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SUMMARY TEST REPORT

ASTM F2100 Testing for Breathability, Flammability, Particulate Filtration Efficiency, Horizontal Synthetic Blood Penetration Resistance, and Bacterial Filtration Efficiency on PrescientX [breathe]2 Bioaerosol Filters

Client **PrescientX**

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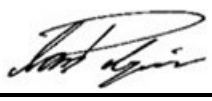
X 

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This document has been reviewed and authorized for release by:

Director Of Engineering Operations

2023-02-27

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Meaghan Coates
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Notes:

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Table of Contents

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1 TESTING SUMMARY

The testing described in this report for 52 PrescientX [breathe]2 bioaerosol filters show the below performance. From this set, 15 samples were sonic welded and tested for particulate filtration efficiency (PFE), breathability (dP), and bacterial filtration efficiency (BFE); while 37 samples were spot welded and tested for horizontal synthetic blood penetration resistance (BP) and flammability. These two types of filters are shown in Figure 1.1 below.

Table 1.1: PrescientX [breathe]2 bioaerosol filter performance summary

	[breathe]2 Bioaerosol filters	**ASTM F2100 Requirements**		
Test Method	**Average Results**	Level 1	Level 2	Level 3
Breathability EN 14683-2019&AC-2019 Annex C	1.36 ± 0.04 mmH_2O/cm^2 **Level 3**	< 5.0 mmH_2O/cm^2	< 6.0 mmH_2O/cm^2	
Flammability 16 CFR Part 1610	**Class 1**	Class 1		
Particulate Filtration Efficiency ASTM F2299-03(2017)	99.053 ± 0.004 % **Level 3**	≥ 95%	≥ 98%	≥ 98%
Horizontal Blood Penetration Resistance ASTM F1862-17	32/32 at 160 mmHg **Level 3**	80 mm Hg	120 mm Hg	160 mm Hg
Bacterial Filtration Efficiency ASTM F2101-19	99.74 ± 0.04% **Level 2 or 3**	≥ 95%	≥ 98%	≥ 98%

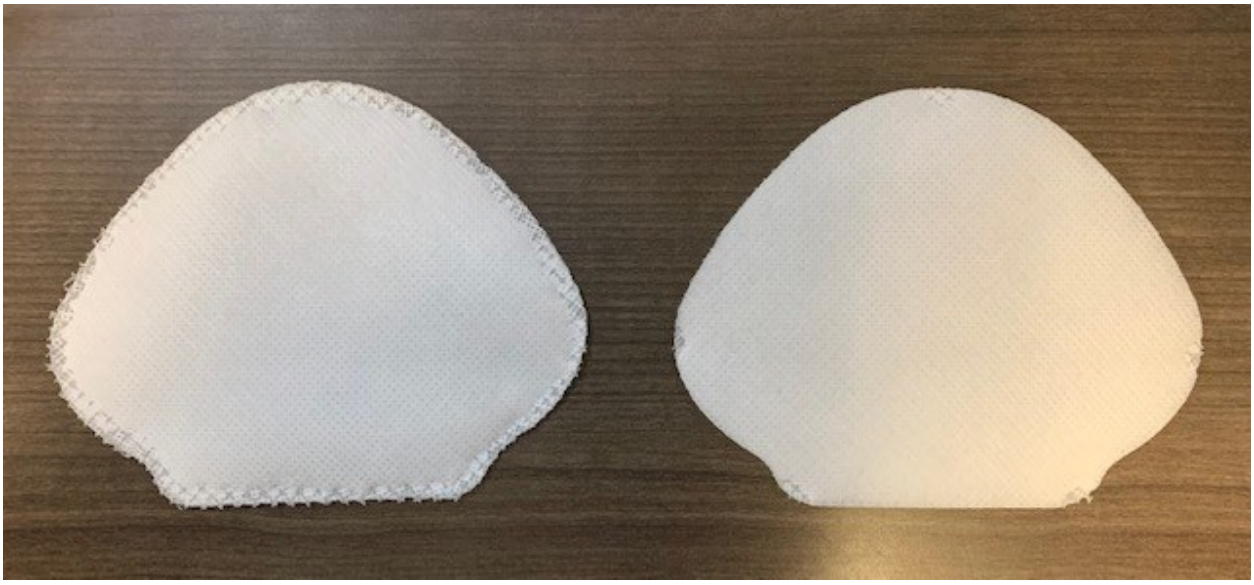

Figure 1.1 Sonic welded (left) and spot welded (right) bioaerosol filters

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2 BREATHABILITY (DIFFERENTIAL PRESSURE)

