampling nozzle is the same as the velocity of the airflow passing around the sampling nozzle.

<sup>&</sup>lt;sup>1</sup> 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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<sup>&</sup>lt;sup>2</sup> 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.

<sup>&</sup>lt;sup>3</sup> The last approved version of this historical standard is referenced on www.astm.org.

- 3.1.3 *monodispersion*, *n*—scattering of discrete particles in an airflow where the size is centralized about a specific particle size.
- 3.1.3.1 *Discussion*—In this test method, the monodispersed particle distribution has a mean diameter size of the aerosol in the 0.1 to 5  $\mu$ m range, with a coefficient of variation of the mean diameter of  $\pm 10$ % or less, as certified by the manufacturer.
- 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 Filtered and dried air is passed through an atomizer to produce an aerosol containing suspended latex spheres.
- 4.1.1 This aerosol is then passed through a charge neutralizer.
- 4.1.2 The aerosol is then mixed and diluted with additional preconditioned air to produce a stable, neutralized, and dried aerosol of latex spheres to be used in the efficiency test.

# 5. Significance and Use

- 5.1 This test method measures the initial filtration efficiency of materials used in medical face masks by sampling representative volumes of the upstream and downstream latex aerosol concentrations in a controlled airflow chamber.
- 5.2 This test method provides specific test techniques for both manufacturers and users to evaluate materials when exposed to aerosol particle sizes between 0.1 and 5.0  $\mu$ m.
- 5.2.1 This test method establishes a basis of efficiency comparison between medical face mask materials.
- 5.2.2 This test method does not establish a comprehensive characterization of the medical face mask material for a specific protective application.
- 5.3 This test method does not assess the overall effectiveness of medical face masks in preventing the inward leakage of harmful particles.
- 5.3.1 The design of the medical face mask and the integrity of the seal of the medical face mask to the wearer's face are not evaluated in this test.
- 5.4 This test method is not suitable for evaluating materials used in protective clothing for determining their effectiveness against particulate hazards.
- 5.4.1 In general, clothing design is a significant factor which must be considered in addition to the penetration of particulates.

# 6. Apparatus

- 6.1 The aerosol test system incorporates the components as shown in Fig. 1. A more detailed diagram of test system components and equipment is found in STP 975.<sup>4</sup>
  - 6.2 Equipment:
  - 6.2.1 Clean, dry compressed air supply,
  - 6.2.2 HEPA filters (2),
- $^4\,\mathrm{Symposium}$  on Gas and Liquid Filtration, ASTM STP 975, ASTM, Vol 11, 1986, pp. 141-164.

- 6.2.3 Aerosol generator,
- 6.2.4 Charge neutralizer,
- 6.2.5 Humidifier.
- 6.2.6 Test filter holder and duct assembly,
- 6.2.7 Pressure drop measuring device,
- 6.2.8 Air flow rate measuring device,
- 6.2.9 Temperature and relative humidity detectors,
- 6.2.10 Air blower (optional for negative pressure system), and
  - 6.2.11 Optical particle counters.

# 7. System Preparation and Control

- 7.1 To test in the aerosol particle size range of 0.1 to 5.0 µm, it is necessary to maintain a very clean inlet air supply. Achieve acceptable levels of background aerosol by passing the atomizing air supply sequentially through a silica gel dryer (for reduction of moisture), a molecular sieve material (for removal of oil vapor), and an ultra-low penetrating aerosol (better than 99.9999 % efficient at 0.6  $\mu m$ ) filter. Then, supply the air to the test chamber of aerosol generator through pressure regulators of  $\pm 7$  kPa [ $\pm 1$  psi] accuracy. For throttling of the main airflow as well as other flow splitting requirements, use needle valves to maintain adequate flow stability and back pressure. For recommended flow control measurement, see 7.6. Monitor and record the temperature and relative humidity at the exhaust port of the test chamber. To avoid interference from the test aerosol. take the humidity measurement from the outlet side of the HEPA filter (see 7.6.2) with an in-line probe.
- 7.1.1 To provide a stable, reproducible aerosol through the test material that remains constant over the sampling time of the efficiency test, maintain the main test duct and filter medium specimen holder in a vertical orientation to minimize aerosol sedimentation losses.

