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Laboratory #: 853381-21
FINAL
Report Date: January 27, 2021
Received Date: January 15, 2021

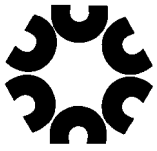
Attention: Ouassim Meguellati
Specimen: #1: Face Masks

TEST REPORT

One specimen, consisting of face masks, was submitted to be tested for bacteria filtration efficiency, differential pressure, particle filtration efficiency, synthetic blood penetration and flame spread to determine barrier classification level as per ASTM F2100-19 requirements.



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Note: This report ONLY contains results for three of the five requirements as per ASTM F2100-19. Unless all the tests are performed, final overall performance level cannot be achieved for the submitted medical mask.

Medical Face Mask Material Requirements

Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier	Summary Results
Bacterial Filtration Efficiency, %	≥95	≥98	≥98	Pass any Level
Differential Pressure, mm H ₂ O/cm ²	<5.0	<6.0	<6.0	Pass any Level
Sub-Micron Particulate Filtration Efficiency at 0.1 micron, %	≥95	≥98	≥98	Pass any Level
Synthetic Blood Penetration minimum pressure in mmHg for pass result	80	120	160	Pass Level 3
Flame Spread	Class 1	Class 1	Class 1	Pass any Level
OVERALL PERFORMANCE LEVEL	Complete - Level 3			



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DIFFERENTIAL PRESSURE

EN 14683:2019 edition Annex C

Each specimen was conditioned for 4 hours minimum at 21+/-5 C and 85+/-5 % R.H.

Requirements ASTM F2100-19:

Differential Pressure (mmH₂O/cm²)

Level 1 Barrier: <5.0

Level 2 Barrier: <6.0

Level 3 Barrier: <6.0

RESULTS

<u>Specimen ID</u>	<u>Area ID</u>	<u>Differential Pressure (mmH₂O/cm²)</u>	<u>Specimen Pass/Fail</u>	<u>FINAL RESULT</u>
1-1	1	3.0	Pass	Pass all Levels
	2	3.5		
	3	3.6		
	4	3.6		
	5	3.4		
	AVERAGE	3.4		
1-2	1	3.5	Pass	
	2	3.5		
	3	3.4		
	4	3.2		
	5	3.5		
	AVERAGE	3.4		
1-3	1	3.0	Pass	
	2	3.0		
	3	3.1		
	4	3.5		
	5	3.5		
	AVERAGE	3.2		
1-4	1	3.0	Pass	
	2	3.0		
	3	2.9		
	4	3.0		
	5	3.0		
	AVERAGE	3.0		
1-5	1	4.0	Pass	
	2	3.4		
	3	3.0		
	4	3.5		
	5	3.1		
	AVERAGE	3.4		

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm²)

Air Flow Rate: 8 L/min

Mask Location Specimen taken from: 5 Areas from each specimen distributed all surface wide

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.



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SYNTHETIC BLOOD PENETRATION

ASTM F1862/F1862M-17 at 160 mmHg pressure

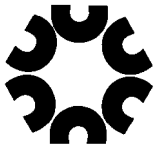
RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens	FINAL RESULT
1	160	32	29	Pass for Level 3

Note: Acceptable Quality Limit of 4.0% is met for single sampling plan when 29 or more of the 32 tested specimens show pass results.

Material construction type	Not provided/unknown
Supplier	Not provided/unknown
Lot number	Not provided/unknown
Date of receipt	January 15, 2021
Date of test	January 18, 2021
Fluid velocity (cm/s)	644
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	Outer blue ripple area (see Note)
Distance from tip cannula to mask (in)	12
Technique to enhance visual detection	Cotton swab used to lightly daub on the surface
Conditioning parameters	21±5°C, 85±5% R.H for minimum of 4 hours

NOTE: The outside surface of the mask is exposed to the blood stream in order to observe whether penetration occurred on the inner surface of the mask that could be contacting the wearer's face. Penetration on the inner facing of the mask constitutes failure (ASTM F1862/F1862M-17 section 4.2).



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FLAME SPREAD

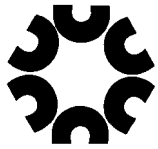
The specimen, consisting of 5 masks, was tested in accordance to 16 CFR 1610 (1-1-16 Edition).

	Specimen #	RESULT	CONCLUSION
Specimen #1	1-1	IBE	Classified as Class 1 Pass for any Level
	1-2	IBE	
	1-3	IBE	
	1-4	IBE	
	1-5	IBE	

IBE: Ignited but extinguished

Test: Flame Resistance 45° angle test. One-Second Flame Impingement.
Type of fabric: Without a raised fiber surface
Surface tested: Face
Type of test: Original State
Direction tested: Length
Testing Conditioning: Specimens conditioned at 105°C for 30 min, then placed in desiccator
Requirements: The flame spread time for textile products without a raised fibre surface must be greater than 3.5 seconds.

Note: For a test plan of 5 specimens, no failure is allowed for an Acceptable Quality Limit of 4.0%.



