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Sponsor:
Martin Wu
Shenzhen Everwin Precision Technology Co.
Building 3, Third Industrial Zone,
Fuqiao
Shenzhen, Guangdong, 518000
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Disposable Face Mask/2020051121
Study Number:	1307503-S01
Study Received Date:	08 Jun 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:	30
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.7°C and 21% 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
1-2, 4-16, 18-32	None Seen
3, 17	Yes

Leah Tiberius electronically approved for — 16 Jul 2020 21:03 (+00:00)
Study Director — James Luskin — Study Completion Date and Time

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Martin Wu
Shenzhen Everwin Precision Technology Co.
Building 3, Third Industrial Zone, Fuqiao
Shenzhen, Guangdong, 518000
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Flammability of Clothing Textiles Final Report

Test Article:	Disposable Face Mask/2020051121
Study Number:	1307505-S01
Study Received Date:	08 Jun 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 ≥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.

Brent Shelley electronically approved for	26 Jun 2020 20:34 (+00:00)
Study Director Curtis Gerow	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

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Shenzhen Everwin Precision Technology Co.
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Shenzhen, Guangdong, 518000
CHINA

Latex Particle Challenge Final Report

Test Article:	Disposable Face Mask/2020051121
Study Number:	1307504-S01
Study Received Date:	08 Jun 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 08
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 (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. 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. During testing and controls, the air flow rate is maintained at 1 cubic foot per minute (CFM) ± 5%.

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:	21°C, 29% relative humidity (RH) at 1601; 21°C, 29% RH at 1708
Average Filtration Efficiency:	99.77%
Standard Deviation:	0.061

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McKenna Wild electronically approved for — 24 Jul 2020 14:43 (+00:00)
Study Director Curtis Gerow — Study Completion Date and Time

Results:

Test Article	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	43	13,652	99.69
2	37	13,960	99.73
3	23	14,707	99.84
4	30	12,695	99.76
5	26	12,993	99.80

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Martin Wu
Shenzhen Everwin Precision Technology Co.
Building 3, Third Industrial Zone, Fuqiao
Shenzhen, Guangdong, 518000
CHINA

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	Disposable Face Mask/2020051121
Study Number:	1307507-S01
Study Received Date:	08 Jun 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 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:	~175 mm x ~155 mm
Positive Control Average:	2.4 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

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McKenna Wild electronically approved for — 16 Jul 2020 20:06 (+00:00)
Study Director James Luskin — Study Completion Date and Time

Results:

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

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:
Martin Wu
Shenzhen Everwin Precision Technology Co.,
Building 3, Third Industrial Zone, Fuqiao
Shenzhen, Guangdong, 518000
CHINA

Differential Pressure (Delta P) Final Report

Test Article:	Disposable Face Mask/2020051121
Study Number:	1307506-S01
Study Received Date:	08 Jun 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 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
Delta P Flow Rate:	8 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:	~173 mm x ~157 mm

Results:

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	4.4	42.8
2	4.5	43.9
3	4.5	44.2
4	4.5	43.7
5	4.4	43.0

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Sean Shepherd electronically approved for James Luskin
Study Director

18 Jun 2020 23:07 (+00:00)
Study Completion Date and Time