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TEST REPORT

ASTM F2100 Testing for Breathability, Particulate Filtration Efficiency, and Resistance to Synthetic Blood Penetration on PrescientX Bioaerosol [breathe]™ Filters Lot # 10-05-22-OWI

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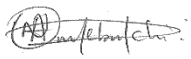
Author	02-09-2022 X  Chinonso Onyebuchi Laboratory Technician	Digitally Signed by Chinonso Onyebuchi

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Notes:

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1 TESTING SUMMARY

The testing described in this report for a set of 42 PrescientX Bioaerosol [breathe]™ from Lot # 10-05-22-OWI show the below performance in Breathability, Particulate Filtration Efficiency and Horizontal Blood Penetration Resistance.

Table 1.1: PrescientX Bioaerosol [breathe]™ filters performance summary

	Lots # (Lot # 10-05-22-OWI)	**ASTM F2100 Requirements**		
Test Method	**Average Results**	Level 1	Level 2	Level 3
Breathability EN 14683 Annex C	1.16 mmH_2O/cm^2 Passed Level 1, 2, or 3	< 5.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	
Particulate Filtration Efficiency ASTM F2299	98.44 % Passed Level 2 or 3	≥ 95%	≥ 98%	≥ 98%
Horizontal Blood Penetration Resistance ASTM F1862	31/32 at 160 mmHg Passed Level 3	80 mm Hg	120 mm Hg	160 mm Hg

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2 ASTM F2100 BREATHABILITY TEST (EN 14683:2019 ANNEX C)

2.1 Test Summary

The filter samples were tested for breathability under ASTM F2100 and EN 14683:2019 Annex C. Differential pressure is a measure of the difficulty or resistance of passing air through a sample material at a constant volumetric flow rate through a known sample surface area. Testing was conducted on a calibrated ATI 100X Automated Filter Tester, manufactured by Air Techniques International with the aerosol generator disabled and system purged. Dried and filtered compressed air was pulled across a filter sample held by two steel plates with a 4.9 cm^2 inner hole (2.5 cm diameter). The filter sample was challenged with a constant 8 liters per minute flow rate controlled by a calibrated AliCat flow controller Model MCR-250SLPM-D contained within the ATI 100X. The differential pressure difference between the inside and outside faces of the filter sample were measured. Filter samples were challenged with air from the inside to the outside as prescribed in the standard. Testing sites were top left, top right, bottom right, bottom left and center locations on each filter. The average differential pressure over all five testing locations was taken as the final measurement for that filter sample.

Table 2.1: ATI 100x Automated Filter Tester Specifications

Manufacturer	Air Techniques International
Model	100X
Equipment ID	PE044
Serial Number	35659
Calibration Date	December 16, 2021
Re-Calibration Due	December 16, 2022

Table 2.2: Alicat Flow Controller Specifications

Manufacturer	AliCat Scientific
Model	MCR-250SLPM-D
Equipment ID	PE055
Serial Number	296206
Calibration Date	October 27, 2021
Re-Calibration Due	October 27, 2022

2.2 Test Results

Table 2.3: Breathability test details

Testing Date	30-08-2022
Manufacturer	PrescientX
Model	Bioaerosol [breathe]™ Filters
Testing Standard	EN 14683:2019 Annex C
Required Conditioning	21°C ± 5°C, 85% ± 5% RH for 4.0 hrs
Oven Details	Memmert HPP 260 W620.0089 0.1°C Accuracy, 0.5% rh Accuracy
Sample Test Duration	~1 min
Test Flow Rate	8 l/min
Jig Serial Number used	2.5cm diameter adapter plates
Acceptance Criteria	< 5.0 mmH2O/cm2 for level 1 < 6.0 mmH2O/cm2 for level 2 or 3

Table 2.4: Breathability test results (Lot # 10-05-22-OWI)

Sample	Breathability (mmH2O /cm^2)	Result	Lot Average
1	1.11	Pass	1.16
2	1.19	Pass	
3	1.18	Pass	
4	1.14	Pass	
5	1.20	Pass	

All 5 filter samples passed the breathability standards for Level 1, 2 or 3 barrier rating outlined in ASTM F2100 with average lot value of 1.16 mmH_2O/cm^2.

