masklab (3i Corporation Ltd.)
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Subject Product: masklab 3-ply Surgical Mask
Project No.: PBR20259-MAS01

Scope

The scope of this document pertains to and is applicable only to the masklab (3i Corporation Ltd.) masklab 3-ply Surgical Mask and includes the following study numbers for the testing performed by Nelson Laboratories:
NL 1333535-S01 Bacterial Filtration Efficiency
NL 1333536-S01 Breathability (Delta P)
NL 1333537 -S01 Particle Filtration Efficiency
NL 1333538-S01 Synthetic Blood Penetration
NL 1333539 -S01 Flammability

Purpose

Testing was selected in accordance with ASTM F2100-19: *Standard Specification for Performance of Materials Used in Medical Face Masks*. The test results will be compared against the ASTM F2100-19 standard. It is important to note that the standard referenced has specific criteria for the sampling plan of products submitted for testing, which is not assessed as part of this summary document.

Testing Results and Discussion

All testing was conducted in accordance with the referenced standards. The results of the testing are outlined in Table 1.

Table 1. ASTM F2100-19 Testing Results

Assay Title	Testing Standard	ASTM F2100-19 Criteria for Level 3 Mask	Study Number	Result*	Acceptance Criteria Met (Y/N)
BFE (%)	ASTM F2101	≥ 98	1333535-S01	99.4 - >99.9	Y
Delta P (mm H_2O/cm^2)	ASTM F2100-19	< 6.0	1333536-S01	3.8 – 4.2	Y
PFE (%)	ASTM F2299	≥ 98	1333537-S01	99.69 – 99.78	Y
Resistance to penetration by synthetic blood	ASTM F1862	≥ 160 mmHg (maximum velocity)	1333538-S01	31 Pass 1 Fail	Y[1]
Flame Spread	16 CFR Part 1610	Class 1	1333539-S01	IBE[2]	Y

**Range of values reported. See full test report for more details*
1) Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when >29 of 32 test articles show passing results. See full test report for more details.
2) IBE = Articles ignited but extinguished. See full test report for more details.

Bacterial Filtration Efficiency (BFE): The BFE test was performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of Staphylococcus aureus was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosol was drawn through a six stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B. A 40 cm^2 surface of the masklab 3-ply Surgical masks were subjected to a flow rate of 28.3 Liters per minute with a positive control average of 1.7 x 10^3 CFU and a mean particle size of 2.8 µm. The test side was the inside surface of the mask. The five test articles showed a BFE greater than or equal to 99.4% and meet the acceptance criteria for ASTM F2100.

Differential Pressure (Delta P): The Delta P test was performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19. The five masklab 3-ply Surgical Masks showed a differential pressure of less than or equal to 4.3 mm H_2O/cm^2 (42.6 Pa/cm^2) from a flow rate of 8 Liters per minute and meet the acceptance criteria for ASTM F2100.

Particle Filtration Efficiency (PFE) (Latex Challenge): This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.
A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. A 91.5 cm^2 surface of the masklab 3-ply Surgical Mask was challenged with 0.1 µm non-neutralized particles. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. The test side was the inside surface of the mask. The five masklab 3-ply Surgical Masks showed a PFE between 99.69 and 99.78% and meet the acceptance criteria for ASTM F2100.

Resistance to penetration by synthetic blood: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. This test method was designed to comply with ASTM F1862 which states that an acceptable quality limit of 4.0% is met for a normal single sampling plan when >29 of 32 test articles show passing results. The outside of the masklab 3-ply Surgical Masks were exposed to 2 mL of synthetic blood at 160 mmHg as outlined for a Level 3 face mask. 31 of 32 test articles showed no synthetic blood penetration seen, meeting the criteria for a Level 3 face mask as outlined in ASTM F2100-19.

Flame Spread: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. Testing was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) Step 1 - testing in the original state. The test criteria for a Class 1 specification requires a burn time of ≥ 3.5 seconds. A Class 3 specification requires a burn time < 3.5 seconds. The outside surface of the masklab 3-ply Surgical Masks ignited, but extinguished, with no flame spread. The masklab 3-ply Surgical Masks meet the criteria for Class 1 as required for a Level 1, Level 2, and Level 3 Face Mask as outlined in ASTM F2100-19.

