Designation: ~~F1670/F1670M – 17a~~ F1670/F1670M – 24

Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood[1]

This standard is issued under the fixed designation F1670/F1670M; 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.

~~Note—A correction was made to 7.1.2 and the year date was changed on Oct. 25, 2017.~~

INTRODUCTION

Workers, primarily those in the healthcare ~~profession,~~profession involved in treating and caring for individuals injured or sick, can be exposed to biological liquids capable of transmitting disease. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This is especially true of blood-borne hepatitis (hepatitis B virus (HBV) and hepatitis C virus (HCV)) and acquired immune deficiency syndrome (AIDS) (human immunodeficiency viruses (HIV)). Since engineering controls ~~can not~~ cannot eliminate all possible exposures, attention is placed on reducing the potential of direct skin contact through the use of protective clothing that resists penetration (29 CFR Part 1910.1030). This test method was developed to help assess the effectiveness of materials used in protective clothing for protecting the wearer against contact with body fluids that potentially contain blood-borne pathogens. Using synthetic blood, this test method is intended to identify protective clothing material candidates for further testing according to a more rigorous procedure involving a surrogate for blood-borne pathogens.

1. Scope

1.1 This test method is used to evaluate the resistance of materials used in protective clothing to penetration by synthetic blood under conditions of continuous liquid contact. Protective clothing pass/fail determinations are based on visual detection of synthetic blood penetration.

1.1.1 This test method is not always effective in testing protective clothing materials having ~~thick,~~thick inner liners which readily absorb the synthetic blood.

1.2 This test method is a means for selecting protective clothing materials for subsequent testing with a more sophisticated barrier test as described in Test Method ~~F1671~~F1671/F1671M.

1.3 This test method does not apply to all forms or conditions of blood-borne pathogen exposure. Users of the test method must review modes for work/clothing exposure and assess the appropriateness of this test method for their specific application.

1.4 This test method addresses only the performance of materials or certain material constructions (for example, seams) used in

[1] This test method is under the jurisdiction of ASTM Committee F23 on Personal Protective Clothing and Equipment and is the direct responsibility of Subcommittee F23.40 on Biological.

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protective clothing. This test method does not address the design, overall construction and components, or interfaces of garments, or other factors which may affect the overall protection offered by the protective clothing.

1.5 The values stated in either SI units or inch-pound units are to be regarded separately as standard. The values stated in each system may not be exact equivalents; therefore, each system shall be used independently of the other. Combining values from the two systems may result in nonconformance with the standard.

1.6 *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.*

1.7 *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]

D1331 Test Methods for Surface and Interfacial Tension of Solutions of Paints, Solvents, Solutions of Surface-Active Agents, and Related Materials

D1777 Test Method for Thickness of Textile Materials

~~D3776~~D3776/D3776M Test Methods for Mass Per Unit Area (Weight) of Fabric

E105 Guide for Probability Sampling of Materials

~~E171~~E171/E171M Practice for Conditioning and Testing Flexible Barrier Packaging

F903 Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Liquids

~~F1671~~F1671/F1671M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

2.2 *Military Standard:*[3]

~~MIL-STD-105~~MIL-STD-105E Sampling Procedures and Tables for Inspection by Attributes

2.3 *ANSI/ASQC Standards:*[4]

ANSI/ASQC Z1.4 Sampling Procedures and Tables for Inspection by Attributes

2.4 *ISO Standard:*[5]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.5 *OSHA Standard:*[6]

29 CFR Part 1910.1030 Occupational Exposure to Blood-Borne Pathogens: Final Rule, *Federal Register*, Vol 56, No 235, Dec. 6, 1991, pp. 6175–64182

3. Terminology

3.1 *blood-borne pathogen, n*—an infectious secreted or excreted bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids.

3.2 *body fluid, n*—any liquid produced, secreted, or excreted by the human body.

3.2.1 *Discussion*—

In this test method, body fluids include those liquids potentially infected with blood-borne pathogens, including, but not limited to, blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid and peritoneal fluid, amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids (see 29 CFR Part 1910.1030).

