SITRA - COE MEDICAL TEXTILE
Testing Facility for
Personal Protective Equipment (PPE)

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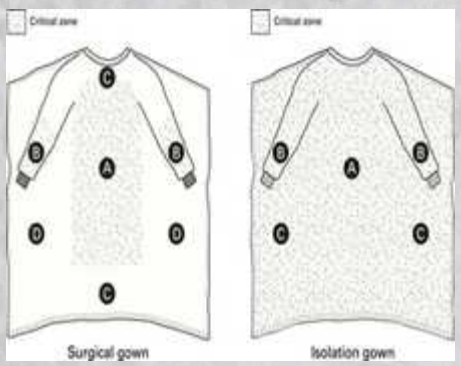
Testing Facility for Personal Protective Equipment

Personal Protective Equipment - Protection against biological hazards

Personal Protective Equipment (PPE) is defined as "any device to be worn or held by the users for protection against one or more health and safety hazards". These hazards may result from contact with chemical, biological, radiological, physical, electrical, mechanical agents and other workplace hazards. With regards biological hazards in professional situations, eg, Microbiology, Biotechnology laboratories etc, the risk of exposure is limited to the occurrence of an accident as the infectious agents can be controlled, and the organisms to which the workers may expose are usually well defined. But, in other type of works, eg. Health care, sewage works, waste treatment sites, etc, the infectious agents cannot be controlled and the workers are continuously exposed to the unknown infectious agents. Protective suits, gloves and masks are therefore lifesaving against these infectious agents. It is necessary to be design and construct these equipment in a safe manner and maintain them in a clean and reliable fashion. Any construction or design failures of PPE, can leave the users exposed dangerously to hazards. Various international standards determine the performance requirements and test methods for PPE against infectious agents. These equipment must prevent infectious agents from coming into contact with the user's skin.

SITRA's biological testing laboratory, in addition to the microbiological and biotechnological testing facilities are upgraded with PPE testing facility. The following instruments have been fabricated according to international standards and having the capabilities to test PPEs which are used to protect users from biological hazards.



- Bacterial Filtration Efficiency (BFE) Tester – ASTM F 2101-07
- Synthetic Blood Penetration Resistance Tester (SBPRT) – ASTM F 1671-07
- Dry Microbial Penetration Resistance Tester (DMPRT) – ISO 22612:2005
- Wet Bacterial Penetration Resistance Tester (WBPRT) – ISO 22610:2006

Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus (ASTM F 2101-07)

Workers, primarily those in the health care profession involved in treating and caring for individuals injured or sick, as well as the patients, can be exposed to biological aerosols capable of transmitting diseases. These diseases, which may be caused by a variety of microorganisms, can pose significant risks to life and health. This test instrument helps to assess the effectiveness of materials used in protective clothing for protecting the wearer against biological aerosol developed using S. aureus (ATCC 6538).

Test materials

Medical face masks

Sample size:

6 test specimens of 110 mm (area)

