

## TEST REPORT

**EN 14126:2003/AC:2004**

### Protective Clothing Against Infective Agents

**Client:** ESTİLO MODA TEKSTİL TARIM HAYVANCILIK İNŞAAT İÇ  
DİŞ TİC. VE SAN. LTD. ŞTİ.

**Address:** Gazi Osman Paşa Mah. Kolej Sok. No:2/A  
Turhal/TOKAT/TÜRKİYE

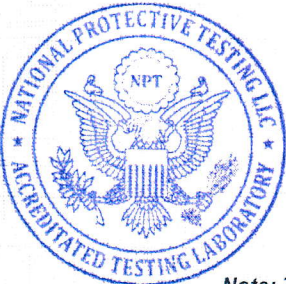
**Sample:** ES6124 Model (White coverall with hood, frontal zipper  
covered by flap and adhesive tape in full length, elasticated cuff,  
hood, ankle, Fabric: 100% PP laminated with PE in size S, M, L,  
XL, XXL, XXL

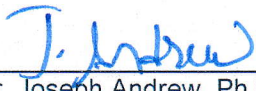
**Sample received on:** April 20, 2020

**Report Number:** NPT/20042012659/2

**Elaborated by:** Ashley Madison

**Place and date of issue:** Sheridan, WY May 05, 2020



  
Dr. Joseph Andrew, Ph.D.  
Head of Testing Laboratory

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**Test Standard:** ISO 16603:2004 / EN 14126:2003/AC:2004- 4.1.4.1  
**Name of tests:** Penetration by blood and body fluids. Synthetic blood method  
**Reference no:** SBM-001

**Test Purpose:**

This test method is used to determinate of the resistance of protective clothing materials to penetration by blood and body fluids - test method using synthetic. This a test conducted using synthetic blood, which establishes at what pressure the liquid will pass through the test material.

**Sampling method:**

3 samples used in this test. Sample size: 75x75mm

**Testing methods used:**

Time and pressure control: Procedure D used. 5 minutes each samples pressure tested.

**Test conditions:**

Min. 24hr, temperature of  $(21 \pm 5) ^\circ\text{C}$  and a relative humidity of air of  $(60 \pm 10) \%$ .

**Test Equipment:**

Penetration test cell.

**Test Procedure:**

ISO 16603 uses synthetic blood in a simple visual penetration test to estimate the pressure at which strike through is likely to occur in ISO 16604. Testing to ISO 16604 can then proceed at this pressure as a starting point.

**Test results:**

The test results obtained are given in the tables as follows

No. of Sample	Hydrostatic pressure	Result
1.sample	0 kPa	Pass
2.sample	0 kPa	Pass
3.sample	0 kPa	Pass
1.sample	1.75 kPa	Pass
2.sample	1.75 kPa	Pass
3.sample	1.75 kPa	Pass
1.sample	3.5 kPa	Pass
2.sample	3.5 kPa	Pass
3.sample	3.5 kPa	Pass
1.sample	7 kPa	Fail
2.sample	7 kPa	Fail
3.sample	7 kPa	Fail

\*Pass: The sample resist to penetration and synthetic blood doesn't pass through the fabric

\*Fail: The sample doesn't resist to penetration and synthetic blood pass through the fabric

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**Test Standard:** ISO 16604:2004 / EN 14126:2003/AC:2004- 4.1.4.1  
**Name of tests:** Penetration by blood and other body fluids-born pathogens. Phi-X174 bacteriophage method  
**Reference no:** PXB-001

**Test Purpose:**  
 This test method is used to determinate of the resistance of protective clothing materials to penetration by blood and body fluids - test method using synthetic. This a test conducted using synthetic blood, which establishes at what pressure the liquid will pass through the test material.

**Sampling method:**  
 3 samples used in this test. Sample size: 75x75mm

**Testing methods used:**  
 Time and pressure control: Procedure D used. 5 minutes each samples pressure tested.  
 Penetration survey method is Plaque-forming units (PFU)  
 Name of test microorganism: Bacteriophage Phi-X 174

**Test conditions:**  
 Min. 24hr, temperature of  $(21 \pm 5) ^\circ\text{C}$  and a relative humidity of air of  $(60 \pm 10) \%$ .

