Analytical and Environmental Services Laboratory

Test Report

Report Number: 20-PPE-00333
Version: 1
Report Date: 24-Nov-2020

Attn: Anwar Selo SELO
Al Ibtkar Medical Accessories Factory
Industrial Area 11, Building No. 1
Sharjah, UAE

Purchase Order: CREDIT CARD

Sample(s) received: 11-Nov-2020

Authorized by:

Rob Taylor
Service Line Leader - Analytical Chemistry
Rob.Taylor@kinectrics.com

Description: ASTM F2100 FULL SUITE - LEVEL 3 ANALYSIS

Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00333-1	BURTLAN MEDICAL MASKS LEVEL 3	Medical Mask		06-Nov-2020

Special Instructions:
Evaluation to ASTM F2100, Standard Specification for Performance of Materials Used in Medical Face Masks
Target ASTM F2100 Level 3
Refer to summary report for details of the tests performed: KIN-975020-20-PPE-00333-Test Summary

Version comment: Initial report.

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Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00333-1	BURTLAN MEDICAL MASKS LEVEL 3	Medical Mask		06-Nov-2020

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
PFE #001	99.33	%				17-Nov-20	ASTM F2299*
PFE #002	99.39	%				17-Nov-20	ASTM F2299*
PFE #003	99.33	%				17-Nov-20	ASTM F2299*
PFE #004	99.37	%				17-Nov-20	ASTM F2299*
PFE #005	99.45	%				17-Nov-20	ASTM F2299*
Differential Pressure #001	1.91	mm H2O/cm^2				19-Nov-20	EN 14683:2019 - Annex C*
Differential Pressure #002	1.82	mm H2O/cm^2				19-Nov-20	EN 14683:2019 - Annex C*
Differential Pressure #003	1.87	mm H2O/cm^2				19-Nov-20	EN 14683:2019 - Annex C*
Differential Pressure #004	1.62	mm H2O/cm^2				19-Nov-20	EN 14683:2019 - Annex C*
Differential Pressure #005	1.72	mm H2O/cm^2				19-Nov-20	EN 14683:2019 - Annex C*
BFE #001	99.37	%				19-Nov-20	ASTM F2101*
BFE #002	100	%				19-Nov-20	ASTM F2101*
BFE #003	99.2	%				19-Nov-20	ASTM F2101*
BFE #004	99.45	%				19-Nov-20	ASTM F2101*
BFE #005	99.79	%				19-Nov-20	ASTM F2101*
Positive Control Average	2373	CFU				19-Nov-20	ASTM F2101*
Negative Control	0	CFU				19-Nov-20	ASTM F2101*
Mean Particle Size (MPS)	3	micron				19-Nov-20	ASTM F2101*
Fluid Resistance @ 160 mmHg #001	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #002	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #003	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #004	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #005	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #006	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #007	Pass					19-Nov-20	ASTM F1862*

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
Fluid Resistance @ 160 mmHg #008	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #009	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #010	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #011	Fail					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #012	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #013	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #014	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #015	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #016	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #017	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #018	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #019	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #020	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #021	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #022	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #023	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #024	Fail					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #025	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #026	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #027	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #028	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #029	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #030	Pass					19-Nov-20	ASTM F1862*

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Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limt	Analyzed On dd-mmm-yy	Method
Fluid Resistance @ 160 mmHg #031	Pass					19-Nov-20	ASTM F1862*
Fluid Resistance @ 160 mmHg #032	Pass					19-Nov-20	ASTM F1862*
Burn Time #001	DNI					12-Nov-20	16 CFR 1610 Flammability*
	DNI: Did not ignite.						
Burn Time #002	DNI					12-Nov-20	16 CFR 1610 Flammability*
Burn Time #003	DNI					12-Nov-20	16 CFR 1610 Flammability*
Burn Time #004	DNI					12-Nov-20	16 CFR 1610 Flammability*
Burn Time #005	DNI					12-Nov-20	16 CFR 1610 Flammability*

