Nelson Labs
A Sotera Health company

Sponsor:
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Bacterial Filtration Efficiency (BFE) GLP Report

Test Article:	3-PLY FACE MASK, Model:MU 115122, Lot No: 2020001
Purchase Order:	20-668A
Study Number:	1348520-S01
Study Received Date:	02 Oct 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.

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 ~156 mm
Positive Control Average:	2.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.3 µm

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Adam Brigham electronically approved — 17 Nov 2020 15:29 (+00:00)
Study Director Adam Brigham — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.5
2	99.6
3	99.7
4	99.4
5	99.6

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

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of the colonies on each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	12 Oct 2020
Phase Inspected by Quality Assurance: Sample Preparation	02 Nov 2020
Audit Results Reported to Study Director	03 Nov 2020
Audit Results Reported to Management	03 Nov 2020

Scientists	Title
Adrianne Sandall	Supervisor
Adam Brigham	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Scott Hammond electronically approved
Quality Assurance

16 Nov 2020 20:30 (+00:00)
Date and Time

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Differential Pressure (Delta P) GLP Report

Test Article:	3-PLY FACE MASK, Model:MU 115122, Lot No: 2020001
Purchase Order:	20-668A
Study Number:	1348519-S01
Study Received Date:	02 Oct 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.

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	4.6	45.3
2	5.1	49.7
3	5.0	49.5
4	5.7	55.9
5	5.2	50.9

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to Delta P testing.

Test Method Acceptance Criteria: The Delta P test flow rate shall be maintained at 8 L/min throughout the testing.

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Sean Shepherd electronically approved — 28 Oct 2020 20:34 (+00:00)
Study Director Sean Shepherd — Study Completion Date and Time

Procedure:

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 and Pa/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{\mathrm{A}}$$

Where: $\bar{M}$ = Average mm of water of the test replicates per test article
A = Area of the test article holder (cm^2)

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	12 Oct 2020
Phase Inspected by Quality Assurance: Delta P Measurements	16 Oct 2020
Audit Results Reported to Study Director	20 Oct 2020
Audit Results Reported to Management	23 Oct 2020

Scientists	Title
Adrianne Sandall	Supervisor
Sean Shepherd	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Erika Shewell electronically approved
Quality Assurance

28 Oct 2020 01:47 (+00:00)
Date and Time

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Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	3-PLY FACE MASK, Model: MU 115122, Lot #2020001
Purchase Order:	20-668A
Study Number:	1348518-S01
Study Received Date:	02 Oct 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: 202001516 Rev 02
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	3.4	3	<3	<6.0	<1.8
2	3.0	<3	<3	<5.8	<1.9
3	3.4	<3	<3	<5.8	<1.7
4	3.5	9	<3	<11.7	<3.3
5	3.5	12	<3	<15.1	<4.3
Recovery Efficiency			%		

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.

Robert Putnam electronically approved
Study Director Robert Putnam

29 Oct 2020 01:30 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
Bacillus atrophaeus	108%

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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Synthetic Blood Penetration Resistance GLP Report

Test Article:	3-PLY FACE MASK, Model:MU 115122, Lot No: 2020001
Purchase Order:	20-668A
Study Number:	1348524-S01
Study Received Date:	02 Oct 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.

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:	23.4°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

Adam Brigham electronically approved — 03 Nov 2020 15:28 (+00:00)
Study Director — Adam Brigham — Study Completion Date and Time

Test Method Acceptance Criteria: The output of synthetic blood passing through the targeting hole before and after every set of test articles must be ≤5% (±0.10 g) in difference from the theoretical output of 2 mL.

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	12 Oct 2020
Phase Inspected by Quality Assurance: Sample Preparation / Conditioning	19 Oct 2020
Audit Results Reported to Study Director	20 Oct 2020
Audit Results Reported to Management	20 Oct 2020

Scientists	Title
Adrianne Sandall	Supervisor
Adam Brigham	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Erika Shewell electronically approved
Quality Assurance

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Date and Time