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Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood Using a Mechanical Pressure Technique[1]

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INTRODUCTION

Workers, primarily those in the health care 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 viruses which cause Hepatitis (Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV)) and Acquired Immune Deficiency Syndrome (AIDS) (Human Immunodeficiency Viruses (HIV)). Since engineering controls cannot eliminate all possible exposures, attention is placed on reducing the potential for 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 determine the amount of mechanical pressure that will cause penetration of a liquid through a material used in protective clothing.

1. Scope

1.1 This test method is used to evaluate the resistance of materials used in protective clothing to synthetic blood under the conditions of liquid contact and increasing direct mechanical pressure. The penetration resistance of protective clothing is based on visual detection of synthetic blood penetration at a specific applied mechanical pressure.

1.2 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.

1.3 This test method addresses only the performance of materials or certain material constructions (for example, seams) used in protective clothing. This test method does not address the design, overall construction, components, or interfaces of garments, or other factors which may affect the overall protection offered by the protective clothing.

1.4 The values in SI units or in other units shall be regarded separately as standard. The values stated in each system must be used independently of the other, without combining values in any way.

1.5 *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:*

D 1331 Test Methods for Surface and Interfacial Tension in Solutions of Surface-Active Agents[2]

D 1777 Test Method for Measuring Thickness of Textile Materials[3]

D 3776 Test Method for Mass Per Unit Area (Weight) of Fabric[4]

E 105 Practice for Probability Sampling of Materials[5]

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

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[2] *Annual Book of ASTM Standards*, Vol. 15.04

[3] *Annual Book of ASTM Standards*, Vol. 07.01

[4] *Annual Book of ASTM Standards*, Vol. 07.02

[5] *Annual Book of ASTM Standards*, Vol. 14.02

E 171 Specifications for Standard Atmospheres for Conditioning and Testing Materials[6]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[5]

F 1494 Terminology Relating to Protective Clothing[7]

F 1670 Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood[7]

F 1671 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[7]

2.2 *ANSI/ASQC Standards*[8]

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

2.3 *ISO Standard*[9]

ISO 2859-1 Sampling Plans for Inspection by Attributes

2.4 *Military Standard*[10]

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

2.5 *OSHA Standard*[11]

CFR Part 1910.1030 Occupational Exposure to Bloodborne Pathogens: Final Rule, *Federal Register*, Vol 56, No 235, Dec. 6, 1991, pp. 64175–64182.

3. Terminology

3.1 *Definitions:*

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

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

3.1.2.1 *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).

3.1.3 *body fluid simulant*, *n*—a liquid which is used to act as a model for human body fluids.

3.1.4 *hydrostatic pressure*, *n*—the force exerted by a static liquid **(1)**[12]

3.1.5 *mechanical pressure*, *n*—the force exerted by one solid object upon another that it is touching. **(1)**

3.1.6 *penetration*, *n*— *for biological protective clothing*, the flow of a body fluid on a non-molecular level through closures, porous materials, seams, and pinholes or other imperfections in protective clothing.

3.1.6.1 *Discussion*—In this test method, the penetration liquid is synthetic blood, a body fluid simulant.

3.1.7 *protective clothing*, *n*—any material or combination of materials used in an item of clothing for the purpose of isolating parts of the body from a potential hazard.

3.1.7.1 *Discussion*—In this test method, the potential hazard of contact with blood or other body fluids is simulated.

3.1.8 *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.

3.1.8.1 *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, content of cell matter.

3.1.9 For definitions of other protective clothing-related terms used in this test method, refer to Terminology F 1494.

4. Summary of Test Method

4.1 Using a special test apparatus, a specimen is contacted with synthetic blood under a continuously increasing mechanical pressure until the synthetic blood penetrates the specimen or a load of 90.7 kg (200 lbs) is applied to a 57.2 mm (2.25 in.) diameter portion of the specimen achieving a pressure on the tested specimen of 345 kPa (50 psig).

4.2 The specimen's non-contact side is observed to determine if visual penetration occurs, and if so, at what mechanical pressure the penetration occurs.

4.3 In conducting a test, the cover plate containing a test head is locked on the two side supports of the base plate of the test apparatus, the multi-position switch is turned to the *manual up* position, and the test button on top of the control box is held down until visible penetration of the test specimen by synthetic blood is observed through the circular test head. Releasing the button stops the drive motor, and the penetration pressure is shown digitally on the display unit and recorded by the technician.

5. Significance and Use

5.1 This test method was modeled after a procedure commonly known as the Elbow Lean Test.[13] The Elbow Lean Test involves the application of synthetic blood to an ink pad, placement of sample fabric over the blood soaked pad, placement of a blotter over the sample fabric, and applying elbow or fingertip pressure on top of the blotter. The blotter is then examined for staining as evidence of blood penetration. This test method provides similar procedures which standardize the test equipment and application of pressure through an adopted methodology.

