TEST REPORT
ref. No. 20042112686/1

Client:	ALTINSU TEKSTIL ENERJI SAN. VE TIC. LTD. STI.
Address:	BOSAB Barakfakih Mah. 5. Cad. No: 2 Kestel/BURSA/TURKEY
Sample:	3ply Face Mask
Sample received on:	April 21, 2020
Test Standard:	EN 14683+AC:2019
Name of tests:	Bacterial Filtration Efficiency(BFE) EN 14683+AC:2019/Annex B
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 30, 2020

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

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Description and identification of samples:

Table I - Description and identification of samples

Sample lot number	Designation of the sample by the client	Description of the given sample
NP/LT/0857346/1	Fabric obtained from antimicrobial yarn produced by adding silver ions into the fiber polymer structurealso round elastic ear loop to give basic protection to the user.	Figure 1

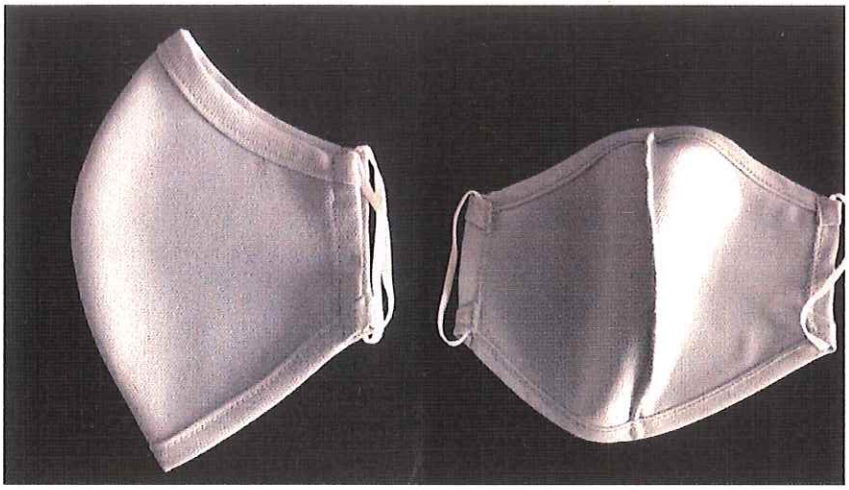

Fig. 1 - Sample Lot No. NP/LT/0857346/1

Bacterial Filtration Efficiency (BFE) Testing:

Test Purpose:
This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials, employing a ratio of the upstream bacterial challenge to downstream residual concentration to determine filtration efficiency of medical face mask materials. And this test method is a quantitative method that allows filtration efficiency for medical face mask materials to be determined. The maximum filtration efficiency that can be determined by this method is 99.9 %

Sampling method:
The samples intended for the tests were selected by the client. The testing laboratory shall not be held liable for any faults caused by an incorrect sampling.

Testing methods used:
A test method for determining Bacterial filtration efficiency (BFE) according to EN 14683+AC: 2019 standard Annex B.

Test conditions:
The test samples were conditioned for the time period of minimum 4 hours at the temperature of (21 ± 5) °C and a relative humidity of air of (85 ± 5) %.

Test Principle:
A sample of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Equipment:

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

This main test equipment consists of a series of stages, each made up of a plate with specific nozzle arrangement and collection surface. Sample laden air is drawn into the impactor, flowing sequentially through the stages with nozzle size and total nozzle area decreasing with stage number.

Summary of Test Method:
The medical face mask material is clamped between a six-stage cascade impactor and an aerosol chamber. The bacterial aerosol is introduced into the aerosol chamber using a nebulizer and a culture suspension of Staphylococcus aureus. The aerosol is drawn through the medical face mask material using a vacuum attached to the cascade impactor. The six-stage cascade impactor uses six agar plates to collect aerosol droplets which penetrate the medical face mask material.

Control samples are collected with no test specimen clamped in the test apparatus to determine the upstream aerosol counts. The agar plates from the cascade impactor are incubated for 48 h and counted to determine the number of viable particles collected. The ratio of the upstream counts to the downstream counts collected for the test specimen are calculated and reported as a percent bacterial filtration efficiency.