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3 PARTICULATE FILTRATION EFFICIENCY (ASTM F 2299)

3.1 Test Summary

An atomizer is loaded with a suspension of polystyrene latex beads at a concentration of 2%. The PSL beads are sized at 0.1 µm. The atomizer airflow passes across a diffusion dryer to remove any moisture from the air and leaves only dry particles. The dry atomized air particles are then mixed with dry filtered air to make the challenge air. The airflow was passed across a filter sample clamped between two round steel adapter plates with 2-inch diameter holes (see Appendix). Test airflow was further diluted using TOPAS 28.3 lpm diluters to avoid concentrations flowing to the particle counter that causes instances of coincidence in the particle counts. A laser counter is used to sample the upstream and downstream air to determine particulate filtration efficiency of the filter sample. Testing was conducted in accordance with ASTM F2299 with the exception that non-neutralized particles were used in the place of neutralized particles as per FDA Guidance Document (FDA-2003-D-0305).

3.1 Test Results

Table 3.1: PFE Testing Details

Testing Date	30-08-2022
Manufacturer	PrescientX
Model	Bioaerosol [breathe]™ Filters
Testing Standard	TEB-APR-STP-0059
Required Conditioning	21°C ± 3°C, 40 ± 10 % RH for 4.0 hrs
Oven Details	Memmert HPP 260 W620.0089 0.1°C Accuracy, 0.5% rh Accuracy
Test Face Velocity	23.3 cm/s
Adapter Plate Hole Diameter	5.08 cm
Sample Test Duration	10 min
Test Flow Rate	28.3 L/min
Testing Notes	Testing at 1.1 Bar 1:100 dilution upstream 1:10 dilution downstream 11 cm diameter sample area
Acceptance Criteria	Level 1: ≥ 95% PFE Level 2: ≥ 98% PFE Level 3: ≥ 98% PFE

Table 3.2: Particulate Filtration Efficiency Test Results (Lot # 10-05-22-OWI)

Sample	% PFE	Result	Lot Avg.
1	98.30	Pass	
2	98.41	Pass	
3	98.50	Pass	98.44
4	98.46	Pass	
5	98.52	Pass	

All 5 filter samples passed the minimum ASTM F2100 requirements for Level 2 or 3 barrier rating with 98.44% Particulate Filtration Efficiency.

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4 HORIZONTAL BLOOD PENETRATION RESISTANCE (ASTM F1862)

4.1 Test Summary

A known volume of synthetic blood is challenged on the outside of a conditioned sample to determine its resistance to penetration by the synthetic blood. This test is conducted to simulate the impact of a spurt of blood or bodily fluid on a medical face masks or medical respirators during surgical procedure. The presence of any synthetic blood on the inside surface of the sample constitutes a failed sample. Samples are tested at velocities of 450 cm/s, 500 cm/s or 635 cm/s (Level 1, 2 or 3) to determine what level of resistance the sample has achieved. These velocities correspond to arterial pressures of 80 mmHg, 120 mmHg and 160 mmHg. Synthetic blood is pressurized in a pressure vessel with a pressure control valve. The spurt of synthetic blood is delivered using a pneumatic valve controller from a cannula at 30.5 cm distance from the challenge surface. Test results are reported at each tested velocity or corresponding pressure and the medical respirator filter is rated at the highest corresponding blood pressure for which the filter demonstrates an acceptable quality level of 4%. The test was conducted in accordance with Test Method ASTM F1862 on calibrated equipment.

4.1 Test Results

Table 4.1: Blood Penetration Resistance Testing details

Date	23-08-2022
Manufacturer	PrescientX
Model	Bioaerosol [breathe]™ Filters
Testing Standard	ASTM F1862
Required Conditioning	21°C ± 5°C, 85% ± 5% RH for 4.0 hrs
Oven Details	Memmert HPP 260 W620.0089 0.1°C Accuracy, 0.5% rh Accuracy
Laboratory Conditions	47% RH; 21.3 °C
Sample Test Duration	10 seconds
Acceptance Criteria	Output of synthetic blood after 16 samples must be within 2% of theoretical output Any blood found on inside surface results in failed test; Cotton swab used to lightly daub interior surface for blood presence. AQL of 4.0% (29 of 32 tests must show passing result) ASTM Level 1: Pass at 80 mm Hg ASTM Level 2: Pass at 120 mm Hg ASTM Level 3: Pass at 160 mm Hg