Instruments Used

Name	Serial Number	Last Calibration	Calibration Due
SphereFlash Auto Colony Counter	10007000/0171	Calibrated Before Use	
Dispensing Controller	KIN-06377	12-Jun-2020	12-Jun-2021
M015 45 Degree Automatic Flammability Tester	KIN-06428	13-Jul-2020	13-Jul-2023
TSI 4045H Mass Flow Meter #10	KIN-04806	07-Jan-2020	07-Jan-2021
TSI 4043 Mass Flow Meter #13	KIN-06465	01-Sep-2020	01-Sep-2021
TSI 4043 Mass Flow Meter #14	KIN-06466	01-Sep-2020	01-Sep-2021
Dwyer Series 475 Mark III Digital Manometer #3	KIN-06373	15-Jun-2020	15-Jun-2021
MET ONE 3411 Particle Counter	2006524001	12-Jun-2020	12-Jun-2021

The Analytical and Environmental Services Laboratory of Kinectrics is accredited by the Standards Council of Canada as conforming with ISO 17025.

The DL is the reported detection limit. All analytical data is subject to uncertainty, and is a function of the sample matrix, method and instrumental variations. As a general guideline, it can be expressed as +/-50% of the result at the detection limit (RDL) and approximately +/-10% of the result at greater than 10 times the RDL. Results in this report relate only to the items/samples tested and to all the items tested, as received. All tests are as defined by our understanding of customer requirements.

TECHNIQUE '*' = ISO 17025 accredited
TECHNIQUE '¤' = Indicates a modified test method
TECHNIQUE '†' = Indicates a sub-contracted analysis

Mask Testing Services
800 Kipling Ave, Unit 2
Toronto, ON M8Z 5G5
416-207-6000

SCC Accredited LAB™

ANALYTICAL REPORT ID	20-PPE-00333	PRODUCT ID	BURTLAN MEDICAL MASKS LEVEL 3
DATE RECEIVED	06-Nov-2020	LOT/BATCH#	n/a
REPORT DATE	23-Nov-2020	MATERIAL	SMS
COMPANY	BURTLAN MEDICAL	DESCRIPTION	Blue; 3-ply

MEDICAL MASK TEST SUMMARY

ASTM F2100: Standard Specification for Performance of Materials used in Medical Face Masks

			ASTM F2100		
Test Method	**AVERAGED RESULT**	Not Rated	Level 1	Level 2	Level 3
Flammability 16 CFR 1610	Class 1	Class 3	Class 1		
Particulate Filtration Efficiency ASTM F2299	99.37	< 95%	≥ 95%	≥ 98%	
Differential Pressure EN 14683 Annex C	1.79	≥ 6.0 mm H_2O/cm^2	< 5.0 mm H_2O/cm^2	< 6.0 mm H_2O/cm^2	
Bacterial Filtration Efficiency ASTM F 2101	99.56	< 95%	≥ 95%	≥ 98%	
Fluid Resistance to Synthetic Blood ASTM F1862	160 mmHg	Failure at 80 mmHg	80 mmHg	120 mmHg	160 mmHg

Highlighted box indicates the performance level of the mask for the given test.

The samples tested meet the acceptance criteria for **ASTM F2100 performance LEVEL 3**

Test results only apply to the samples submitted for analysis. Samples are randomly selected for each test from the submitted batch. It is the responsibility of the distributor to ensure the tested batch is compliant to the required sampling methodology as per ANSI/ASQ Z1.4. Additional test information is available upon request. Kinectrics is accredited to ISO 17025 by the Standards Council of Canada for ASTM F2100

Reviewed By: Ruwan Wijesundera 2020.11.23 15:50:38 -05'00'

Approved By: Rob Taylor 2020.11.23 16:43:11 -05'00'