Acceptance Criteria:
The BFE control average was within 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at sponsor's approval.
The mean particle size (MPS) of the challenge challenge aerosol was maintained at (3,0 ± 0,3) µm.

The average % BFE for the reference material was within the upper and lower control limits established for the BFE test.

Test Procedure:
Culture of Staphylococcus aureus ATCC 6538 was diluted in peptone water to give a concentration of approximately 5 × 105 CFU/ml and the bacterial challenge shall be maintained at $1,7 \times 10^3$ to $3,0 \times 10^3$ CFU per test. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant-challenge delivery, at a fixed air pressure, formed aerosol droplets with a mean particle size of approximately 3,0 ± 0,3 µm.

The aerosol droplets were generated in a glass aerosol chamber and were drawn through a six-stage Anderson sampler (a sieve sampler) for collection. The collection flow rate through the test sample and Anderson sampler was maintained at 1 cubic foot/min [28.3 litres/min]. Test controls and test samples were challenged for a 2-min period.

The delivery rate of the challenge also produced a consistent challenge level of 2200 ± 500 CFU on the test control plates. A test control (no filter medium in the air streams) and reference material were included after five to ten test samples. The Andersen sampler impinged the aerosol droplets onto six agar plates based on the size of each droplet. The agar medium used was soybean casein digest agar (SCDA). The agar plates were incubated at 37 ± 2 °C for 48 ± 4 h and the colonies formed by each bacteria-laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen.

These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates was used to calculate the mean particle size MPS of the challenge aerosol. The bacterial filtration efficiencies (BFE) were calculated as the percentage difference between test sample runs and the control average using the following equation:

$$\%BFE=[(C - T) / C] \times 100$$

C = is the mean of the total plate counts for the two positive control runs
T = is the total plate count for the test sample

Summary:
The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of Staphylococcus aureus was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 pm. The aerosols were drawn through a sixstage, viable particle, Andersen sampler for collection. This test method complies with EN 14683:2019, Annex B. All test method acceptance criteria were met.

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

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

Table I – Surgical Face Mask, registration No. 20042112686/1/1

Test Article Number	Unit	Test results (% BFE)	Requirement (%)	Assessment
1	pc	99,08	≥ 95/98/98	Type II
2	pc	99,03	≥ 95/98/98	Type II
3	pc	99,03	≥ 95/98/98	Type II
4	pc	99,98	≥ 95/98/98	Type II
5	pc	98,88	≥ 95/98/98	Type II

Test Report Information	Values
Lot number of tested samples	NP/LT/0857346/1
Conditioning Parameters	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Mean plate count of the negative controls	<1 CFU
Dimensions of the test specimens and the size of the area tested;	~40 cm²
Which side of the test specimen was facing towards the challenge aerosol;	Either side
Flow rate during testing;	28.3 Liters per minute (L/min)
Mean particle size (MPS)	3,2 µm
Mean of the total plate counts of the positive controls	1,96x10³ CFU (Test Article 1-2-3-4-5)
Total Plate Count for the test sample	18 CFU (1) 19 CFU (2) 19 CFU (3) 20 CFU (4) 22 CFU (5)
Sample dimensions	120mm x 120mm

Conformity assessment carried out by:

Ing. Ashley Madison
Head of Laboratory of Protective/MDD

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

TEST REPORT
ref. No. 20042112686/2

Client:	ALTINSU TEKSTIL ENERJI SAN. VE TIC. LTD. STI.
Address:	BOSAB Barakfakih Mah. 5. Cad. No: 2 Kestel/BURSA/TURKEY
Sample:	3ply Face Mask
Sample received on:	April 21, 2020
Test Standard:	EN 14683+AC:2019
Name of tests:	Differential Pressure (Delta P) EN 14683+AC:2019/Annex C
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 30, 2020

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

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Description and identification of samples:

