Designation: D7161 – 16

Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions[1]

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 12 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 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

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 Attributes[3]

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 12 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.

4. Significance and Use

4.1 This practice provides a study design for determining shelf life of medical gloves using product in its final packaging configuration that has been stored under typical warehouse conditions.

5. General Information

5.1 For each glove type to be evaluated for expiration dating, select not less than three (3) lots from finished goods

[1] This practice 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 International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, Case postale 56, CH-1211, Geneva 20, Switzerland, http://www.iso.ch.

TABLE 1 Tests Required

Gloves	Sample Size and Specification
Test Method D5151	Sample Size: per ISO 2859, Inspection Level S-3 AQL = 1.50 (Surgeon's) AQL = 2.50 (Exam)
Test Methods D412	Sample Size: per ISO 2859, Inspection Level S-3, but not less than 32 gloves. Specified values for physical requirements per appropriate ASTM glove standard. (Specifications D3577, D3578, D5250, D6319, and so forth.) AQL = 4.00
Sterile Packaging	**Sample Size and Specification**
Impermeable Package—Test Method D3078	Sample Size: per ISO 2859, Inspection Level S-4, but not less than 50 packages. AQL = 0.65 (Surgeon's) AQL = 1.50 (Exam)
Permeable Package—Test Method F1929	Sample Size: per ISO 2859, Inspection Level S-4, but not less than 50 packages. AQL = 0.65 (Surgeon's) AQL = 1.50 (Exam)
All Package Types—Test Method F88	Sample Size: per ISO 2859, Inspection Level S-4, but not less than 50 packages. AQL = 0.65 (Surgeon's) AQL = 1.50 (Exam)

inventory for which there are documented conditions of storage. The conditions to be documented are:

5.1.1 Date of manufacture.

5.1.2 Length of storage in warehouse.

5.1.3 Location of warehouse.

5.1.4 Temperature control at warehouse (controlled or uncontrolled). If controlled, indicate the controlled temperature and record the rationale why this temperature is representative of typical warehouse conditions. If uncontrolled, provide the average annual temperature for the warehouse location during the period of storage.

NOTE 2—May use data from http://www.cdc.noaa.gov/Usclimate/states.fast.html.

5.1.5 Humidity control at the warehouse (controlled or uncontrolled). If controlled, indicate the controlled relative humidity.

6. Materials and Equipment

6.1 Refer to the individual procedures and standards referenced.

7. Test Methods

7.1 *All Gloves*—Each of the three (3) lots of finished product must be tested in accordance with Table 1.

8. Acceptance Criteria

8.1 Glove samples must meet the requirements of the appropriate ASTM product specifications with respect to water leak testing and "before aging" physical properties.

8.2 Sterile product packaging must demonstrate predetermined requirements for seal strength and the ability to maintain package integrity.

9. Real Time Stability Study

9.1 If product test data meet the acceptance requirements in 8.1, then the initial product shelf life, as determined by real time aging, is that of the *shortest* storage period of the three (3) test lots. Assuming there are enough gloves in the test lots to continue testing on at least an annual basis, the mature glove study may be extended up to a maximum of five (5) years. However, no glove may be labeled with an expiration date of more than five (5) years from its date of manufacture.

10. Keywords

10.1 expiration date; medical gloves; shelf life; storage conditions