
Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration

Champs chirurgicaux, casaques et tenues de bloc, utilisés en tant que dispositifs médicaux, pour les patients, le personnel et les équipements — Méthode d'essai de résistance à la pénétration de la barrière bactérienne à l'état humide



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Published in Switzerland

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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 22610 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in collaboration with Technical Committee ISO/TC 94, *Personal safety — Protective clothing and equipment*, Subcommittee SC 13, *Protective clothing*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Introduction

There are numerous examples of situations where bacteria carried by a liquid may migrate through a barrier material in the wet state. The wet penetration of skin flora through a covering material is one example.

European Medical Device regulations specifically place the responsibility for avoiding device-related infections on the manufacturer. In order to demonstrate compliance with this requirement and to describe a product to the user, there is a need to use harmonized and recognized international test methods.

The test method described in this international standard uses microbiological techniques and is therefore intended to be performed exclusively by laboratories experienced in and equipped for such work.

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Surgical drapes, gowns and clean air suits, used as medical devices, for patients, clinical staff and equipment — Test method to determine the resistance to wet bacterial penetration

WARNING — The use of this standard may involve hazardous materials, operations and equipment. This standard does not purport to address all of the safety problems associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and to determine the applicability of regulatory limitations prior to use.

1 Scope

This International Standard specifies a test method, with associated test apparatus (see Annex A), which is used to determine the resistance of a material to the penetration of bacteria, carried by a liquid, when subjected to mechanical rubbing.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 139, *Textiles — Standard atmospheres for conditioning and testing*

ISO 6330, *Textiles — Domestic washing and drying procedures for textile testing*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13683, *Sterilization of health care products — Requirements for validation and routine control of moist heat sterilization in health care facilities*

ISO 13934-1, *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method*

ISO 13937-2, *Textiles — Tear properties of fabrics — Part 2: Determination of tear force of trouser-shaped test specimens (Single tear method)*

ISO 15797, *Textiles — Industrial washing and finishing procedures for testing of workwear*

EN 554, *Sterilization of medical devices — Validation and routine control of sterilization by moist heat*

3 Terms and definitions

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

3.1

agar plate

Petri dish containing sterile nutrient agar medium

NOTE See Annex B for composition of nutrient media.

3.2

carrier material

material used to prepare the donor

3.3

covering material

material, e.g. surgical drapes, used for covering the patient, equipment and certain surfaces to prevent the patient's skin bacteria and/or bacteria from other non-sterile sources from reaching the operation wound

3.4

donor

material that has been contaminated with a known number of viable cells of a defined strain of test bacterium

3.5

finger

part of the apparatus for testing resistance to wet bacterial penetration, used to bring donor and test specimen into contact with the surface of an agar plate

3.6

replicate test

one complete evaluation of a single test piece, from the test specimen, comprising five plate counts directly against the donor and a sixth plate to estimate the residual bacterial challenge on the reverse of the test piece

3.7

test material

piece of covering material, 25 cm × 25 cm, for which the resistance to wet bacterial penetration is being determined

3.8

reference material

standardized material to assess the precision of the laboratory when performing the test for resistance to wet bacterial penetration

3.9

resistance to wet bacterial penetration

the resistance of a barrier to the penetration of bacteria, carried by a liquid, when subjected to mechanical rubbing

4 Principle

A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 µm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface.

After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time.

Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique.

The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

The results may be processed in accumulated form in order to characterize the barrier capability and penetration over time of the material (see Annex C).

5 Reagents and materials ¹⁾

- 5.1 Five sets of 6 agar plates**, 14 cm diameter, filled with nutrient agar (see B.4 and 7.1).
- 5.2 Five pieces of carrier material**, 25 cm × 25 cm, to produce donors (see 7.2).
- 5.3 Five pieces of HDPE film**, 25 cm × 25 cm, or with a diameter of 25 cm, of approximate thickness 10 µm, for use as finger covers. The HDPE film shall have a density of (950 ± 2) kg/m³ and a mass flow rate (190 °C, 5 kg) of 0,027 g/min.
- 5.4 *Staphylococcus aureus* ATCC 29213 strain.**
- 5.5 Five test specimens**, 25 cm × 25 cm (see 7.3).
- 5.6 Reference material** (for use in 10.3) comprising a 135 g/m² microfilament polyester fabric, washed three times in accordance with an appropriate wash process in ISO 6330 or ISO 15797.