3.3 *body fluid simulant, n*—a liquid ~~which~~that is used to ~~act as a model for~~ mimic aspects of human body fluids.

3.3.1 *Discussion*—

In this test method, synthetic blood is used as a body fluid simulant.

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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~~ Standardization Documents Order Desk, Bldg. 4 Section D, 700 Robbins Ave., Philadelphia, PA ~~19111-5094, Attn: NPODS.~~19111-5094. Document Status: Canceled.

[4] Available from American Society for Quality Control, 611 E. Wisconsin Ave., Milwaukee, WI 53202.

[5] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[6] Available from ~~Supt. of Documents,~~ U.S. Government ~~Printing~~Publishing Office, Washington, DC ~~20402.~~20402, http://www.gpo.gov.

3.4 *penetration, n*—the movement of matter through closures, porous materials, seams, and pinholes or other imperfections in protective clothing on a nonmolecular level.

3.4.1 *Discussion*—

For this test method, the specific matter is synthetic blood.

3.4.2 *Discussion*—

In this test method, the penetration liquid is synthetic blood.

3.5 *protective clothing, n*—an item of clothing that is specifically designed and constructed for the intended purpose of isolating all or part of the body from a potential hazard; or, isolating the external environment from contamination by the wearer of the clothing.

3.5.1 *Discussion*—

The potential hazard is contact with blood.

3.6 *synthetic blood, n*—a mixture of a red dye/surfactant, thickening agent, and distilled water having a surface tension and viscosity representative of blood and some other body fluids, and the color of blood.

3.6.1 *Discussion*—

The synthetic blood in this test method does not simulate all of the characteristics of real blood or body fluids, for example, polarity (a wetting characteristic), coagulation, and content of cell matter.

4. Summary of Test Method

4.1 A specimen is subjected to a body fluid simulant (synthetic blood) for a specified time and pressure.

4.2 Visual observation is made to determine when, or if, penetration occurs.

4.3 Any evidence of synthetic blood penetration constitutes failure. Results are reported as pass/fail.

5. Significance and Use

5.1 This test method is based on Test Method F903 for measuring resistance of chemical protective clothing materials to penetration by liquids. This test method is normally used to evaluate specimens from individual finished items of protective clothing and individual samples of materials that are candidates for items of protective clothing.

5.1.1 Finished items of protective clothing include gloves, arm shields, aprons, gowns, coveralls, hoods, and boots.

5.1.2 The phrase “specimens from finished items” encompasses seamed and other discontinuous regions as well as the usual continuous regions of protective clothing items.

5.2 Medical protective clothing materials are intended to be a barrier to blood, body fluids, and other potentially infectious materials. Many factors can affect the wetting and penetration characteristics of body fluids, such as surface tension, viscosity, and polarity of the fluid, as well as the structure and relative hydrophilicity or hydrophobicity of the materials. The surface tension range for blood and body fluids (excluding saliva) is approximately ~~0.042 to 0.060 N/m~~42 to 60 dyn/cm (0.042 to 0.060 N/m) (**1**).[7] To help simulate the wetting characteristics of blood and body fluids, the surface tension of the synthetic blood is adjusted to approximate the lower end of this surface tension range. The resulting surface tension of the synthetic blood is approximately ~~0.042 ± 0.002 N/m.~~40 ± 5 dyn/cm (0.040 ± 0.005 N/m).

5.3 The synthetic blood mixture is prepared with a red dye to aid in visual detection and a thickening agent to simulate the flow characteristics of blood.

5.4 Part of the protocol in Procedures A and B in Table 1 for exposing the protective clothing material specimens with synthetic blood involves ~~pressurization of~~ pressurizing the test cell to 13.8 kPa ~~[2~~[2.0 psig]. This hydrostatic pressure has been documented to discriminate between protective clothing material performance and to correlate with visual penetration results that are obtained

[7] The boldface numbers in parentheses refer to the list of references at the end of this standard.

