



Report For: ProCare Corporation
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Laboratory #: 841554-20
FINAL
Report Date: August 14, 2020
Received Date: July 31, 2020

Attention: Wasim Toama
Specimen: #1: Proserva Medical Masks, Lot #220720ING

TEST REPORT

One specimen, consisting of Medical Masks, was submitted to be tested for bacteria filtration efficiency, differential pressure, particle filtration efficiency, synthetic blood penetration and flame spread to determine acceptability with level barrier classification under ASTM F2100-19 requirements.

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 Level 2 and 3
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 - Pass Level 2 and 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

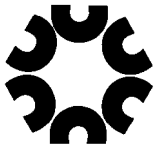
<u>Specimen ID</u>	<u>Area ID</u>	<u>Differential Pressure (mmH₂O/cm²)</u>	<u>Specimen Pass/Fail</u>	<u>FINAL RESULT</u>
1	1	6.0	PASS	PASS Level 2 and Level 3
	2	5.6		
	3	5.9		
	4	5.8		
	5	5.5		
	AVERAGE	5.8		
2	1	5.7	PASS	
	2	5.8		
	3	6.1		
	4	5.4		
	5	5.7		
	AVERAGE	5.7		
3	1	6.0	PASS	
	2	5.7		
	3	5.4		
	4	5.2		
	5	6.6		
	AVERAGE	5.8		
4	1	6.1	PASS	
	2	6.1		
	3	6.1		
	4	5.5		
	5	5.7		
	AVERAGE	5.9		
5	1	5.3	PASS	
	2	6.2		
	3	6.4		
	4	4.6		
	5	6.2		
	AVERAGE	5.7		

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	30	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	July 31, 2020
Date of test	August 4, 2020
Fluid velocity (cm/s)	645
Volume of impact fluid (ml)	2
Angle of pneumatic valve to horizontal	2°
Description target area mask	Blue ripple area
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



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 fiber 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 (PFE)

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
Particle Size: 0.1 µm
Laboratory Conditions: 22.4°C, 44.6% relative humidity (RH)

Requirements ASTM F2100-19:
Particle filtration efficiency at 0.1 micron (%)
Level 1 Barrier: ≥95
Level 2 Barrier: ≥98
Level 3 Barrier: ≥98

RESULTS

Specimen #	Average Control Counts	Specimen Counts	Filtration Efficiency (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	78,718	238	99.7	Pass	PASS Any Level
1-2	75,988	551	99.3	Pass	
1-3	76,658	315	99.6	Pass	
1-4	76,553	652	99.1	Pass	
1-5	75,724	839	98.9	Pass	

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



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BACTERIA FILTRATION EFFICIENCY (BFE)

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

A Bacterial Filtration Efficiency (BFE) test was completed according to the procedure in ASTM F2101-19 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: User side facing challenge
Area Tested: $\sim 38.5 \text{ cm}^2$
Flow Rate: 28.3 LPM
Test Article Conditioning: $85 \pm 5\% \text{ RH}$ at $25.0 \pm 0.5^\circ\text{C}$ for a minimum of 4 hours
Challenge Level: $1.955 \times 10^3 \text{ CFU}$
Mean Particle Size: $3.24 \mu\text{m}$

Requirements ASTM F2100-19:

Bacteria filtration efficiency (%)
Level 1 Barrier: ≥ 95
Level 2 Barrier: ≥ 98
Level 3 Barrier: ≥ 98

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)	Specimen (Pass/Fail)	FINAL RESULT
1-1	<1	>99.95	Pass	PASS Any Level
1-2	<1	>99.95	Pass	
1-3	<1	>99.95	Pass	
1-4	<1	>99.95	Pass	
1-5	<1	>99.95	Pass	

The filtration efficiency percentages were calculated using the following equation:

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

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