# 7.2 Aerosol Generation:

- 7.2.1 The aerosol generator must be capable of a latex sphere count concentrations output of 10<sup>7</sup> to 10<sup>8</sup> particles/m<sup>3</sup>. The suspension reservoir must be large enough to sustain a stabilized output greater than 1 h. Two commercially available atomizing techniques that provide these concentrations of the latex spheres are presented in Figs. 2 and 3.
- 7.2.2 As viewed in Figs. 2 and 3, these techniques utilize the atomizing of suspended uniform latex spheres from dilute water suspensions. One-liter quantities of these suspensions can be made by diluting the 10 %-by-volume solids of the uniform latex spheres at 1000:1 or greater dilution ratios in deionized, filtered distilled water.

Note 1—The suspensions have a three- to six-month usable life. Ideal suspension dilutions are a function of the latex particle size to the aerosol generator droplet size. In order to minimize the atomization of doublets or higher aerosol multiples in the drying process, a recommended latex suspension dilution ratio has been established so that dilution ratios are on the order of 1000:1 to 10 000:1. Other aerosols produced from these atomizers can be classified into monodispersed systems, but for an industrially recognized standard of particle size and composition, the uniform latex spheres are the most reproducible and readily available particles.

<sup>&</sup>lt;sup>5</sup> Raabe, O., "The Dilution of Monodispersed Suspensions for Aerosolization," American Industrial Hygiene Association Journal, Vol 29, 1968, pp. 439–443.

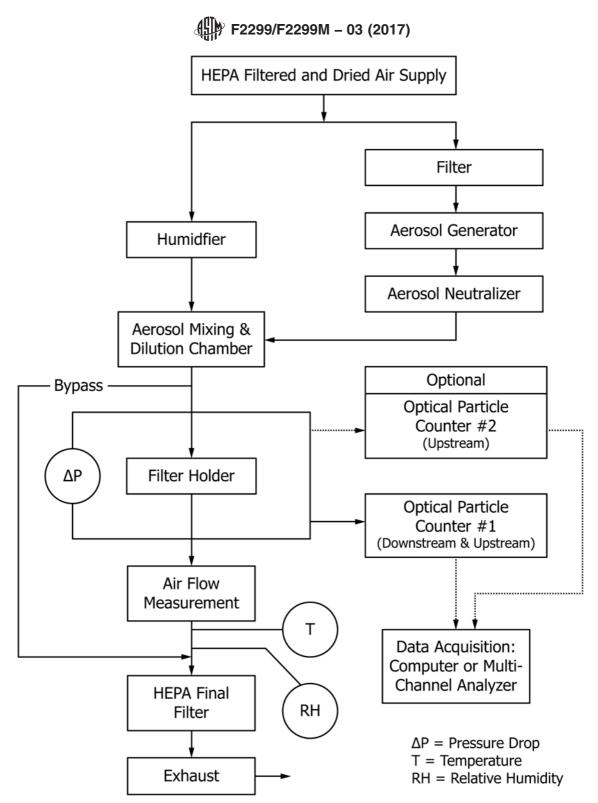
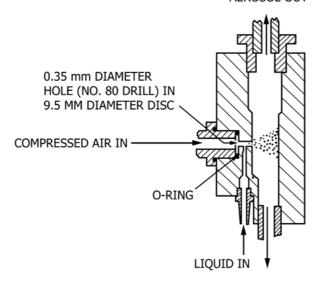


FIG. 1 Schematic of Test Method

7.3 Aerosol Neutralizer—This procedure recommends the use of an aerosol charge neutralizer at the inlet of the test

system. This technique generally will ensure aerosol surface charge stability. The aerosol neutralizer can be in the form of a

AEROSOL OUT



EXCESS LIQUID TO CLOSED RESERVIOR

FIG. 2 Atomizer

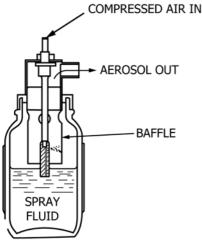


FIG. 3 Collision Atomizer

radioactive decay ionizer. The desired Boltzmann's charge equilibrium for the aerosol has been described.<sup>6</sup> Typically, an ionizing flux of 10<sup>3</sup> mCi/m<sup>3</sup>/s provides the required aerosol neutralization.