6 Apparatus

- 6.1 Cylindrical body**, approximately 9 cm in diameter and 4 cm in height.
- 6.2 Apparatus**, as shown in Annex A.

The apparatus has an electrically-driven, timer-controlled turntable which holds a 14 cm diameter agar plate. A horizontal lever with a vertical finger at its end is fitted to a pivot, allowing sideways movements of the finger from the centre to the periphery and back of the rotatable (60 r/min) agar plate. A weight can be slid along the lever to adjust the force exerted by the finger on the materials. The lever is guided by an eccentric cam rotating at 5,60 r/min. The finger, which has a semi-spherical, polished end of radius 11 mm, is removable and shall be disinfected between tests.

The force of $(3 \pm 0,02)$ N exerted by the finger on the materials may be measured by a dynamometer attached to the lever, or by a balance placed on the turntable, and shall be set using the slidable weight.

The material being tested shall only be in contact with the agar at one point at any given time. To ensure that the finger moves over the entire surface, it shall be regularly monitored using the method described in Clause 10. By applying this method, a quality record is obtained which shall be retained.

7 Preparation of test samples and pieces

7.1 Agar plates

6 Petri dishes, 14 cm in diameter, are filled with nutrient agar (see B.4) to $(3 \pm 0,2)$ mm from the brim. The agar plates (see 5.1) shall be prepared (24 ± 4) h before the test is performed and stored over water, so that mass loss is minimized. Each plate is left to dry without a lid for 20 min at room temperature on a clean bench. No visible fluid (condensate) shall be present on the agar surface. The height of Petri dishes is not industrially standardized, so different suppliers' dishes may have different heights. It is therefore necessary to determine the mass or volume of agar that will result in each dish being filled to the correct distance from the brim. Volumetric or gravimetric methods shall be used when pouring the agar into the dishes. To monitor the distance from agar to brim, a razor blade may be put on the centre of the agar surface and a steel ruler standing on the dish brim across the dish. The distance between the ruler and the blade is calculated using wire gauges or a dial indicator. This distance shall be determined for each batch of plates and noted in the test report.

1) Reagents and materials are available from Schütt Labortechnik, Rudolf-Wissel-Straße 11, D-37079 Göttingen, Germany. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.

7.2 Carrier material

The carrier material (see 5.2) shall be wettable, solvent-cast polyurethane (PU) film of 30 µm thickness, with an elongation in the machine direction 350 % ± 50 %, and cross direction 400 % ± 75 %, and carried on paper.

Cut the carrier material into pieces 25 cm × 25 cm. Put each piece, held between sheets of filter paper, into a paper sterilizing bag. Sterilize by steam at 121 °C, in accordance with ISO 13683.

7.3 Test specimen

Five pieces, 25 cm × 25 cm (see 5.5), sampled in accordance with ISO 13937-2 or ISO 13934-1, or with a diameter of 25 cm, shall be cut randomly from the material to be tested under aseptic conditions.

8 Procedure

8.1 Preparation of donor

Culture *Staphylococcus aureus* ATCC 29213 for 18 h to 24 h at (36 ± 1) °C on tryptic soy agar. Suspend 2 or 3 colonies in 3 ml tryptic soy broth (see B.2). Incubate at (36 ± 1) °C for 18 h to 24 h. Dilute with peptone water (see B.3) in 1:10 steps to yield a concentration of 1 × 10⁴ to 4 × 10⁴ CFU/ml. Perform a viable count from the final suspension.

Open the sterilizer bag and extract the PU film still on its paper carrier. Place the piece of carrier material on a clean tray, wettable PU side up. For ease of handling, fix the carrier material to the tray using double-sided adhesive tape in each corner. On the carrier, mark an area corresponding to the lid of the agar plate. Distribute 1,0 ml of the *Staphylococcus aureus* suspension over this area of the carrier. Dry the donor at 56 °C for approximately 30 min. Continue spreading the *Staphylococcus aureus* suspension on the polymer film during the drying stage by means of a disinfected glass spreader, to ensure an even distribution.

Use the donor the day it is prepared.

8.2 Conditioning

If required, condition the test specimens in accordance with ISO 139. Otherwise, conditioning and testing can be carried out at normal room temperature. The method for conditioning shall be recorded in the test report.