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PARTICLE FILTRATION EFFICIENCY

Particles: Monodispersed polystyrene latex spheres (PSL)
Particles Counter: TSI scanning mobility particle sizer spectrometer 3082 and CPC
Tested as per ASTM F2299, non-neutralized aerosol challenge measured over 3 minutes (test specimen / control counts before and after test specimen and averaged)

Test Side: Inside
Area Tested: 21.7 cm² with a cross-sectional diameter of 5.25 cm
Particle Size: 0.1 µm (100 nm)
Laboratory Conditions: 23.9°C, 36.0% relative humidity (RH)

RESULTS

Specimen #	Particle Diameter / Standard Deviation*	Average Control Counts	Specimen Counts	Face Velocity (cm/s)	Pressure drop (KPa)	Filtration Efficiency (%)	Specimen Pass/ Fail	FINAL RESULT
1-1	99.9 nm / 0.01 nm	67,531	100	4	0.02	99.9	Pass	Pass any Level
1-2	99.9 nm / 0.01 nm	92,593	50	4	0.02	99.9	Pass	
1-3	99.9 nm / 0.01 nm	89,438	401	4	0.02	99.6	Pass	
1-4	99.9 nm / 0.01 nm	95,146	595	4	0.02	99.4	Pass	
1-5	99.9 nm / 0.01 nm	89,271	201	4	0.02	99.8	Pass	

Note: The PFE equipment was outsourced and located at University of Toronto, 223 College Street, Toronto, ON M5T 1R4.

* Note: Nanobead NIST traceable Particle Size Standards 100NM, Cat# 64010, Lot#: A776757.



BACTERIAL FILTRATION EFFICIENCY

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19^d to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts recovered downstream. A suspension of *S. aureus* was aerosolized using a nebulizer and delivered to the test article at a constant rate with a target delivery rate of $1.7 \times 10^3 - 3.0 \times 10^3$ colony forming units (CFU) per test article with a mean particle size of $3.0 \pm 0.3 \mu\text{m}$. The aerosolized suspension was drawn through the test article which was clamped in a six stage Andersen air sampler, at a constant flow rate of 28.3 liters per minute (LPM), for collection on bacteriological agar plates.

Challenge Microbe: *Staphylococcus aureus* ATCC 6538
Test Side^a: Blue side
Area Tested^b: ~38.5 cm²
Flow Rate^c: 28.3 LPM
Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours
Challenge Level^e: 1.7×10^3 CFU
Mean Particle Size^f: 3.1 μm
Negative Control Count^g: <1 CFU

Requirements ASTM F2100-19:
Bacterial filtration efficiency (%)
Level 1 Barrier: ≥95
Level 2 Barrier: ≥98
Level 3 Barrier: ≥98

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%) ^h	Specimen (Pass/Fail)	FINAL RESULT
1-1	<1	>99.9	Pass	Pass for all Levels
1-2	<1	>99.9	Pass	
1-3	<1	>99.9	Pass	

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Challenge Level
T = Total CFU recovered downstream of test article

$$MPS = \frac{(P1 \times C1) + (P2 \times C2) + (P3 \times C3) + (P4 \times C4) + (P5 \times C5) + (P6 \times C6)}{C1 + C2 + C3 + C4 + C5 + C6}$$

Px = 50% effective cut-off diameter for the xth stage as indicated by the manufacturer
Cx = raw count (on stages 1 and 2) or the "probable hit" count determined using the positive hole conversion chart from the cascade impactor manual (for stages 3 through 6) on the xth stage.



Bacterial Filtration Efficiency (Continued)

Notes: a) ASTM F2101-19 Section 14.9, b) ASTM F2101-19 Section 14.2, c) ASTM F2101-19 Section 14.3, d) ASTM F2101-19 Section 14.1, e) ASTM F2101-19 Section 14.6, f) ASTM F2101-19 Section 14.4, g) ASTM F2101-19 Section 14.7, h) ASTM F2101-19 Section 14.5, i) ASTM F2101-19 Section 14.8

Appendix ⁱ

Table 1: Raw counts from each stage of the 6 stage cascade air sampler. The numbers presented for stage 1 and 2 represent the total bacterial colonies present and stages 3 through 6 represent a "positive-hole" count. or stages 3 through 6, the air flow through the impactor follows the jet pattern produced by the 400-holes present in these stages. As a result, the count must be corrected using a positive hole correction table based on the principle where the chance of a viable cell/particle impacting in a new, unoccupied, "jet" hole decreases as the total viable particles increase.

Stage Number	Test Article		
	1	2	3
1 - Raw Count	0	0	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	0	0
4 - Positive Hole	0	0	0
5 - Positive Hole	0	0	0
6 - Positive Hole	0	0	0

Table 2: Counts obtained from each stage, including the "positive-hole" correction for stages 3 through 6

Stage Number	Test Article		
	1	2	3
1 - Raw Count	0	0	0
2 - Raw Count	0	0	0
3 - Positive Hole	0	0	0
4 - Positive Hole	0	0	0
5 - Positive Hole	0	0	0
6 - Positive Hole	0	0	0

Note: Testing performed by GAP EnviroMicrobial Services Ltd., 1020 Hargrieve Road, Unit 14, London, Ontario, Canada, N6E 1P5