Note 2—A Krypton 85 source, a Polonium 210 source, or a Corona electrical discharge, A-C source have been found satisfactory for this purpose.

7.4 Aerosol Dilution and Humidity Control—Prior to injection or dispersion of the initial aerosol concentration into the main test chamber, dry or dilute the aerosol with make-up airflow for the final test aerosol concentration as needed. Conduct material testing in a relative humidity range of 30 to 50 % and hold the relative humidity  $\pm 5$  % during a given test.

Complete the aerosol mixing a minimum of 8 duct diameters distance before the inlet sampling probe and the material specimen.

### 7.5 Material Specimen Holder:

7.5.1 The material specimen holder and test section shall be a continuous straight-walled vessel, interrupted only by the filter medium sample throughout its length. The material specimen holder must provide an uninterrupted airflow, passage without measurable peripheral air leakage. Use a 50- to 150-mm [2- to 6-in.] cross-sectional diameter for the medium sample size. Choose the specimen size to ensure that the test specimen is representative of the overall material and provides enough rigidity to be self-supporting.

Note 3—The recommended filter medium cross sections allow face velocities of 0.5 to 25 cm/s [approximately 1 to 50 ft/min] at flow rates of 1 L/min to 1  $\rm m^3/min$  [approximately 0.035 to 35 ft<sup>3</sup>/min] to be developed in testing.

7.5.2 Introduce the latex aerosol a minimum of 10 duct diameters upstream of the material specimen and at a sufficient distance to provide thorough mixing before the upstream sampling probe.

#### 7.6 Airflow Metering:

7.6.1 Use a positive pressure (compressed air) or a negative pressure (exhaust fan or blower) system for the airflow to the main test chamber. For the application of any of these techniques of airflow measurement and calibration, refer to the standards and practices of the American Society of Mechanical Engineers.

7.6.2 Use a high efficiency particulate aerosol (HEPA)-type filter (99.97 % efficiency on 0.3- $\mu m$  aerosol) upstream of the systems airflow measurement. Size the HEPA-type filter to provide adequate system collection of the exhausting test aerosol.

<sup>&</sup>lt;sup>6</sup> Liu, B. Y. H. and Piu, D. Y. H., "Electrical Neutralization of Aerosols," *Aerosol Science*, Vol 5, 1974, pp. 465–472.

### 7.7 Pressure Drop Measurement:

7.7.1 Use static pressure taps that are flush with the duct walls at a distance of 1 duct diameter upstream and downstream of the filter medium faces.

7.7.2 With no filter medium in the sample holder, there shall be no measurable pressure loss between the inlet-side and outlet-side pressure taps. Use a pressure-measuring instrument capable of being read to  $\pm 0.025$  cm of water gauge to make this determination.

7.8 Aerosol Sample Extraction and Transport—Use geometrically and kinematically identical centerline probes to extract representative aerosols from the inlet and outlet sides of the material specimen test section. Use probes that have a radius of curvature (R) of 12 cm or R/D (Diameter) > 20:1 and present a cross-sectional area of less than 10 % of the cross-sectional area of the test system ducting. Locate the upstream probe 8 duct diameters (minimum) downstream of the aerosol injection point and 2 duct diameters ahead of the material specimen. Locate the downstream probe 3 duct diameters downstream of the filter medium specimen. To minimize aerosol sampling transport line losses due to settling, diffusion, and inertia for the aerosol particle size range of the test method, use the following characteristics of the sampling.

7.8.1 Maintain the sampling line flow in the laminar flow regime; that is, the Reynolds number must be less than 1000. Calculate the Reynolds number in accordance with the following formula:

$$Re\# = \frac{\rho_g V D_1}{\mu_g} \tag{1}$$

where:

 $\rho_g$  = gas density (kg/m<sup>3</sup>),

V = gas velocity (m/s),

 $D_1$  = inside diameter of sampling lines (m), and

 $\mu_g$  = gas viscosity (kg/m-s).