8.3 Test set-up

Adjust the weight on the lever so that the force from the finger on the agar plate is (3 ± 0,02) N.

Place the first agar plate on the turntable.

8.4 Application of materials

The following technique, which makes use of a circular weight consisting of an outer and an inner ring together weighing (800 ± 1) g (see Figures A.2 and A.3), enables the material stretching force to be standardized.

Put a test specimen on the ring, then remove the paper carrier from the PU film (donor) and put the donor, contaminated side down, on the specimen. Cover the PU film with a piece of HDPE film (see 5.3), then push the outer ring down firmly so that the three materials are securely held between the two rings.

8.5 Test

With the materials slightly slack, place the ring on the first lidless agar plate, such that the steel ring hangs freely outside the rotatable disk. Apply the finger to the HDPE film just inside the brim in such a way that the test specimen comes into contact with the agar surface. Run the test as described for 15 min with a finger pressure of 3 N.

After 15 min, remove the ring and the assemblage immediately and retain.

Remove the first agar plate from the rotatable disk and seal it with its lid. Immediately put the second agar plate on the rotatable disk, together with the retained ring assemblage.

Perform the above-mentioned procedure on the same test assemblage using the next four plates.

When five plates have been tested, remove and discard the donor, turn the test specimen upside down and cover it with the HDPE film.

Run the sixth plate for 15 min on the first replicate to complete the test run.

Run the sixth plate for 15 min on the other four test specimens in the same way, using a freshly prepared donor with each test specimen.

If liquid has accumulated on the agar surface, dry the plate(s) on a clean bench and incubate the six agar plates with their lids on for 48 h at (36 ± 1) °C.

Count the colonies of *Staphylococcus aureus* on each plate. Disregard the count in the area with a radius of 15 mm around the centre of the plate.

If one or more plates has a count greater than 750 CFU (excluding the central area already described), the test may be rerun. If on retest one or more plates has a count greater than 750 CFU, the material is unlikely to exhibit adequate barrier properties and the test may be terminated.

9 Test report

The test report shall include the following:

- a) reference to this International Standard;
- b) reference to checks in accordance with 10.2 and 10.3;
- c) test conditions, i.e. temperature and humidity;
- d) distance from agar surface to brim of Petri dish;
- e) identification of tested material;
- f) confirmation that the five pieces have been cut in accordance with 7.3;
- g) confirmation that the carrier material conforms to 7.2;
- h) colony counts from the six test plates for each of the five test specimens (replicates);
- i) viable counts of the *Staphylococcus aureus* suspensions used.

NOTE For the use of test results to characterize the material, see Annex C.

10 Performance monitoring

10.1 General

The two methods below shall be used to assess the performance of the laboratory. There shall be a documented programme of performance monitoring and the date for the latest assessment shall be recorded.

10.2 With carbon paper

Prepare an assembly using the steel rings specified in 8.4, consisting of one sheet of white paper, one sheet of carbon paper and one sheet of HDPE film in that order. Put the bottom part of a 14 cm Petri dish upside down on the rotatable disk and the assembly over it, as described in 8.4. Apply the finger to the HDPE film and run the apparatus for 15 min. Extract the white paper and ensure that the finger has left an even contact pattern over the whole surface of the plate.

