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Standard 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[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 Virus (HIV)). Since engineering controls can not 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 assess the effectiveness of materials used in protective clothing for protecting the wearer against contact with blood-borne pathogens using a surrogate microbe suspended in a body fluid simulant under conditions of continuous contact.

1. Scope

1.1 This test method is used to measure the resistance of materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe under conditions of continuous liquid contact. Protective clothing material pass/fail determinations are based on the detection of viral penetration.

1.1.1 This test method is not always effective in testing protective clothing materials having thick, inner liners which readily absorb the liquid assay fluid.

1.2 This test method does not apply to all forms or conditions of blood-borne pathogen exposure. Users of the test method should review modes for worker/clothing exposure and assess the appropriateness of this test method for their specific applications.

1.3 This test method has been specifically defined for modeling the viral penetration of Hepatitis (B and C) and Human Immunodeficiency Viruses transmitted in blood and other potentially infectious body fluids. Inferences for protection from other pathogens must be assessed on a case-by-case basis.

1.4 This test method addresses only the performance of materials or certain material constructions (for example, seams) used in protective clothing and determined to be viral resistant. 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 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.

1.6 *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*

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

D3862 Test Method for Retention Characteristics of 0.2-µm Membrane Filters Used in Routine Filtration Procedures for the Evaluation of Microbiological Water Quality

E105 Guide for Probability Sampling of Materials

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

F1670/F1670M Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

2.2 *Military Standard:*[3]

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

2.3 *ANSI/ASQ Standard:*[4]

ANSI/ASQ 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 Bloodborne Pathogens

3. Terminology

3.1 *Definitions:*

3.1.1 *agar, n*—a semisolid culture medium used to support the growth of bacteria and other microorganisms.

3.1.2 *aseptic, adj*—sterile, free from viable microbiological contamination.

3.1.3 *assay, n*—analysis of a mixture to determine the presence or concentration of a particular component.

3.1.3.1 *Discussion*—In this test method, the component being analyzed is a microorganism, Phi-X174 Bacteriophage.

3.1.4 *assay fluid, n*—a sterile liquid used to wash the test specimen surface to determine microbiological penetration.

3.1.4.1 *Discussion*—In this test method, the assay fluid is bacteriophage nutrient broth and the microorganism is the Phi-X174 Bacteriophage. The assay fluid is used to wash the Phi-X174 Bacteriophage from the normal inside surface of the test specimen.

3.1.5 *bacteriophage, n*—a type of virus which infects bacteria.

3.1.5.1 *Discussion*—In this test method, the bacteriophage is Phi-X174. The Phi-X174 Bacteriophage is not pathogenic to humans, but serves to simulate viruses that are pathogenic to humans.

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

3.1.6.1 *Discussion*—For the purpose of this test method, the primary blood-borne pathogens include Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human Immunodeficiency Virus (HIV). Other microorganisms must be considered on a case-by-case basis.

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

3.1.7.1 *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, peritoneal fluid, amniotic fluid, saliva in dental procedures, 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 section 29 CFR Part 1910.1030).

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

3.1.8.1 *Discussion*—In this test method, the body fluid simulant is bacteriophage nutrient broth, which is intended as a model for human body liquids as it approximates the lower end of the surface tension range for blood and body fluids (excluding saliva), 0.042 ± 0.002 N/m.

3.1.9 *challenge suspension, n*—a liquid containing an agent that is used to test the penetration resistance of materials.

3.1.9.1 *Discussion*—In this test method, the challenge suspension is the bacteriophage challenge suspension, a nutrient broth containing the Phi-X174 Bacteriophage.

3.1.10 *lawn, n—as in microbiology*, a cloudy, uniform growth of bacteria in a thin layer of top agar in a petri dish.

3.1.10.1 *Discussion*—In this test method, *E. coli C.* has been selected as the bacterium used to produce the lawn.

3.1.11 *lysis, n*—the disintegration or destruction of whole bacterial cells.

3.1.11.1 *Discussion*—In this test method, the lysis of the host bacteria, *E. coli C.*, is caused by Phi-X174 Bacteriophage.

3.1.12 *medium (plural, media), n*—a nutrient system for the cultivation of cells or organisms, and especially bacteria.

3.1.12.1 *Discussion*—In this test method, the term media is

[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, DODSSP, Bldg. 4, Section D, 700 Robbins Ave., Philadelphia, PA 19111-5098, http://dodssp.daps.dla.mil.

[4] Available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203, http://www.asq.org.

[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 U.S. Government Printing Office Superintendent of Documents, 732 N. Capitol St., NW, Mail Stop: SDE, Washington, DC 20401, http://www.access.gpo.gov.