

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 4.1×10^3 colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. 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.

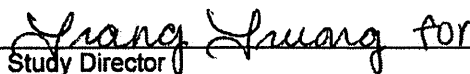
The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test complies with EN 14683:2019, Annex C and ASTM F2100-19.

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 $1.7\text{-}3.0 \times 10^3$ 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: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 170 \text{ mm} \times \sim 167 \text{ mm}$
Positive Control Average: 4.1×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $2.7 \mu\text{m}$




Study Director

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 ₂ O/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:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

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 $21 \pm 5^\circ\text{C}$ and a relative humidity of $85 \pm 10\%$. 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 $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ 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.

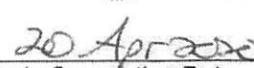
Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-9, 11-19, 21-32	None Seen
10, 20	Yes



Study Director


James W. Luskin


Study Completion Date



1285388-S01

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FRT0012-0002 Rev 13
Page 1 of 1

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.



Carl Danielson electronically approved for
Study Director

Robert Putnam

21 Apr 2020 16:11 (+00:00)
Study Completion Date and Time

Method Suitability:

Organism	Percentage
<i>Bacillus atrophaeus</i>	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 TweenTM
- 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.