10.3 With reference material

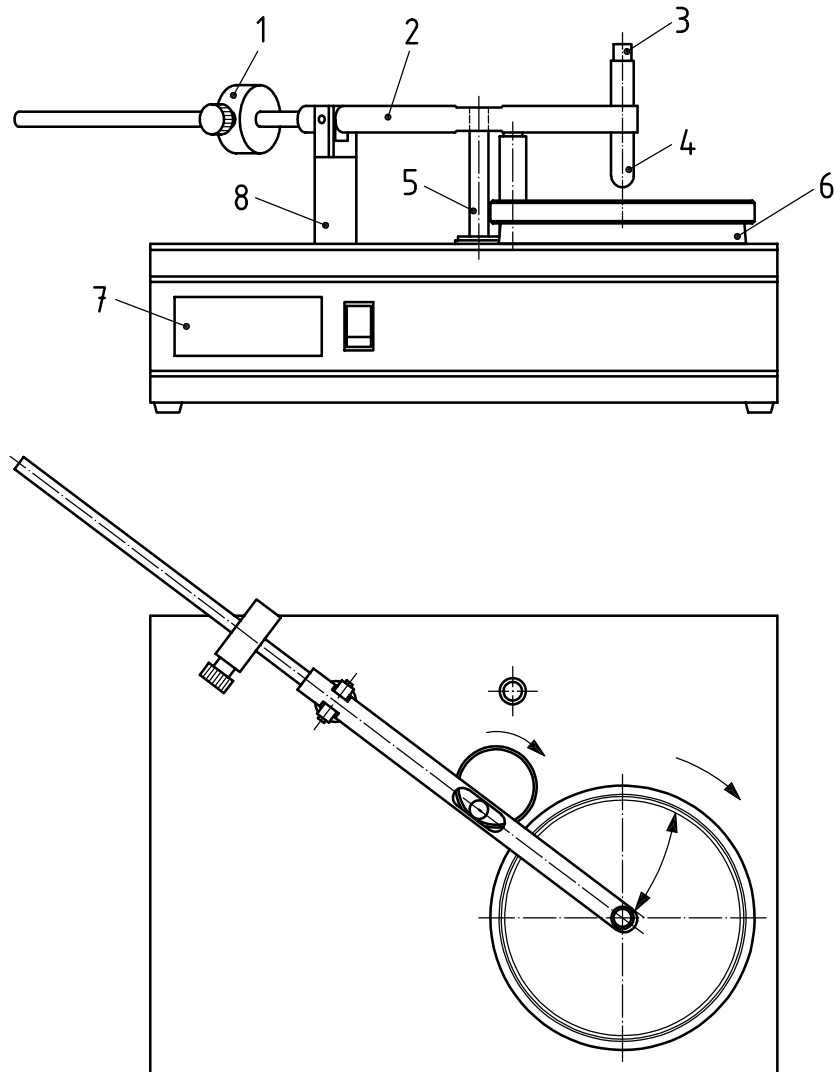
The precision of the laboratory shall be assessed using the reference material specified in 5.6, in combination with test method described in this International Standard. The frequency of assessments shall be in accordance with ISO 13485. This will allow the laboratory to check the precision and bias of its own operators. It will not be possible to infer any information about the test method in general use without conducting further inter-laboratory trials.

The reference material shall be packed in a sterilizer bag that conforms to ISO 11607 and sterilized with moist heat at 121 °C, in accordance with EN 554.

The result of the test with the reference material shall be in the range 0,70 – 0,96, expressed as CUM5 (see Annex C).

Annex A (normative)

Apparatus for testing resistance to wet bacterial penetration



Key

- 1 counterweight
- 2 balancing arm with finger
- 3 loop for spring balance
- 4 stainless steel finger
- 5 eccentric
- 6 turntable
- 7 electronic timer
- 8 ball bearing

