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Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, FL 33610

Flammability of Clothing Textiles Final Report

Test Article:	T10809090510110420
Purchase Order:	Nelson111320A
Study Number:	1363960-S01
Study Received Date:	17 Nov 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 07
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, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

Adam Brigham electronically approved — 17 Dec 2020 15:53 (+00:00)
Study Director Adam Brigham — Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE
6	IBE
7	IBE
8	IBE
9	IBE
10	IBE
11	IBE
12	IBE
13	IBE
14	IBE
15	IBE
16	IBE
17	IBE
18	IBE
19	IBE
20	IBE
21	IBE
22	IBE
23	IBE
24	IBE
25	IBE
26	IBE
27	IBE
28	IBE
29	IBE
30	IBE
31	IBE
32	IBE

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Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St., Ste. 1000
Tampa, FL 33610

Flammability of Clothing Textiles Final Report

Test Article:	T20809090510102720
Purchase Order:	Nelson111320C
Study Number:	1363964-S01
Study Received Date:	17 Nov 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 07
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
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

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Sean Shepherd electronically approved for Adam Brigham — Study Director

17 Dec 2020 21:47 (+00:00) — Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE
6	IBE
7	IBE
8	IBE
9	IBE
10	IBE
11	IBE
12	IBE
13	IBE
14	IBE
15	IBE
16	IBE
17	IBE
18	IBE
19	IBE
20	IBE
21	IBE
22	IBE
23	IBE
24	IBE
25	IBE
26	IBE
27	IBE
28	IBE
29	IBE
30	IBE
31	IBE
31	IBE
32	IBE

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A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, FL 33610

Flammability of Clothing Textiles Final Report

Test Article:	T10809090510103020
Purchase Order:	Nelson111320B
Study Number:	1364030-S01
Study Received Date:	17 Nov 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 07
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:	Cross

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds, IBE, or DNI
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

DNI = Test Article did not ignite
IBE = Test Article ignited, but extinguished

Adam Brigham electronically approved — 17 Dec 2020 15:54 (+00:00)
Study Director Adam Brigham — Study Completion Date and Time

Results: Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing. The test articles submitted by the sponsor achieved a Class 1 flammability rating.

Replicate Number	Time of Flame Spread
1	IBE
2	IBE
3	IBE
4	IBE
5	IBE
6	IBE
7	IBE
8	IBE
9	IBE
10	IBE
11	IBE
12	IBE
13	IBE
14	IBE
15	IBE
16	IBE
17	IBE
18	IBE
19	IBE
20	IBE
21	IBE
22	IBE
23	IBE
24	IBE
25	IBE
26	IBE
27	IBE
28	IBE
29	IBE
30	IBE
31	IBE
32	IBE

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Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St., Ste. 1000
Tampa, FL 33610

Synthetic Blood Penetration Resistance Final Report

Test Article:	T20809090510102720
Purchase Order:	Nelson111320C
Study Number:	1363961-S01
Study Received Date:	17 Nov 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:	31
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	22.9°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
1-17, 19-32	None Seen
18	Yes

James Luskin electronically approved for — 29 Dec 2020 15:23 (+00:00)
Study Director — Leah Tiberius — Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, Florida
33610, United States of America

Synthetic Blood Penetration Resistance Final Report

Test Article:	T10809090510110420
Purchase Order:	Nelson111320A
Study Number:	1363997-S01
Study Received Date:	18 Nov 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:	23.0°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
1-32	None Seen

James Luskin electronically approved for
Study Director — Leah Tiberius

29 Dec 2020 15:19 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa Florida 33610
United States of America

Synthetic Blood Penetration Resistance Final Report

Test Article:	T10809090510103020
Purchase Order:	Nelson111320B
Study Number:	1364033-S01
Study Received Date:	17 Nov 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:	22.9°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
1-32	None Seen

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James Luskin electronically approved for — 29 Dec 2020 15:21 (+00:00)
Study Director Leah Tiberius — Study Completion Date and Time

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, Florida 33610
United States of America

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	T20809090510102720
Purchase Order:	Nelson111320C
Study Number:	1363963-S01
Study Received Date:	17 Nov 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:	~172 mm x ~162 mm
Positive Control Average:	1.8 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

Mikell Goldsberry electronically approved — 30 Dec 2020 23:22 (+00:00)
Study Director — Mikell Goldsberry — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	99.5	17	99.6
2	99.7	18	99.8
3	99.6	19	99.6
4	99.6	20	99.8
5	99.7	21	99.5
6	99.8	22	99.5
7	99.8	23	99.8
8	99.6	24	99.9
9	99.4	25	99.6
10	99.7	26	99.6
11	99.8	27	99.7
12	99.5	28	99.4
13	99.7	29	99.7
14	99.6	30	99.6
15	99.7	31	99.7
16	99.7	32	99.8

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

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, Florida 33610
United States of America

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	T10809090510110420
Purchase Order:	Nelson111320A
Study Number:	1363999-S01
Study Received Date:	17 Nov 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 ~160 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

Mikell Goldsberry electronically approved	30 Dec 2020 03:38 (+00:00)
Study Director Mikell Goldsberry	Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	99.7	17	99.4
2	99.1	18	99.7
3	99.5	19	99.5
4	99.7	20	99.3
5	99.8	21	99.5
6	99.6	22	99.6
7	99.4	23	99.4
8	99.6	24	99.5
9	99.7	25	99.6
10	99.8	26	99.4
11	99.7	27	99.9
12	99.7	28	99.7
13	99.5	29	99.5
14	99.4	30	99.8
15	99.8	31	99.5
16	99.2	32	99.3

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

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St Suite 1000
Tampa, Florida 33610
United States of America

Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	T10809090510103020
Purchase Order:	Nelson111320B
Study Number:	1364034-S01
Study Received Date:	17 Nov 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:	~172 mm x ~163 mm
Positive Control Average:	2.2 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

Mikell Goldsberry electronically approved — 30 Dec 2020 23:26 (+00:00)
Study Director — Mikell Goldsberry — Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)	Test Article Number	Percent BFE (%)
1	99.7	17	99.8
2	99.8	18	99.8
3	99.7	19	99.9
4	99.6	20	99.7
5	99.8	21	>99.9
6	99.7	22	99.6
7	99.9	23	99.8
8	99.8	24	99.9
9	99.6	25	99.8
10	99.7	26	99.4
11	99.7	27	99.5
12	99.8	28	99.7
13	99.8	29	99.5
14	99.5	30	99.7
15	99.6	31	99.7
16	99.8	32	99.8

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

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St., Ste. 1000
Tampa, FL 33610

Latex Particle Challenge Final Report

Test Article:	T20809090510102720
Purchase Order:	Nelson111320C
Study Number:	1363965-S01
Study Received Date:	17 Nov 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:	22.3°C, 21% relative humidity (RH) at 0640; 22.3°C, 21% RH at 0743; 22.5°C, 21% RH at 0921; 22.5°C, 21% RH at 1021
Average Filtration Efficiency:	99.38%
Standard Deviation:	0.088

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Cameron Brierley electronically approved for — 04 Jan 2021 20:24 (+00:00)
Study Director — Christopher Acker — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	63	10,910	99.42
2	72	11,469	99.37
3	80	11,766	99.32
4	64	11,684	99.45
5	88	11,212	99.22
6	75	11,200	99.33
7	74	12,095	99.39
8	86	13,107	99.34
9	83	13,209	99.37
10	91	13,296	99.32
11	72	13,401	99.46
12	77	14,019	99.45
13	79	13,833	99.43
14	65	13,567	99.52
15	99	13,423	99.26
16	95	13,245	99.28
17	53	13,453	99.61
18	83	13,574	99.39
19	88	13,300	99.34
20	105	13,881	99.24
21	89	14,151	99.37
22	75	14,326	99.48
23	85	13,467	99.37
24	81	13,439	99.40
25	81	13,801	99.41
26	105	14,035	99.25
27	88	14,138	99.38
28	97	13,586	99.29
29	69	13,029	99.47
30	76	12,822	99.41
31	62	12,443	99.50
32	68	12,057	99.44

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St., Ste. 1000
Tampa, FL 33610

Latex Particle Challenge Final Report

Test Article:	T10809090510110420
Purchase Order:	Nelson111320A
Study Number:	1363996-S01
Study Received Date:	17 Nov 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:	21.4°C, 22% relative humidity (RH) at 2231; 21.4°C, 22% RH at 0012; 21.4°C, 22% RH at 0130; 21.5°C, 22% RH at 0306
Average Filtration Efficiency:	99.45%
Standard Deviation:	0.114

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Cameron Brierley electronically approved for — 31 Dec 2020 18:08 (+00:00)
Study Director — Christopher Acker — Study Completion Date and Time

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	67	11,913	99.44
2	57	12,245	99.53
3	47	12,669	99.63
4	76	12,978	99.41
5	44	13,248	99.67
6	61	12,286	99.50
7	89	11,429	99.22
8	69	11,660	99.41
9	63	12,459	99.49
10	79	11,086	99.29
11	80	12,051	99.34
12	57	12,012	99.53
13	76	12,119	99.37
14	85	11,885	99.28
15	82	12,317	99.33
16	86	12,776	99.33
17	86	14,229	99.40
18	44	11,866	99.63
19	58	11,654	99.50
20	55	11,763	99.53
21	59	12,584	99.53
22	100	12,994	99.23
23	71	12,889	99.45
24	73	12,730	99.43
25	74	13,529	99.45
26	76	12,763	99.40
27	49	11,157	99.56
28	51	11,259	99.55
29	63	11,470	99.45
30	49	11,949	99.59
31	66	13,014	99.49
32	76	12,844	99.41

Nelson Labs
A Sotera Health company

Sponsor:
Aaron Watanabe
American Surgical Mask Company
5508 N 50th St., Ste. 1000
Tampa, FL 33610

Latex Particle Challenge Final Report

Test Article:	T10809090510103020
Purchase Order:	Nelson111320B
Study Number:	1364032-S01
Study Received Date:	17 Nov 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:	22.2°C, 21% relative humidity (RH) at 0756; 23.8°C, 21% RH at 0936; 23.1°C, 21% RH at 0947; 22.7°C, 21% RH at 1046; 22.7°C, 21% RH at 1157
Average Filtration Efficiency:	99.1%
Standard Deviation:	0.41

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Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	173	13,449	98.7
2	201	14,473	98.6
3	160	13,675	98.8
4	238	13,262	98.2
5	88	13,813	99.36
6	87	13,807	99.37
7	176	13,219	98.7
8	179	13,369	98.7
9	99	14,163	99.30
10	77	14,652	99.47
11	72	14,856	99.52
12	82	11,935	99.31
13	85	12,238	99.31
14	161	12,655	98.7
15	149	12,963	98.9
16	149	12,947	98.8
17	167	13,183	98.7
18	62	14,005	99.56
19	75	14,565	99.49
20	75	14,573	99.49
21	66	14,195	99.54
22	73	14,246	99.49
23	53	11,267	99.53
24	54	11,241	99.52
25	80	11,626	99.31
26	79	11,929	99.34
27	69	12,188	99.43
28	65	11,869	99.45
29	71	11,784	99.40
30	184	11,964	98.5
31	175	11,707	98.5
32	158	11,731	98.7