

## Synthetic Blood Penetration Resistance Final Report

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Test Article: Face Mask  
Purchase Order: DCG Holdings  
Study Number: 1301682-S01  
Study Received Date: 20 May 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  $21 \pm 5^\circ\text{C}$  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 per test pressure  
Number of Test Articles Passed: 32 (80 mmHg (10.7 kPa))  
32 (120 mmHg (16.0 kPa))  
31 (160 mmHg (21.3 kPa))  
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: 21.0°C and 22% RH (80 mmHg (10.7 kPa) and 120 mmHg (16.0 kPa))  
20.6°C and 22% RH (160 mmHg (21.3 kPa))



Adam Brigham electronically approved for  
Study Director

James Luskin

27 May 2020 19:52 (+00:00)  
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**Results:** Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when  $\geq 29$  of 32 test articles show passing results.

Test Pressure: 80 mmHg (10.7 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Test Pressure: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-13, 15-32	None Seen
14	Yes

## Flammability of Clothing Textiles Final Report

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Test Article: Face Mask  
 Study Number: 1301701-S01  
 Study Received Date: 20 May 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  
 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 $\geq 3.5$ 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.



Adam Brigham electronically approved for  
Study Director

Curtis Gerow

02 Jun 2020 16:02 (+00:00)  
Study Completion Date and Time

**Results:**

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

IBE = Test Article ignited, but extinguished

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

Test Article: Face Mask  
Study Number: 1301711-S01  
Study Received Date: 20 May 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  $1.7 - 3.0 \times 10^3$  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 F2101-19 and EN 14683:2019, Annex B.

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  
BFE Test Area:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 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:  $\sim 172 \text{ mm} \times \sim 157 \text{ mm}$   
Positive Control Average:  $2.3 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $2.9 \mu\text{m}$



Reid Jones electronically approved for  
Study Director

James Luskin

10 Jun 2020 19:23 (+00:00)  
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**Results:**

Test Article Number	Percent BFE (%)
1	99.4
2	99.4
3	99.1
4	99.4
5	99.6

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	4.6	44.9
2	4.4	42.8
3	4.7	45.7
4	4.2	41.1
5	4.5	44.3

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

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Test Article: Face Mask  
Study Number: 1301716-S01  
Study Received Date: 20 May 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: 91.5 cm<sup>2</sup>  
Particle Size: 0.1 µm  
Laboratory Conditions: 21°C, 30% relative humidity (RH) at 2121; 20°C, 30% RH at 2218  
Average Filtration Efficiency: 99.73%  
Standard Deviation: 0.069



Robert Dieker electronically approved for  
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**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	34	10,782	99.68
2	21	10,768	99.80
3	24	10,917	99.78
4	31	11,061	99.72
5	41	11,289	99.64



## MEM Elution Final Report

Test Article: Face Mask  
 Study Number: 1301722-S01  
 Study Received Date: 20 May 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: STP0032 Rev 10  
 Deviation(s): None

**Summary:** The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances. An extract of the test article was added to cell monolayers and incubated. The cell monolayers were examined and scored based on the degree of cellular destruction. 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.

**Results:**

Test Article:

Dilution	Results Pass/Fail	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
		#1	#2	#3	Average		
Neat	Pass	0	0	0	0	3 cm <sup>2</sup> /mL	576.5 cm <sup>2</sup> / 192.2 mL
1:2	Pass	0	0	0	0		
1:4	Pass	0	0	0	0		
1:8	Pass	0	0	0	0		
1:16	Pass	0	0	0	0		

Note: An additional 10 mL of media was added to account for absorbency.



McKenna Wild electronically approved  
Study Director

McKenna Wild

26 May 2020 19:05 (+00:00)  
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**Controls:**

Identification	Scores				Extraction Ratio	Amount Tested / Extraction Solvent Amount
	#1	#2	#3	Average		
Negative Control - Polypropylene Pellets	0	0	0	0	0.2 g/mL	4 g / 20 mL
Media Control	0	0	0	0	N/A	20 mL
Positive Control - Latex Natural Rubber	4	4	4	4	0.2 g/mL	4 g / 20 mL

**Test Method Acceptance Criteria:** The United States Pharmacopeia & National Formulary (USP <87>) states that the test article meets the requirements, or receives a passing score (**Pass**) if the reactivity grade is not greater than grade 2 or a mild reactivity. The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade greater than 2 is considered a cytotoxic effect, or a failing score (**Fail**).

Nelson Laboratories acceptance criteria was based upon the negative and media controls receiving "0" reactivity grades and positive controls receiving a 3-4 reactivity grades (moderate to severe). The test was considered valid as the control results were within acceptable parameters.

The cell monolayers were examined microscopically. The wells were scored as to the degree of discernable morphological cytotoxicity on a relative scale of 0 to 4:

Conditions of All Cultures	Reactivity	Grade
No cell lysis, intracytoplasmic granules.	None	0
Less than or equal to 20% rounding, occasional lysed cells.	Slight	1
Greater than 20% to less than or equal to 50% rounding, no extensive cell lysis.	Mild	2
Greater than 50% to less than 70% rounding and lysed cells.	Moderate	3
Nearly complete destruction of the cell layers.	Severe	4

The results from the three wells were averaged to give a final cytotoxicity score.

**Procedure:** The amount of test material extracted was based on ANSI/AAMI/ISO and USP surface area or weight recommendations. Test articles and controls were extracted in 1X Minimal Essential Media with 5% bovine serum for 24-25 hours at  $37 \pm 1^\circ\text{C}$  with agitation. Multiple well cell culture plates were seeded with a verified quantity of industry standard L-929 cells (ATCC CCL-1) and incubated until approximately 80% confluent. The test extracts were held at room temperature for less than four hours before testing. The extract fluids were not filtered, centrifuged or manipulated in any way following the extraction process. The test extracts were added to the cell monolayers in triplicate. The cells were incubated at  $37 \pm 1^\circ\text{C}$  with  $5 \pm 1\%$   $\text{CO}_2$  for  $48 \pm 3$  hours.

Pre and Post Extract Appearance		
Test Articles	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted
Controls	Pre extract	Clear with no particulates present
	Post extract	Clear with no particulates present No color change noted