7.8.2 Limit horizontal sampling line length to less than 100 cm and the total sample transport line to less than 2 m.

7.8.3 Maintain all radius of curvatures to greater than 12 cm.

Note 4—Isokinetic aerosol sampling is recommended to minimize probe inlet losses. However, in those cases where isokinetic conditions cannot be met, it is recommended that the operation of these probes be  $\pm\,10~\%$  of isokinetic or that the particle Stokes number at the probe inlet be held to less than 1.0 in order to minimize inertial losses at the probe inlet. It is also recommended that the Reynolds number of the sample flow lines be held to less than 2000. The Stokes number is calculated using the following formula:

$$St\# = \frac{D_p^2 \rho_p VC}{9\mu_o D_n} \tag{2}$$

where:

 $D_n$  = particle diameter (m),

 $\rho_n^p$  = particle density (kg/m),

 $\vec{V}$  = velocity of approach (m/s),

 $\mu_o$  = gas viscosity (kg/m-s),

 $\vec{D}_n$  = diameter of sampling nozzle (m), and

C = Cunningham correction factor, which for particles larger than  $1.0 \times 10^{-6}$  m (1  $\mu$ m) is assumed to be 1.0.

Note 5-Recommended sampling flow rates for extraction of the

mounting volume are to be less than  $10\,\%$  of the total test system flow rate.

## 7.9 Aerosol Concentration Counting:

7.9.1 This practice is structured for utilizing automatic, single particle light-scattering counters. For an illustration of the application, calibration, and analyses by these instruments, refer to Practices F50 and F328.

7.9.2 Generally, single particle light-scattering counters measure in the range of 0.1 to 15  $\mu$ m equivalent spherical diameter, with a single particle measurement dynamic range of 50 to 1. These instruments shall be calibrated within the test system, similar to the manufacturer's standard calibration and with the test aerosol as conditioned for the efficiency testing. For efficiencies approaching 99.9 % and greater, a higher test inlet aerosol concentration is usually required to maintain reasonable sampling times at the outlet. If these conditions exceed the suggested coincidence limits for the single particle counters, an inlet dilution at the optical particle counter of the aerosol is required. Achieve inlet dilution by passing some portion of the conditioned inlet aerosol through a HEPA-grade filter and remixing it with the sampled inlet aerosol to the light-scattering particle counter.

7.9.3 Establish accurate dilution ratios in order to specify the exact aerosol sample volume extracted from the inlet flow for aerosol particle counting. Recommended sampling times are on the order of 10 to 60 s. If separate particle counters are used for inlet and outlet aerosol concentrations, they must be calibrated for the aerosol particle size and concentration response needed within the test system.

Note 6—The flow rate of the respective optical particle counter must be measured and recorded.

Note 7—For test system changes in sampling configuration, that is, alternate upstream and downstream sampling or opening and closing the aerosol flow system, allow a purge time so that 25 sampling line volume changes can occur before counting resumes. (For flow rates of 7 L/min in 6 mm ID samplings, the purge time will be between 10 to 15 s.)

#### 8. Number of Downstream/Upstream Sampling Intervals

8.1 The statistical selection of the number of downstream/ upstream sampling intervals is based on no specimen present in the filter holder. The test apparatus must meet a  $100 \pm 1 \%$  penetration average with a coefficient of variation of 3 %. Use the procedure in 8.2 to obtain this selection. Run this procedure twice and use the number of the two results.

# 8.2 Procedure:

8.2.1 Obtain two consecutive downstream/upstream (100 %) penetration sample observations. Calculate their average.

8.2.2 If the average is between 99 and 101 %, proceed to 8.2.4. If the average is not between 99 and 101 %, run another sample and average it with the previous two samples.

8.2.3 If the new average is between 99 and 101 %, proceed to 8.2.4. If not, continue this process until 100  $\pm$  1 % penetration is achieved. If 100 % penetration is not achieved, the test apparatus is biased and must be corrected.

8.2.4 Subtract the highest test sample observation from the lowest sample to give the sample range at that certain number of sample observations. Go to Table 1 for that number of observations and read the adjustment number.

TABLE 1 Number of Sampling Intervals<sup>4</sup>

	J
Number of	Adjust if Range
Observations	is Greater Than
2	4.155
3	4.965
4	5.445
5	5.790
6	6.045
7	6.255
8	6.435
9	6.585
10	6.705
11	6.825
12	6.930
13	7.035
14	7.110
15	7.200
16	7.275
17	7.335
18	7.395
19	7.455
20	7.515

<sup>&</sup>lt;sup>A</sup> Compare the sample range to the adjustment number.

