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A Sotera Health company

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PEOPLE'S REPUBLIC OF CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article:	Product Name: Non Woven Face Mask Lot #2020030103
Study Number:	1285390-S01
Study Received Date:	07 Apr 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 4.1 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; with the exception of the higher challenge level, which may represent a more severe test.

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.

The positive control average was out of specification per STP0004 Rev 18 section 6.1 which states, "The BFE positive control average shall be maintained at 1.7-3.0 x 10^3 CFU." Testing with a more severe challenge to the test articles represents a worse case. The sponsor accepted the use of the higher challenge; therefore, the results are considered valid at the testing conditions that occurred.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~170 mm x ~167 mm
Positive Control Average:	4.1 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.7 µm

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Study Director: Trang Truong for James W. Luskin — 28 APR 2020 Study Completion Date

1285390-S01

Results:

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

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	5.6	54.6
2	5.4	52.6
3	5.3	51.8
4	5.2	50.8
5	5.7	55.6

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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Synthetic Blood Penetration Resistance Final Report

Test Article:	Product Name: Non Woven Face Mask Lot #2020030103
Study Number:	1285388-S01
Study Received Date:	07 Apr 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:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	20.3°C and 22% 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
1-9, 11-19, 21-32	None Seen
10, 20	Yes

Study Director James W. Luskin

20 Apr 2020
Study Completion Date

1285388-S01

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Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	Product Name: Non Woven Face Mask Lot No.:2020030103
Study Number:	1285389-S01
Study Received Date:	07 Apr 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: 202001633 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.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.8	<3	<3	<5.9	<1.5
2	3.8	<3	<3	<6.0	<1.6
3	3.9	<3	<3	<5.7	<1.5
4	3.8	<3	<3	<6.1	<1.6
5	4.0	<3	<3	<5.7	<1.4
Recovery Efficiency	UTD[a]				

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

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Carl Danielson electronically approved for — 21 Apr 2020 16:11 (+00:00)
Study Director — Robert Putnam — Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	116%

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:	Potato Dextrose Agar Tryptic Soy Agar
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.