



Standard Test Method for Residual Powder on Medical Gloves¹

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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 These test methods cover 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 *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:

D 4483 Practice for Determining Precision for Test Method Standards in the Rubber and Carbon Black Industries²

2.2 Other Documents:

American National Standard ANSI/ASQC Z1.9–1993 Sampling Procedures and Tables for Inspection by Variables for Percent Nonconforming³

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.

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.

¹ This test method is under the jurisdiction of Committee D11 on Rubber, and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

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² *Annual Book of ASTM Standards*, Vol 09.01.

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