- 8.2.5 The adjustment number is the greatest range for a coefficient of variation of 3 % at a penetration of  $100 \pm 1$  % for the specified number of observations.
- 8.2.6 If the sample range is equal to or less than the adjustment number, the number of sample observations is the number of downstream/upstream sampling intervals for filter testing. If the sampling range is greater than the adjustment number, then another 100~% penetration sampling observation must be run.
- 8.2.7 If the new penetration is greater or less than the bounds of the past data, a new range is calculated. If, at the new number of sample observations, the new range is greater than the new adjustment number, this process is repeated until the sample range is less than the adjustment number. That number of sample observations is the number of downstream/upstream sampling intervals used for filter testing.
- 8.2.8 If in a suitable number of intervals it is found that the sample range will always be greater than the adjustment number at 20 observations, then the 100 % penetration data is too variable and action must be taken to correct the particle concentration variability or the particle-counting methodology.

## 9. Material Specimen Selection and Conditioning

- 9.1 Measure material thickness and unit area weight in accordance with Test Methods D1777 and D3776/D3776M, respectively.
- 9.2 Apply a sealing force that does not distort or influence the integrity or continuity of the material specimen.
- 9.3 Use a total of five different material specimens. For statistical-based sampling, choose a number of material specimens as indicated in Practice D2905 or Methods F778.
- 9.4 If no prior efficiency criteria are available for a specific material, sample to establish a 95 % confidence level about the mean efficiency.
- 9.5 Precondition each material specimen at the test duct conditions at 30 to 50  $\pm$  5% relative humidity and a temperature of 21  $\pm$  3 °C [70  $\pm$  5 °F]. Retain all specimens in

an individual closed container to avoid unnecessary contamination and handling prior to testing.

### 10. Test Procedure

- 10.1 System Start-Up:
- 10.1.1 Set main airflow, dilution airflow, and aerosol generator airflow to test conditions,
- 10.1.2 Establish airflow controls at required test face velocities as to have air dilution (drying) for aerosol generation of 2:1 or greater. Purge main airflow for 10 to 15 min,
- 10.1.3 Warm up optical particle counter (OPC) for 15 to 30 min.
- 10.1.4 After OPC warm-up, check built-in calibration signal or OPC output signal on an oscilloscope for stable gain on photomultiplier tube or other optical detectors.

Note 8—This test is conducted with filtered ambient air flowing through the OPC.

- 10.1.5 Switch the OPC into the main airflow and balance OPC airflow against the main airflow. Observe OPC count data.
  - 10.2 Aerosol Drying Verification:
- 10.2.1 Set up the aerosol generator with a nominal volume of the distilled water to be used in the latex dilutions.
- 10.2.2 Without a material specimen in the test system, establish the main system airflow and the OPC sampling airflow for the upstream sampling probe.
- 10.2.3 Sample the upstream and downstream airflow for 1 min each.
- 10.2.4 Verify complete drying of the aerosol droplets by comparing these counts to counts obtained in 10.1.5.
- 10.2.5 Record the relative humidity and the temperature of the airflow.
- 10.2.6 Run this drying test for approximately 1 h, sampling every 15 min for upstream and downstream counting and record aerosol stability and system relative humidity. Measure the water consumption of the aerosol generator.
- 10.2.7 Record any dilution airflow and the required air pressure for the aerosol generator.
  - 10.3 Aerosol Stability and Zero Efficiency Check:
- 10.3.1 Fill the aerosol generator with the desired dilution of latex suspension, Without a filter media sample in the test system, close the system and establish the required system airflows.
- 10.3.2 Stabilize the system airflow with the aerosol suspension for approximately 5 min, then begin successive 1-min upstream and downstream counts for 15 min or until reproducible counts are established. Reproducibility is to meet the sampling criteria in Section 8.
- 10.3.3 Verify that counting is within a 10% coincidence of the OPC.

Note 9—The OPC channels to be used for counting include channels either side of the maximum count channel that produce a count of  $50\,\%$  of the maximum channel count or greater.

Note 10—There must be a clear minimum channel separation in the OPC between any residue particle distribution and the latex particle distribution in the test aerosol. If necessary, adjust the gain on the OPC to establish this separation.