Recommendations

If the results listed above are intended to be used for submission to the FDA it is recommended that the sponsor repeat the testing above with an appropriate sample size based on production lot size, as outlined in ANSI/ASQC Z1.4 and ISO 2859-1, using an AQL of 4% as recommended in ASTM F2100-19. The FDA is also recommending testing three separate lots to demonstrate lot-to-lot performance and consistency.

It is recommended to assess the biocompatibility of the masklab 3-ply Surgical Masks with at a minimum a cytotoxicity test and a material review to ensure a low risk of sensitization or irritation response from the user of the mask.

While not required by ASTM, Face Masks are medical devices which are under the requirement to have biocompatibility assessed according to ISO 10993-1. Typically, the biocompatibility evaluation for a face mask would include cytotoxicity, sensitization, and irritation testing. However, in light of the current COVID-19 pandemic, many regulatory agencies are accepting a risk based approach consisting of a cytotoxicity test and a review of the materials used in construction of the face mask which will have contact with the face to ensure that they are not known sensitizers or irritants. For product which is expected to remain on the market after the pandemic, it is recommended to pursue irritation and sensitization testing in order to fully meet ISO 10993-1 requirements.

Conclusion

The masklab (3i Corporation Ltd.) 3-ply Surgical Masks submitted for testing meets the Level 3 performance criteria for BFE, PFE, breathability (Delta P), synthetic blood penetration, and flammability, as outlined in ASTM F2100-19.

The discussion and conclusion generated in this report apply only to the masklab (3i Corporation Ltd.) 3-ply Surgical Masks which has been subjected to the testing reported in **Table 1**. The performance testing outlined above was conducted in accordance ASTM F2100-19. Any requirements for sample size and labeling are the responsibility of the sponsor in order to comply with current laws and regulations.

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A Sotera Health Company

References

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance for Industry and Food and Drug Administration Staff. Reissued April 2, 2020. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health

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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	masklab 3-ply Surgical Mask LOT #2020-08
Purchase Order:	3i-2020081601
Study Number:	1333535-S01
Study Received Date:	20 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~150 mm x ~165 mm
Positive Control Average:	1.7 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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James Luskin electronically approved — 10 Sep 2020 19:34 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.5
3	>99.9
4	99.5
5	99.4

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

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Differential Pressure (Delta P) Final Report

Test Article:	masklab 3-ply Surgical Mask LOT #2020-08
Purchase Order:	3i-2020081601
Study Number:	1333536-S01
Study Received Date:	20 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Delta P Flow Rate:	8 Liters per minute (L/min)
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~177 mm x ~168 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.8	37.5
2	4.3	42.6
3	3.9	38.7
4	4.2	41.6
5	3.9	38.3

Sean Shepherd electronically approved for James Luskin
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28 Aug 2020 15:00 (+00:00)
Study Completion Date and Time

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Latex Particle Challenge Final Report

Test Article:	masklab 3-ply Surgical Mask LOT #: 2020-08
Purchase Order:	3i-2020081601
Study Number:	1333537-S01
Study Received Date:	20 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 08
Deviation(s):	None

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side:	Inside
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 32% relative humidity (RH) at 1557; 21°C, 32% RH at 1653
Average Filtration Efficiency:	99.73%
Standard Deviation:	0.033

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Christopher Acker electronically approved for Curtis Gerow — Study Director

02 Sep 2020 00:45 (+00:00) — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	33	11,417	99.71
2	26	11,574	99.78
3	30	11,763	99.74
4	31	11,923	99.74
5	36	11,573	99.69

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Synthetic Blood Penetration Resistance Final Report

Test Article:	masklab 3-ply Surgical Mask LOT #2020-08
Purchase Order:	3i-2020081601
Study Number:	1333538-S01
Study Received Date:	20 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5°C and a relative humidity of 85 ± 10%. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	32
Number of Test Articles Passed:	31
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.2°C and 21% RH

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-5, 7-32	None Seen
6	Yes

Leah Tiberius electronically approved for
Study Director James Luskin

04 Sep 2020 14:49 (+00:00)
Study Completion Date and Time

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Flammability of Clothing Textiles Final Report

Test Article:	Masklab 3-ply Surgical Mask LOT #: 2020-08
Purchase Order:	3i-2020081601
Study Number:	1333539-S01
Study Received Date:	20 Aug 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

Trang Truong electronically approved for Study Director Curtis Gerow	29 Aug 2020 00:04 (+00:00) Study Completion Date and Time

Results:

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE

IBE = Test Article ignited, but extinguished