Designation: D 6124 – 01

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

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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 Industries[2]

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.

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.

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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.

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 recessed neck beaker/flask with pouring rim. Water used in this procedure should be at 20-25°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 beaker/flask with a rubber stopper with a polypropylene rim shroud or equivalent and agitate for 30 seconds on a mechanical shaker with a minimum side to side or rotational speed of 1.7 Hz (100 cycles/minute).

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*:

6.4.1 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*:

6.6.1 The report shall include the type of medical glove tested, the lot number, and the average powder mass per glove in mg.

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 minutes 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 seconds on a mechanical shaker with a minimum side to side or rotational speed of 1.7 Hz (100 cycles/min).

NOTE 2—Securing the flask at a 45° angle has been noted to improve the slosh effect and reduce the tendency for twisting at the cuff.

7.3.5 Remove the cap and pour the water from the inside of the glove through the suction filtration unit containing the weighed filter. Remove the glove from the beaker/flask and drain the remaining inside water from the glove through the suction filtration unit. Pour the beaker/flask water contents through the suction filtration unit.

7.3.6 Place 500 mL fresh deionized or distilled water into the same 1000 mL recessed neck beaker/flask.

7.3.7 Replace the test glove into the same beaker/flask with 1 to 3 cm of the cuff 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 fresh deionized or distilled water to the inside of the glove. Additional water may be used if coverage is insufficient. However, space must be adequate to allow agitation.

7.3.8 Cap the beaker/flask with the same rubber stopper with a polypropylene rim shroud or equivalent, agitate for 30 s on a mechanical shaker with a minimum speed of 1.7 Hz (100 cycles/minute).

7.3.9 Remove the cap and pour the water from the inside of the glove through the suction filtration unit containing the

weighed filter. Remove the glove from the beaker/flask and drain the remaining inside water from the glove through the suction filtration unit. Pour the beaker/flask water contents through the suction filtration unit.

7.3.10 Repeat 7.3.6-7.3.9 on the same glove for an additional two fresh water rinses, constituting a total of four fresh water rinses per single glove.

7.3.11 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.

7.3.12 Repeat 7.3-7.3.11 for the second glove, utilizing the same filter and suction device used for the first glove. Only two (2) gloves shall be evaluated per filter.

7.3.13 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 a minimum of 30 minutes prior to weighing. Weigh immediately after desiccation to prevent moisture absorption.

7.4 *Calculation of Results*:

7.4.1 Compute the mass change in the test filter. The difference is the accumulated powder residue found for the two gloves in the sample. Divide the total powder mass by two (2) to determine the average mass per glove in milligrams.

7.4.2 Report the average powder mass per glove as determined in 7.3.

7.5 *Interpretaton of Results*:

7.5.1 A result of average powder mass less than or equal to 90 % of the recommended maximum limit will allow immediate acceptance.

7.5.2 A result of average powder mass greater than 5 % above the recommended maximum limit will be considered a failure.

7.5.3 A result of average powder mass that exceeds 90 % of the recommended maximum limit, but that is less than or equal to 105 % of the recommended maximum limit may be retested as follows:

7.5.3.1 Randomly select two sets of two gloves from the lot to be retested.

7.5.3.2 Test each set of two gloves according to 7.1.

7.5.3.3 Calculate the arithmetic mean of the results from 7.5.3 and 7.5.3.2.

7.5.3.4 A calculated arithmetic mean is acceptable if:

(*a*) The quantity $(U- \bar{X})/s$ equals or exceeds the acceptability constant (*k*) as follows:

$$(U- \bar{X})/s \geq k = 0.34$$

where:

n = sample size = 3 (3 sets of 2 gloves),
s = standard deviation of the sample (three determinations),
$\bar{X}$ = mean of the sample (three determinations), and
U = recommended maximum limit.

NOTE 3—The acceptability constant (*k*) is obtained from Table B-2 of ANSI/ASQC Z1.9–93 in Section B, Part 1.

7.6 *Report*:

7.6.1 The report shall include the type of medical glove tested, the lot number, and the average powder mass per glove in mg.

7.6.2 Results of any retest shall be included according to (*a*) from 7.5.3.4, and a statement whether the result is acceptable or not acceptable.

8. Precision and Bias

8.1 The precision and bias section has been prepared in accordance with Practice D 4483. Refer to Practice D 4483 for terminology and other statistical details.

