







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

Test Article: WK018-238/235
3-PLY FACE MASK WITH EARLOOP
Purchase Order: WK-TEST-20180912
Study Number: 1098109-S01
Study Received Date: 17 Sep 2018
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 15
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 $1.7 - 2.7 \times 10^3$ 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 F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

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: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 Liters per minute (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: $\sim 174 \text{ mm} \times \sim 157 \text{ mm}$
Positive Control Average: 2.5×10^3 CFU
Negative Monitor Count: < 1 CFU
MPS: $3.2 \mu\text{m}$




Study Director

Janelle R. Bentz, M.S.


Study Completion Date



1098109-S01

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.9	3.0	29.8
2	>99.9	3.1	30.3
3	99.8	3.0	29.4
4	99.9	3.0	29.1
5	99.8	2.9	28.3

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

Latex Particle Challenge Final Report

Test Article: WK018-238/235
3-PLY FACE MASK WITH EARLOOP
Purchase Order: WK-TEST-20180912
Study Number: 1098108-S01
Study Received Date: 17 Sep 2018
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 05
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, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average number of particles penetrating the test article compared to the average of the control values.

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 cm²
Particle Size: 0.1 µm
Laboratory Conditions: 26 Sep 2018: 21°C, 23% relative humidity (RH) at 1500; 21°C,
23% RH at 1601
27 Sep 2018: 21°C, 25% relative humidity (RH) at 0654; 21°C,
24% RH at 1119
Average Filtration Efficiency: 98.98%
Standard Deviation: 0.420




Study Director

Brandon L. Williams

01 Oct 2018
Study Completion Date



1098108-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	101	10,852	99.07
2	74	10,866	99.32
3	123	11,849	99.0
4	127	13,530	99.06
	89	10,600	99.16
5 ^a	197	10,139	98.1
	99	12,408	99.20

^a Additional testing results reported. The initial result and one of the four investigational results were determined to be outliers.

Synthetic Blood Penetration Resistance Final Report

Test Article: WK018-238/235
3-PLY FACE MASK WITH EARLOOP
Purchase Order: WK-TEST-20180912
Study Number: 1098110-S01
Study Received Date: 17 Sep 2018
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 08
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 14683:2014 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: 29
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: 19.3°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
1-5, 7-10, 12-19, 21-32	None Seen
6, 11, 20	Yes

Janelle Bentz for
Study Director

Brandon L. Williams

24 Sep 2018
Study Completion Date



1098110-S01