



Report For: United Canada Inc
 111 Granton Drive, Unit 412
 Richmond Hill, Ontario
 L4B 1L5
 Phone: 647-910-5999 x 221
 Email: accounting@unitedcanadainc.ca
 alaina@unitedcanadainc.ca

Laboratory #: 855935-21
Report Date: February 23, 2021
Received Date: February 11, 2021

Attention: Alaina McKenzie
Specimen: #2: Disposable Surgical 3 Ply Mask. Manufacturer: United Canada Inc. Lot#: XSORH0221

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 F2100-20 requirements.



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Per Stephen Brown
 Authorized By Stephen Brown
 Per Diana Kalinowski
 Technician, Diana Kalinowski



Medical Face Mask Packaging Requirements

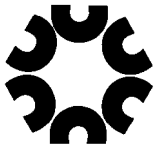
Package Information	Packaging Displayed Information
Manufacturer Name	United Canada Inc.
Product / Style Name	Disposable Surgical 3 Ply Mask
Lot Number	XSORH0221
Graphical representation indicating the performance level met with the technical requirements of the indicated performance level including a prominent visual indication of the performance level.	Yes
Requirements (Pass / Fail)	Pass

Note: ASTM F2100-20 requires verification of packaging, which prominently displays the above packaging information.

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 Level 3
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	Level 3			

Note: All five tests must be performed and meet with the requirements of ASTM F2100-20 in order to determine the final overall performance level of the mask, otherwise, the performance level is deemed, "Undetermined".



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.

RESULTS

<u>Specimen ID</u>	<u>Area ID</u>	<u>Differential Pressure (mmH2O/cm²)</u>
1-1	1	3.7
	2	4.6
	3	5.1
	4	6.0
	5	5.1
	AVERAGE	4.9
1-2	1	4.5
	2	6.0
	3	5.6
	4	4.0
	5	4.6
	AVERAGE	4.9
1-3	1	5.3
	2	5.1
	3	5.1
	4	5.1
	5	4.0
	AVERAGE	4.9
1-4	1	5.1
	2	5.1
	3	5.1
	4	4.1
	5	5.1
	AVERAGE	4.9
1-5	1	4.4
	2	4.0
	3	5.8
	4	5.3
	5	5.0
	AVERAGE	4.9

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%.



SYNTHETIC BLOOD PENETRATION

ASTM F1862/F1862M-17 at 160 mmHg pressure

RESULTS

Specimen #	Test Pressure (mmHg)	Total Number of Specimens	Number of Pass Specimens
1	160	32	32

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	United Canada Inc.
Lot number	XSORH0221
Date of receipt	February 11, 2021
Date of test	February 22, 2021
Fluid velocity (cm/s)	637
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).



FLAME SPREAD

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

Specimen #1	Specimen #	RESULT	CONCLUSION
	1-1	IBE	Classified as Class 1
	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%.



PARTICLE FILTRATION EFFICIENCY

Description of Material Tested

Material Identification: Disposable Surgical 3 Ply Mask
Material Description: Not provided/unknown
Manufacturer: United Canada Inc.
Lot #: XSORH0221
Thickness: 0.70 mm
Basis Weight: 75.3 g/m²
Treatment Prior to Testing: None

Challenge Particles

Challenge Particle Composition: Monodispersed polystyrene latex spheres (PSL)
Particle Size Distribution:
Particle Size: 0.100 um
% Concentration: 0.01 nm sd.
Source: Nanobead NIST traceable 100NM, Cat# 64010
Lot Identification: Lot#: A776757

Aerosol Generator

System Flow Meters: MKS Mass Flow Meter 0558A/247D (calibrated Jan-2021)
Particle Counter: TSI scanning mobility particle sizer spectrometer 3082 and CPC (calibrated Jun-2020)

Test Method

Standard Test Method Used: ASTM F2299/F2299M-03 (2017)
Deviation from Standard Test Method: non-neutralized aerosol challenge measured over 3 minutes, Temperature and Humidity: 21.3°C, 37.0% relative humidity (RH)

Test Parameters:

Exposed Specimen Area: 21.7 cm² with a cross-sectional diameter of 5.25 cm
Flowrate: 10 L/min
Test Duration: 3 minutes
Test Sensitivity: 0.1 % detectable percentage penetration
Control Used: Two sampling upstream intervals counted and averaged with a deviation demonstrating reproducibility of the test.

Test Results

Date Tested: February 17, 2021
Number of Specimens Tested: 5
Location of Specimens: Inside

RESULTS

Specimen #	Challenge Particle Diameter / Standard Deviation*	Average Control Counts	Specimen Counts	Face Velocity (cm/s)	Filtration Efficiency (%)
1-1	99.9 nm / 0.01 nm	310,063	6,905	8	98
1-2	99.9 nm / 0.01 nm	284,981	5,474	8	98
1-3	99.9 nm / 0.01 nm	347,731	6,490	8	98
1-4	99.9 nm / 0.01 nm	246,510	5,323	8	98
1-5	99.9 nm / 0.01 nm	207,016	5,148	8	98

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



BACTERIAL FILTRATION EFFICIENCY

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: Blue side

Area Tested: ~38.5 cm²

Flow Rate: 28.3 LPM

Test Article Conditioning: 85 ± 5% RH at 25.0 ± 0.5°C for a minimum of 4 hours

Challenge Level: 2.8×10^3 CFU

Mean Particle Size: 3.1 μm

Negative Control Count: <1 CFU

RESULTS

Specimen #	Total CFU Recovered	Percent BFE (%)
1-1	8	99.7
1-2	6	99.8
1-3	9	99.7

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.

Appendix

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. For 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	2	1	0
5 - Positive Hole	4	2	8
6 - Positive Hole	2	3	1

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	2	1	0
5 - Positive Hole	4	2	8.1
6 - Positive Hole	2	3	1

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