10.4 Efficiency Test:

- 10.4.1 Install the material specimen in the test system and re-establish the required airflows.
- 10.4.2 Monitor the OPC airflow and adjust for the added material specimen *P* on the sample flow.
- 10.4.3 Record the temperature, the relative humidity of the test airflow, and the P of the filter media.
- 10.4.4 Sample and record the upstream and downstream aerosol counts for a minimum of five counts at each position using a 1-min sampling time.
- Note 11—If the downstream count is less than 100, extend the sampling time until 100 counts are obtained. However, do not count longer than 5 min to avoid loading the material specimen.
- 10.4.5 Monitor the upstream counts; if these counts fall outside the criteria of 8.1, stop the test and check the system for aerosol generation instability.
- 10.4.6 Average the upstream counts and the downstream counts, then calculate the decimal efficiency by the following definition:

$$Efficiency = 1 - penetration = 1 - \frac{(average downstream counts)}{(average upstream counts)}$$

#### 11. Calculations

11.1 Prior to the calculations of efficiency, any corrections for background aerosol or apparent background aerosol must be made to the single particle light-scattering counters. If the background count aerosol exceeds 1 % of the outlet concentration, verify the integrity of the light-scattering particle counter, then make corrections through the following equations:

inlet concentration = inlet aerosol count - inlet background count, and outlet concentration - outlet aerosol count - inlet background count

11.2 Calculate the aerosol filtration efficiency for a specific particle size using the following formula:

$$\eta(D_n) = [1 - P(D_n)] 100 \tag{3}$$

where:

 $P(D_n)$  = the penetration, and

 $P(D_p^P)$  = (downstream particle concentration) / (upstream particle concentration).

### 12. Report

- 12.1 Report the following information:
- 12.1.1 Description of the medical face mask material tested, including its identification, description, manufacturer, lot identification or manufacture date, thickness, basis weight, and an indication of any treatment prior to testing.
- 12.1.2 A description of the specific challenge particles used, including the size distribution, and percent concentration.
- 12.1.3 Details for the specific testing conducted including the temperature, relative humidity, exposed specimen area, flowrate, pressure drop, test duration, test sensitivity, and controls used in the testing.
- 12.1.4 An identification of the aerosol generator, the system flow meters and the particle counters with their current calibrations.

**TABLE 2 Calculated Efficiencies Versus Particle Diameter** 

Material Particle Diameter/ Std. Deviation		Face Velocity	Pressure Drop	Efficiency	
identification –	$D_p$ , $\mu m$ Std. Deviation		cm/s	kPa	%
ABC-1	1.0	0.001	10	0.25	95

**TABLE 3 High Variability Range** 

	Mean	Standard Deviation	Percent Variation 95 % Confidence Level
Laboratory 1	-0.5.599	0.1328	4.76
Laboratory 2	-0.5.969	0.2241	<u>7.54</u>
	Average		6.15

**TABLE 4 Low Variability Range** 

	Mean	Standard Deviation	Percent Variation 95 % Confidence Level
Laboratory 3	-1.6429	0.0310	3.80
Laboratory 4	-1.6961	0.0273	3.24
Laboratory 5	-1.7057	0.0272	<u>3.20</u>
	Average		3.41

**TABLE 5 Components of Variance** 

Source	Component of Variance	Percent of Total Variance	Estimated Standard Deviation
Laboratory	0.067362	66.54	0.259542
Sample	0.012329	12.18	0.111037
Run	0.021543	21.28	0.146776
Total	0.101235		0.318174

**TABLE 6 Components of Variance** 

Source	Component of Variance	Percent of Total Variance	Estimated Standard Deviation
Laboratory	0.001088	55.15	0.329880
Sample	0.000386	19.54	0.019636
Run	0.000499	25.31	0.022345
Total	0.001973		0.044420

12.1.5 Test results showing the date tested, number of specimens tested, the location of the specimens from the material or protective clothing sample, and the percent penetration for each particle size on each specimen. Prepare a table listing the calculated efficiencies versus the particle diameter, the face velocity (flow rate) and the pressure drop. See Table 2. 12.1.6 Document results in accordance with Guide F2053.

