Consolidated Mask Testing COA

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SAMPLE INFORMATION:

Sample No. 517783

Product: Face Mask

Product Description: Face Mask, Individually Wrapped

Date Collected: 12/08/2020

Date Received 12/08/2020

Date Reported: 1/15/2020
Amended: 2/25/2021

Summary of results and tests performed per **Standard Specification for Performance of Materials Used in Medical Face Masks** (ASTM F2100-19):

Method of testing	Specimens tested	Findings	ASTM F2100-19 Specification Requirements		
			Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
Mask Bacterial Filtration (BFE) (ASTM F2101-19)	5	**99.2%**	≥ 95%	≥ 98%	≥ 98%
			Pass	**Pass**	**Pass**
Face Mask Particulate Filtration Efficiency (PFE) (ASTM F2299/F2299M-03)	5	**98.3%**	≥ 95%	≥ 98%	≥ 98%
			Pass	**Pass**	**Pass**
Face Mask Air Flow Resistance and Differential Pressure (EN 14683)	5	**4.8 mm H_2/cm^2**	< 5 mm H_2O/cm^2	< 6 mm H_2O/cm^2	< 6 mm H_2O/cm^2
			Pass	**Pass**	**Pass**
Mask Synthetic Blood Penetration (ASTM F1862/F1862M-17)	32	**Pass**	80 mmHg	120 mmHg	160 mmHg
			Pass	**Pass**	**Pass**
Face Mask Flame Retardant (16 CFR 1610)	5	**Pass**	> 3.5 seconds	> 3.5 seconds	> 3.5 seconds
			Pass	**Pass**	**Pass**

Note: Face Mask Particulate Filtration Efficiency (PFE) (ASTM F2299/F2299M-03) restested and revised on 2/25/2021

Reported by

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TEST DETAILS

I. Mask Bacterial Filtration (BFE)

Method: ASTM F2101-19

Instrument:

Test summary: This test method is used to measure the bacterial filtration efficiency (BFE) of medical face mask materials using the ratio of upstream bacterial challenge to downstream residual concentration to determine the filtration efficiency of medical face mask materials. This method was specifically designed using *Staphylococcus aureus* as a challenge organism. Materials to be tested were conditioned at 21 ± 5 ^{O}C at 85 ± 5% Relative Humidity (RH) using a humidity chamber for 4 hours.

Temperature during testing: 24 ^{O}C		Relative Humidity during testing: 88 % RH	
Area of the test specimen tested:	approximately 40 cm^2	BFE flow rate:	28.3 Liters per minute
Particle size of the challenge aerosol:	1700 to 3000 particles	Side of specimen tested:	either
Positive Control Average	184 cfu	Negative Control	No Growth
Number of Mask Tested	5	Instrument	GBPI - GB-XF1000

Results:

Specimen	Percent BFE (%)
1	98.75
2	99.04
3	99.38
4	99.04
5	100.00

Result Comment: Masks met Level 1,2,3 Barrier specifications of ASTM F2100-19

II. Face Mask Particulate Filtration Efficiency (PFE)

Method: ASTM F2299/F2299M-03

Test summary: This test is to determine the ability of the mask material to filter particles. Latex particles used for the testing are purchased from Sigma Aldrich (LB1-1ML) with a particle size of 0.10-0.12 micron. Suspensions of the latex spheres are prepared by diluting the 10 % by volume solids with water by the factor of 1000:1. The test specimens were conditioned at 21 +/- 5 ^{O}C and 82 +/- 5 % RH for 4 hours prior to testing.

Area of the test specimen tested: approximately 100 cm^2	Particle size: 0.10 micron
Temperature during testing: 23 ^{O}C	Relative Humidity during testing: 40 % RH
Number of specimens tested: 5	Instrument: GB-KF30010

Result: Average Filtration Efficiency: 98.33% (average from 5 masks tested)

Specimen	Percent PFE (%)
1	98.42
2	98.37
3	98.26
4	98.44
5	98.17

Result Comment: Masks met Level 1 Barrier specification of ASTM F2100-19
Retested: 2/25/2021

III. Face Mask Air Flow Resistance and Differential Pressure

Method: EN 14683:2014

Test Summary: This test is to determine the breathability of the mask material. The procedure is performed on both sides of the mask using a constant flow rate of 8 Liters per minute for 10 seconds. Test area is 4.9 cm^2. The test specimens were conditioned at 21 +/- 5 ^{O}C and 82 +/- 5 % RH for 4 hours prior to testing.

Temperature during testing: 23 OC
Relative Humidity during testing: 40 % RH
Instrument: GBN701 & GBN702

Results:

Specimen	Delta P (Pa/cm^2)	Delta P ($mm\ H_2/cm^2$)
1	44.4	4.5
2	50.8	5.2
3	47.6	4.8
4	48.3	4.9
5	44.3	4.5

Result Comment: Masks met Level 1 Barrier specification of ASTM F2100-19

IV. Mask Synthetic Blood Penetration

Method: ASTM F1862/F1862M-17

Test Summary: This test is to evaluate the resistance of the mask material to penetration of biological liquids using synthetic blood. Only the outer part of the mask was tested. The test specimens were conditioned at 21 +/- 5 ^{O}C and 82 +/- 5 % RH (Relative Humidity) for 4 hours prior to testing. A 2 mL volume of synthetic blood is disbursed at the mask with a set and verified pressure. The analyst observes each specimen to determine whether the synthetic blood penetrated the mask based on the method specification. The instrument is set to test at three specific velocities: 450, 500 and 635 cm/s which correspond to a pressure of 80, 120, 160 mmHg, respectively.

Test distance: 30.5 cm
Temperature during testing: 23 ^{O}C
Relative Humidity during testing: 40 % RH
Number of specimens tested: 32
Instrument: GB-BF20010

Results: Number of masks passed: 32 **Number of masks failed: 0**

	80 mmHg	120 mmHg	160 mmHg
Pass	0	0	32
Fail	0	0	0

Result Comment: Masks met Level 1,2,3 Barrier specification of ASTM F2100-19

V. Face Mask Flame Retardant

Method: 16 CFR 1610

Test summary: This procedure is to evaluate the flammability of a textile. The test procedure requires that a 16 mm (5/8 in) flame impinge on a specimen mounted at a 45-degree angle for 1 second at a distance of 127 mm (5 in). The results provide a classification of flammability performance of the textile products.

Temperature during testing: 23 ^{O}C
Relative Humidity during testing: 40 % RH
Number of specimens tested: 5
Instrument: GBN-ZR01

Results:

	Mask #1	Mask #2	Mask #3	Mask #4	Mask #5
Findings	Pass	Pass	Pass	Pass	Pass
Burn duration	NA	NA	NA	NA	NA

Result Comment: Masks met 16 CFR 1610 specification. No burn/flame over 3.5 seconds observed.

End of Report