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Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article:	Product name: Air Queen Breeze Mask
Study Number:	1286324-S01
Study Received Date:	09 Apr 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: STP0010 Rev 15
Deviation(s):	None

Summary: This test procedure was performed to evaluate the VFE of test articles at an increased challenge level. A suspension of ΦX174 bacteriophage was delivered to the test article at a challenge level of greater than 10^6 plaque-forming units (PFU) to determine the filtration efficiency. The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test procedure in order to employ a more severe challenge than would be experienced in normal use. 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.

Challenge Flow Rate:	30 LPM
Area Tested:	~40 cm^2
Side Tested:	Smooth Side
Challenge Level:	2.2 x 10^6 PFU
MPS:	~3.0 µm
Test Monitor Results:	Acceptable

(RWJ) for
Study Director — James W. Luskin

28 Apr 2020
Study Completion Date

1286324-S01

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	5.3×10^3	99.76
2	5.4×10^3	99.75
3	4.2×10^2	99.981

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total PFU recovered downstream of the test article

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Latex Particle Challenge Final Report

Test Article:	Air Queen Breeze Mask	
Study Number:	1286325-S01	
Study Received Date:	09 Apr 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:	Smooth Side
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	20°C, 26% relative humidity (RH) at 1956; 21°C, 26% RH at 2110
Average Filtration Efficiency:	97.8%
Standard Deviation:	0.64

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Study Director — Curtis Gerow, B.S.

29 Apr 2020
Study Completion Date

1286325-S01

Deviation Details: Control and test article 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	176	11,395	98.5
2	332	12,283	97.3
3	173	12,078	98.6
4	327	11,616	97.2
5	282	12,066	97.7

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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	Product name: Air Queen Breeze Mask
Study Number:	1286320-S01
Study Received Date:	09 Apr 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:	Smooth Side
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
Positive Control Average:	2.1 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.9 µm

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Study Director James W. Luskin — for

06 May 2020
Study Completion Date

1286320-S01

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9
3	>99.9
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

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

Test Article:	Product name: Air Queen Breeze Mask
Study Number:	1286323-S01
Study Received Date:	09 Apr 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.

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:	Smooth Side
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
Positive Control Average:	1.9 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.1 µm

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David B... for
Study Director James W. Luskin

06 May 2020
Study Completion Date

1286323-S01

Results:

Test Article Number	Percent BFE (%)
1	>99.9[a]
2	>99.9[a]
3	>99.9[a]
4	>99.9[a]
5	>99.9[a]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	8.8	85.9
2	8.8	86.1
3	8.7	85.5
4	8.8	86.3
5	8.9	87.2

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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Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article:	Product name: Air Queen Breeze Mask
Study Number:	1286321-S01
Study Received Date:	09 Apr 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: STP0009 Rev 14
Deviation(s):	None

Summary: This test procedure was performed to evaluate the BFE of test articles at an increased challenge level. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article at a challenge level of greater than 10^6 colony forming units (CFU). The challenge was aerosolized using a nebulizer and delivered to the test article at a fixed air pressure and flow rate of 30 liters per minute (LPM). The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) for collection. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 LPM using a six-stage, viable particle, Andersen sampler for collection.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. 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.

Challenge Flow Rate:	30 LPM
Area Tested:	~40 cm^2
Side Tested:	Smooth Side
Challenge Level:	3.4 x 10^6 CFU
MPS:	~2.8 µm
Test Monitor Results:	Acceptable

Study Director James W. Luskin Study Completion Date 04 May 2020

1286321-S01

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	4.9×10^2	99.986
2	5.4×10^2	99.984
3	3.2×10^2	99.9903

The filtration efficiency percentages were calculated using the following equation:

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

C = Challenge Level
T = Total CFU recovered downstream of the test article

Chemical Safety Data Sheet

Section 1 IDENTIFICATION

GHS Product identifier: PTFE DF204

Other means of identification: N/A

Recommended use of the chemical and restrictions on use: This material can be used in machinery, electronic, chemical industries and so on.

Supplier's

Emergenc

Section 2 HAZARDS IDENTIFICATION

Classification of the substance or mixture: N/A

GHS Label elements, including precautionary statements: N/A

Other hazards which do not result in classification: N/A

Section 3 COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	Concentration%
PTFE DF204	9002-84-0	≥99.96%

Section 4 FIRST AID MEASURES

Description of necessary first aid measures

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

If Ingestion: Rinse mouth with water. Induce vomit. Consult a physician.