FLAMMABILITY

Test Summary A conditioned mask or test specimen was affixed to a sample holder and placed in a flammability test chamber. The specimen was exposed to a 16 mm flame for 1 second at an angle of 45°. If the material ignited during this exposure, it was noted whether the flame extinguished before spreading, or if it continued to burn. If the specimen continued to burn, the time of flame spread was measured. Any observations of burning behavior were also recorded. The specimen was tested in its original state as directed in 16 CFR Part 1610.6 (a) step 1 - 'Testing in the original state', (2) 'Plain surface textile fabrics'. As medical masks are intended for one-time use 16 CFR Part 1610.6 (b) step 2- 'Refurbishing and testing after refurbishing' was not performed. The tests were performed in accordance with 16 CFR Part 1610 'Standard for the Flammability of Clothing Textiles'

Date Tested 12-Nov-2020
Test Side: Outside
Test Type Original State
Direction Tested: Length
Conditioning Parameters 105 +/- 3°C for 30 +/- 2 minutes
Acceptance Criteria Class 1: Burn time ≥ 3.5s
Class 3: Burn time < 3.5s

TEST LOT NUMBER

Article No.	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

Article No.	Time of Flame Spread
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

DNI: Did not ignite
IBE: Ignited, but extinguished

PARTICULATE FILTRATION EFFICIENCY (PFE)

Test Summary Filtered and dried air was passed through an atomizer to produce an aerosol containing suspended polystyrene latex (PSL) spheres. The aerosol was then mixed and diluted with additional preconditioned air to produce a stable, non-neutralized, and dried aerosol of latex spheres. The aerosol was passed through the mask material. An optical particle counter was used to sample upstream and downstream aerosol concentrations to determine the particulate filtration efficiency of the mask. The test was conducted in accordance with Test Method ASTM F2299 with the exception that a non-neutralized particle challenge was used in place of a neutralized challenge as per FDA guidance document on surgical facemasks (FDA-2003-D-0305)

Date Tested 17-Nov-2020

Test Side and Area Inside, Centre (28.3 cm^2)

Conditioning Parameters 30-50% ± 5% relative humidity and 21 ± 3^oC

Face Velocity 6 to 7 cm/s

Laboratory Conditions 28.6 % Relative Humidity; 24.3 °C

Particle Size 0.1 µm

Acceptance Criteria ASTM Level 1: ≥ 95% PFE

ASTM Level 2,3: ≥ 98% PFE

TEST LOT NUMBER

Article No.	PFE %
1	99.33
2	99.39
3	99.33
4	99.37
5	99.45

Article No.	PFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.37

Standard Deviation 0.05

DIFFERENTIAL PRESSURE

Test Summary Differential pressure testing was performed to determine the breathability of the sample material. Air was passed through a prescribed surface area of the sample material at a constant air flow rate of 8 litres per minute, measured by a calibrated flow meter. A manometer was used to measure the differential pressure across the sample.
The test was conducted as directed in EN 14683:2019 Annex C

Date Tested 19-Nov-2020
Test Side and Area Inside, Centre (4.9 cm^2)
Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h
Flow Rate 8 L/min
Acceptance Criteria Flow rate must be maintained at 8 L/min throughout testing
ASTM Level 1: < 5.0 mm H_2O/cm^2
ASTM Level 2,3: < 6.0 mm H_2O/cm^2

TEST LOT NUMBER

Article No.	Delta P (mm H_2O/cm^2)
1	1.91
2	1.82
3	1.87
4	1.62
5	1.72

Article No.	Delta P (mm H_2O/cm^2)
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Delta P 1.79
Standard Deviation 0.118

BACTERIAL FILTRATION EFFICIENCY (BFE)

Test Summary The mask was clamped between a six-stage cascade impactor and an aerosol chamber. A bacterial suspension of *Staphylococcus aureus* was introduced into the aerosol chamber using a four-Jet atomizer. The aerosol was drawn through the sample material using a vacuum pump attached to the cascade impactor. The cascade impactor collects aerosol droplets that penetrate the mask material onto agar plates and sorts them by particle size. Positive control samples were also collected with no test specimen clamped in the test apparatus to verify the bacterial challenge rate (upstream counts). Following the incubating period, the colony forming units (CFU) on the agar plates were counted (downstream counts). The ratio of the upstream counts from the positive control, to the downstream counts collected for the test specimen, was calculated and reported as the bacterial filtration efficiency (BFE). This test was conducted in accordance with Test Method ASTM F2101.