2.1 Test Summary

The filter samples were tested for breathability under ASTM F2100 and EN 14683-2019&AC-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 (2.54 cm or one inch 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 tester uses an integrated circuit based differential pressure sensor that provides a real-time measurement of the pressure differential generated across a sample. 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.

2.2 Test Results

Table 2.1: Breathability test details

Testing Date	2022-12-06
Manufacturer	PrescientX
Model	[breathe]2 bioaerosol filters – sonic welded
Testing Standard	EN 14683-2019&AC-2019 Annex C
Required Conditioning	21°C ± 5°C, 85% ± 5% RH for 4.0 hrs
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 2.2: Breathability test results

Sample	Laboratory Ambient		dP [mm H2O /cm²]	Lot Average
	Temp (°C)	RH (%)		
1	21.8	30.5	1.38	1.36
2	22.3	32.1	1.39	
3	21.9	31.9	1.36	
4	22.4	31.9	1.30	
5	22.3	31.0	1.35	

Measurement Uncertainties		
Measurand	**Value ±**	**Absolute or Relative**
Diff. Pressure	0.04	Absolute

All filter samples passed the breathability standards for Level 3 barrier rating outlined in ASTM F2100 with average value of 1.36 ± 0.04 mmH_2O/cm^2.

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3 FLAMMABILITY

3.1 Test Summary

Flammability testing finds the amount of time a 5/8" sized flame with a 1 second ignition time will take to travel across a 2" x 6" fabric sample held at a 45° angle. The travel, or action of the flame, is noted for each sample which gives the flammability rating of the sample material. Each sample was conditioned at 105°C for 30 minutes prior to testing. After conditioning was completed, the samples are held in a desiccator until ready for testing. Each sample was tested within 45 seconds of being removed from the desiccator. The behavior of the flame was noted for each sample to determine the class rating. ASTM F2100 dictates class 1 flammability performance is required for surgical respirator filters. This translates to a burn time ≥ 3.5 seconds for plain surface fabrics. The filter samples were tested in their original state as specified in 16 CFR Part 1610.6 (a) step 1 – 'Testing in the original state', (2) 'Plain surface textile fabrics'. The client specified that these filters were intended for single use, therefore 16 CFR Part 1610.6 (b) step 2 'Refurbishing and testing after refurbishing' was not performed. The tests were performed according to 16 CFR Part 1610 – Standard for the Flammability of Clothing Textiles. Testing was performed on calibrated equipment.

3.2 Preliminary Trials

Preliminary trials were conducted to determine the fastest burning area and direction of the filter fabric. Two sample directions were cut from filter samples—one vertical and one horizontal. The filters were inserted into the specimen holders with the outside facing towards the flame. Testing revealed a larger burn pattern on vertical filter sections and as a result, vertical sample direction cuts were chosen for the remainder of testing.

