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Daisy Lei
Xiantao Yi-Ya Protective Products Co., Ltd
7-17 Modern Sino
Canada Science & Technology City
Xiantao, Hubei,
CHINA

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

Test Article:	YY-1 YY-2 YY-3 YY-4 YY-5
Purchase Order:	PO-20180523
Study Number:	1055740-S01
Study Received Date:	30 May 2018
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 15
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 - 2.7 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 F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

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)
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:	~153 mm x ~153 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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Study Director — Janelle R. Bentz, M.S. — 14 JUN 2018 — Study Completion Date

1055740-S01

Results:

Test Article	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
YY-1	>99.9	2.6	25.5
YY-2	>99.9	2.6	25.4
YY-3	99.9	2.7	26.0
YY-4	>99.9	2.6	25.8
YY-5	99.8	2.5	24.4

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

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Sponsor:
Daisy Lei
Xiantao Yi-Ya Protective Products Co., Ltd
7-17 Modern Sino
Canada Science & Technology City
Xiantao, Hubei,
CHINA

Flammability of Clothing Textiles Final Report

Test Article:	YY-FTS101
Purchase Order:	PO-20180523
Study Number:	1057819-S01
Study Received Date:	05 Jun 2018
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 ≥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.

Janelle Bentz for
Study Director Brandon L. Williams

13 Jun 2018
Study Completion Date

1057819-S01

Results:

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

IBE = Test Article ignited, but extinguished

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Daisy Lei
Xiantao Yi-Ya Protective Products Co., Ltd
7-17 Modern Sino
Canada Science & Technology City
Xiantao, Hubei,
CHINA

Latex Particle Challenge Final Report

Test Article:	YY-1 YY-2 YY-3 YY-4 YY-5
Purchase Order:	PO-20180523
Study Number:	1057817-S01
Study Received Date:	05 Jun 2018
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 05
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, 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, 25% relative humidity (RH) at 1154; 21°C, 25% RH at 1321
Average Filtration Efficiency:	99.70%
Standard Deviation:	0.080

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Janelle Bentz for
Study Director Brandon L. Williams

15 Jun 2018
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1057817-S01

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	33	13,526	99.76
2	33	14,392	99.77
3	44	13,124	99.66
4	55	12,920	99.58
5	32	11,553	99.73

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A Sotera Health company

Sponsor:
Daisy Lei
Xiantao Yi-Ya Protective Products Co., L
7-17 Modern Sino
Canada Science & Technology City
Xiantao, Hubei,
CHINA

Microbial Cleanliness (Bioburden) of Medical Masks Final Report

Test Article:	YY-MCM100
Purchase Order:	PO-20180523
Study Number:	1057820-S01
Study Received Date:	05 Jun 2018
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: STP0036 Rev 14 Customer Specification Sheet (CSS) Number: 201803736 Rev 01
Deviation(s):	None

Summary: The testing was conducted in accordance with EN 14683:2014, with the exception of approximate volumes of eluent used when performing the extraction procedure and a temperature range of 30-35°C used for aerobic incubation.

When bioburden results are calculated using a software program, manual calculations may differ slightly due to rounding. The counts determined on products are colony forming units and may not always reflect individual microorganisms. The sponsor performs any statistical analysis and determines the acceptable limits. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Results:

Unit Number	Weight (g)	Aerobic	Fungal	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	<3	<3	<5.8	<1.8
2	3.4	<3	<3	<5.9	<1.7
3	3.3	<3	<3	<5.7	<1.7
4	3.2	<3	<3	<6.2	<1.9
5	3.3	<3	<3	<5.7	<1.7
Recovery Efficiency	UTD[a]				

< = No Organisms Detected
Note: The results are reported as colony forming units (CFU) per mask.
Note: Sample positive testing was performed using *Bacillus atrophaeus*. The test article was not inhibitory using this test method.
UTD = Unable to determine
[a] UTD due to zero count on the first rinse. An alternate method or inoculated product recovery efficiency is recommended.

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Study Director Robert J. Putnam, B.S.

18 JUN 2018
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1057820-S01

Test Method Acceptance Criteria: If applicable, anaerobic controls are acceptable for the bioburden test results. The number of masks to be tested shall be a minimum of 5 or more to meet an acceptable quality level of 4%. The bioburden of the medical mask shall be < 30 cfu/g tested.

Procedure:

Positive Controls/Monitors:	*Bacillus atrophaeus*
Extract Fluid:	Peptone Tween® with Sodium Chloride
Extract Fluid Volume:	~300 mL
Extract Method:	Orbital Shaking for 5 minutes at 250 rpm
Plating Method:	Membrane Filtration
Agar Medium:	Tryptic Soy Agar Sabouraud Dextrose Agar with Chloramphenicol
Recovery Efficiency:	Exhaustive Rinse Method
Aerobic Bacteria:	Plates were incubated 3 days at 30-35°C, then enumerated.
Fungal:	Plates were incubated 7 days at 20-25°C, then enumerated.

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Sponsor:
Moody Shaw
Xiatao Yi - Ya Protective Products Co., Ltd
7-17 Modern Sino Canada Science & Technology City
Liukou Industrial Park
Xiantao, Hubei, 86-433000
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	YY-SBP210-32
Purchase Order:	PO-20181112
Study Number:	1124093-S01
Study Received Date:	21 Nov 2018
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 08
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 14683:2014 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:	20.3°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

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

03 Dec 2018
Study Completion Date

1124093-S01