**Test Equipment:**  
 Penetration test cell.

**Test Procedure:**  
 It can be clearly seen that only the ISO 16604 test uses a contaminant – a bacteriophage (that is, a virus that parasitises a bacteria by infecting it, in this case Phi X174, selected, according to the standard, for its small size) – that is considerably smaller than the Coronavirus now filling the news. The other tests use bacteria considerably larger than Coronavirus. Thus, ISO 16604 is the only test providing a clear indication of effective resistance to penetration of that size of infectious agent.  
 It also describes a laboratory test method used to measure the resistance of the materials used in protective clothing to penetration by blood-borne pathogens using a surrogate microbe with continuous liquid contact. Protective clothing either passes or fails depending on whether viral penetration at a specific hydrostatic pressure can be detected.

**Test results:**  
 The test results obtained are given in the tables as follows

No. of Sample	Hydrostatic pressure	Result
1.sample	3.5 kPa	Pass
2.sample	3.5 kPa	Pass
3.sample	3.5 kPa	Pass
Negative control(PE 10µm)		Pass
Positive control		Fail

\*Pass: The sample resist to penetration and synthetic blood doesn't pass through the fabric  
 \*Fail: The sample doesn't resist to penetration and synthetic blood pass through the fabric

Pre-test bacteriophage titer: 4.5E+008 PPU/ml  
 Post-test bacteriophage titer: 4.5E+008 PPU/ml

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**Test Standard:** EN ISO 22610:2006 / EN 14126:2003/AC:2004- 4.1.4.2  
**Name of tests:** Wet Bacterial penetration  
**Reference no:** WBP-001

**Test Purpose:**

This test method is designed to determine a material's resistance to penetration of bacteria in a liquid.

**Sampling method:**

Five pieces 25 cm x 25 cm or with a diameter of 25 cm shall be randomly cut under aseptic conditions from the material to be tested.

**Testing methods used:**

Testing time: 5 steps of 15 minutes

S. aureus strain, ATCC 29213, is cultured 18 to 24 h at  $(36 \pm 1)$  °C on tryptic soy agar.

Culture medium: Nutrient agar

Donor material: Polyurethane membrane; 30 µm

Distance from agar surface to brim of petri dish: 3mm

Concentration of test suspension:  $2.9 \times 10^4$  CFU/ml

**Test conditions:**

Min. 24hr, temperature of  $(20 \pm 2)$  °C and a relative humidity of air of  $(65 \pm 5)$  %.

**Test Equipment:**

The turntable consists of three parts:

- the motor compartment;
- the agar plate holder;
- the finger holder arm.

**Test Procedure:**

The material to be tested is put on a lidless agar plate, on a rotating disk on top of the test specimen, a piece of donor material and a piece of approximately 10 µm thick HD polyethylene film of corresponding size is placed and materials are fixed using a double steel ring. An abrasion resistant finger is placed on top of the donor material to exert a specified force on the donor and test specimen to bring them into contact with the agar.

The finger is applied to the material by a pivoted lever moved by an excenter cam in such a way that it moves over the entire surface of the plate within 15 minutes. The assemblage of materials is stretched by the weight of the steel ring so that only a small area of the test specimen is brought into contact with the agar surface at a time. Due to the combined effect of rubbing and liquid migration bacteria may spread from the donor material through the test specimen down to the agar surface.

After 15 minutes of testing, the agar plate is replaced and the test repeated. Within five periods of 15 minutes each, tests are performed with the same pair of donor material and test specimen. In that way the test allows for an estimation of the penetration over time. Finally the bacterial contamination on the test specimen is estimated using the same technique. The agar plates are incubated to visualise the bacterial colonies, which are then enumerated. The results are processed in accumulated form to characterize the barrier capability and penetration kinetics of the material.

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## Test results:

The test results obtained are given in the tables as follows

	Interval (Min)	n° colonies 1st sample	n° colonies 2nd sample	n° colonies 3rd sample	n° colonies 4th sample	n° colonies 5th sample	average
Petri dish 1 (X1)	0-15	18	12	18	13	19	16
Petri dish 2 (X2)	15-30	23	15	22	20	18	19,6
Petri dish 3 (X3)	30-45	33	20	21	25	21	24
Petri dish 4 (X4)	45-60	33	17	26	28	23	25,4
Petri dish 5 (X5)	60-75	40	45	50	44	43	44,4
Petri dish 6 (ref. Z)		138	148	150	162	165	152,6
T		285	257	287	292	289	282
b (EPP)		4,64	4,99	4,80	4,90	4,90	4,85

## Legend

b (EPP) = Barrier index

$b (EPP) = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

where

$CUM1 = X1/T$

$CUM2 = (X2 + X1) / T$

$CUM3 = (X3 + X2 + X1) / T$

$CUM4 = (X4 + X3 + X2 + X1) / T$

$CUM5 = (X5 + X4 + X3 + X2 + X1) / T$

$T = Z + X1 + X2 + X3 + X4 + X5$

X1, X2, X3, X4, X5: number of colonies on the five plates from one of five samples

Z = number of colonies from the top side (plate nr. 6 reference)

Item	Unit	Result
Breakthrough time	min	15<T<30

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**Test Standard:** ISO/DIS 22611:2003 / EN 14126:2003/AC:2004- 4.1.4.3  
**Name of tests:** Penetration by biologically contaminated aerosols  
**Reference no:** PBA-001

**Test Purpose:**  
This test method is designed to determine a material's resistance to penetration by biologically contaminated aerosols.