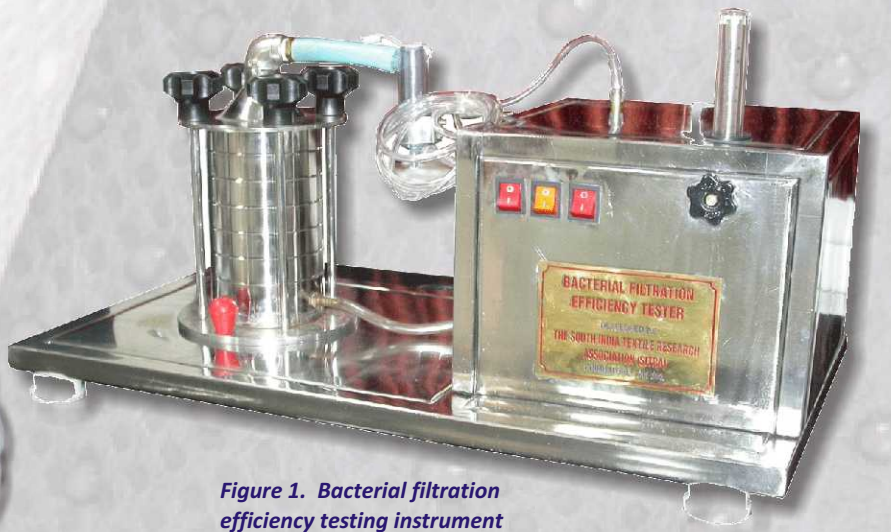


Figure 1. Bacterial filtration efficiency testing instrument

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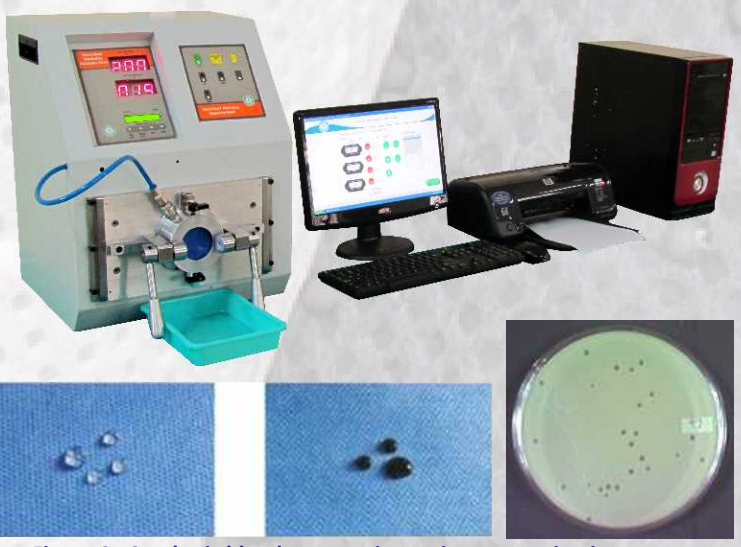
Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System (ASTM F 1671-07)

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 (HBV and HCV), AIDS (HIV). This test instrument helps 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 simulated under conditions of continuous contact.



Test materials

Protective clothing materials (gowns, drapes, gloves etc)

Sample size:

10 test specimens of 100 mm dimensions

Figure 2. Synthetic blood penetration resistance testing instrument

Clothing for Protection against infectious agents – Test method for resistance to dry microbial penetration (ISO 22612:2005 (E)

- The test method is designed to determine the ability of materials to resist penetration of particles carrying microorganisms under dry fabric conditions.
- The method establishes the quantity of microorganisms that can penetrate through the test material being carried on talcum powder.
- Test results are expressed in CFU (colony forming units) that are observed on the agar plate.

Sample size and test materials : 18 pieces of 200 mm x 200 mm sizes of surgical gowns, surgical drapes, clean air-suits and other clothing used to protect against infectious agents.

The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate. The sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

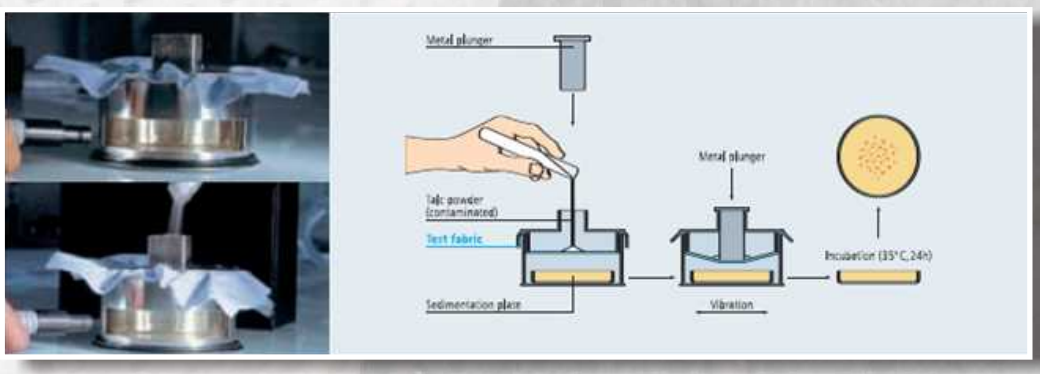
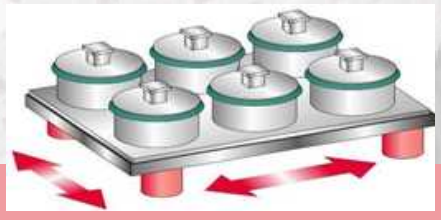
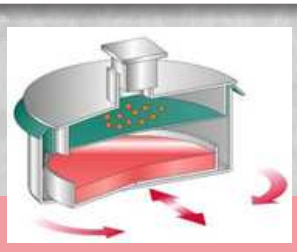
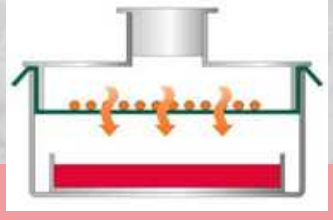


