NELSON LABORATORIES

Sponsor:
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Latex Particle Challenge GLP Report

Test Article:	16-40348/201603200-100 16-40345/201603200-400 20130040-002/201603200-416A 20130040-005/201603200-416B
Purchase Order:	16-000533
Study Number:	889570-S01
Study Received Date:	28 Apr 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0005 Rev 05 Protocol Detail Sheet (PDS) Number: 201601655 Rev 01

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.

Test Side:	Outside (16-40348/201603200-100, 16-40345/201603200-400) Inside (20130040-002/201603200-416A, 20130040-005/201603200-416B)	
Area Tested:	Entire Mask	
Particle Size:	0.1 µm	
Laboratory Conditions:	11 May 2016:	21°C, 27% relative humidity (RH) at 0859; 21°C, 24% RH at 1341; 21°C, 24% RH at 1645
	17 May 2016:	21°C, 30% RH at 0837; 21°C, 30% RH at 0911

ANAB ACCREDITED TESTING LABORATORY

Study Director Brandon L. Williams

23 May 2016
Study Completion Date

889570-S01

Results:

16-40348/201603200-100:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	1	13,725	99.9951
2	<1	13,860	>99.9976
3	<1	13,272	>99.9975
4	1	12,391	99.989
5	1	11,456	99.9942

Average Filtration Efficiency: >99.9947%
Standard Deviation: 0.00341

16-40345/201603200-400:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	18	13,555	99.87
2	14	13,688	99.90
3	6	13,206	99.955
4	11	12,686	99.913
5	7	12,366	99.946

Average Filtration Efficiency: 99.915%
Standard Deviation: 0.0361

20130040-002/201603200-416A:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	5	12,060	99.961
2	122	11,117	98.9
3	20	13,300	99.85
4	2	13,114	99.987
5	12	13,440	99.908

Average Filtration Efficiency: 99.722%
Standard Deviation: 0.4597

20130040-005/201603200-416B:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	12	11,944	99.90
2	14	12,655	99.89
3	16	13,666	99.88
4	63	14,359	99.56
5[a]	12	12,733	99.903
	39	12,849	99.70

Average Filtration Efficiency: 99.81%
Standard Deviation: 0.142

[a] Additional testing was conducted for this sample as the original result was determined to be invalid. Only the additional testing results are reported.

Acceptance Criteria: Ambient background particles detected through the test system must be below 1% of the challenge total (<100 particles).

Procedures:

Test Set-up: Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 µm rated air filter. The particle generator outlet was clamped off and the number of background particles within the test system was verified to be <1 particles at 1 cubic foot per minute (CFM). The flow rate through the test system was maintained at 1 CFM ± 5%.

An aliquot of the PSL aerosolized using a particle generator, mixed with additional filtered air, dried and passed through the test system. The particles delivered were enumerated using a laser based particle counter.

Test Procedure: A test article was placed into the holder and the system was allowed to stabilize. The average number of particles being delivered to the test article was determined (no medium in air stream) as triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000-15,000 particles per cubic foot. Triplicate one-minute counts were recorded for the test article between the control counts.

The PFE of each test article was determined by using the following equation:

$$\% PFE = \frac{C - T}{C} x\ 100$$

Where: C = Combined average of the control counts
T = Average test article counts

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: Latex Test	11 May 2016
Audit Results Reported to Study Director	19 May 2016
Audit Results Reported to Management	20 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.

Quality Assurance

24 May 2016
Date

NELSON LABORATORIES

Sponsor:
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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article:	16-40348/201603200-100 16-40345/201603200-400 20130040-002/201603200-416A 20130040-005/201603200-416B
Purchase Order:	16-000533
Study Number:	889565-S01
Study Received Date:	28 Apr 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 13 Protocol Detail Sheet (PDS) Number: 201601653 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability 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.

All test method acceptance criteria were met.

BFE Area Tested:	Entire Test Article (Samples glued to plates)
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.
Negative Monitor Count:	<1 CFU

ANAB ACCREDITED TESTING LABORATORY

Trang Truong
Study Director — Trang Truong, B.S.

