



Designation: D7103 – 19 (Reapproved 2023)

Standard Guide for Assessment of Medical Gloves¹

This standard is issued under the fixed designation D7103; 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.

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 health-care 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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *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

- [D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension](#)
- [D573 Test Method for Rubber—Deterioration in an Air Oven](#)

¹ This guide is under the jurisdiction of ASTM Committee D11 on Rubber and Rubber-like Materials and is the direct responsibility of Subcommittee D11.40 on Consumer Rubber Products.

Current edition approved Sept. 1, 2023. Published September 2023. Originally approved in 2006. Last previous edition approved in 2019 as D7103 – 19. DOI: 10.1520/D7103-19R23.

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.

- [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 Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method](#)
- [D6124 Test Method for Residual Powder on Medical Gloves](#)
- [D6319 Specification for Nitrile Examination Gloves for Medical Application](#)
- [D6355 Test Method for Human Repeat Insult Patch Testing of Medical Gloves](#)
- [D6499 Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber \(HNR\) and its Products](#)
- [D6977 Specification for Polychloroprene Examination Gloves for Medical Application](#)
- [D6978 Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs](#)
- [D7102 Guide for Determination of Endotoxin on Sterile Medical Gloves](#)
- [D7160 Practice for Determination of Expiration Dating for Medical Gloves](#)
- [D7161 Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions](#)
- [D7198 Specification for Disposable Embalming Gloves for Single-Use Applications](#)
- [D7427 Test Method for Immunological Measurement of Four Principal Allergenic Proteins \(Hev b 1, 3, 5 and 6.02\) in Hevea Natural Rubber and Its Products Derived from Latex](#)
- [D7558 Test Method for Colorimetric/Spectrophotometric Procedure to Quantify Extractable Chemical Dialkylthiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators in Natural Rubber Latex and Nitrile Gloves](#)
- [D7866 Specification for Radiation Attenuating Protective Gloves](#)
- [D7907 Test Methods for Determination of Bactericidal Efficacy on the Surface of Medical Examination Gloves](#)

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

F2547 Test Method for Determining the Attenuation Properties in a Primary X-ray Beam of Materials Used to Protect Against Radiation Generated During the Use of X-ray Equipment

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

Acceptance Program Guidelines Infection Control Products³ Specification No. 76 Non-Sterile Natural Rubber Latex Gloves for Dentistry³

Specification No. 102 Non-Sterile Nitrile Gloves for Dentistry³

Specification No. 103 Non-Sterile Poly(vinyl chloride) Gloves for Dentistry³

2.3 *International Standards Organization (ISO) Standard: ISO 2859 Sampling Procedures and Tables for Inspection by Attributes³*

2.4 *National Fire Protection Association (NFPA) Standard: NFPA 1999 Standard on Protective Clothing for Emergency Medical Operations⁴*

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 *synthetic 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**, **D6977**, and **D7198**.

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**.

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.