Figure A.1 — Apparatus

Dimensions in millimetres

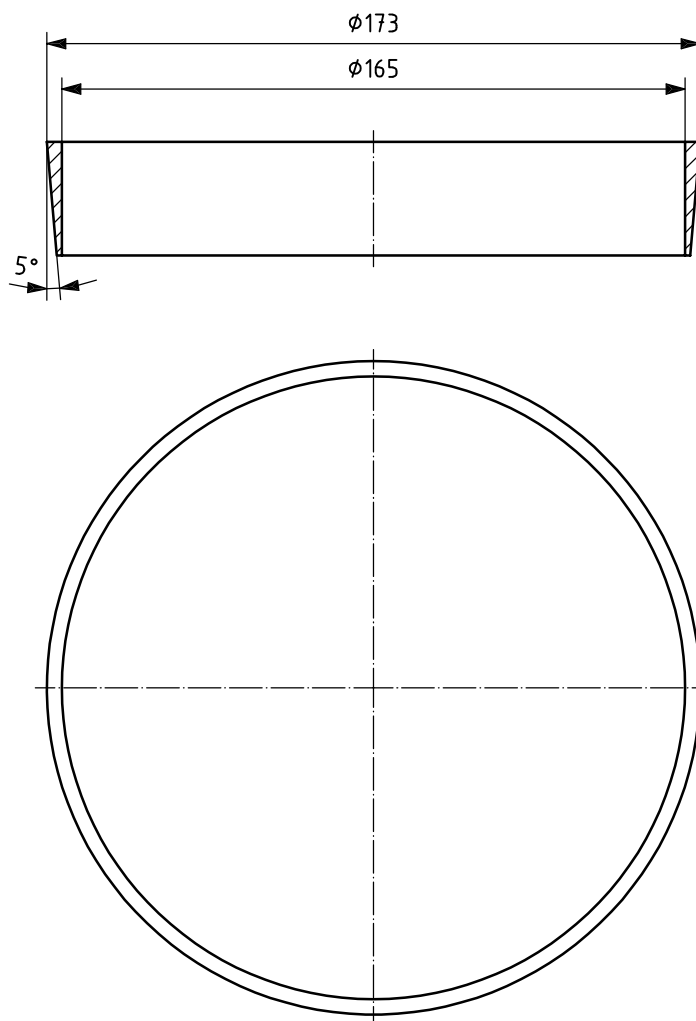


Figure A.2 — Inner ring

Dimensions in millimetres

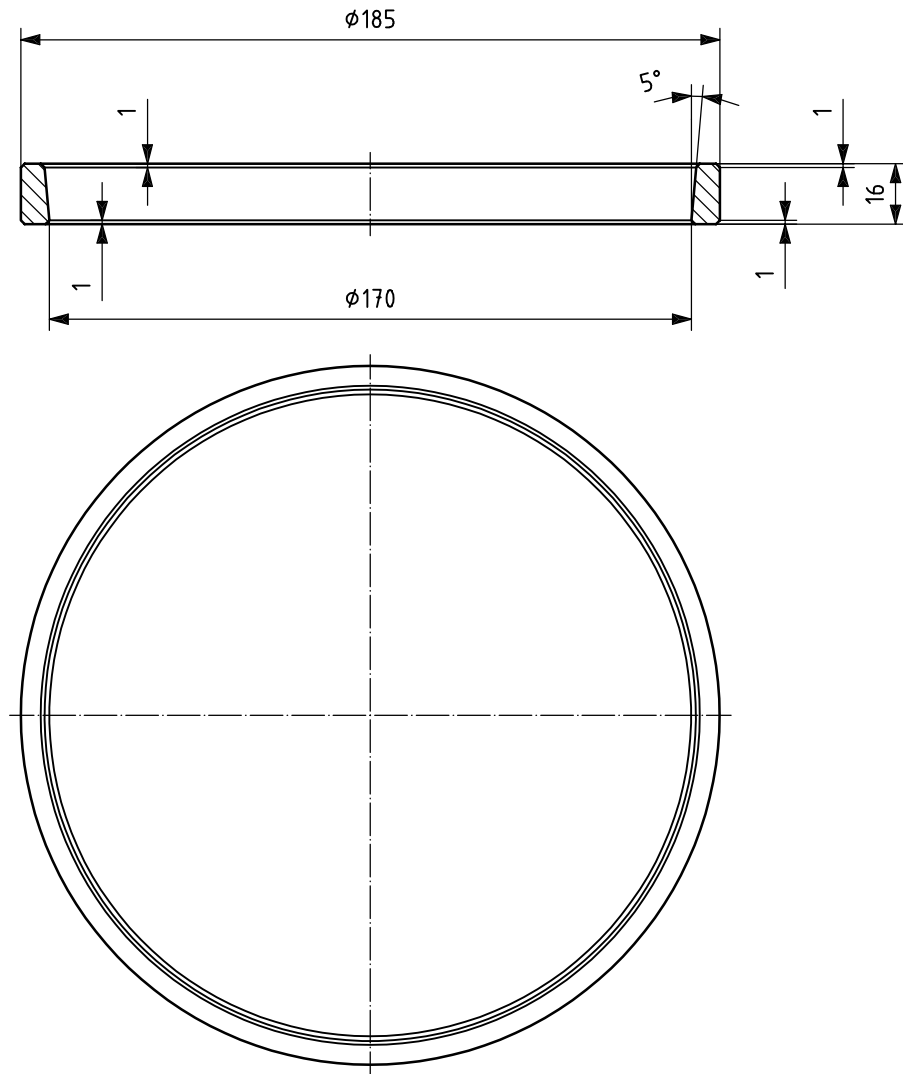


Figure A.3 — Outer ring

Annex B (normative)

Nutrient media

B.1 Tryptic soy agar

Tryptone	15 g
Papaic digest of soybean meal	5 g
Sodium chloride	5 g
Agar	17 g
Distilled water	1 000 ml

Suspend dry ingredients in water and heat while swirling to dissolve and mix. Sterilize at 121 °C for 15 minutes, swirl thoroughly and dispense.

