Nelson Labs
A Sotera Health company

Sponsor:
Frank Law
SSE Care Solutions Inc
185 Bullock Dr., Unit 8
Markham, ON L3P7R4
CANADA

# Bacterial Filtration Efficiency (BFE)
# Final Report

| | |
|---|---|
| Test Article: | SSE-001 |
| Purchase Order: | 052520 |
| Study Number: | 1303662-S01 |
| Study Received Date: | 27 May 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>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: | ~170 mm x ~155 mm |
| Positive Control Average: | 2.0 x $10^3$ CFU |
| Negative Monitor Count: | <1 CFU |
| MPS: | 3.3 µm |

Sean Shepherd electronically approved for James Luskin
Study Director

01 Jun 2020 18:34 (+00:00)
Study Completion Date and Time





Nelson Labs
A Sotera Health company



**Results:**

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

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:
Frank Law
SSE Care Solutions Inc
185 Bullock Dr., Unit 8
Markham, ON L3P7R4
CANADA

# Synthetic Blood Penetration Resistance Final Report

| | |
|---|---|
| Test Article: | SSE-001 |
| Purchase Order: | 052520 |
| Study Number: | 1303664-S01 |
| Study Received Date: | 27 May 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>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: | 32 |
| Test Side: | Outside |
| Pre-Conditioning: | Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH) |
| Test Conditions: | 21.1°C and 24% 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: 160 mmHg (21.3 kPa)

| Test Article Number | Synthetic Blood Penetration |
|---|---|
| 1-32 | None Seen |

James Luskin electronically approved
Study Director James Luskin

29 May 2020 19:02 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Frank Law
SSE Care Solutions Inc
185 Bullock Dr., Unit 8
Markham, ON L3P7R4
CANADA

Nelson Labs
A Sotera Health company



# Flammability of Clothing Textiles Final Report

| | |
|---|---|
| Test Article: | SSE-001 |
| Purchase Order: | 052520 |
| Study Number: | 1303663-S01 |
| Study Received Date: | 27 May 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0073 Rev 06 |
| Deviation(s): | None |

**Summary:** This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested: Outside Surface
Orientation: Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

| Class | Plain Surface Textile Fabric |
|---|---|
| 1 | Burn time ≥3.5 seconds |
| 2 | Not applicable to plain surface textile fabrics |
| 3 | Burn time <3.5 seconds |

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

**Results:**

| Replicate Number | Time of Flame Spread |
|---|---|
| 1 | IBE |
| 2 | IBE |
| 3 | IBE |
| 4 | IBE |
| 5 | IBE |

IBE = Test Article ignited, but extinguished

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Sean Shepherd electronically approved for Curtis Gerow
Study Director

29 May 2020 15:52 (+00:00)
Study Completion Date and Time

Sponsor:
Frank Law
SSE Care Solutions Inc
185 Bullock Dr., Unit 8
Markham, ON L3P7R4
CANADA

# Latex Particle Challenge Final Report

| | |
|---|---|
| Test Article: | SSE-001 |
| Purchase Order: | 052520 |
| Study Number: | 1303665-S01 |
| Study Received Date: | 27 May 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>Salt Lake City, UT 84123 U.S.A. |
| Test Procedure(s): | Standard Test Protocol (STP) Number: STP0005 Rev 07 |
| Deviation(s): | Quality Event (QE) Number(s): QE22125 |

**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.

A one-minute count was performed, with the test article in the system. A one-minute control count was 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 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, 33% relative humidity (RH) at 0838; 20°C, 32% RH at 0955 |
| Average Filtration Efficiency: | 99.23% |
| Standard Deviation: | 0.033 |

Sean Shepherd electronically approved for
Study Director Curtis Gerow

29 May 2020 20:47 (+00:00)
Study Completion Date and Time





**Deviation Details:** Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

**Results:**

| Test Article Number | Test Article Counts | Average Control Counts | Filtration Efficiency (%) |
|---|---|---|---|
| 1 | 99 | 12,955 | 99.24 |
| 2 | 96 | 11,808 | 99.19 |
| 3 | 82 | 11,332 | 99.28 |
| 4 | 95 | 12,075 | 99.21 |
| 5 | 99 | 12,885 | 99.23 |