26 May 2016
Study Completion Date

889565-S01

Results:

16-40348/201603200-100:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9	5.4[c]	53.2[c]
2	99.5	4.8[c]	47.5[c]
3	>99.9[ab] >99.9[b]	4.9[c]	47.9[c]
4	>99.9[b] >99.9[ab]	5.1[c]	50.5[c]
5	98.7	5.0[c]	49.6[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
Test Article Dimensions: ~120 mm x ~125 mm
Positive Control Average: 2.4×10^3 CFU, 2.1×10^3 CFU (3, 4)
MPS: 3.1 µm, 2.9 µm (3, 4)

16-40345/201603200-400:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9[a]	3.7[c]	36.1[c]
2	99.6	3.3[c]	32.0[c]
3	>99.9[b] >99.9[b]	3.3[c]	32.2[c]
4	>99.9	3.3[c]	32.7[c]
5	>99.9[a]	3.9[c]	37.9[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
Test Article Dimensions: ~100 mm x ~100 mm
Positive Control Average: 2.4×10^3 CFU, 2.1×10^3 CFU (3)
MPS: 3.1 µm, 2.9 µm (3)

20130040-002/201603200-416A:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	7.7[b]	75.2[b]
		7.7[b]	75.2[b]
2	>99.9[a]	7.7[c]	75.7[c]
3	99.8	7.7[b]	75.2[b]
		7.8[b]	76.8[b]
4	>99.9	7.5[c]	73.7[c]
5	98.6	7.0[c]	68.8[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
Test Article Dimensions: ~135 mm x ~135 mm
Positive Control Average: 2.4×10^3 CFU
MPS: 3.1 µm

20130040-005/201603200-416B:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9[a]	3.2[c]	31.7[c]
2	>99.9[a]	3.3[c]	32.4[c]
3	>99.9[a]	2.9[c]	28.6[c]
4	>99.9	4.0[c]	39.0[c]
5	99.5	4.0[c]	39.1[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
Test Article Dimensions: ~105 mm x ~100 mm
Positive Control Average: 2.4×10^3 CFU
MPS: 3.1 µm

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

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average must be 1.7 - 2.7 x 10^3 CFU. Other positive control averages may be used as approved by the sponsor.

The average MPS of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.

The Delta P test flow rate must be maintained at 8 liters per minute throughout the testing.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to a precise concentration to yield challenge level counts of 1.7 - 2.7 x 10^3 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of colonies for each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{Test\ Area}$$

Where: $\bar{M}$ = Average mm water or Pa of test replicates.

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: BFE Challenge	06 May 2016
Audit Results Reported to Study Director	17 May 2016
Audit Results Reported to Management	17 May 2016

Scientists	Title
Adam Meese	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.

Quality Assurance

26 May 2016
Date

NELSON LABORATORIES

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Flammability of Clothing Textiles GLP Report

Test Article: 20130040-003/201603200-416C
Purchase Order: 16-000533
Study Number: 889567-S01
Study Received Date: 28 Apr 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0073 Rev 06
Protocol Detail Sheet (PDS) Number: 201601821 Rev 01

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.

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
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

16 CFR Part 1610 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.

Results:

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

DNI = Test Article did not ignite

Study Director Brandon L. Williams

13 May 2016
Study Completion Date

889567-S01

Acceptance Criteria: Flame length must be approximately 16 mm (~⅝ in) from the flame tip to the opening in the gas nozzle.

Procedure: Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the side of the test article to test was performed. The side that burned the fastest was used to test the test articles. Testing in the machine direction was not performed, as the 150 mm length could not be achieved. Only the cross direction was tested. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to testing.

The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	10 May 2016
Phase Inspected by Quality Assurance: Preliminary Test	11 May 2016
Audit Results Reported to Study Director	11 May 2016
Audit Results Reported to Management	11 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.

Jonalyn Stonebrook
Quality Assurance

16 May 2016
Date

NELSON LABORATORIES

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Synthetic Blood Penetration Resistance GLP Report

Test Article:	20130040-002/201603200-416A
Purchase Order:	16-000533
Study Number:	889568-S01
Study Received Date:	28 Apr 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 06
	Protocol Detail Sheet (PDS) Number: 201601657 Rev 01

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) 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.

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:	21.8°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 mm Hg

Test Article Number	Synthetic Blood Penetration
1-32	None Seen

Note: All blood spurts were directed at the center seam of the masks.

Acceptance Criteria: The output of synthetic blood through the targeting hole before and after every 16 test articles must be within 2% (± 0.04 g) of the theoretical output of 2 mL.

Study Director Brandon L. Williams

12 May 2016
Study Completion Date

889568-S01

Procedure: A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 specimens, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the specimen holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

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Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	02 May 2016
Phase Inspected by Quality Assurance: Penetration Test	10 May 2016
Audit Results Reported to Study Director	11 May 2016
Audit Results Reported to Management	11 May 2016

Scientists	Title
Adam Meese	Supervisor
Brandon Williams	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at NLI or an approved off-site location.

Quality Assurance

13 MAY 2016
Date