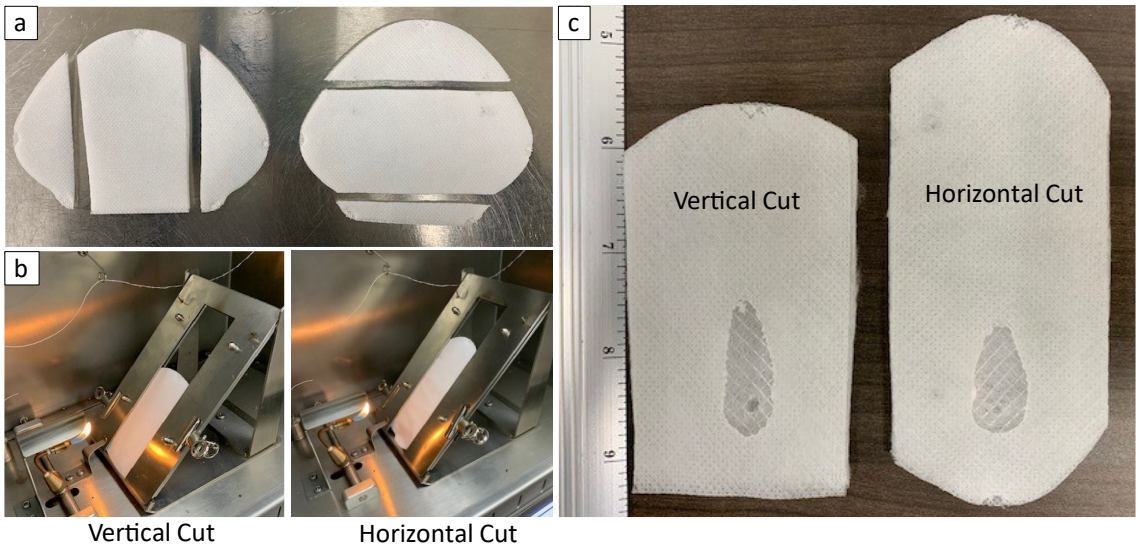

Figure 3.1 Preliminary Trials samples showing (a) test sections cut vertically and horizontally from filter samples, (b) test sections mounted into specimen holder and into test chamber (c) flammability test results showing a larger burn area in the vertical cut section

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3.3 Test Results

Table 3.1: Flammability test details

Testing Date	2022-12-08
Manufacturer	PrescientX
Model	[breathe]2 bioaerosol filters – spot welded
Testing Standard	16 CFR Part 1610 - Flammability
Required Conditioning	105 deg C for 30 minutes
Sample Test Duration	1 second ignition
Equipment Used	M015 45 Degree Automatic Flammability Tester
Acceptance Criteria	Class 1 flame spread Average burn time ≥ 3.5s

Table 3.2: Flammability test results

Sample	Time of Flame Spread	Result
1	DNI	Pass
2	DNI	Pass
3	DNI	Pass
4	DNI	Pass
5	DNI	Pass

DNI refers to “Did not ignite” (when samples melt on flame contact)

The burn pattern on the filter samples is shown in Figure 3.2. The filter samples did not ignite and instead melted on flame contact. All samples passed the requirements in 16 CFR part 1610.

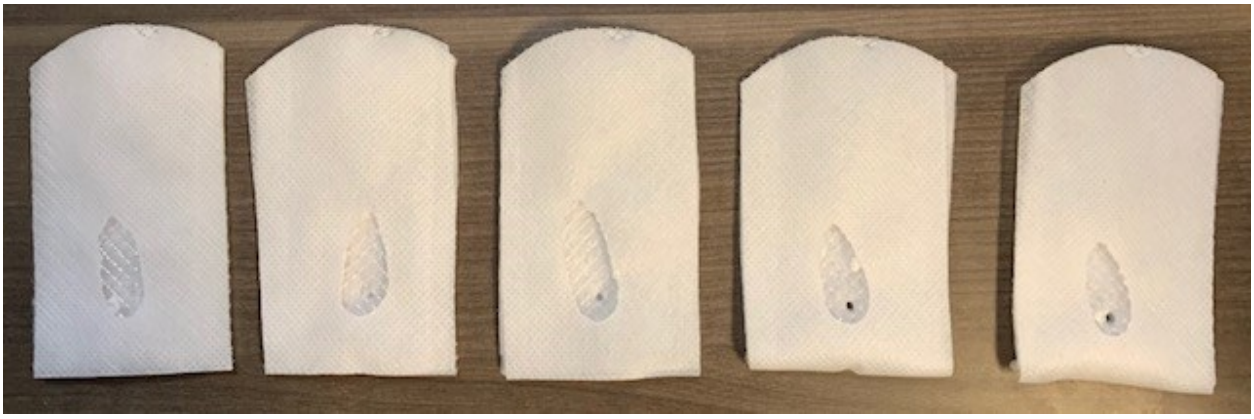

Figure 3.2 Flammability tested samples

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4 PARTICULATE FILTRATION EFFICIENCY

