Designation: D6978 – 05 (Reapproved 2013)

Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs[1]

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 and health practices and determine the applicability of regulatory limitations prior to use.*

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 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 μg/cm^2/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 continuously passes through the sample material, its concentration increases over time. The collection medium shall be sampled at recorded time intervals and analyzed quantitatively to determine the concentration of the permeated drug. The concentration of the drug in the collection medium shall be used to calculate the breakthrough detection time and permeation rate (see 3.1.3), in accordance with Test Method F739.

[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.

Current edition approved Jan. 1, 2013. Published April 2013. Originally approved in 2005. Last previous edition approved in 2005 as D6978 – 05. DOI: 10.1520/D6978-05R13.

[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.

5.2 *Test Protocol:*

5.2.1 *Test Material Selection:*

5.2.1.1 Three medical gloves that meet the appropriate ASTM standards (Specifications D3577, D3578, D5250, D6319, and D6977) shall be selected and used to produce test samples. Manually measure each glove thickness with a thickness gage that has a presser foot pressure that meets the requirement of Practice D3767, and graduations to 20 µm. For each medical glove, record manual thickness measurements from two distinct areas of the medical glove: palm and cuff. From these measurements determine the thinner area of the glove between the palm and cuff. Obtain test samples from the thinner area of the glove.

5.2.1.2 Cut one 5 by 5-cm piece of material from the palm or cuff of each test medical glove, whichever area measured thinnest. Identify the outer side of the sample.

5.2.1.3 One test sample shall be obtained from each of the three test medical gloves. As a result, there will be a minimum of 27 test samples obtained when testing against the nine test drugs. The number of test drugs, nine, is a minimum.

5.2.2 *Representative Drugs to be Tested:*

5.2.2.1 The chemotherapy drugs used in testing shall incorporate the different classes of clinical drugs. The number of drugs tested shall reflect a minimum of nine currently used clinical drugs.

5.2.2.2 The clinical drugs selected shall include at least the following seven drugs: Carmustine, Cyclophosphamide, Doxorubicin, Etoposide, Fluorouracil, Paclitaxel, and Thiotepa. See Table 1.

5.2.2.3 The testing shall be completed with an additional two clinical drugs that can be selected by the user of this practice. Table 2 is available as a guide for selecting additional chemotherapy drugs.

5.2.2.4 The clinical drugs called for in this practice shall be purchased from pharmaceutical drug manufacturers or authorized distributors of pharmaceuticals. Each test drug shall be prepared using the manufacturer's recommended solvent. The preparation procedure shall be documented.

5.2.2.5 The drug solution shall be prepared with the recommended solvent and at the highest concentration of the drug to which a healthcare worker might be exposed during handling as referenced in the most recent edition of Physicians' Desk Reference, or the package insert of the test drug (see Table 1).

5.2.3 *Test Conditions:*

5.2.3.1 The test shall be conducted at 35 ± 2°C and the temperature recorded.

TABLE 1 List of the Required Chemotherapy Drugs and Their Concentrations as Typically Prepared for Clinical Use

Chemotherapy Drugs	Concentration (mg/mL)[A]
Carmustine	3.3
Cyclophosphamide	20.0
Doxorubicin HCl (Adriamycin)	2.0
Etoposide	20.0
Fluorouracil (Adrucil)	50.0
Paclitaxel (Taxol)	6.0
ThioTEPA	10.0

[A] Initial reconstitution or commercially available concentration.

TABLE 2 Sample List of Additional Chemotherapy Drugs and Their Concentrations as Typically Prepared For Clinical Use

Chemotherapy Drugs	Concentration (mg/mL)[A]
Bleomycin sulfate	15.0
Carboplatin	10.0
Cisplatin	1.0
Cytarabine HCl	100.0
Dacarbazine	10.0
Daunorubicin HCl	5.0
Docetaxel	10.0
Gemcitabine	38.0
Idarubicin	1.0
Ifosfamide	50.0
Irinotecan	20.0
Mechlorethamine HCl	1.0
Melphalan	5.0
Methotrexate	25.0
Mitomycin	0.5
Mitoxantrone	2.0
Vincristine sulfate	1.0

[A] Initial reconstitution or commercially available concentration.

5.2.3.2 The outer surface of the glove material shall contact the donor solution of the test drug.

5.2.3.3 The collection medium shall be mixed continuously.

5.2.3.4 The test duration shall be 4 h, during which an aliquot of an appropriate volume of the collection medium shall be removed at least every 30 min from the collection cell for the measurement of the concentration of the test drug in the collection medium based on drug manufacturer's recommended detection method.

5.2.3.5 The collection cell shall be replenished immediately with the same volume of the liquid removed from the collection medium.

5.2.4 *Test Termination:*

5.2.4.1 The test shall be terminated after 4 h.

5.2.4.2 The breakthrough shall be deemed to have occurred when the quantitative analysis based on drug manufacturer's recommended detection method, detects a permeation rate of 0.01 µg/cm^2/min.

5.2.4.3 Each test glove material shall be inspected at the end of the test period for physical changes, such as signs of flaking, swelling, disintegration, embrittlement, discoloration, or other physical changes. The changes shall be recorded in accordance with Test Method D471.

6. Expression of Test Results

6.1 The minimum breakthrough detection time (the time, expressed in minutes, at which the permeation rate reaches 0.01 µg/cm^2/min; see 3.1.2) of each of the nine drugs tested during the 4-h test duration, as determined from the triplicate sample tested (see 5.2.1.3), shall be reported for each glove material.

6.2 If retesting is going to be performed, an objective rationale shall be provided addressing why the original data is not an outlier or is not correct. This rationale shall have a validated statistical basis (see 3.1.3).

7. Report

7.1 For each glove material tested, a report shall be prepared that describes the resistance of the medical glove material to

the drugs tested (see 6.1 and 6.2) and the information of the gloves used for testing. The report shall include at least the following:

7.1.1 The glove manufacturer's reference for the glove material submitted for test, that is, type of glove (for example, examination or surgeon's gloves), glove material (for example, natural rubber latex, nitrile, and so forth), glove physical specifications (for example, tensile strength, elongation), pinhole AQL, lot, and batch number,

7.1.2 The location of the area (that is, palm or cuff) where the 5 by 5-cm glove material specimen was obtained for testing,

7.1.3 The thickness of the test sample measured manually within nearest 20-µm graduation,

7.1.4 The name of the nine clinical drugs tested, name of manufacturers, lot number, expiration date, the concentration (mg/mL) at which the drug is tested, and the chemical name of the solvent used,

7.1.5 The solvent used as a collection medium (for example, distilled water or other liquids),

7.1.6 The breakthrough detection time (see 3.1.2),

7.1.7 If no permeation was detected or the permeation rate did not reach 0.01 µg/cm^2/min, report the fact that no permeation was detected or that the permeation rate did not reach the prescribed permeation rate of 0.01 µg/cm^2/min during the 4-h test period,

7.1.8 Whether permeation takes place or not, the duration of the test period shall be reported (for example, 4 h), and

7.1.9 Any observed physical changes of the test samples shall be documented. Such physical changes include but are not limited to signs of flaking, swelling, disintegration, embrittlement, or discoloration in accordance with Test Method D471.

8. Keywords

8.1 breakthrough detection time; chemotherapy; patient examination glove; permeation rate; surgeon's glove

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