Most important symptoms/effects, acute and delayed: N/A

Indication of immediate medical attention and special treatment needed, if necessary: N/A

Section 5 FIREFIGHTING MEASURES

Suitable extinguishing media: Use foam, chemical power or water.

Special hazards arising from the chemical: The material can burn in fire and release toxic fumes.

Special protective actions for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary. Use water spray to cool unopened containers.

Section 6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas.

Environmental precautions: Do not enter into spillage area. Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

Methods and materials for containment and cleaning up: Contain spillage, and then collect in

a clean container according to local regulations.

Section 7 HANDLING AND STORAGE

Precautions for safe handling: Wear protective gloves/eye protection/face protection/protective clothing. Avoid contact with skin and eyes. Avoid inhalation of vapor or mist. Keep away from sources of ignition - No smoking.

Conditions for safe storage, including any incompatibilities: Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Keep away from flammable materials, acid and oxidizer.

Section 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters:

Source	Material	TWA ppm	TWA mg/m³	STEL ppm	STEL mg/m³	Peak ppm	Peak mg/m³	TWA F/CC	Notes
China Occupational Exposure Limits for Hazardous Agents in the Workplace	polytetrafluoroethylene		2						

Appropriate engineering controls: Local exhaust ventilation or a process enclosure ventilation system may be required.

Individual protection measures

Eye/face protection: Safety glasses with side shields. Chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.

Skin protection: Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber. Impervious clothing,

Respiratory protection: Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant.

Thermal hazards: /

Section 9 PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, colour etc)	White solid powder.
Odour	NO DATA
Odour Threshold	NO DATA
pH	NO DATA
Melting point/freezing point	NO DATA
Initial boiling point and boiling range	NO DATA
Flash point	NO DATA
Evaporation rate	NO DATA
Flammability (solid, gas)	NO DATA
Upper/lower flammability or explosive limits	NO DATA
Vapour pressure	NO DATA
Vapour density	NO DATA
Relative density	2.152.
Solubility(ies)	Insoluble in water.
Partition coefficient: n-octanol/water	NO DATA
Auto-ignition temperature	NO DATA
Decomposition temperature	NO DATA
Viscosity	NO DATA

Section 10 STABILITY AND REACTIVITY

Reactivity: N/A
Chemical stability: The material is stable in normal temperature.
Possibility of hazardous reactions: N/A
Conditions to avoid: High temperature.
Incompatible materials: N/A
Hazardous decomposition products: CO, CO_2 and so on.

Section 11 TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure: Inhaled, swallowed, skin, eyes.
Symptoms related to the physical, chemical and toxicological characteristics: N/A
Acute health effects: Accidental ingestion of the material may be harmful and cause cough and throat pain. Oral intake may cause headache, vomit and other symptoms. This material may produce skin and eyes irritation.
Chronic health effects: N/A
Numerical measures of toxicity(such as acute toxicity estimates): N/A

Section 12 ECOLOGICAL INFORMATION

Toxicity: /
Persistence and degradability: High.
Bioaccumulative potential: Low.
Mobility in soil: Medium.
Other adverse effects: N/A

Section 13 DISPOSAL CONSIDERATIONS

Disposal methods: Burial in a land-fill specifically licensed to accept chemical. Reuse of broken container is forbidden.

Section 14 TRANSPORT INFORMATION

UN number: N/A
UN proper shipping name: N/A
Transport hazard class(es) : N/A
Packing group, if applicable: N/A
Environmental hazards: N/A
Special precautions for user:N/A

Section 15 REGULATORY INFORMATION

Regulations: This safety data sheet is in compliance with the following national standards: GB 16483-2008, GB 13690-2009, GB/T 15098-2008, GB 18218-2009, GB 15258-2009, GB 6944-2012, GB 190-2009, GB 191-2009, GB 12268-2008, GA 57-1993, GBZ 2-2007 as well as the following national regulations: Dangerous Goods Transport Administrative Regulation [Published by the Ministry of Railways, 2008], Dangerous Chemicals Safety Administrative Regulation [Published by the State Council, 2011].