5.2 This test method is intended to simulate actual use conditions wherein areas of the health care worker's protective clothing are soaked with blood and compressed between the

[6] *Annual Book of ASTM Standards*, Vol. 15.09

[7] *Annual Book of ASTM Standards*, Vol. 11.03

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

[9] Available from American National Standards Institute, 11 W. 42nd St., 13th Floor, New York, NY 10036.

[10] Available from Standardization Documents Order Desk, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5094, Attn: NPODS.

[11] Available from Supt. of Documents, U.S. Government Printing Office, Washington, DC 20402.

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

[13] Originally developed by W.L.Gore and Assoc., Inc., Elkton, MD 21921.

patient's body and that of the health care worker, or similarly between the health care worker and instruments. In both cases, unconfined blood moves away from the pressure point taking the path of least resistance rather than being contained as in Test Methods F 1670 and F 1671.

5.3 This test method uses predominately mechanical pressure as opposed to contained, hydrostatic pressure to demonstrate liquid penetration resistance **(1,2)**. It simulates actual use conditions with a single insult where free flowing liquids on the outer surfaces of a protective clothing item are momentarily pressurized against the item by the body and other objects.

5.4 Because this test method provides quantitative results, it is useful for discriminating differences in the liquid barrier performance of protective clothing materials. This test method can be used for measuring differences in the penetration pressure for protective clothing materials which do not pass Test Method F 1670.

5.5 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.

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

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

5.6 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 **(3)**. 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 0.042 ± 0.002 N/m.

5.7 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. The synthetic blood may not duplicate the polarity, and thus wetting behavior and subsequent penetration, of real blood and other body fluids through protective clothing materials.

5.8 It is known that body fluids penetrating protective clothing materials are likely to carry microbiological contaminants; however, visual detection methods are not sensitive enough to detect minute amounts of liquid containing microorganisms **(4,5,6)**. No viral resistance claims can be made based on this test method as materials can pass this test method and fail Test Method F 1671.

5.9 Part of the protocol for exposing the protective clothing material specimens to synthetic blood involves applying mechanical pressure up to 345 kPa (50 psig). This mechanical pressure has been documented to discriminate between protective clothing material performance and correlate with visual penetration results that are obtained with human factors validation.[1] Some studies suggest that mechanical pressures exceeding 345 kPa (50 psig) can occur during clinical use **(8,9)**.

NOTE 1—The mechanical pressure tester can be adjusted to evaluate materials at higher pressures.

5.10 Testing prior to 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 clothing can also be compromised during use by such effects as flexing and abrasion **(10)**. It is also possible that prewetting by contaminants such as alcohol and perspiration can compromise the integrity of the protective clothing. Furthermore, high relative humidity may also affect the resistance of materials used in protective clothing to penetration by blood and other body fluids. If these conditions are of concern, evaluate the performance of protective clothing for synthetic blood penetration following an appropriate pretreatment technique representative of the expected conditions of use.

5.11 This test method involves a quantitative determination of a protective clothing penetration resistance to synthetic blood under specific test conditions. It can also be used as a qualitative method for comparing the penetration resistance characteristics of similar materials and as a material quality control or assurance procedure.

5.12 If this test method is used for quality control, perform proper statistical design and analysis of larger data sets where more than three specimens are tested. This type of analysis includes, but is not limited to, reporting the number of individual specimens tested and the average penetration pressure of specimens with a standard deviation. Data reported in this way helps establish confidence limits concerning product performance. Examples of acceptable sampling plans are found in references such as MIL-STD-105, ANSI/ASQC Z1.4, and ISO 2859–1.

5.13 In the case of a dispute arising from differences in reported results when using this test method for acceptance testing of commercial shipments, the purchaser and the supplier should conduct comparative tests to determine if there is a statistical bias between their laboratories. Competent statistical assistance is recommended for investigation of bias. As a minimum, the two parties should take a group of test specimens which are as homogeneous as possible and which are from a lot of the product of the type in question. The test specimens should then be randomly assigned in equal numbers to each laboratory for testing. The average results from the two laboratories should be compared using a non-parametric test for unpaired data and an acceptable probability level chosen by the two parties before testing is begun. If a bias is found, either its cause must be found and corrected or the purchaser and the supplier must agree to interpret future test results with consideration to the known bias.

6. Apparatus

6.1 *Thickness Gage*, suitable for measuring thickness to the nearest 0.02 mm (0.001 in.), in accordance with Test Method

D 1777, used to determine the thickness of each protective clothing material specimen tested.

6.2 *Mechanical Penetration Tester,*[14,15], shown in Fig. 1, consisting of a base plate, a variable speed drive motor, a belted gear driven screw, a lower platform, load cell, upper platform, cover plate, control box, and display unit. The driver motor is connected to the screw through a belted gear. The screw is then connected to the underside of the lower platform which moves up and down, in tubular sleeves when the screw turns at a rate of 827.5 RPM which corresponds to a platform vertical speed of ± 0.20 mm/min (0.479 ± 0.008 in./min). The top of the lower platform is fastened to the bottom of the load cell, and the top of the load cell is fastened to the underside of the upper platform. The upper platform provides a location for resting the petri dish containing a foam pad and synthetic blood and the specimen. The control box has a test button and multi-position switch with settings for *down, off, auto up,* and *manual up*. A display unit indicates the load (weight) from the load cell in lbs.