**Sampling method:**  
Four pieces diameter 25 mm material tested.

**Testing methods used:**  
S. aureus strain, ATCC 6538  
Culture medium: Nutrient agar

**Test conditions:**  
Min. 24hr, temperature of  $(20 \pm 2) ^\circ\text{C}$  and a relative humidity of air of  $(65 \pm 5) \%$ .

**Test Equipment:**  
Perspex box with collision atomizer

**Test Procedure:**  
The barrier effect of the test material, against biologically contaminated aerosols, is measured using a bacterium solution of Staphylococcus Aureus, which is suspended in an aerosol and sprayed onto both an unprotected cellulose-nitrate membrane and one covered with the test barrier material (the pore size of the membrane is approx.  $0.45 \mu\text{m}$ ). The test takes place within a sealed chamber.

Both membranes are subsequently analysed to establish their bacterial load by culturing on an agar plate. In order to classify the results, the penetration ratio (ratio of the load of the unprotected cellulose-nitrate membrane to the load of the membrane protected with the test material) is calculated and presented in log units.

**Test results:**  
The test results obtained are given in the tables as follows

Microorganisms extract to membrane Reference (Value A)		
No. of Sample	Unit	Result
1.sample	CFU	530,0
2.sample	CFU	470,0
3.sample	CFU	540,0
4.sample	CFU	430,0
Average	CFU	492,5
Microorganisms extract to membrane sample (Value B)		
No. of Sample	Unit	Result
1.sample	CFU	43
2.sample	CFU	50
3.sample	CFU	42
4.sample	CFU	38
Average	CFU	46
Penetration ratio (A/B)	Log10 CFU	1,03

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**Test Standard:** ISO/DIS 22612:2005 / EN 14126:2003/AC:2004- 4.1.4.4  
**Name of tests:** Penetration by biologically contaminated powders  
**Reference no:** PBP-001

**Test Purpose:**  
This test method is designed to determine a material's resistance to penetration by biologically contaminated powders.

**Sampling method:**  
Ten samples material tested, Sample size: 200x200mm

**Testing methods used:**  
Test time: 30 minutes  
Spores of Bacillus subtilis, ATCC 9372, Culture medium: TGE agar

**Test conditions:**  
Min. 24hr, temperature of  $(20 \pm 2) ^\circ\text{C}$  and a relative humidity of air of  $(65 \pm 5) \%$ .

**Test Equipment:**  
Vibrating apparatus

**Test Procedure:**  
To measure the barrier against contaminated dust, the test materials is pre-sterilised and then fixed into the test apparatus and dosed with contaminated (Bacillus Subtilis) talcum powder. An agar culture plate is located underneath.

The test apparatus is agitated or shaken. The particles which penetrate the material are cultured and counted after incubation of the agar plate and a non-contaminated test specimen is run as a control. The results (mean values from 10 single results at a given time) are measured in penetration log units

**Test results:**  
The test results obtained are given in the tables as follows

No. of Sample	Unit	Result
1.sample	CFU	18,0
2.sample	CFU	16,0
3.sample	CFU	10,0
4.sample	CFU	11,0
5.sample	CFU	12,0
6.sample	CFU	15,0
7.sample	CFU	19,0
8.sample	CFU	9,0
9.sample	CFU	13,0
10.sample	CFU	14,0
Average	CFU	13,7
No. of Sample	Unit	Result
1.sample	Log10 CFU	1,3
2.sample	Log10 CFU	1,2
3.sample	Log10 CFU	1,0
4.sample	Log10 CFU	1,0
5.sample	Log10 CFU	1,1
6.sample	Log10 CFU	1,2
7.sample	Log10 CFU	1,3
8.sample	Log10 CFU	1,0
9.sample	Log10 CFU	1,1
10.sample	Log10 CFU	1,1
Average	Log10 CFU	1,1
Talcum Concentration	CFU/g	7.7E+007

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