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# Standard Guide for Assessment of Medical Gloves[1]

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## 1. Scope

1.1 This guide is intended to assist in the identification and application of the most appropriate ASTM and associated standards for the assessment, development of specifications, and selection of medical gloves with the ultimate goal of maintaining the safety and health of healthcare workers who may come into contact with biological and chemical hazards.

1.2 No guidance document or assessment protocol can ensure the selection of medical gloves that guarantees healthcare worker protection. The purpose of testing and assessing medical gloves is to generate the performance data and quality information that will allow the most appropriate assessment and selection of medical gloves. Ultimately, the selection of medical gloves shall be based on the evaluation of available technical data, quality information, and professional assessment of risk.

1.3 *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:*[2]

D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

D573 Test Method for Rubber—Deterioration in an Air Oven

D3577 Specification for Rubber Surgical Gloves

D3578 Specification for Rubber Examination Gloves

D3767 Practice for Rubber—Measurement of Dimensions

D5151 Test Method for Detection of Holes in Medical Gloves

D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application

D5712 Test Method for Analysis of Aqueous Extractable Protein in Natural Rubber and Its Products Using the Modified Lowry Method

D6124 Test Method for Residual Powder on Medical Gloves

D6319 Specification for Nitrile Examination Gloves for Medical Application

D6499 Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products

D6977 Specification for Polychloroprene Examination Gloves for Medical Application

F739 Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Continuous Contact

F1342 Test Method for Protective Clothing Material Resistance to Puncture

F1383 Test Method for Permeation of Liquids and Gases through Protective Clothing Materials under Conditions of Intermittent Contact

F1671 Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

2.2 *American National Standards Institute/American Dental Association (ANSI/ADA) Standards:*

Acceptance Program Guidelines Infection Control Products[3]

Specification No. 76 Non-Sterile Natural Rubber Latex Gloves for Dentistry[3]

Specification No. 102 Non-Sterile Nitrile Gloves for Dentistry[3]

Specification No. 103 Non-Sterile Poly(vinyl chloride) Gloves for Dentistry[3]

2.3 *International Standards Organization (ISO) Standard:*

ISO 2859 Sampling Procedures and Tables for Inspection by Attributes[3]

2.4 *National Fire Protection Association (NFPA) Standard:*

NFPA 1999 Standard on Protective Clothing for Emergency Medical Operations[4]

[1] This guide is under the jurisdiction of ASTM Committee D11 on Rubber 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 (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.

[4] Available from National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02269-9101.

## 3. Terminology

3.1 *Definitions:*

3.1.1 *medical gloves*—surgeon's (surgical) and patient examination (examination) gloves for use in medical applications. Medical gloves are medical devices that are regulated by The Food and Drug Administration (FDA).

3.1.2 *natural rubber latex (NRL) gloves*—gloves manufactured from natural rubber latex (latex).

3.1.3 *syntheic plastic gloves*—gloves manufactured from a synthetic plastic material such as poly(vinyl chloride).

3.1.3.1 *Discussion*—The actual name of the plastic material must be stated on the packaging.

3.1.4 *synthetic rubber gloves*—gloves manufactured from a synthetic rubber material, such as (1) polychloroprene and (2) acrylonitrile butadiene (nitrile).

3.1.4.1 *Discussion*—The actual name of synthetic rubber must be stated on the packaging.

## 4. Significance and Use

4.1 The standards under the jurisdiction of Committee D11.40 and other technical committees can be used individually or as part of an integrated protocol in the assessment and selection of medical gloves.

4.2 The intended use of the standards is as a means by which information can be requested, generated, and reported in a consistent, comparable manner.

4.3 The suggested assessments and test methods are recommended guidelines.

4.4 Test methods offer procedures for assessing medical gloves at standardized conditions to allow comparison.

4.5 The information on medical glove performance must be combined with professional judgment, and a clear understanding of the application, in order for the medical glove to provide the best performance.

4.6 Medical gloves intended for use during emergency medical operations may be evaluated and their performance certified to NFPA 1999, Standard on Protective Clothing for Emergency Medical Operations. This certification program is voluntary.

## 5. Assessment of the Quality

5.1 Each of the following medical glove standards provides minimum quality specifications for the medical glove that it describes: Specifications D3577, D3578, D5250, D6319, and D6977.

5.2 Each medical glove standard listed in 5.1 also provides material-specific performance specifications.

5.3 Each of the medical glove standards listed in 5.1 contains minimum quality standards, which include an assigned inspection level and AQL (acceptable quality level) per ISO 2859 for each of the following:

5.3.1 *Holes:*

5.3.1.1 Test Method D5151 describes how to detect holes in medical gloves.

5.3.1.2 Each medical glove standard listed in 5.1 has assigned a minimum inspection level and an associated minimum AQL to be used when assessing medical gloves for holes.

5.3.2 *Dimensions:*

5.3.2.1 Practice D3767 describes how to properly determine the geometrical dimensions of rubber products for physical tests.

5.3.2.2 Each medical glove standard listed in 5.1 provides material specific specifications for palm width, length, and thickness.

5.3.3 *Physical Properties*—The primary physical properties for medical gloves include tensile strength and ultimate elongation.

NOTE 1—Medical gloves manufactured from natural rubber latex also include a before-accelerated-aging test that measures the stress at 500 % elongation.

5.3.3.1 This test measure is determined by measuring the stress at 500 % elongation in accordance with Test Methods D412.