TABLE 1 Specimen Exposure Procedures

Procedure	Pressure/Time Sequence and Retaining Screen Options
~~A~~	~~0 kPa [0 psig] for 5 min, followed by 13.8 kPa [2 psig] for 1 min, followed by 0 kPa [0 psig] for 54 min.~~
A	0 kPa [0 psig] for 5 min, followed by 13.8 kPa [2.0 psig] for 1 min, followed by 0 kPa [0 psig] for 54 min. A retaining screen is not used to support the sample.
~~B~~	~~0 kPa [0 psig] for 5 min, followed by 13.8 kPa [2 psig] for 1 min, followed by 0 kPa [0 psig] for 54 min.~~
B	0 kPa [0 psig] for 5 min, followed by 13.8 kPa [2.0 psig] for 1 min, followed by 0 kPa [0 psig] for 54 min. A retaining screen is used to support the sample. The type must be specified in the report.

with a human factors validation (**2**). Some studies, however, suggest that mechanical pressures exceeding 345 kPa [50 psig] can occur during clinical use (**3, 4**). Therefore, it is important to understand that this test method does not simulate all the physical stresses and pressures that are exerted on protective clothing garments during actual use. This test method is offered to identify those protective clothing materials that warrant further evaluation with a microbiological challenge.

5.5 Since this test method uses visual observation rather than analytical measurements ~~for determination of~~ to determine penetration, use this test method as a preliminary evaluation for possible penetration of blood and other body fluids. Perform subsequent testing with a microbiological challenge and analytical technique using Test Method ~~F1671~~F1671/F1671M.

NOTE 1—No viral resistance claims can be made based on this test method, as materials can pass the test method and fail Test Method ~~F1671~~F1671/F1671M.

5.6 Testing without considering degradation by physical, chemical, and thermal stresses which could negatively impact the performance of the protective barrier could lead to a false sense of security. Consider tests which assess the impact of storage conditions and shelf life for disposable products, and the effects of laundering and sterilization for reusable products. The integrity of the protective barrier can also be compromised during use by such effects as flexing and abrasion (**5**). It is also possible that prewetting by contaminating materials such as alcohol and perspiration can also compromise the integrity of the protective barrier. If these conditions are of concern, evaluate the performance of protective clothing materials for synthetic blood penetration following an appropriate preconditioning technique representative of the expected conditions of use.

5.7 While this test method involves a qualitative determination of the protective clothing material resistance to penetration by synthetic blood under specific test conditions, it is possible to use this test method as a material quality control or assurance procedure.

5.7.1 If this procedure is used for quality control, perform proper statistical design and analysis of the data when more than three specimens are tested. This type of analysis includes, but is not limited to, the number of individual specimens tested, the average percent passing or failing, or both, with a standard deviation. Data reported in this way helps to establish confidence limits concerning product performance. Examples of acceptable sampling plans are found in references such as ~~MIL-STD-105,~~MIL-STD-105E, ANSI/ASQC Z1.4, and ISO 2859-1.

6. Apparatus

6.1 *Thickness Gauge,* suitable for measuring thickness to the nearest 0.02 mm [or nearest 0.001 in.], in accordance with Test Method D1777 (optional).[8]

6.2 *Penetration Test Cell,*[9] to restrain the specimen during contact with the pressurized ~~test~~ synthetic blood. In the test cell, the specimen acts as a partition separating synthetic blood from the view side of the test cell. It consists of a cell body that is fastened to a cell support. The cell body has a capacity of approximately 60 mL [2.0 oz] for synthetic blood. A flange ~~cover,~~cover with an

[8] Thickness of each protective clothing material specimen tested may be determined prior to performing the test procedure, but is not required to comply with this test method. The thickness data for the material may be available from the manufacturer.

[9] The sole source of supply of the penetration test apparatus known to the committee at this time is Wilson Road Machine Shop, 1170 Wilson Road, Rising Sun, MD 21911. If you are aware of alternative suppliers, please provide this information to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee,[1] which you may attend.

