Nelson Labs.
A Sotera Health company

Sponsor:
Terry Jackson
Bossong Medical
840 W. Salisbury St.
Asheboro, NC 27203

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

Test Article:	190
Purchase Order:	30689
Study Number:	1284799-S01
Study Received Date:	04 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 3.7×10^3 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; 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 1.7-3.0 x 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:	Side with Ear Loops
BFE Test Area:	~7.1 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~195 mm x ~113 mm
Positive Control Average:	3.7×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

for
Study Director — James W. Luskin
14 Apr 2020
Study Completion Date

1284799-S01

Results:

Test Article Number	Percent BFE (%)
1	98.0
2	98.5
3	97.9
4	96.0
5	97.6

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	17.2	168.4
2	18.0	176.3
3	18.5	181.0
4	17.7	173.1
5	21.3	208.5

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

Nelson Labs.
A Sotera Health company

Sponsor:
Terry Jackson
Bossong Medical
840 W. Salisbury St.
Asheboro, NC 27203

Flammability of Clothing Textiles Final Report

Test Article:	190
Purchase Order:	30699
Study Number:	1284793-S01
Study Received Date:	04 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: STP0073 Rev 06 Customer Specification Sheet (CSS) Number: 202002072 Rev 01
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

<u>Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):</u>

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.

Study Director — Curtis Gerow, B.S.

28 Apr 2020
Study Completion Date

1284793-S01

Results:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite

Nelson Labs
A Sotera Health company

Sponsor:
Terry Jackson
Bossong Medical
840 W. Salisbury St.
Asheboro, NC 27203

Latex Particle Challenge Final Report

Test Article:	190
Purchase Order:	30899
Study Number:	1284798-S01
Study Received Date:	04 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: 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:	91.6 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 30% relative humidity (RH) at 1053; 22°C, 30% RH at 1308
Average Filtration Efficiency:	78%
Standard Deviation:	5.4

Study Director

Curtis Gerow, B.S.

Study Completion Date

1284798 S01

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	2,385	10,627	78
2[a]	1,670	11,957	86
	2,027	11,884	83
3	2,995	11,317	74
4	2,926	10,862	73
5	2,968	11,717	75

[a] The original result for this test article was unexpected when compared to the other test articles. Investigational testing was performed on the same test article in duplicate and it was determined that the original result was invalid. Only the investigational test results are reported.

Nelson Labs
A Sotera Health company

Sponsor:
Terry Jackson
Bossong Medical
840 W. Salisbury St.
Asheboro, NC 27203

Synthetic Blood Penetration Resistance Final Report

Test Article:	#190
Purchase Order:	30699
Study Number:	1284803-S01
Study Received Date:	04 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 8280 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:	32
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	21.2°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: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Study Director

James W. Luskin

Study Completion Date

1284803-S01

MANUFACTURING
SOLUTIONS CENTER
301 Conover Station SE; Conover, NC 28613

Kathy Mabe
Bossong Hosiery Mills INC.
P.O. Box 789
Asheboro, NC 27204

RECEIVED DATE: April 16, 2020
COMPLETED DATE: April 20, 2020

REFERENCE: TS 157450
Style: # 190
Color: White
Description: Protective Barrier Face Mask

Sample Type: Knitted Fabric
Sample Form: Mask
Size: One Size Fits Most

TEST RESULTS:

Absorbency:

• Absorbency of Textiles - AATCC Test Method 79-2018 - Option A

Testing Results:

Sample Prep:	Original/As Received State	
Area Tested:	Technical Face	Technical Back
Specimen 1	DNA sec	DNA sec
Specimen 2	DNA sec	DNA sec
Specimen 3	DNA sec	DNA sec
Specimen 4	DNA sec	DNA sec
Specimen 5	DNA sec	DNA sec
Average	DNA sec	DNA sec

Testing Information:

- Option A: Burette stand
- The Shorter the average time, the more absorbent the fabric
- DNA = Did not Absorb after 1 minute
- Sample brought to moisture equilibrium; Testing Conditions: 21°C (± 2°C) and 65%RH (± 5%RH)

Absorbency:

• Absorbency of Textiles - AATCC Test Method 79-2018 - Option A

Testing Results:

Sample Prep:	After Laundering	
Area Tested:	Technical Face	Technical Back
Specimen 1	DNA sec	DNA sec
Specimen 2	DNA sec	DNA sec
Specimen 3	DNA sec	DNA sec
Specimen 4	DNA sec	DNA sec
Specimen 5	DNA sec	DNA sec
Average	DNA sec	DNA sec

Testing Information:

- AATCC Monograph M6, "Standardization of Home Laundry Test Conditions", July, 31, 2013
- Home Laundered 20 times using AATCC Monograph M6 "Standardization of Home

MANUFACTURING
SOLUTIONS CENTER
301 Conover Station SE; Conover, NC 28613

Laundry Test Conditions: load size = 1.8kg (4lbs.). Launder Right Side Out
Top Loading Machine Wash Permanent Press Cycle Warm 105±5°F
using 20±1g Liquid AATCC Standard Reference Detergent WOB
A Tumble Dry Normal 1X

- Ballast Wash Load Type 3 - 50/50 polyester/cotton bleached plain weave
- Option A: Burette stand
- The Shorter the average time, the more absorbent the fabric
- DNA = Did not Absorb after 1 minute
- Sample brought to moisture equilibrium; Testing Conditions: 21°C (± 2°C) and 65%RH (± 5%RH)

Jodi B. Geis

Jodi B. Geis
Testing Lab Manager
Manufacturing Solutions Center/HTC – Testing Lab
(828) 327-7000 ext. 4115
jbgeis@manufacturingsolutionscenter.com
www.manufacturingsolutionscenter.org
www.cpsource.com