4.1 Test Summary

An atomizer was loaded with a suspension of polystyrene latex beads at a concentration of 2%. The PSL beads were sized at 0.1 µm. The atomizer airflow passed across a diffusion dryer to remove any moisture from the air leaving only dry particles. The dry atomized air particles were then mixed with dry filtered air to make the challenge air. The airflow was passed across a filter sample clamped between two adapter plates with two-inch diameter holes so that the test opening area was 20.25 cm^2, maximizing the testing area while keeping below the maximum allowable face velocity of 25 cm/s. 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 was 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/F2299M-03(2017) with the exception that non-neutralized particles were used in the place of neutralized particles as per FDA Guidance Document (FDA-2003-D-0305).

4.2 Test Results

Table 4.1: PFE Testing Details

Testing Date	2022-12-05
Manufacturer	PrescientX
Model	[breathe]2 bioaerosol filters – sonic welded
Testing Standard	ASTM F2299/F2299M-03(2017)
Required Conditioning	Yes 21°C, 40% RH for 4 hrs
Oven Details	Memmert HPP 260 W620.0155 0.1°C Accuracy, 0.5% rh Accuracy
Test Opening Diameter	5.08 cm (2 inches)
Test Face Velocity	23.27 cm/s
Sample Test Duration	22 min
Test Flow Rate	28.3 L/min
Testing Notes	Testing at 0.5 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 4.2: Particulate Filtration Efficiency Test Results

Sample	Laboratory Ambient		Flow Rate (L/min)	Face Velocity. (cm/s)	Filtration Efficiency (%)
	Temp (°C)	RH (%)			
1	21.6	31.7	28.3	23.27	99.126
2	22.1	30.8	28.3	23.27	98.941
3	21.6	31.0	28.3	23.27	99.125
4	21.7	31.6	28.3	23.27	99.051
5	21.9	30.9	28.3	23.27	99.022

Measurement Uncertainties

Measurand	Value ±	Absolute or Relative
Efficiency	0.004	Absolute

All filter samples passed the minimum ASTM F2100 requirements for Level 1, 2 or 3 barrier rating with an average of 99.053 ± 0.004 % Particulate Filtration Efficiency.

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5 HORIZONTAL BLOOD PENETRATION RESISTANCE

5.1 Test Summary

A known volume of synthetic blood was challenged on the outside of a conditioned filter sample to determine its resistance to penetration by the synthetic blood. This test was conducted to simulate the impact of a spurt of blood or bodily fluid on a medical respirator. The presence of any synthetic blood on the inside surface of the filter sample constitutes a failed sample. Samples are tested at fluid 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 was pressurized in a pressure vessel with a pressure control valve. The spurt of synthetic blood was delivered using a pneumatic valve controller from a cannula at 30.5 cm distance from the challenge surface. Test samples were mounted into the supplied fixture consisting of a backing plate and snap on frame and then placed in front of the target area, as shown in Figure 5.1. Test results are reported at each tested fluid 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/F1862M-17 on calibrated equipment.

Figure 5.1 front of filter sample in fixture (left), back of filter sample in fixture (middle), fixtured filter sample placed into testing apparatus (right)

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5.1 Test Results

Table 5.1: Blood Penetration Resistance Testing details

Date	2022-12-08
Manufacturer	PrescientX
Model	[breathe]2 bioaerosol filters – spot welded
Testing Standard	ASTM F1862/F1862M-17
Sample Conditioning Parameters	Yes 21 deg C 85 % rh 4 hrs min
Laboratory Conditions	32.5 % RH; 22.1 °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

Table 5.2: Horizontal Synthetic Blood Penetration Resistance Test Results

PrescientX [breathe]2 bioaerosol filters – spot welded			
Sample	**160 mm Hg**	**Sample**	**160 mm Hg**
1	Pass	17	Pass
2	Pass	18	Pass
3	Pass	19	Pass
4	Pass	20	Pass
5	Pass	21	Pass
6	Pass	22	Pass
7	Pass	23	Pass
8	Pass	24	Pass
9	Pass	25	Pass
10	Pass	26	Pass
11	Pass	27	Pass
12	Pass	28	Pass
13	Pass	29	Pass
14	Pass	30	Pass
15	Pass	31	Pass
16	Pass	32	Pass