B.2 Tryptic soy broth

Tryptone	17 g
Papaic digest soybean meal	3 g
Dextrose	2,5 g
Sodium chloride	5 g
Dipotassium phosphate	2,5 g
Distilled water	1 000 ml

B.3 Peptone water

Peptone	10 g
Sodium chloride	5 g
Polysorbate 80	1 g
Distilled water	1 000 ml

B.4 Nutrient agar

Beef extract	3 g
Peptone	5 g
Sodium chloride	8 g
Agar	17 g
Distilled Water	1 000 ml

For preparation, see B.1. Use plates within a day of preparation.

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Annex C (informative)

Examples of how to use the test results to characterize a barrier material

C.1 Calculation of estimated bacterial challenge

The estimated bacterial challenge, T , is calculated as follows:

$$T = Z + X_1 + X_2 + X_3 + X_4 + X_5 \quad (\text{C.1})$$

where

Z is the number of colonies from the top side (plate 6) of the test specimen that are left over after the five agar plates have been run, measured on the sixth agar plate;

X_1, \dots, X_5 are the numbers of colonies on the 5 plates in one replicate test, using the same test specimen and donor.

C.2 Calculation of cumulative penetration ratio

The cumulative penetration ratio of plates 1 to 5, $R_{\text{CUM}1}, \dots, R_{\text{CUM}5}$, is calculated as follows:

$$R_{\text{CUM}1} = \frac{X_1}{T} \quad (\text{C.2})$$

$$R_{\text{CUM}2} = \frac{(X_1 + X_2)}{T} \quad (\text{C.3})$$

$$R_{\text{CUM}3} = \frac{(X_1 + X_2 + X_3)}{T} \quad (\text{C.4})$$

$$R_{\text{CUM}4} = \frac{(X_1 + X_2 + X_3 + X_4)}{T} \quad (\text{C.5})$$

$$R_{\text{CUM}5} = \frac{(X_1 + X_2 + X_3 + X_4 + X_5)}{T} \quad (\text{C.6})$$

where $R_{\text{CUM}5}$ is an estimate of the fraction of the bacterial challenge that has penetrated the barrier.

C.3 Calculation of barrier penetration coefficient

The barrier penetration coefficient, C_{BP} , describing the time-dependent penetration, is weighted towards the earlier counts and is not dependent on the estimated bacterial challenge.

C_{BP} may be represented in several ways, including those shown in Equations (C.7) and (C.8):

$$C_{\text{BP}} = \frac{(R_{\text{CUM}1} + R_{\text{CUM}2} + R_{\text{CUM}3} + R_{\text{CUM}4})}{R_{\text{CUM}5}} + \frac{1}{2} \quad (\text{C.7})$$

or

$$C_{BP} = \frac{(4X_1 + 3X_2 + 2X_3 + X_4)}{(X_1 + X_2 + X_3 + X_4 + X_5)} + \frac{1}{2} \quad (\text{C.8})$$

Equation (C.8) shows that C_{BP} is independent of the estimated bacterial challenge, which is likely to be an underestimate. Furthermore it shows that if there is no penetration on plates 1 to 4, $C_{BP} = 1/2$ and will also be independent of the count on plate 5, whatever it is.

C.4 Calculation of barrier index

The barrier index, I_B , describes the fraction of the bacterial challenge which has not penetrated the barrier material, but does not take into account whether penetration occurs at an early or a late stage in the test specimen. The value of I_B has been found to give an acceptable ranking of materials. C_{BP} and R_{CUM5} decrease as barrier performance increases. I_B increases as barrier performance increases.

I_B may be represented in several ways, including those shown in Equations (C.9) and (C.10). It is related to C_{BP} and R_{CUM5} by Equation (C.9), so that I_B is dependent on the estimated bacterial challenge.

$$I_B = 6 - \left[(C_{BP} \times R_{CUM5}) + \frac{R_{CUM5}}{2} \right] \quad (\text{C.9})$$

or

$$I_B = 6 - (R_{CUM1} + R_{CUM2} + R_{CUM3} + R_{CUM4} + R_{CUM5}) \quad (\text{C.10})$$

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