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Table 4.2: Blood Penetration Resistance Test Results

PrescientX Bioaerosol [breathe]™ Lot # 10-05-22-OWI							
Sample	**80 mm Hg**	**120 mm Hg**	**160 mm Hg**	**Sample**	**80 mm Hg**	**120 mm Hg**	**160 mm Hg**
1	n/a	n/a	Pass	17	n/a	n/a	Pass
2	n/a	n/a	Pass	18	n/a	n/a	Pass
3	n/a	n/a	Pass	19	n/a	n/a	Pass
4	n/a	n/a	Pass	20	n/a	n/a	Pass
5	n/a	n/a	Pass	21	n/a	n/a	Pass
6	n/a	n/a	Pass	22	n/a	n/a	Pass
7	n/a	n/a	Pass	23	n/a	n/a	Pass
8	n/a	n/a	Pass	24	n/a	n/a	Pass
9	n/a	n/a	Pass	25	n/a	n/a	Pass
10	n/a	n/a	Pass	26	n/a	n/a	Fail
11	n/a	n/a	Pass	27	n/a	n/a	Pass
12	n/a	n/a	Pass	28	n/a	n/a	Pass
13	n/a	n/a	Pass	29	n/a	n/a	Pass
14	n/a	n/a	Pass	30	n/a	n/a	Pass
15	n/a	n/a	Pass	31	n/a	n/a	Pass
16	n/a	n/a	Pass	32	n/a	n/a	Pass

Total Pass at 80 mm Hg: n/a
Total Pass at 120 mm Hg: n/a
Total Pass at 160 mm Hg: 31/32 Passed Level 3

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5 APPENDIX

Figure 5.1 Adapter plates with 2-inch diameter holes used to clamp filters for PFE and Breathability Testing

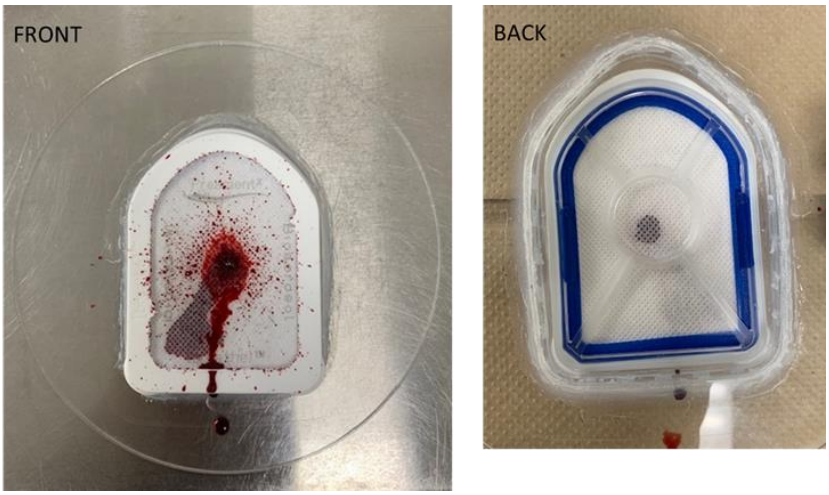

Figure 5.2 Example of a passed blood penetration resistance testing sample held in a filter holder adapter showing blood trapped between the middle and back layer of the sample without penetration

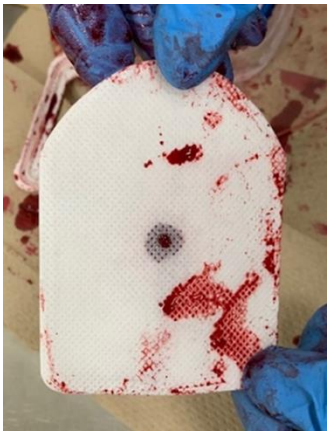

Figure 5.3 the back of a failed blood penetration resistance testing sample showing blood penetration through the back layer

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6 CHANGES TO DOCUMENT

Rev. To	Rev. From	Sec/Paragraph Changed	Change(s) Made	Date Implemented	Approval
A	N/A	N/A	Initial Release.	02-09-2022	M.C.