Total Pass at 160 mm Hg: 32/32

Figure 5.2 Example of a passing test sample showing blood impact on front of sample (left) and no penetration on back (right)

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6 BACTERIAL FILTRATION EFFICIENCY

6.1 Test Summary

A syringe is loaded with a solution of Tryptic Soy Broth cultured with *S. Aureus* (Rosenbach ATCC 6538). A syringe pump pushes the bacterial solution at a constant rate into an air-powered nebulizer to create a moist diffusion of bacteria-laden droplets inside a stainless-steel aerosol chamber (BFE system, CH Technologies). The aerosol stream is mixed with dilution air filtered with a HEPA filter to make the challenge air. The airflow is passed through a filter clamped within a flange of the aerosol chamber. The airflow is then passed through a 6-stage Andersen Sampling (Cascade) Impactor (Tisch Environmental) containing 6 agar plates. The agar plates were incubated for 24 hours to allow individual bacterial colonies to form. Bacterial colonies are counted and compared against the control plates (no filter) to calculate bacterial filtration efficiency. The pre-test negative control sample is obtained by running the BFE apparatus without the addition of bacteria-laden aerosol. A positive control sample is then obtained by running the BFE apparatus with the introduction of the moist diffusion of bacteria-laden droplets inside the stainless-steel aerosol chamber. A post-test negative control sample is then obtained after filter tests are completed, in the same manner as the pre-test sample. The test was conducted in accordance with ASTM 2101-19 on calibrated equipment.

6.2 Test Results

Table 6.1: Bacterial Filtration Efficiency Test Details

Testing Date	2023-02-25
Manufacturer	PrescientX
Model	[breathe]2 bioaerosol filters – spot welded
Testing Standard	ASTM F2101-19
Required Conditioning	21°C ± 5°C, 85% ± 5% RH for 4.0 hrs
Sample Test Duration	3 min
Vacuum Flow Rate	28.3 L/min
Nebulizer Pressure	18 psi
Syringe Pump Rate	0.05 mL/min
Bacterial solution	McFarland Solution 0.5 to crease $1.5x10^8$ CFU/mL diluted to $5x10^5$ CFU/mL with peptone water; made with 5% glycerol.
Pre-Test Negative Control CFUs	1
Positive Control CFUs	2302
Mean Particle Size	3.01 µm
Post-Test Negative Control CFUs	2
Mean Negative Control CFUs	1.5
Acceptance Criteria	≥ 95% BFE for level 1 ≥ 98% BFE for level 2 or 3

Table 6.2: Bacterial Filtration Efficiency Test Results

Sample	% BFE	Result	Lot Avg.
1	99.93	Pass	99.74
2	99.87	Pass	
3	99.40	Pass	
4	99.90	Pass	
5	99.61	Pass	

Measurement Uncertainties		
Measurand	**Value ±**	**Absolute or Relative**
Efficiency	0.04	Absolute

Mean plate count for the negative control samples was 1.5 CFU. The positive control falls within the acceptable range of 1700-3000 CFU, as outlined in ASTM F2101-19. The mean particle sizes fall within the acceptable range of 3.0 µm ± 0.3 µm prescribed in ASTM F2101-19.

All filter samples passed the minimum ASTM F2100-19 requirements for Level 2 or 3 barrier rating with 99.74 ± 0.04% Bacterial Filtration Efficiency. Uncertainty in efficiency was measured as the value of expanded measurement uncertainty using a coverage factor k=2.

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7 CHANGES TO DOCUMENT

Rev. To	Rev. From	Sec/Paragraph Changed	Change(s) Made	Date Implemented	Approval
A	N/A	N/A	Initial Release.	2022-12-14	M. Coates
B	A	6	Added Bacterial Filtration Efficiency results	2023-02-27	M. Coates