Designation: D6124 – 06 (Reapproved 2022)

Standard Test Method for Residual Powder on Medical Gloves[1]

This standard is issued under the fixed designation D6124; 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.

INTRODUCTION

This standard is designed to determine the amount of residual powder (or filter-retained mass) found on medical gloves. This standard consists of two test methodologies. Procedure I is a method for the quantification of residual powder on gloves described as non-powdered, powder-free, powderless, no powder, or other words to that effect. Procedure II is a test method for the quantitation of powder (and other filter-retained mass) on powdered gloves.

1. Scope

1.1 This test method covers the determination of average powder or filter-retained mass found on a sample of medical gloves as described in the introduction.

1.2 The average powder mass per glove is reported in milligrams.

1.3 The safe and proper use of medical gloves is beyond the scope of this test method.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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.*

1.6 *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]

D4483 Practice for Evaluating Precision for Test Method Standards in the Rubber and Carbon Black Manufacturing Industries

2.2 *Other Documents:*

American National Standard ANSI/ASQC Z1.9–1993 Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *medical gloves*—as used in this test method, refer to both surgical and examination gloves.

3.1.2 *powder*—any water insoluble, filter-retained residue remaining on the glove after the manufacturing process.

3.1.3 *powder-free*—is also referred to as powderless, no powder, non-powdered, or words to that effect.

4. Significance and Use

4.1 This test method is designed to determine the amount of residual powder and non-powder solids found on medical gloves.

4.2 This test method is suitable and designed as a reference method to evaluate samples of medical gloves.

4.3 The mass found using Procedure II, for powdered gloves, is assumed to be a combination of water-insoluble residue remaining after the manufacturing process, former release agents and donning powder.

5. Apparatus

5.1 *Analytical Balance* capable of readability and repeatability to 0.1 mg.

[1] This test method is under the jurisdiction of Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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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.

[3] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

5.2 *Reciprocal or Rotator Mechanical Shaker* capable of a minimum speed of 1.7 Hz (100 cycles/min).

5.3 *Gravimetric convection oven.*

6. Procedure I, for Quantitation of Powder on Powder-free Gloves

6.1 *Powder Test, Powder-Free Gloves—Total Glove:*

6.1.1 Prior to use, all glassware and tweezers shall be rinsed with deionized or distilled water.

6.2 *Filter Preparation:*

6.2.1 Use a 47 mm, 2.7 µm pore size glass microfiber filter and a suction filtration apparatus. Use of a TFE-fluorocarbon or equivalent-rimmed housing base is recommended if filters adhere or tear upon removal from glass-rimmed surface.

6.2.2 Insert the filter disk in the filtration apparatus. Apply suction and wash the filter disk with three successive 50 mL portions of deionized or distilled water. Continue suction to remove all traces of water and discard the washings. Remove the filter from the filtration apparatus and transfer it to a rinsed and dried glass petri dish or equivalent. Dry in an oven at 100 ± 5°C for 1 h. Store the dried filter in a desiccator prior to use. Before use, pre-weigh the dried filter, weighing immediately after removal from the desiccator.

6.3 *Sample Selection and Test:*

6.3.1 Randomly select five gloves from each lot to be evaluated. Gently remove glove from original container.

6.3.2 Place 500 mL of deionized or distilled water into a 1000 mL flask. Water used in this procedure should be at 20 to 25°C.

6.3.3 Place a glove into the beaker/flask with 1 to 3 cm of the cuff area stretched over the lip. Hold a portion of the cuff away from the lip to vent air from the beaker/flask and add 250 mL of deionized or distilled water to the inside of the glove, making certain the upper cuff is rinsed as the water is poured. Additional water may be used if coverage on the glove exterior is insufficient, or as needed for vacant space within the glove. However, space must be adequate to allow agitation.

6.3.4 Cap the flask with a rubber stopper or other secure cover and agitate for 30 s on a mechanical shaker with a minimum side-to-side or rotational speed of 1.7 Hz (100 cycles/min).

NOTE 1—Securing the flask at a 45° angle has been noted to improve the slosh effect and reduce the tendency for twisting at the cuff.

6.3.5 Remove the cap and pour the water from the inside of the glove into a 600 mL glass beaker. Repeat 6.3.3 – 6.3.5 with the remaining four samples using the same 250 mL of water contained in the 600 mL glass beaker and the same 500 mL of original water added in 6.3.2.

6.3.6 Pour the water from the 600 mL glass beaker and the beaker/flask through the suction filtration unit containing the weighed filter.

6.3.7 Rinse the 600 mL glass beaker with 250 mL of deionized or distilled water. Successively add the rinse water to the beaker/flask and into the suction filtration unit containing the weighed filter.

6.3.8 Rinse the beaker/flask, cap, filter housing and any other portions of the test apparatus that may contain residual powder to ensure all powder extract is filtered.

6.3.9 Continue suction to remove all traces of water and discard the washings. Remove the filter from the filtration apparatus and transfer it to a rinsed and dried glass petri dish or equivalent. Dry in an oven at 100 ± 5°C for 1 h. Cool in a desiccator for 30 min prior to weighing. Weigh immediately after removal from the desiccator.

6.4 *Blank Control*—Using a beaker/flask and water identical to that described in 6.3.2 and filter identical to that described in 6.2.1, establish a Blank Control for each of lot of water tested using the same techniques described above. That is, filter 1000 mL of the water. Dry, desiccate, and weigh the filter as described in 6.2.2.

6.5 *Calculation of Results:*

6.5.1 Compute the mass change in the test filter. Subtract any positive mass change of the Blank Control Filter. The difference is the accumulated powder residue found for all five (5) gloves in the sample. Divide the total powder mass by five (5) to determine the average mass per glove in milligrams.

6.5.2 Report the average powder mass per glove as determined in 6.3.

6.6 *Report*—The report shall include the type of medical glove tested, the lot number, and the average powder mass per glove in milligrams.

7. Procedure II, for Quantitation of Powder on Powdered Gloves

7.1 *Powder Test, Powdered Glove—Total Glove:*

7.1.1 Prior to use, all glassware and tweezers shall be rinsed with deionized or distilled water.

7.2 *Filter Preparation:*

7.2.1 Use a 90 mm, 2.7 µm pore size glass microfiber filter and a suction filtration apparatus. Use of a TFE-fluorocarbon or equivalent rimmed housing base is recommended if filters adhere or tear upon removal from glass rimmed surface.

7.2.2 Prepare filter by desiccation a minimum of 30 min prior to use. Before use, pre-weigh the filter, weighing immediately after removal from the desiccator.

7.3 *Sample Selection and Test:*

7.3.1 Randomly select two gloves from each lot to be evaluated. Gently remove glove from original container.

7.3.2 Place 500 mL of deionized or distilled water into a 1000 mL recessed neck beaker/flask with pouring rim. All water used in this procedure should be at or below room temperature.

7.3.3 Place a glove into the beaker/flask with 1 to 3 cm of the cuff area stretched over the lip. Hold a portion of the cuff away from the lip to vent air from the beaker/flask and add 250 mL of deionized or distilled water to the inside of the glove, making certain to rinse the upper cuff as the water is poured. Additional water may be used if coverage is insufficient on the glove exterior or as needed for vacant space within the glove. However, space must be adequate to allow agitation.

7.3.4 Cap the beaker/flask with a rubber stopper with a polypropylene rim shroud or equivalent, agitate for 30 s on a