#### 13. Precision and Bias

- 13.1 No justifiable statement of accuracy can be made since the filtration penetration of a material cannot be established by an independent referee method and since no reproducible standard material specimens exist.
  - 13.2 Precision Analysis:
- 13.2.1 Filtration penetration mechanisms through flat-sheet fibrous filter material is an exponential function with changes in filter structure (basis weight, fiber size, and/or porosity) and with changes in filter challenge (face velocity, particle size,

particle structure and/or particle electrostatic charge). The statistical distribution function for penetration data is, therefore, approximated as log-normal. This means that the penetration data must be transformed prior to statistical manipulation by taking the natural logarithm of each measured penetration fraction (% $P(D_p)$  / 100). After statistical manipulation, take the antilog of the natural logarithm of the mean penetration (geometric mean) and use this mean penetration to calculate the efficiency. If the antilog of the standard deviation of the transformed data is taken, it is called the geometric standard deviation. If the data are not transformed, then variability is an exponential function with penetration range, creating a situation where the lower the penetration, the greater the variability.

- 13.2.2 Variability in this section is reported as the percent coefficient of variation of the transformed data at the 95 % confidence level. Means are negative, since the natural logarithms of numbers less than one are negative.
- 13.2.3 A first multilaboratory experiment, published in STP 975<sup>7</sup> showed that when sphere diameter and face velocity are varied, a high region of variability (large spheres, low face velocity) and a low region of variability (small spheres, high face velocity) exist. Precision statements for each of these regions would provide the range of possible variability for this test.
- 13.2.4 A second multilaboratory experiment was performed in the format of two three-level completely nested designed experiments. The output from these designs gave the single laboratory/single operator precision, the multilaboratory/single laboratory precision, and also an analysis of the contribution of the separate components of the total variance—laboratory, sample, and run duplication. One experiment was run at the region of high variability, the other was run in the region of low variability. The filters used were of flat fiberglass paper of low variability. Standard deviations presented here are based on n, not (n-1).
- 13.3 *Single Laboratory/Single Operator Precision*—Two regimes of variability are presented.
- 13.3.1 High Variability Range (Large Spheres, Low Face Velocity)—The average single laboratory/single operator percent variation of the natural logarithms of the penetration

 $^7$  Symposium on Gas and Liquid Filtration, ASTM STP 973, ASTM, Vol 1, 1986, pp. 141–151.

- fraction of this test at a challenge of 2.0-µm sphere diameter and 1-cm/s face velocity is  $6.15\,\%$  at the  $95\,\%$  confidence level. See Table 3.
- 13.3.2 Low Variability Range (Small Spheres, High Face Velocity)—The average single laboratory/single operator percent variation of the natural logarithms of the penetration fraction of this test at a challenge of 0.62-µm sphere diameter and 25-cm/s face velocity is 3.41 % at the 95 % confidence level. See Table 4.
- 13.4 Multilaboratory-Single Operator Precision—Two regimes of variability are presented.
- 13.4.1 High Variability Range (Large Spheres, Low Face Velocity)—The multilaboratory/single operator percent variation of the natural logarithms of the penetration fraction of this test between two laboratories is 8.95 % at the 95 % confidence level.
- 13.4.2 Low Variability Range (Small Spheres, High Face Velocity)—The multilaboratory/single operator variation of the natural logarithms of the penetration fraction of this test between three laboratories is 3.94 % at the 95 % confidence level.
  - 13.5 Analysis of Component of Variance:
- 13.5.1 High Variability Range (Large Spheres, Low Face Velocity)—Two laboratories ran data on two runs of 25 fiberglass paper filters of low variability challenged with 2.02-µm spheres at 1-cm/s face velocity. Results on the different components of variance of the natural logarithms of the penetration fractions are presented in Table 5.
- 13.5.2 Low Variability Range (Small Spheres, High Face Velocity)—Three laboratories ran data on two runs of 25 fiberglass paper filters of low variability challenged with 0.62-µm spheres at 25-cm/s face velocity. Results on the different components of variance of the natural logarithms of the penetration fraction are presented in Table 6.
- 13.5.3 *Discussion*—In each of these regimes of high and low variabilities, over 80 % of the variance is attributable to differences between laboratories and their ability to reproduce data.

Note 12—An analysis of variance gives a standard deviation based on not (n-1).

#### 14. Keywords

14.1 filtration; medical face mask; particle filtration efficiency; particles; particulate

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