First edition
2004-04-01

Clothing for protection against contact with blood and body fluids — Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

Vêtements de protection contre les contacts avec le sang et les fluides corporels — Détermination de la résistance à la pénétration par des pathogènes véhiculés par le sang des matériaux entrant dans la fabrication des vêtements de protection — Méthode d'essai utilisant le bactériophage Phi-X174

Reference number
ISO 16604:2004(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16604 was prepared by Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*. It is based on ASTM F1671-97b.

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 of direct skin contact through the use of protective clothing.

This International Standard is concerned with protective clothing and related protective devices designed to protect against the penetration of blood or body fluids.

Given the variety of health care settings, activities, and the potential for exposure to blood or body fluids, the barrier requirements for protective clothing materials will change with the application.

This International Standard describes a hydrostatic pressure test for measuring the viral penetration resistance of clothing materials to a surrogate virus. The choice of an appropriate test method depends on the specific application of protective clothing and its intended use. A risk assessment should be performed to determine the level of risk for determining the appropriate test method.[1]

This test method does not apply to all forms or conditions of blood-borne pathogen exposure. Users of this test method should review modes for worker/clothing exposure and assess the appropriateness of this test method for their specific applications. This test method has been specifically defined for modelling the viral penetration of hepatitis (B and C) and human immunodeficiency viruses transmitted in blood and other potentially infectious body fluids. The surrogate microbe, Phi-X174 bacteriophage, used in this test method, is similar to HCV in size and shape but also serves as a surrogate for HBV and HIV. Inferences for protection from other pathogens should be assessed on a case-by-case basis.

This test method addresses only the performance of materials or certain material constructions (e.g. seams) used in 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. It is emphasized that the test does not necessarily simulate conditions that clothing materials are likely to be exposed to in practice. The use of test data should therefore be restricted to broad comparative assessment of such material according to their viral penetration resistance characteristics.

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 sterilization, storage conditions, and shelf life on the penetration resistance for disposable products, and the effects of laundering and sterilization on the penetration resistance for reusable products. The integrity of the protective barrier can also be compromised during use by such effects as flexing and abrasion.[1] It is also possible that pre-wetting by contaminating materials such as alcohol and perspiration also compromises the integrity of the protective barrier. If these conditions are of concern, evaluate the performance of protective clothing materials for Phi-X174 bacteriophage penetration following an appropriate preconditioning technique representative of the expected conditions of use.

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 N/m to 0,060 N/m.[2] In order to help simulate the wetting characteristics of blood and body fluids, the surface tension of the Phi-X174 bacteriophage challenge suspension is adjusted to approximate the lower end of this surface tension range. The resulting surface tension of the Phi-X174 bacteriophage challenge suspension is (0,042 $\pm$ 0,002) N/m.

Part of this method for exposing the protective clothing material specimens with Phi-X174 bacteriophage challenge suspension involves pressurization of the test cell to 14,0 kPa (in Procedures A and B). This hydrostatic pressure has been documented to produce test results that correlate with visual penetration results that are obtained with a human factors validation.[3] Some studies, however, suggest that mechanical pressures exceeding 345 kPa can occur during clinical use.[4] [5] 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. Procedures C and D use a stepped pressurization approach with pressures up to 20,0 kPa. These procedures simulate a range of possible pressures for ranking material performance.