NOTE 2—If desired the mechanical pressure tester can be adjusted to achieve lower or higher application speeds. A separate control is provided for this purpose.

6.2.1 Since small differences in the screw and control box may exist between different mechanical pressure testers, ensure that the platform moves at a speed of 12.17 ± 0.20 mm/min (0.479 ± 0.008 in/min).

6.3 *Circular Test Head*, transparent, with a diameter of 57.2 mm (2.25 in.) and a surface area of 2570 mm^2 (3.976 $in.^2$).

6.4 *Petri Dish*, plastic, 93 × 93 × 15 mm.

6.5 *Foam Pad*, polyester, 0.64 mm (0.25 in.) thick, non-reticulated, with 90 pores/in., a compression ration of 3:1, and free of surfactants and other additives, cut to fit the petri dish dimensions.[15,16]

6.6 *Rod*, poly (methyl methacrylate) (PMMA), approximately 2.5 mm in diameter by 300 mm in length, for saturating the foam pads with synthetic blood and removing air bubbles.

6.7 *Bubble Level*, for leveling instrument.

6.8 *Ruler*, graduated in 1 mm (0.05 in.) increments, for measuring the height of the synthetic blood in the petri dish.

7. Reagents

7.1 *Synthetic Blood*[15,17]—If synthetic blood is not purchased, prepare using following ingredients:

7.1.1 *High Performance Liquid Chromatography (HPLC)*, quality distilled water (1.0 L, pH 7.0 ± 0.5)

7.1.2 *Thickening agent,*[17,15] 25.0 g.

7.1.3 *Red dye*[15,17] containing colorant and surfactant, 10.0 g.

7.1.4 To reduce biological contamination, boil the distilled water for 5 min and allow to cool to room temperature before mixing. Measure amount of distilled water at 20°C (± 1°C) after boiling.

7.1.5 Add the thickening agent to the distilled water and mix 45 min at room temperature on a magnetic stirring plate.

7.1.6 Add the red dye and mix 1 h or more.

NOTE 3—The red dye will stain skin, clothes, and work surfaces.

7.1.7 Determine the corrected surface tension of the solution using Test Method D 1331. The expected value of the corrected surface tension is 0.042 ± 0.002 N/m. Do not use synthetic blood solutions unless within the specified range of surface tension.

7.1.7.1 The amount of surfactant in the red dye may vary significantly causing unacceptable surface tension variability from batch to batch. If the corrected surface tension is too high, discard the batch of prepared synthetic blood. If the corrected surface tension is too low, remove excess surfactant from the red dye by mixing 25 g of red dye with 1 L of 90 % isopropanol, decant 80 % of the tainted alcohol, and discard or save for distillation. Pour dye - alcohol solution into an evaporation dish, spread thin, and cover with filter paper to allow residual alcohol to completely evaporate. The red dye is ready for use when dry.

7.1.7.2 Remove excess surfactant from the synthetic blood by allowing the mixture to settle for 24 h and then by carefully decanting the top 10 % of the mixture.

7.1.8 Store synthetic blood in a clear glass container at room temperature.

7.1.9 Shake synthetic blood well before using to prevent its separation.

7.1.10 Discard the solution if a gel-like precipitate forms.

7.2 *Isopropanol*, laboratory grade, for cleaning of circular test head.

8. Hazards

8.1 Because the synthetic blood readily stains clothing, wear a laboratory coat or similar cover during testing.

8.2 Keep fingers and hands away from the gears, drive belt, and test head when the tester motor is running. Place a safety shield or panel between the apparatus and the operator to minimize this hazard. See Note 4.

NOTE 4—**Warning:** Ensure that the cover plate is properly secured before operating the apparatus.

9. Test Specimen

9.1 Specimens selected from single material samples or individual protective clothing items consist of either a single layer or a composite of multiple layers that is representative of an actual protective clothing construction with all layers arranged in proper order.

9.1.1 If, in the design of an item of protective clothing, different materials or thicknesses of material are specified at different locations, select specimens from each location.

[14] Apparatus available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.

[15] The supplier named is the sole source of supply known to the committee at this time. If you are aware of alternative suppliers, please provide this information to ASTM Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee' which you may attend.

[16] A suitable pad is a Foamex Product #3-900C custom felt, polyester, beige color foam for medical end use. Foam pads are available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.

[17] Prepared synthetic blood meeting this specification, small quantities of Direct Red 081, CI #28160 (Morfast Red 8BL), and Acrysol G110 are available from Johnson, Moen & Co., 2505 Northridge Lane NE, Rochester, MN 55906.