Table I - Description and identification of samples

Sample lot number	Designation of the sample by the client	Description of the given sample
NP/LT/0857346/2	Fabric obtained from antimicrobial yarn produced by adding silver ions into the fiber polymer structurealso round elastic ear loop to give basic protection to the user.	Figure 1

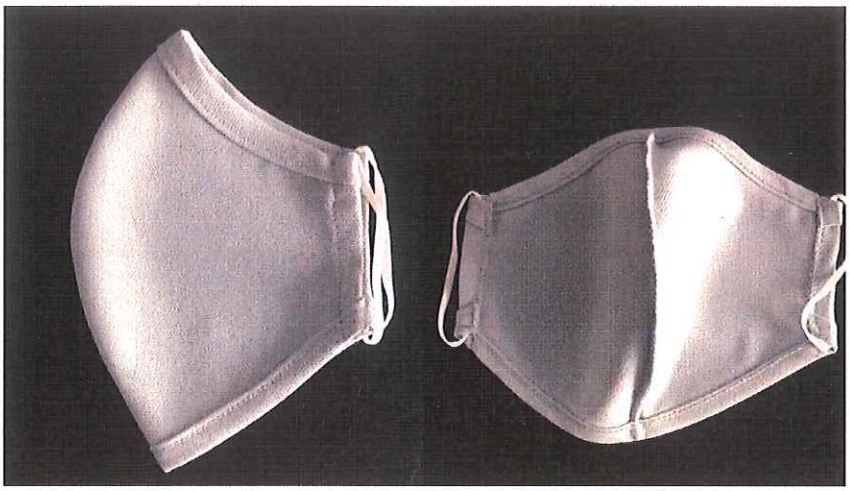

Fig. 1 – Sample Lot No. NP/LT/0857346/2

Differential Pressure (Delta P) Testing:

Test Purpose:
It measures the air flow resistance of the mask and is an objective measure of breathability. A controlled flow of air is driven through a mask and the pressure on either side of the mask is determined. The difference in pressure is measured and divided by the surface area (cm^2) of the mask segment tested. The higher the Delta P value, the harder it is for the wearer to breathe. The Delta P is measured in units of mm H_2O/cm^2.

The differential pressure (Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material at a constant flow rate.

Sampling method:
The samples intended for the tests were selected by the client. The testing laboratory shall not be held liable for any faults caused by an incorrect sampling.

Testing methods used:
A test method for determining Differential Pressure (Delta P) according to EN 14683+AC: 2019 standard Annex C.

Test conditions:
The test samples were conditioned for the time period of minimum 4 hours at the temperature of (21 ± 5) °C and a relative humidity of air of (85 ± 5) %.

Test Principle:
A device which measures the differential pressure required to draw air through a measured surface area at a constant air flow rate is used to measure the air exchange pressure of the medical face mask material. A water-filled (or digital) differential manometer is used to measure the differential pressure. A mass flow meter is used for measurement of the airflow. An electric vacuum pump draws air through the test apparatus and a needle valve is used to adjust the airflow rate.

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Sample:

The extremities removed from complete medical face mask and it was laid as flat with all layers incorporated. There are 5 samples which have been tested. The testing has been performed with the airflow direction from the inside of the mask to the outside of the mask.

Acceptance Criteria:
Differential Pressure (Delta-P) is the measured pressure drop across a surgical facemask material. Delta-P determines the resistance of the surgical facemask to air flowing through the mask. Pressure drop also relates to the breathability and comfort of the surgical mask. In general, a lower Delta-P translates to increased breathability.

Test Procedure:
Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 l/min. The holder is opened and the test specimen is placed across the 25 mm diameter orifice (total area 4,9 cm^2) between the top and bottom parts of the holder. Then it is clamped in place using a mechanical clamp with sufficient pressure to avoid air leaks.

The flow rate was appropriate and not seen any leak. The differential pressure was read using a differential pressure manometer and recorded as M1 and M2 for each pressure.

$$\Delta P = (X_{m1} - X_{m2})/4,9$$

X_{m1} is the pressure in Pa, measured by manometer M1 – low pressure side of the material
X_{m2} is the pressure in Pa, measured by manometer M2 – high pressure side of the material
4,9 is the area (in cm^2) of the test material
ΔP is the differential pressure per cm^2 of test material expressed in Pa.

