



Report For: Dent-X Canada
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Laboratory #: 841948-20
Report Date: August 7, 2020
Received Date: August 7, 2020

Attention: Angelina W.
Specimen: #1: Medical Masks, Supplier: Dent-X Canada/Lot # 071320/ Materials of construction: Nonwoven (SP/SMMMS/SP)

TEST REPORT

One specimen, consisting of Medical Masks, was submitted to be tested for bacterial filtration efficiency, differential pressure, particulate filtration efficiency, synthetic blood penetration and flame spread to determine acceptability with level 3 barrier classification under ASTM F2100-19 requirements.

Medical Face Mask Material Requirements

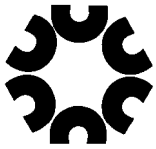
Characteristic	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier	Summary Results
Bacterial Filtration Efficiency*, %	≥95	≥98	≥98	Pass Level 2 and 3
Differential Pressure ^Δ , mm H ₂ O/cm ²	<5.0	<6.0	<6.0	Pass Level 2 and 3
Sub-Micron Particulate Filtration Efficiency at 0.1 micron*, %	≥95	≥98	≥98	Pass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

* Results tested under Laboratory #841259 (dated August 7/20)

^Δ Results tested under Laboratory #840137 (dated July 28/20)

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Per Janet Glover
Authorized By Janet Glover
Per Derek Wild
Technician, Derek Wild



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	Nonwoven (SP/SMMMS/SP)
Supplier	Dent-X-Canada
Lot number	071320
Date of receipt	July 14, 2020
Date of test	July 15, 2020
Fluid velocity (cm/s)	644
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

^Δ Results tested under Laboratory #840137 (dated July 28/20)



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 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.

^Δ Results tested under Laboratory #840137 (dated July 28/20)



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 #</u>	<u>Differential Pressure (mm H₂O/cm²)</u>	<u>Specimen (Pass/Fail)</u>	<u>FINAL RESULT</u>
1-1	5.7	Pass	PASS for Level 2 and 3
1-2	5.5	Pass	
1-3	5.2	Pass	
1-4	5.4	Pass	
1-5	5.7	Pass	
Average	5.5		

Mask Surface Area: 25mm diameter (4.9 cm²)

Air Flow Rate: 8 L/min

Mask Location Specimen taken from: Each specimen from middle of the mask.

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

^Δ Results tested under Laboratory #840137 (dated July 28/20)



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.

Received Date: July 29, 2020

Test Date: July 30, 2020

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: $85 \pm 5\%$ RH at $25.0 \pm 0.5^\circ\text{C}$ for a minimum of 4 hours

Challenge Level: 1.963×10^3 CFU

Mean Particle Size: $3.11 \mu\text{m}$

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	25	98.71	Pass	PASS for All Levels
1-2	13	99.33	Pass	
1-3	20	98.96	Pass	
1-4	11	99.43	Pass	
1-5	18	99.08	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

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PARTICLE FILTRATION EFFICIENCY (PFE)

Particles: Monodispersed polystyrene latex spheres (PSL)
 Particles Counter: TSI scanning mobility particle sizer spectrometer 3082 and 3752
 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: 23.9°C, 33% 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	85,144	841	99	Pass	PASS for All Levels
1-2	89,027	1,061	99	Pass	
1-3	85,969	796	99	Pass	
1-4	85,825	746	99	Pass	
1-5	82,914	1,317	98	Pass	

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

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