Nelson Labs
A Sotera Health company

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	WLM2002
Purchase Order:	WL201906-1121T
Study Number:	1253866-S01
Study Received Date:	26 Dec 2019
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:	~174 mm x ~154 mm
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Dorow — Study Director

For Janelle R. Bentz, M.S.

07 Jan 2020 — Study Completion Date

1253866-S01

Results:

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

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

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

Nelson Labs.
A Sotera Health company

Sponsor:
Celine Huang
Hubei Wanli Protective Products Co., Ltd
Yuanshi, Ganhe
Xiantao, Hubei, 433000
CHINA

Latex Particle Challenge Final Report

Test Article:	WLM2002
Purchase Order:	WL201906-1121T
Study Number:	1253865-S01
Study Received Date:	26 Dec 2019
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 07
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 (atomized), 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 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20°C, 24% relative humidity (RH) at 0951; 20°C, 24% RH at 1242
Average Filtration Efficiency:	99.920%
Standard Deviation:	0.0358

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Grow — Study Director

For Janelle R. Bentz, M.S.

02 Jan 2020 — Study Completion Date

1253865-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	9	12,401	99.927
2	7	13,042	99.949
3	17	13,496	99.87
4	14	13,570	99.90
5	6	13,926	99.957

Nelson Labs
A Sotera Health company

Synthetic Blood Penetration Resistance Final Report

Test Article:	WLM2002
Purchase Order:	WL201906-0920
Study Number:	1225963-S01
Study Received Date:	26 Sep 2019
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:	20.6°C and 23% RH (Units 1-16) 22.1°C and 21% RH (Units 17-32)

Curtis Doran For — 11 Nov 2019

Study Director — Janelle R. Bentz, M.S. — Study Completion Date

1225963-S01

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 Date: 03 Oct 2019

Test Article Number	Synthetic Blood Penetration
1-3, 5-16	None Seen
4	Yes

Test Pressure: 120 mmHg (16.0 kPa)
Test Date: 07 Nov 2019

Test Article Number	Synthetic Blood Penetration	Test Article Number	Synthetic Blood Penetration
17-27, 29-32	None Seen		
28	Yes		

Nelson Labs
A Sotera Health company

Differential Pressure (Delta P) Final Report

Test Article:	SAMPLE ID: WLM2002
Purchase Order:	WL201906-0920
Study Number:	1225964-S01
Study Received Date:	26 Sep 2019
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 17
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
Test Article Dimensions:	~176 mm x ~159 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	3.0	29.2
2	3.0	29.8
3	3.0	29.8
4	3.0	29.0
5	3.0	29.2

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Curtis Gerow For Janelle R. Bentz, M.S.
Study Director

04 Oct 2019
Study Completion Date

1225964-S01