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**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**

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In the event of any doubts arising as to the contents,
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Foreword

This translation has been made based on the original Japanese Industrial Standard revised by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Japan Safety Appliances Association (JSAA)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 8061 : 2007** has been replaced with this Standard.

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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

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 16604 published in 2004 with some modifications of the technical contents.

The portions underlined with dots in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard describes a laboratory test method for measuring the resistance of materials used in protective clothing to penetration by blood-borne pathogens. This test method uses a surrogate microbe (Phi-X174 bacteriophage) under conditions of continuous liquid contact. Protective clothing performance evaluation is based on the detection of viral penetration at a specific hydrostatic pressure using the JIS T 8031 test apparatus.

This test method is not always effective in testing protective clothing materials having thick, inner liners that readily absorb the challenge fluid. Because of the length of time required to complete this test method, it might not be suitable for use as a material or protective clothing quality control or assurance procedure.

This test method requires the knowledge about the basic microbiological techniques such as culture of bacteriophage.

NOTE : The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 16604 : 2004 *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* (MOD)

In addition, symbols which denotes the degree of correspondence in contents between the relevant International Standard and JIS, are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of indicated year shall apply but the revision (including amendments) made thereafter shall not apply. The normative references without the indication of the year shall apply only to the most recent editions (including amendments).

JIS K 3362 *Test method of household synthetic detergent*

JIS K 3605 *General rules for autoclaving*

JIS K 8008 *General rules for biochemical reagents*

JIS L 1018 *Test methods for knitted fabrics*

NOTE : Corresponding International Standard : **ISO 5084** *Textiles — Determination of thickness of textiles and textile products* (MOD)

JIS L 1096 *Testing methods for woven fabrics*

NOTE : Corresponding International Standard : **ISO 3801** *Textiles — Woven fabrics—Determination of mass per unit length and mass per unit area* and **ISO 5084** *Textiles—Determination of thickness of textiles and textile products* (Overall evaluation : MOD)

JIS T 8031 *Clothing for protection against liquid chemicals—Determination of the resistance of protective clothing materials to penetration by liquids under pressure*

NOTE : Corresponding International Standard : **ISO 13994** *Clothing for protection against liquid chemicals— Determination of the resistance of protective clothing materials to penetration by liquids under pressure* (MOD)

JIS T 8060 *Clothing for protection against contact with blood and body fluids— Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood*

NOTE : Corresponding International Standard : **ISO 16603** *Clothing for protection against contact with blood and body fluids—Determination of the resistance of protective clothing materials to penetration by blood and body fluids—Test method using synthetic blood* (MOD)

ISO 3696 : 1987 *Water for analytical laboratory use—Specification and test methods*

3 Terms and definitions

For the purposes of this Standard, the following terms and definitions apply.

3.1 agar

semi-solid culture medium used to support the growth of bacteria and other microorganisms, in which agar is used

3.2 assay

analysis of a mixture to determine the presence of or concentration of a particular component

NOTE : In this test method, the particular component is a microorganism, Phi-X174 bacteriophage.

3.3 assay fluid

sterile liquid used to wash the test material surface to determine microbiological penetration

NOTE : In this test method, the assay fluid is nutrient broth and the bacterial virus is the Phi-X174 bacteriophage. The assay fluid is used to wash the Phi-X174 bacteriophage from the inside surface of the test specimen.

3.4 bacteriophage

one type of virus that infects bacteria

NOTE : The bacteriophage used in this test method is Phi-X174 bacteriophage (ATCC 13706-B1) (hereafter referred to as Phi-X174 bacteriophage). The Phi-X174 bacteriophage is not pathogenic to humans, but serves to simulate viruses that are pathogenic to humans.

3.5 blood-borne pathogen

infectious secreted or excreted bacterium, virus, or other disease-inducing microbe carried in blood or other body fluids

3.6 body fluid

any liquid produced by the body

3.7 body fluid simulant

liquid that is used to act as a model for human body liquids

NOTE : 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.

3.8 challenge suspension

liquid containing an agent that is used to test the penetration resistance of materials

NOTE : In this test method, the challenge suspension is a nutrient broth containing the Phi-X174 bacteriophage.

3.9 lawn

cloudy, uniform growth of bacteria in a thin layer of top agar in a petri dish

NOTE : (microbiological term) In this test method, *Escherichia coli* C. [*E.coli*.C (ATCC 13706)](hereafter referred to as "*E. coli*. C.") has been selected as the bacterium used to produce the lawn.

3.10 lysis

disintegration or destruction of whole bacterial cells

NOTE : In this test method, the lysis of the host bacteria, *E. coli* C., is caused by Phi-X174 bacteriophage.

3.11 medium, media

mixtures compounded to support the growth of specific microorganisms, for example, bacteriophage nutrient broth and top agar.

3.12 morphology

form and structure of a particular organism

3.13 nutrient broth

liquid medium

NOTE : In this test method, the nutrient broth is used to culture the host bacteria, *E. coli* C. It is used to produce the Phi-X174 bacteriophage suspension, and to serve as the washing recovery liquid or diluent in each step of this test.

3.14 penetration

process in which particles or liquids flow through porous materials, seams, pinholes or other imperfections in a protective clothing

3.15 plaque

visible, clear area that is theoretically the result of the infection and lysis of host cells by a single viable virus

NOTE : (virological term) In this test method, the plaque means a visible, clear area, in the lawn of *E. coli* C. in top agar which is theoretically the result of a single viable Phi-X174 bacteriophage, where the bacteria have been destroyed by bacteriophage infection and lysis.

3.16 plaque-forming unit PFU

a unit of virus particle capable of producing plaques

NOTE : Theoretically one PFU in a lawn corresponds to a single viable virus.

3.17 plate

Petri dish containing agar culture medium

NOTE : (biological term)

3.18 protective clothing

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

3.19 surrogate microbe

microorganism that is used in this test to act as a simulant for other microorganisms that are pathogenic to humans

NOTE : In this test method, the Phi-X174 bacteriophage is a surrogate microbe.

3.20 titre

quantity of a substance required to react with, or to correspond to, a given amount of another substance

NOTE : In this test method, titre is used to describe the concentration of viable bacteriophage as measured in plaque-forming units per millilitre (PFU/ml).

3.21 virus

microbe, which lacks independent metabolism and is only able to replicate within a living host cell