8.2 The precision results in this precision and bias section give an estimate of the precision of these test methods with the materials used in the particular interlaboratory program as described below. The precision parameters should not be used for acceptance/rejection testing of any group of materials without documentation that the parameters are applicable to those particular materials and the specific testing protocols that include these test methods.

8.3 Procedure for quantitation of powder on powder-free gloves.

8.3.1 A Type 1 precision was evaluated in 1999. Both repeatability and reproducibility are short term. A period of a few days separates replicate test results. Test result is the mean value, as specified by this test method, obtained on two determination(s) or measurements(s) of the property or parameter in question.

8.3.2 Three powder-free glove types in Procedure I and three powdered glove types in Procedure II were used in this interlaboratory program. Testing was performed in 7 laboratories.

8.3.3 For Procedure I, Quantitation of Powder on Powder-free Gloves, one lot of powder-free synthetic examination gloves, one lot of powder-free latex surgical gloves and one lot of powder-free latex examination gloves were utilized.

8.3.4 For Procedure II, Quantitation of Powder on Powdered Gloves, one lot of powdered synthetic examination gloves, one lot of powdered latex surgical gloves and one lot of powdered latex examination gloves were utilized.

8.3.5 The results of the precision calculations for repeatability and reproducibility are given in Tables 1 and 2, in ascending order of powder average or level, for each of the materials evaluated.

8.3.6 The precision of this test method may be expressed in the format of the following statements that use what is called an "appropriate value" of *r*, *R*, (*r*), or (*R*). That is, that value to be used in decisions about test results (obtained with the test method). The appropriate value is that value of *r* or *R* associated with a mean level in Tables 1 and 2 closest to the mean level under consideration at any given time, for any given material in routine testing operations.

8.3.7 *Repeatability*—The repeatability, *r*, of this test method has been established as the appropriate value tabulated in Tables 1 and 2. Two single test results, obtained under normal test method procedures, that differ by more than this tabulated *r* (for any given level) must be considered as derived from different or nonidentical sample populations.

8.3.8 *Reproducibility*—The reproducibility, *R*, of this test method has been established as the appropriate value tabulated in Tables 1 and 2. Two single test results obtained in two

TABLE 1 Procedure I - Quantitation of Powder on Powder-free gloves

Sr = repeatability standard deviation
r = repeatability = 2.83 times the square root of the repeatability variance
(r) = repeatability (as percentage of material average)
SR = reproducibility standard deviation
R = reproducibility = 2.83 times the square root of the reproducibility variance
(R) = reproducibility (as percentage of material average)

	Within Laboratories				Between Laboratories		
Material	Average[A]	*Sr*	*r*	(*r*)	*SR*	*R*	(*R*)
1. Powder-free Latex Exam	0.20	0.05	0.21	105 %	0.09	0.26	130 %
2. Powder-free Latex Surgical	0.35	0.04	0.13	37 %	0.13	0.36	103 %
3. Powder-free Synthetic Exam	0.63	0.13	0.36	57 %	0.19	0.52	82 %

[A]Expressed in mg.

TABLE 2 Procedure II - Quantitation of Powder on Powdered gloves

Sr = repeatability standard deviation
r = repeatability = 2.83 times the square root of the repeatability variance
(r) = repeatability (as percentage of material average)
SR = reproducibility standard deviation
R = reproducibility = 2.83 times the square root of the reproducibility variance
(R) = reproducibility (as percentage of material average)

	Within Laboratories				Between Laboratories		
Material	Average[A]	*Sr*	*r*	(*r*)	*SR*	*R*	(*R*)
1. Powdered Latex Surgical	109	7	21	19 %	26	71	65 %
2. Powdered Latex Exam	180	10	28	16 %	27	75	42 %
3. Powdered Synthetic Surgical	222	22	62	28 %	28	78	28 %

[A]Expressed in mg.

different laboratories, under normal test method procedures, that differ by more than the tabulated *R* (for any given level) must be considered to have come from different or nonidentical sample populations.

8.3.9 Repeatability and reproducibility expressed as a percentage of the mean level, (*r*) and (*R*), have equivalent application statements as above for *r* and *R*. For the (*r*) and (*R*) statements, the difference in the two single test results is expressed as a percentage of the arithmetic mean of the two test results.

8.3.10 *Bias*—In test method terminology, bias is the difference between an average test value and the reference (or true) test property value. Reference values do not exist for this test method since the value (of the test property) is exclusively defined by the test method. Bias, therefore, cannot be determined.

9. Keywords

9.1 quantitation; detection; filter; gloves; medical; powder; powder-free