



**Report For:** Breathe Medical Manufacturing Limited  
#110-250 Beaver Lake Road  
Kelowna, British Columbia  
V4V 1S7  
Phone: 778 870 2603  
Email: shane@breathemedical.ca

**Laboratory #:** 841570A-20  
REVISED  
**Report Date:** August 24, 2020  
**Received Date:** August 4, 2020

**Attention:** Shane Broesky  
**Specimen:** #1: Medical Masks, Description: Surgical Mask ASTM Level 3, Code: SM99-L3-BR

### TEST REPORT

One specimen, consisting of Medical Masks, was submitted to be tested for bacteria filtration efficiency, differential pressure, synthetic blood penetration and flame spread.

#### 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	29

<b>Material construction type</b>	Not provided/Unknown
<b>Supplier</b>	Not provided/Unknown
<b>Lot number</b>	Not provided/Unknown
<b>Date of receipt</b>	August 4, 2020
<b>Date of test</b>	August 7, 2020
<b>Fluid velocity (cm/s)</b>	639
<b>Volume of impact fluid (ml)</b>	2
<b>Angle of pneumatic valve to horizontal</b>	2°
<b>Description target area mask</b>	Blue ripple area
<b>Distance from tip cannula to mask (in)</b>	12
<b>Technique to enhance visual detection</b>	Cotton swab used to lightly daub on the surface
<b>Conditioning parameters</b>	21±5°C, 85±5% R.H for minimum of 4 hours

Revision: Added description and product code.  
Revision Date: August 24, 2020

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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.

**RESULTS**

<u>Specimen ID</u>	<u>Area ID</u>	<u>Differential Pressure (mmH2O/cm<sup>2</sup>)</u>
<b>1</b>	1	5.3
	2	5.0
	3	5.2
	4	4.7
	5	6.1
	AVERAGE	5.3
<b>2</b>	1	5.6
	2	4.7
	3	4.9
	4	5.0
	5	5.5
	AVERAGE	5.1
<b>3</b>	1	5.6
	2	5.1
	3	4.9
	4	5.6
	5	6.1
	AVERAGE	5.4
<b>4</b>	1	5.7
	2	4.7
	3	5.6
	4	5.7
	5	5.5
	AVERAGE	5.4
<b>5</b>	1	4.7
	2	4.8
	3	5.4
	4	5.8
	5	4.6
	AVERAGE	5.1

Mask Surface Area: 25mm diameter (x5 test areas) (4.9 cm<sup>2</sup>)

Air Flow Rate: 8 L/min

Mask Location Specimen taken from: 5 Areas from each specimen distributed all surface wide



**FLAME SPREAD**

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

	<b>Specimen #</b>	<b>RESULT</b>	<b>CONCLUSION</b>
<b>Specimen #1</b>	1-1	IBE	<b>Classified as Class 1</b>
	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.



Laboratory # 841570A-20  
Breathe Medical Manufacturing Limited

**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:  $1.944 \times 10^3 \text{ CFU}$   
Mean Particle Size:  $2.73 \mu\text{m}$

**RESULTS**

Specimen #	Total CFU Recovered	Percent BFE (%)
1-1	3	99.85
1-2	2	99.90
1-3	2	99.90
1-4	1	99.95
1-5	2	99.90

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



# Analytical and Environmental Services Laboratory

## Test Report

Report Number: 20-PPE-00109

Version: 1

Report Date: 24-Aug-2020

Attn: Shane Broesky  
Breathe Medical Manufacturing Ltd.  
#110 - 250 Beaver Lake Road  
Kelowna, BC  
V4V 1S7  
Purchase Order: PAID

Sample(s) received: 20-Aug-2020

Authorized by:

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

Description: PPE FILTER FOR ASTM F2299 (PFE) ANALYSIS. Description: Surgical Mask ASTM Level 3. Product Code: SM99-L3-BR

Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00109-1	202000728-01-04-0800	Medical Mask		19-Aug-2020

Special Instructions: ANALYZE AT FACE VELOCITY OF 5 cm/s

Version comment: Initial report.

This test report shall not be reproduced except in full without written authorization of Kinectrics Inc.



# Analytical and Environmental Services Laboratory

## Test Report

Report Number: 20-PPE-00109

Version: 1

Report Date: 24-Aug-2020

Sample ID	Sample Name	Matrix	Sample Point	Sample Date
20-PPE-00109-1	202000728-01-04-0800	Medical Mask		19-Aug-2020

Parameter / Analyte	Result	Units	Uncert.	DL	Spec. Limit	Analyzed On dd-mmm-yy	Method
PFE #001	99.3	%				24-Aug-20	ASTM F2299
Face Velocity = 5 cm/s							
PFE #002	99.46	%				24-Aug-20	ASTM F2299
PFE #003	99.44	%				24-Aug-20	ASTM F2299
PFE #004	99.42	%				24-Aug-20	ASTM F2299
PFE #005	99.44	%				24-Aug-20	ASTM F2299
PFE #006	99.35	%				24-Aug-20	ASTM F2299
PFE for this mask performed at 6.5 cm/s'							

### Instruments Used

Name	Serial Number	Last Calibration	Calibration Due
TSI 4045H Mass Flow Meter #10	KIN-04806	07-Jan-2020	07-Jan-2021
TSI 4045 Mass Flow Meter #9	KIN-04557	07-Jan-2020	07-Jan-2021
MET ONE 3411 Particle Counter	2006524001	12-Jun-2020	12-Jun-2021

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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 'x' = Indicates a modified test method

TECHNIQUE '+' = Indicates a sub-contracted analysis

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