Nelson Labs
A Sotera Health company

Sponsor:
Alina Liotto
Portwest UC
IDA Business Park Westport Co
Mayo, F28 FY88
IRELAND

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	SAMPLE ID : P030, P029 LOT NR : Aug 2020
Purchase Order:	P030_NELSON_08_03_2020
Study Number:	1341302-S01
Study Received Date:	14 Sep 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:	~175 mm x ~155 mm
Positive Control Average:	3.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong electronically approved for — 21 Oct 2020 22:11 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.6
2	99.7
3	99.7
4	99.7
5	99.8

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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Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	SAMPLE ID : P030, P029 LOT NR : Aug 2020
Purchase Order:	P030_NELSON_08_03_2020
Study Number:	1341298-S01
Study Received Date:	14 Sep 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: STP0036 Rev 15 Customer Specification Sheet (CSS) Number: 202004965 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2019, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Robert Putnam electronically approved — 14 Oct 2020 22:18 (+00:00)

Study Director Robert Putnam — Study Completion Date and Time

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.1	38	<3	<40.7	<13.1
2	3.2	<3	<3	<5.8	<1.8
3	3.2	<3	<3	<6.1	<1.9
4	3.2	11	<3	<14.4	<4.5
5	3.1	<3	<3	<5.9	<1.9
Recovery Efficiency	UTD[a]				

Note: The results are reported as colony forming units (CFU) per mask.
< = No Organisms Detected
UTD = Unable to Determine
[a] UTD due to zero count on the first rinse. An alternative method or inoculated product recovery efficiency is recommended

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	92%

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 CFU/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween®
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 15 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Potato Dextrose Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3-7 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 5-7 days at 20-25°C, then enumerated.

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Differential Pressure (Delta P) Final Report

Test Article:	SAMPLE ID : P030/P029 LOT NR : Aug 2020
Purchase Order:	P030_NELSON_08_03_2020
Study Number:	1341300-S01.1 Amended
Study Received Date:	14 Sep 2020
Study Completion Date:	28 Sep 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

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.1	40.7
2	4.0	39.5
3	3.8	36.8
4	4.5	44.5
5	4.0	38.8

Amendment Justification: At the request of the sponsor, “P029” was added to the existing test article ID.

David Brown electronically approved for
Study Director James Luskin

01 Oct 2020 21:56 (+00:00)
Amended Report Date and Time

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Synthetic Blood Penetration Resistance Final Report

Test Article:	SAMPLE ID : P030, P029 LOT NR : Aug 2020
Purchase Order:	P030_NELSON_08_03_2020
Study Number:	1341299-S01
Study Received Date:	14 Sep 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:	32
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: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Sean Shepherd electronically approved for James Luskin
Study Director

01 Oct 2020 15:41 (+00:00)
Study Completion Date and Time