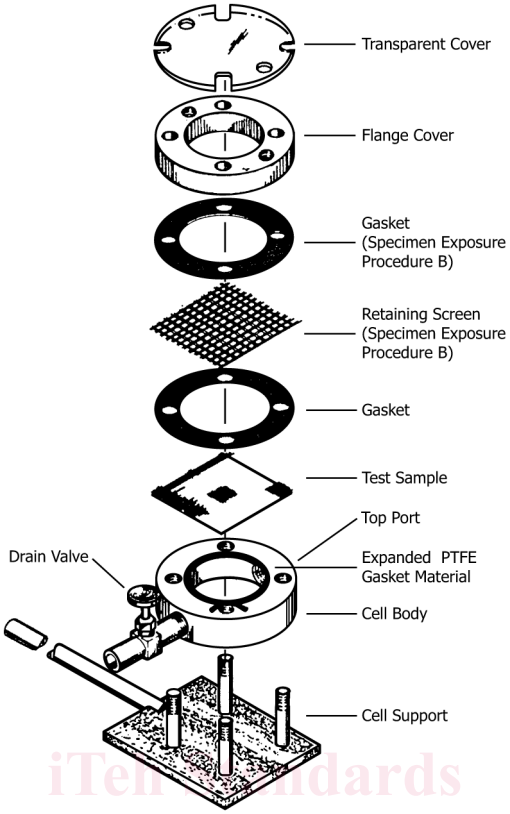

FIG. 1 —~~Exploded~~Exploded View of the Penetration Test Cell with Retaining Screen

open area to allow visual observation and a transparent cover are included. The cell body has a top port for filling and a drain valve for draining the penetration test cell. Other items, such as a fitting to allow attachment of the air line to the top port in the cell body, gaskets, and the retaining screen are also required. Specifications for the penetration test cell are provided in Test Method F903. A diagram of the test cell and apparatus are provided in Figs. 1 and 2, respectively.

6.3 *Retaining Screen,* a smooth-finish plastic or metal ~~square~~ mesh screen meeting the following specifications used for Procedure B from Table 1:

% open area	>50
~~Should limit deflection of sample to~~	~~<= 5.0 mm [0.2 in.]~~
Should limit deflection of sample to	≤ 5.0 mm [0.2 in.]

6.3.1 The retaining screen shall allow clear observation of liquid penetration and shall not compromise the sealing of the specimen in the test cell.

6.3.2 The retaining screen shall have a means for preventing the specimen from being forced into the mesh, which may cause damage or prevent effective sealing.

NOTE 2—For some materials, a gasket between the screen and the specimen is usually sufficient.

6.3.3 The recommended retaining screen design shall have hexagonal holes that measure 3 by 3 mm [or 0.125 by 0.125 in.], have greater than 65 % open area, have a smooth and flat surface in the sealing area that prevents damage to the specimen while under compression, and be made of 316 stainless steel.[10]

[10] ~~Acceptable retaining screen materials are 11 by 11 nylon screen (No. 9818T12), 14 by 14 polypropylene screen (No. 9275T11), and 13 by 13 polyester screen (No. 9218T12) from McMaster-Carr Supply Co., P.O. Box 4355, Chicago, IL 60680.~~An acceptable retaining screen is available from KCB Laser Cutting and Manufacturing, 27320 Meines St, Highland, CA 92346 (www.kcblaser.com).

