



Designation: D6978 – 05 (Reapproved 2023)

Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs¹

This standard is issued under the fixed designation D6978; 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 a protocol for the assessment of resistance of medical glove materials to permeation by potentially hazardous cancer chemotherapy drugs under conditions of continuous contact. An assessment is made based on the permeation (breakthrough) of nine chemotherapy drugs through the glove material over a certain period of time.

1.2 It is emphasized that the conditions used in this assessment are intended to approximate the worst-case condition for clinical uses. The data should be restricted to use on a relative basis when comparing glove materials.

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

- D471 Test Method for Rubber Property—Effect of Liquids
- D3577 Specification for Rubber Surgical Gloves
- D3578 Specification for Rubber Examination Gloves
- D3767 Practice for Rubber—Measurement of Dimensions
- D5250 Specification for Poly(vinyl chloride) Gloves for Medical Application
- D6319 Specification for Nitrile Examination Gloves for

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.

Medical Application

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

3. Terminology

3.1 Definitions:

3.1.1 See Test Method F739, Section 3 on Terminology for a full list of terms and definitions.

3.1.2 *breakthrough detection time, n*—the time in minutes measured from the start of the test to the sampling time that immediately precedes the sampling time at which the permeation rate reaches 0.01 $\mu\text{g}/\text{cm}^2/\text{min}$. See Test Method F739, section 12.4.2 for calculation of permeation rate with replenishment.

3.1.3 *validated statistical rationale, n*—requires that an objective cause or reason be stated as to why the initial test was incorrect.

4. Significance and Use

4.1 The objective of this practice is to provide a uniform procedure for assessing the resistance of medical glove materials to permeation by chemotherapy drugs, and to establish a consistent reporting of the test data.

5. Test Protocol

5.1 Summary of Test Method:

5.1.1 The gloves in question shall be tested in accordance with the method set out in Test Method F739, Procedure A.

5.1.2 The resistance of a medical glove material to permeation by chemotherapy drugs shall be determined by measuring the breakthrough detection time of the drugs through the glove material. The test method involves using the test material serve as a membrane (partition) between the two halves of a test cell. One half of the cell shall contain the donor solution of the test drug and the other half shall contain the appropriate collection medium, that is, distilled water or other liquid, which does not influence the permeation of the drug being tested. A test drug permeates through the sample material when the test drug is able to pass through the test material. As the test drug