



Designation: D7161 – 16 (Reapproved 2023)

Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions¹

This standard is issued under the fixed designation D7161; 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 practice covers all surgeon's and examination gloves, made from either synthetic or natural rubber latex, marketed at the time this practice is published, for which there is no previous real time aging data available, and for which there are at least twelve months of storage as finished goods under typical warehouse conditions. This practice describes how to develop real time aging data for gloves that are part of finished goods inventory (including gloves that may no longer be manufactured) in order to verify the estimated expiration date (see [Note 1](#)). Manufacturers may use this data as a starting point for real time aging studies as described in Practice [D7160](#).

NOTE 1—Accelerated aging for three-year shelf life is described in Practice [D7160](#).

1.2 *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.*

1.3 *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

¹ This practice 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 May 1, 2023. Published June 2023. Originally approved in 2005. Last previous edition approved in 2016 as D7161 – 16. DOI: 10.1520/D7161-16R23.

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.

[D3078](#) Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission

[D3577](#) Specification for Rubber Surgical Gloves

[D3578](#) Specification for Rubber Examination Gloves

[D5151](#) Test Method for Detection of Holes in Medical Gloves

[D5250](#) Specification for Poly(vinyl chloride) Gloves for Medical Application

[D6319](#) Specification for Nitrile Examination Gloves for Medical Application

[D7160](#) Practice for Determination of Expiration Dating for Medical Gloves

[F88](#) Test Method for Seal Strength of Flexible Barrier Materials

[F1929](#) Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

2.2 ISO Standard:

[ISO 2859](#) Sampling Procedures for Inspection by Attributes³

3. Terminology

3.1 Definitions of Terms Specific to This Standard:

3.1.1 *date of manufacture*—the date of the final processing step. For sterile products, the last processing step would be sterilization.

3.1.2 *mature medical gloves*—those that have at least twelve months of storage as finished goods under warehouse conditions.

3.1.3 *real time expiration date*—calculated by adding the shelf life to the date of manufacture

3.1.4 *shelf life*—determined by the longest storage interval of the mature gloves (from the date of manufacture) for which there is data demonstrating that the product meets the specifications defined in this practice. The data should be generated utilizing the test plan and methods defined in this practice.

³ Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, <http://www.iso.ch>.