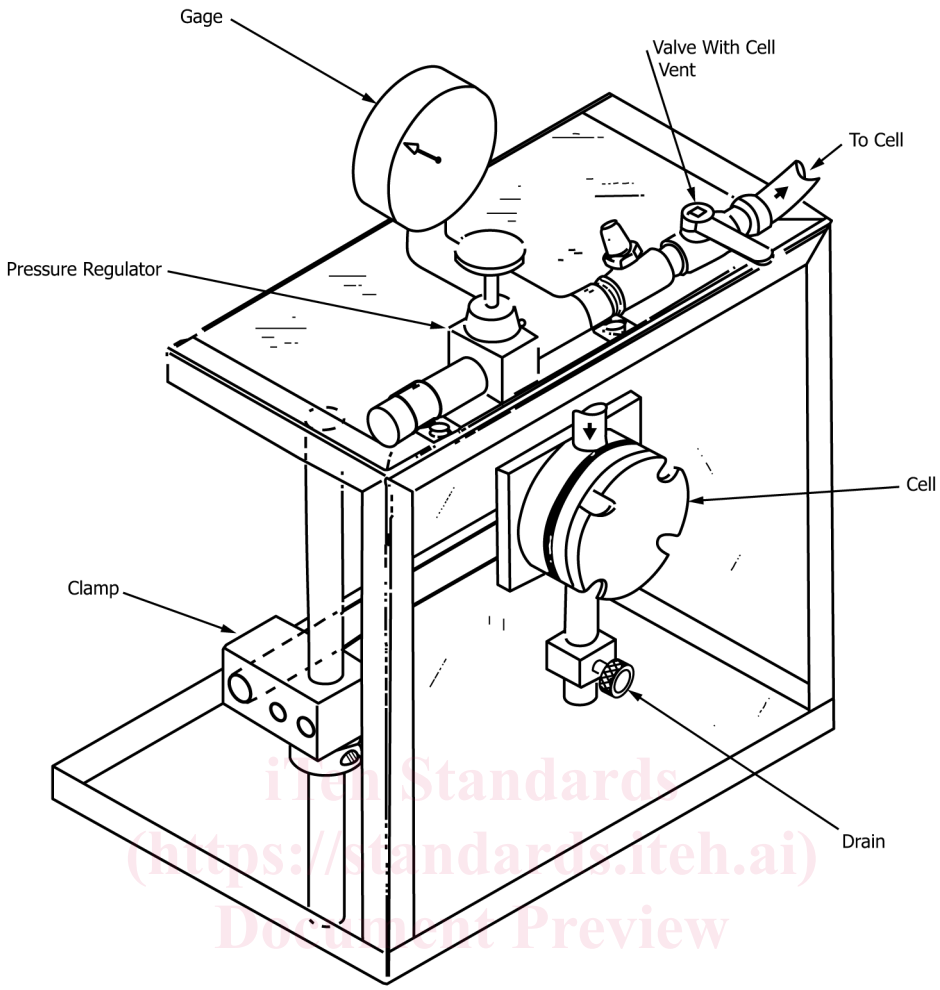

FIG. 2 ~~Three Dimensional~~ Three-Dimensional Side View of Apparatus

NOTE 3—The screen design criteria were updated in F903–24.

6.4 *Air Pressure Source,* capable of providing air at 13.8 ± 1.38 kPa [2.0 ± 0.2 psig].

6.5 *Stopwatch,* or electronic timer.

6.6 *Balance,* analytical, with precision of 0.001 g and suitable for measuring weight of each specimen to the nearest 10 g/m^2 [0.1 oz/yd^2] in accordance with Test Methods ~~D3776~~D3776/D3776M (optional).[11]

6.7 *Vessel,* graduated to measure water with a precision of 1 mL.

7. Reagents

7.1 *Synthetic Blood.*[12] Prepare using following ingredients:

7.1.1 *High Performance Liquid Chromatography ~~(HPLC),~~ (HPLC) Quality Distilled Water,* ~~quality distilled water (0.975~~ 0.975 L, pH 7.0 ± ~~0.5).~~0.5.

[11] The weight of each specimen may be determined prior to performing the test procedure, but is not required to comply with this test method. The basis weight of the material may be available from the manufacturer.

[12] Prepared synthetic blood meeting this specification, and small quantities of Direct Red 081, CI No. 28160 (Morfast Red 8BL) are available from JM & Co., 507-208-6390. Acrysol G111 is available from Dow Chemical Company.