



Designation: D7160 – 16 (Reapproved 2023)

Standard Practice for Determination of Expiration Dating for Medical Gloves¹

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1. Scope

1.1 This practice covers all surgeon's and examination gloves made from either synthetic or natural rubber latex. The purpose of this practice is to establish methods for testing medical gloves and analyzing the data to determine their shelf life.

1.2 *This standard does not purport to address all of the label claims and 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

D573 Test Method for Rubber—Deterioration in an Air Oven

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

D7161 Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions

F88 Test Method for Seal Strength of Flexible Barrier Materials

F1929 Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

F1980 Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices

2.2 *ISO Standards:*³

ISO 2859 Sampling Procedures for Inspection by Attributes

ISO 4074 Natural Latex Rubber Condoms—Requirements and Test Methods

2.3 *Other:*

ICH Q1D Bracketing and Matrixing designs for Stability Testing of Drug Substances and Drug Products⁴

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *accelerated aging*—conducted by storing samples at an elevated temperature for a reduced amount of time to simulate a longer period of real time aging.

3.1.2 *date of manufacture*—date of the final processing step. For sterile products, the last processing step is sterilization.

3.1.3 *real time aging*—the storage of samples under conditions that the product is expected to experience over its shelf life. Storage conditions should include exposure to elevated temperatures that product may experience during shipping.

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

3.1.5 *shelf life*—determined by the longest storage interval (from time zero) for which there is data demonstrating that the product meets the specifications defined in this practice. The

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.

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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>.

⁴ Available from International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), ICH Secretariat, 9, chemin des Mines, P.O. Box 195, 1211 Geneva 20, Switzerland, <http://www.ich.org>.

data should be generated utilizing the test plan and methods defined in this practice.

3.1.6 *time zero*—the date of manufacture and the starting point for the shelf life studies.

4. General Information

4.1 The need for an expiration date is primarily based on the potential for a critical aspect of the product to deteriorate, resulting in a patient/user safety risk. The potential for product deterioration is determined from exposure to the actual or simulated handling and environmental conditions the product would most likely encounter after release for sale.

4.2 Because real time testing is often impractical, accelerated aging techniques must be used. For some medical devices, the Arrhenius equation found in Guide F1980 is an acceptable predictor of real time aging.

4.3 Real time aging of medical gloves that have been marketed prior to the publication of this practice may be performed in accordance with Practice D7161.

5. Materials and Equipment

5.1 Refer to the individual procedures and standards referenced.

6. Tests for Stability and Shelf Life

6.1 Manufacturers shall verify that gloves comply with the requirements of the applicable ASTM standard until the end of the labeled shelf life. Shelf life claims shall not exceed five years.

6.2 A modified glove design is one in which there have been significant changes to the formulation, manufacturing process, or individual sealed containers. Before a new or modified glove design is placed on the market, the following requirements shall be met:

6.2.1 The glove shall be tested for the minimum stability requirements as described in 6.4.

6.2.2 A real time study as described in 6.5 to determine shelf life must be initiated.

6.2.3 Pending completion of the real time study, a provisional shelf life claim shall be substantiated as described in 6.4.

6.3 The product to be considered for storage stability testing is categorized into family groupings that represent a worst or limit case for a given set of common characteristics to the gloves within that family group of gloves. These groupings are formed with consideration to the type of latex formulations used, types of processing such as chlorination or coatings, packing methods, sterilization, and the product's intended use. Typical groups or product family categories are summarized in Annex A1.

6.4 Accelerated Stability Test:

6.4.1 A minimum of three discrete finished product lots must be tested. ICH Q1D may be used for bracketing and matrixing designs. Only lots meeting the requirements of the applicable ASTM standard at time zero shall be included in this test. Data from formal stability studies should be provided on lots manufactured by using the actual method of manufacture and procedure used for production lots.

6.4.2 A sufficient number of samples shall be incubated at the applicable conditions listed in Table 1. Samples must be incubated in the final packaging configuration. Alternative methods for accelerated aging studies are described in 9.1.3.

6.4.3 At the end of the incubation periods, test the gloves per Section 7. Note that the measurement of physical properties should be performed no earlier than 16 h and no later than 96 h from the time of removal from the oven in accordance with Test Method D573. During this period, the oven-aged gloves should be conditioned at room temperature.