Figure 3. Dry microbial penetration tester







Testing Facility for Personal Protective Equipment

Performance requirement

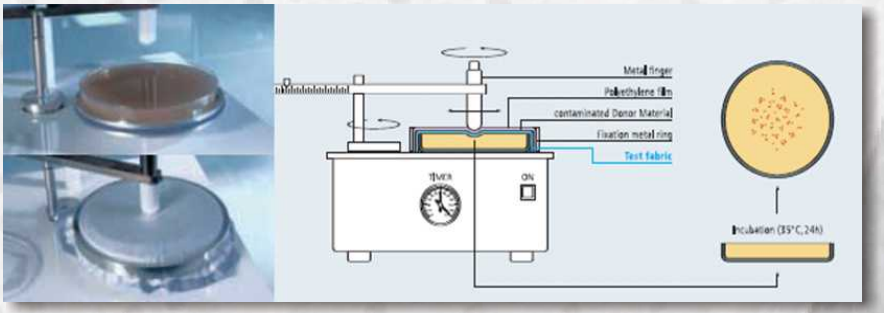
	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard performance		High performance		Standard performance		High performance		Requirement*
	Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	
Log 10 (CFU)	N/A	≤2 [a,c]	N/A	≤2 [a,c]	N/A	≤2 [a,c]	N/A	≤2 [a,c]	≤2 [a,c]

a Test conditions: challenge concentration 102 CFU/g talc. And 30 mins vibration time. c For the purpose of this standard, log10 CFU ≤2 means maximum 300 CFU.
** Performance requirements apply for all product areas of clean air suits, as clean air suits should be used in addition to surigcal gowns and not as a substitute.*

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 (ISO 22610:2006)

- It evaluates the ability of fabrics to resist microbial penetration under conditions of liquid pooling on the fabric and mechanical stress.
- Test results are expressed in BI "Barrier Index".

Sample size and test materials : 10 test specimens of 25 cm x 25 cm of surgical gowns, surgical drapes, clean air-suits and other equipments used to protect against infectious agents.



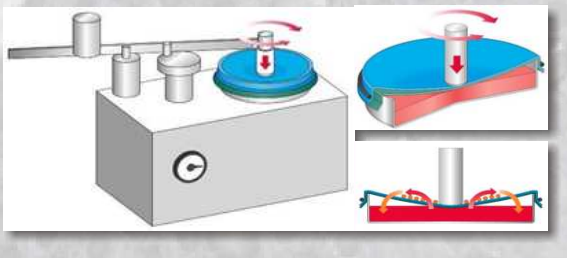


Figure 4. Wet bacterial penetration tester

Performance requirement

	Surgical gowns				Surgical drapes				Clean air suits
Unit	Standard performance		High performance		Standard performance		High performance		Requirement*
	Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	Critical area	Less critical area	
BI	≥2,8[b]	N/A	6,0[b,d]	N/A	≥2,8[b]	N/A	6,0[b,d]	N/A	N/A

b The Least Significance Difference (LSD) for BI when estimated using EN ISO 22610, was found to be 0,98 at the 95 % confidence level. This is the minimum difference needed to distinguish between two materials thought to be different. This means materials varying by up to 0,98 BI are probably not different; materials varying by more than 0,98 BI probably are different (The 95 % confidence level means that an observer would ne correct 19 times out of 20 to accept these alternatives).

d BI = 6,0 for the purpose of this standard means : no penetration. BI = 6,0 is the maximum achievable value.

For more details, please contact:

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