5.3.3.2 Medical gloves are tested for physical properties before and after accelerated aging.

5.3.3.3 Before accelerated aging tests are performed in accordance with Test Methods D412.

5.3.3.4 After accelerated aging tests are performed in accordance with Test Method D573.

## 6. Assessment of Powder Residue on Powder-free Medical Gloves

6.1 The powder residue on powder-free medical gloves shall be measured in accordance with Test Method D6124.

6.2 The recommended powder residue limit for powder-free medical gloves is not more than 2 mg per glove.

## 7. Assessment of the Amount of Powder on Powdered Medical Gloves

7.1 The amount of powder on powdered medical gloves shall be measured in accordance with Test Method D6124.

7.2 The recommended powder amount limit for powdered examination gloves is not more than 10 mg/dm$^2$.

7.2.1 A unit of measure used to denote surface area is dm$^2$ = square decimetre.

7.3 The recommended powder amount limit for powdered surgical gloves is not more than 15 mg/dm$^2$.

7.3.1 A unit of measure used to denote surface area is dm$^2$ = square decimetre.

## 8. Assessment of Extractable Protein for Natural Rubber Latex Medical Gloves

8.1 In accordance with Specification D3578, the content of aqueous soluble protein in natural rubber latex medical gloves shall be determined using Test Method D5712.

NOTE 2—The FDA requires that Test Method D5712 be performed in support of a 510(k) Premarket Notification submission.

8.2 The recommended aqueous soluble protein content limit for natural rubber latex medical gloves is not more than 200 µg/dm$^2$.

8.2.1 This recommended aqueous soluble protein content limit is in accordance with the performance requirements set forth in the performance requirements section of Specification D3578.

8.3 The FDA regulates extractable protein content label claims. The lowest protein content label allowed by the FDA is 50 μg/dm$^2$ of glove.

## 9. Assessment of Antigenic Protein for Natural Rubber Latex Medical Gloves

9.1 In accordance with Specification D3578, the amount of extractable antigenic protein in natural rubber latex medical gloves shall be determined using Test Method D6499.

9.2 The recommended antigenic protein content limit for natural rubber latex medical gloves is not more than 10 μg/dm$^2$ per Test Method D6499.

9.2.1 This recommended antigenic protein content limit is in accordance with the performance requirements set forth in the performance requirements section of Specification D3578.

## 10. Assessment of Resistance to Viral Penetration

10.1 Medical gloves may be evaluated for resistance to viral penetration in accordance with Test Method F1671.

10.1.1 Test Method F1671 measures the resistance of materials to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact.

10.1.1.1 Test material pass/fail determinations are based on the detection of viral penetration.

10.1.1.2 This test method has been specifically defined for modeling the viral penetration of Hepatitis (B and C) and Human Immunodeficiency Viruses transmitted in blood and other potentially infectious body fluids.

10.1.2 This test system does not allow for a whole glove to be tested; however, a representative specimen of the medical glove material may be tested.

## 11. Assessment of Chemical Resistance

11.1 The two most commonly used chemical resistance test methods to measure the chemical resistance of medical gloves are continuous contact (Test Method F739) and intermittent contact (Test Method F1383).

11.1.1 *Test Method F739:*

11.1.1.1 This test method measures breakthrough detection time, normalized breakthrough detection time, and subsequent permeation rate through replicate specimens of the test material to assess the resistance of a test material to permeation by a test chemical.

11.1.1.2 Test Method F739 allows several configurations of the test, including the choice of collection media, detection systems, the test temperature, and length of the test.

11.1.2 *Test Method F1383:*

11.1.2.1 This test method is a variation of Test Method F739 and is used to measure breakthrough detection time and permeation rate through material specimens under the conditions of intermittent contact of the test chemical with the material specimen.

11.1.2.2 Test Method F1383 is designed to simulate the type of chemical exposures where chemical contact occurs through periodic exposure through repeated splashes depending on the type of task in which the healthcare worker is involved.

## 12. Assessment of Puncture Resistance

12.1 The puncture resistance of elastomeric materials such as those used to manufacture medical gloves can be tested using Test Method F1342.

12.1.1 Test Method F1342 measures the puncture resistance of a material specimen by measuring the force required to cause a specifically defined puncture probe to penetrate through the material specimen.

NOTE 3—Test Method F1342 is not designed to detect resistance to puncture by sharps, such as needles.

## 13. Assessment of Examination Gloves for Emergency Medical Services (EMS) per NFPA

13.1 The NFPA 1999 standard allows for examination gloves to be certified to its listed quality and performance criteria via the use of an independent, third party certification organization that is approved by NFPA.

13.1.1 The certification organization determines whether or not the product is compliant with the requirements in NFPA 1999 and includes a labeling/listing/follow-up program.

## 14. Assessment of Medical Gloves per ANSI/ADA

14.1 The ADA also lists specification standards for medical gloves: ANSI/ADA Specification No. 76, ANSI/ADA Specification No. 102, and ANSI/ADA Specification No. 103.

## 15. Selection of Medical Gloves

15.1 There is no one single type of medical glove that will meet the needs of every application.

15.2 The selection of medical gloves shall be based on the evaluation of available technical data, quality information, overall medical glove design, and the professional assessment of risk.

## 16. Keywords

16.1 assessment; barrier properties; latex; medical gloves; natural rubber latex; nitrile; performance; physical properties; polychloroprene; quality; selection; vinyl