6.5 Real Time Stability Studies:

6.5.1 Real time studies of gloves sampled from the same three lots should be initiated at the same time as the accelerated studies.

6.5.2 Sufficient samples shall be stored under conditions that are representative of the actual storage conditions the product is expected to experience over its shelf life. Storage conditions should be monitored and recorded. Testing shall be performed no sooner than 24 h from date of manufacturing at the initiation of the study and, at a minimum, tested at yearly intervals up to five years. Testing may occur at more frequent intervals if desired. The samples must be incubated in the final packaging configuration and be representative of the finished product.

6.5.3 Testing shall be performed at each interval on each of three lots per Section 7.

6.5.4 If the real time data indicates a shorter shelf life than that established by accelerated aging, the manufacturer shall change the shelf life for the product to that which is supported by the real time study. The shelf life shall not exceed five years regardless of supporting data.

7. Test Program for Accelerated and Real Time Aging

7.1 *All Gloves*—Each of the three (3) lots of finished product must be tested in accordance with Table 2 and documented according to appropriate procedures.

8. Acceptance Criteria for Real Time and Accelerated Aged Gloves

8.1 Glove samples aged at less than 50 °C must meet the requirements of the appropriate ASTM product type specification with respect to water leak testing and “before aging” physical properties.

8.2 Glove samples aged at 50 °C ± 2 °C or greater must meet the requirements of the appropriate ASTM product type specification with respect to water leak testing and “after accelerated aging” physical properties.

8.3 If a 25 % or greater change in physical properties from the initial value is observed, an investigation should be initiated to determine if the change is an indication of an

TABLE 1 Incubation Conditions

Time Interval	Temperature
Time Zero (control group, no aging, all materials)	Ambient
72 h ± 2 h (vinyl only)	70 °C ± 2 °C
166 h ± 2 h (except vinyl)	70 °C ± 2 °C
90 days ± 1 day (all materials)	50 °C ± 2 °C



TABLE 2 Tests Required

Gloves		Sample Size and Specification
Test Method D5151		Sample Size: per ISO 2859, Inspection Level S-3, but not less than 32 gloves. 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 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)

increased rate of degradation. If an increase in the rate of degradation of physical properties is confirmed, then the previous test interval should be used to determine the shelf life.

NOTE 1—The percent change of physical properties between two intervals is based on the average values of the samples tested.

8.4 Sterile product packaging must demonstrate predetermined requirements for seal strength and the ability to maintain sterility (package integrity).

9. Expiration Date Determination

9.1 Accelerated Stability:

9.1.1 Pending the completion of real time studies, accelerated stability studies shall be used to estimate shelf life.

9.1.2 A maximum shelf life of three (3) years shall be assigned based on accelerated studies. The shelf life may be extended as real time data is generated.

9.1.3 In addition to the Accelerated Stability Test method outlined in 6.4, there are several accelerated aging models that may be used. A model using Arrhenius shift factors is included

in ISO 4074, Annex L “Guidance on Conducting and Analyzing Accelerated Aging Studies.” Alternatively, the shift factor can be verified and the shelf life estimated using the method described in this practice in Annex A2. Another method based on activation energy is included in this practice as Annex A3. Manufacturers may chose other accelerated aging models that can be validated with real-time data. As manufacturers, standard developing groups, and regulatory agencies accumulate data, a consensus method will be developed.

9.2 *Real Time Aging*—The maximum shelf life for medical gloves is five years. The shelf life of a test lot is determined by selecting the longest test interval from time zero for which all requirements are met at the end of the entire test interval as well as for each intermediate test interval. The shelf life of the product is the shortest shelf life obtained for the three test lots.

10. Keywords

10.1 expiration date; medical gloves; shelf life

ANNEXES

A1. POSSIBLE GROUPINGS FOR TYPICAL MEDICAL GLOVE PRODUCT FAMILIES

NOTE 1—Factors to consider include glove thickness, chlorination levels, and coatings or surface treatments.

Material Type	Chlorinated	Coating	Packaging Type	Sterile
NRL Latex Compound				
Neoprene				
Nitrile				
Vinyl				
Other				

FIG. A1.1 Possible Groupings for Typical Medical Glove Product Families