Date Tested 19-Nov-2020

Test Side and Area Inside, Centre (40 cm^2)

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5^{o}C for a minimum of 4h

Flow Rate 28.3 L/min

Mean Particle Size (MPS) 3 µm

Negative Control Count 0 CFU

Positive Control Average 2373 CFU

Acceptance Criteria Control average must be 1.7 to 3.0 x 10^3 CFU

MPS of aerosol must be 3.0 ± 0.3 µm

ASTM Level 1: ≥95% BFE

ASTM Level 2 and 3: ≥98% BFE

TEST LOT NUMBER

Article No.	BFE %
1	99.37
2	100
3	99.2
4	99.45
5	99.79

Article No.	BFE %
6	n/a
7	n/a
8	n/a
9	n/a
10	n/a

Average Filtration Efficiency 99.56

Standard Deviation 0.326

BLOOD PENETRATION RESISTANCE

Test Summary A volume of synthetic blood was disbursed at the mask to simulate the impact (splatter) of blood or other body fluid onto the specimen. Any evidence of synthetic blood penetration on the inner facing of the mask (side contacting the wearer's face) constitutes a failure. Samples are evaluated at one or more velocities of 450, 500, and 635 cm/s, corresponding to the velocity of blood exiting a small arterial puncture at human blood pressures of 80, 120, and 160 mmHg. The distance from the target area to the tip of the cannula is 30.5 cm, with the impact of the spurt normal to the target area. Test results are reported at each tested velocity or corresponding pressure, and the medical face mask is rated at the highest corresponding blood pressure for which the mask demonstrates an acceptable quality limit of 4.0. The test was conducted in accordance with Test Method ASTM F1862.

Date Tested 19-Nov-2020

Test Side and Area Outside, Centre

Conditioning Parameters 85 ± 5% relative humidity and 21 ± 5°C for a minimum of 4h

Laboratory Conditions 26.2 % Relative Humidity; 22.8 °C

Acceptance Criteria The output of synthetic blood before and after 16 articles must be within 2% of theoretical output
29 of 32 tests must show passing result
ASTM Level 1: Pass at 80 mmHg
ASTM Level 2: Pass at 120 mmHg
ASTM Level 3: Pass at 160 mmHg

TEST LOT NUMBER

Article No.	80 mmHg	120 mmHg	160 mmHg	Article No.	80 mmHg	120 mmHg	160 mmHg
1	n/a	n/a	Pass	17	n/a	n/a	Pass
2	n/a	n/a	Pass	18	n/a	n/a	Pass
3	n/a	n/a	Pass	19	n/a	n/a	Pass
4	n/a	n/a	Pass	20	n/a	n/a	Pass
5	n/a	n/a	Pass	21	n/a	n/a	Pass
6	n/a	n/a	Pass	22	n/a	n/a	Pass
7	n/a	n/a	Pass	23	n/a	n/a	Pass
8	n/a	n/a	Pass	24	n/a	n/a	Fail
9	n/a	n/a	Pass	25	n/a	n/a	Pass
10	n/a	n/a	Pass	26	n/a	n/a	Pass
11	n/a	n/a	Fail	27	n/a	n/a	Pass
12	n/a	n/a	Pass	28	n/a	n/a	Pass
13	n/a	n/a	Pass	29	n/a	n/a	Pass
14	n/a	n/a	Pass	30	n/a	n/a	Pass
15	n/a	n/a	Pass	31	n/a	n/a	Pass
16	n/a	n/a	Pass	32	n/a	n/a	Pass

Passes at 80 mmHg n/a
Passes at 120 mmHg n/a
Passes at 160 mmHg 30/32

NOTES

This section is to provide general comments on observations and/or exceptions that were noted during analysis.

No observations or exceptions to report