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:	Sample ID #190
Purchase Order:	30693
Study Number:	1284601-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: 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:	20.1°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
1-32	None Seen

Study Director — James W. Luskin — 15 Apr 2020 — Study Completion Date

1284601-S01

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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 08
Customer Specification Sheet (CSS) Number: 202002D72 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

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.

Study Director

Curtis Gerow, B.S.

Study Completion Date

1284793-S01

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

Test Article:	190
Purchase Order:	30699
Study Number:	1284799-SC1
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 as 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:	~185 mm x ~113 mm
Positive Control Average:	3.7×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

Study Director | James W. Luskin | Study Completion Date

1284799-SC1

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)	Delta P (Pa)
1	17.2	168.4
2	18.0	176.8
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