Summary:
The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.

All test method acceptance criteria were met.

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

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

Table I – Surgical Face Mask, registration No. 20042112686/2

Test Article Number	Unit	Test results (ΔP)mm H_2O/cm^2	Test results (ΔP)Pa/cm^2	Requirement (%)
1	pc	0,85	8,3	< 40/40/60
2	pc	0,78	7,6	< 40/40/60
3	pc	0,80	7,8	< 40/40/60
4	pc	0,83	8,1	< 40/40/60
5	pc	0,81	7,9	< 40/40/60

Test Report Information	Values
Lot number of tested samples	NP/LT/0857346/2
Conditioning Parameters	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Number and Date of this European Standard	EN 14683+AC:2019/Annex C
Number and general location of the areas of the mask the differential measurements were taken	5
Tested area (in cm^2) of the test material	4,9
Delta P flow rate during testing;	8 Liters per minute (L/min)
Sample dimensions	105mm X 100mm

Conformity assessment carried out by:

Ing. Ashley Madison
Head of Laboratory of Protective/MDD

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TEST REPORT
ref. No. 20042112686/3

Client:	ALTINSU TEKSTIL ENERJI SAN. VE TIC. LTD. STI.
Address:	BOSAB Barakfakih Mah. 5. Cad. No: 2 Kestel/BURSA/TURKEY
Sample:	3ply Face Mask
Sample received on:	April 21, 2020
Test Standard:	EN 14683+AC:2019
Name of tests:	Microbial Cleanliness (Bioburden) EN 14683+AC:2019/Annex D, EN 11737-1:2018
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 30, 2020

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

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Description and identification of samples:

Table I - Description and identification of samples

Sample registration number	Designation of the sample by the client	Description of the given sample
NP/LT/0857346/3	Fabric obtained from antimicrobial yarn produced by adding silver ions into the fiber polymer structurealso round elastic ear loop to give basic protection to the user.	Figure 1

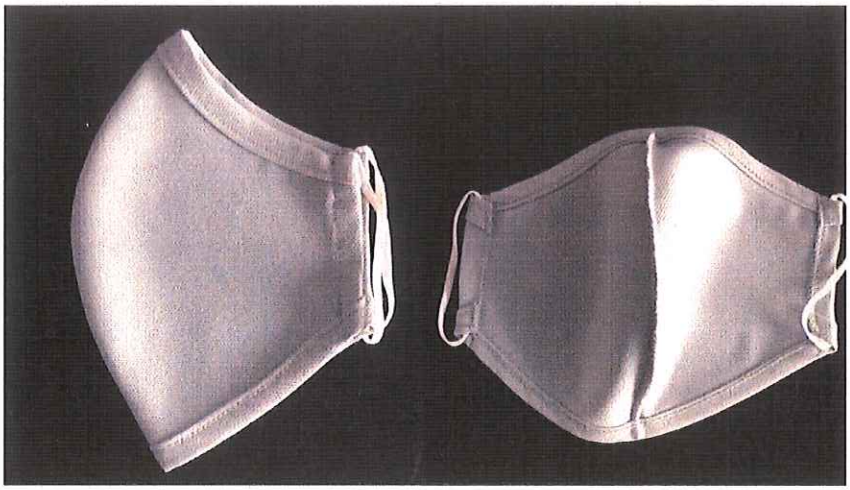

Fig. 1 - Sample Lot No. NP/LT/0857346/3

Microbial Cleanliness (Bioburden) Testing:
The term bioburden is used to describe the population of viable microorganisms present on or in product and/or a sterile barrier system. Bioburden is the sum of the microbial contributions from a number of sources, including raw materials, manufacturing of components, assembly processes, manufacturing environment, assembly/manufacturing aids (e.g., compressed gases, water, lubricants), cleaning processes and packaging of finished product.

Test Purpose:
This test method is used to determine the total number of viable microorganisms on the face mask using an extraction method. The total viable aerobic microbial count and fungal enumeration is determined. Based on the weight of the mask, the results are reported as the total bioburden per gram tested for each mask

Sampling method:
Mask samples for testing should be provided in the original primary packaging (dispenser box or equivalent) as offered to the end user. When 5 samples are selected take the top, bottom and 3 randomly chosen masks. If the mask contains a visor or other accessories it should be included in the testing.

Testing methods used:
A test method for determining Microbial Cleanliness (Bioburden) according to EN 14683+AC: 2019 standard Annex D.

Test conditions:
The test samples were conditioned for the time period of minimum 4 hours at the temperature of (21 ± 5) °C and a relative humidity of air of (85 ± 5) %.

Test Principle:
Microbial characterization of bioburden (staining properties, cell morphology, colony morphology and so on), a validation of method used to determine the bioburden is performed and a correction factor (numerical value applied to compensate for incomplete removal from product and/or culture of microorganisms) is calculated. Then using the validated method and the calculated correction factor the bioburden is calculated for each device.

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Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Determination of bioburden has been done using EN ISO 11737-1:2018 A.6.1.1 decision tree selection method. And mask is solid item and use shaking and followed by filtration/plating method has been determined.
Tryptic soy agar solid media has been selected as culture media and incubation conditions for aerobic bacteria. And Sabouraud dextrose agar has been selected as culture media and incubation conditions for fungi enumeration.

Shaking method used and mask was immersed in a known volume of eluent within a suitable vessel and shaken on a orbital for a defined time/number of cycles in order to assist the removal of microorganisms.

Membrane filtration of an eluent, followed by incubation of the filter on an appropriate growth medium to give visible colonies, is an effective means of enumerating viable microorganisms. A filter of appropriate nominal pore size used as 0,45µ and it is generally adequate to capture microorganisms; however, consideration should be given to the use of a smaller pore size if it is expected that the microorganisms present on or in the product warrant this.

Test Equipments:
This test equipment consists of a Laminar Air flow, Incubators, Shaking Device, Filtration unit, Common equipment of microbiological laboratory.

Acceptance Criteria:
If applicable, anaerobic controls are acceptable for the bioburden test results.

Test Procedure:
Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20.

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count.

Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

An alternative and equivalent extraction method may be used. If this is the case, the chosen extraction method shall be documented in the test report.
The total bioburden is expressed by addition of the TSA and SDA counts.

Summary
The testing was conducted in accordance with EN 14683+AC: 2019 standard Annex D and EN ISO 11737-1:2018, with the exception of bottle size, approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation, and 20-25°C used for fungi incubation. When bioburden results are calculated using a validated software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits.

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Test results:

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

Table I – Surgical Face Mask, registration No. 20042112686/3

Test Unit Number	Weight (gr)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/gr)
1	5,1	26[a]	21[a]	51	10
2	5,0	22[a]	23[a]	45	9
3	5,0	26[a]	34[a]	60	12
4	5,1	41[a]	35,5[a]	76,5	15
5	5,1	38[a]	33,4[a]	71,4	14
Recovery Efficiency	12%[b]				

No Organisms Detected Note: The results are reported as colony forming units (CPU) per mask.
Note: Sample positive testing was performed using Bacillus atrophaeus. The test article was not inhibitory using this test method.
[a]Spreader. Count is considered a minimum estimate due to swarming of certain colonies on the membrane.
Per EN 11737-1, when a Recovery Efficiency is below 50 percent, additional testing should be considered to improve the efficiency.

Parameters and Used Materials	Values
Lot number of tested samples	NP/LT/0857346/3
Conditioning Parameters	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Positive Controls/Monitors	Bacillus atrophaeus
Extract Fluid	Peptone Tween® with Sodium Chloride
Extract Fluid Volume	500 mL
Extract Method	Orbital Shaking for 5 minutes at 250 rpm
Plating Method	Membrane Filtration
Agar Medium	Tryptic Soy Agar, Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency:	Repetitive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated..

Conformity assessment carried out by:

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Head of Laboratory of Protective/MDD

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