Section 16 OTHER INFORMATION

References	UN Recommendations on the Transport of Dangerous Goods Model Regulations UN Globally Harmonized System of Classification and Labelling of Chemicals
Form Date	02-Jul-2013

Note 1: When products contain two or more hazardous substances, Safety Data Sheets should be prepared based on the risk of the mixture.
Note 2: Manufacturer / supplier should ensure the correctness of the information contained in the safety data sheets, and updated in a timely manner.
Note 3: As a result of product features without the existence of certain information or no data available (such as boiling point does not exist for the solid) in the table with "/" logo.

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Sodium Chloride (NaCl) Aerosol Test Final Report

Test Article:	Air Queen Breeze Mask
Study Number:	1295789-S01
Study Received Date:	04 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: STP0014 Rev 09
Deviation(s):	None

Summary: This procedure was performed to evaluate particulate filter penetration as specified in 42 CFR Part 84 and TEB-APR-STP-0059 for requirements on a N95 respirator. Respirators were conditioned then tested for particle penetration against a polydispersed, sodium chloride (NaCl) particulate aerosol. The challenge aerosol was dried, neutralized, and passed through the test article at a concentration not exceeding 200 mg/m^3. The initial airflow resistance and particle penetration for each respirator was determined.

According to 42 CFR Part 84.64, pretesting must be performed by all applicants as part of the application process with NIOSH. Results seen below are part of that pretesting and must be submitted to and accepted by NIOSH for respirator approval.

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.

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Robert Dieker electronically approved for	02 Jun 2020 15:37 (+00:00)
Study Director Curtis Gerow	Study Completion Date and Time

Results: The NIOSH N95 filter efficiency as stated in 42 CFR Part 84.181 is a minimum efficiency for each filter of ≥95% (≤5% penetration). The test articles submitted by the sponsor conform to the NIOSH N95 criteria for filter efficiency.

Test Article Number	Corrected[a] Initial Airflow Resistance (mm H_2O)	Maximum Particle Penetration (%)	Filtration Efficiency (%)
1	14.5	1.59	98.41
2	15.8	1.54	98.46
3	15.4	1.88	98.12
4	13.4	1.93	98.07
5	11.5	3.79	96.21
6	12.2	2.98	97.02
7	12.4	3.40	96.60
8	12.6	2.42	97.58
9	12.6	2.06	97.94
10	12.1	3.77	96.23
11	12.0	3.97	96.03
12	13.2	2.04	97.96
13	14.4	2.12	97.88
14	13.6	2.46	97.54
15	2.0	0.306	99.694
16	11.9	2.43	97.57
17	14.4	2.03	97.97
18	14.2	2.47	97.53
19	12.7	2.14	97.86
20	12.0	2.25	97.75

[a] The final airflow resistance value for each test article was determined by subtracting out the background resistance from the system.

Test Method Acceptance Criteria: The filter tester must pass the "Tester Set Up" procedure. The airflow resistance and particle penetration of the reference material must be within the limits set by the manufacturer.

Filter Test Procedure: Prior to testing, respirators were taken out of their packaging and placed in an environment of 85 ± 5% relative humidity (RH) and 38 ± 2.5°C for 25 ± 1 hours.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (µm) and a geometric standard deviation not exceeding 1.86 µm. The mass median diameter was approximately 0.26 µm, which is generally accepted as the most penetrating aerosol size. The reservoir was filled with a 2% NaCl solution and the instrument allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure was set to approximately 35 psi. The NaCl aerosol generator pressure was set to approximately 30 psi and the make-up airflow rate was set to approximately 70 liters per minute (L/min).

The NaCl concentration of the test aerosol was determined in mg/m^3 by a gravimetric method prior to the load test assessment. An entire respirator was mounted on a test fixture, placed into the filter holder, and the NaCl aerosol passed through the outside surface of the test article at a continuous airflow rate of 85 ± 4 L/min. In accordance with NIOSH policy, three respirators were challenged until 200 ± 5 mg of NaCl had contacted each test article. Based upon the load pattern of NIOSH Type 1, the initial penetration reading of the remaining 17 respirators was recorded.

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Viral Filtration Efficiency (VFE) Final Report

Test Article:	Air Queen Breeze Mask
Study Number:	1286322-S01
Study Received Date:	09 Apr 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: STP0007 Rev 16
Deviation(s):	None

Summary: The VFE test is performed to determine the filtration efficiency of test articles by comparing the viral control counts upstream of the test article to the counts downstream. A suspension of bacteriophage ΦX174 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 1.1 - 3.3 x 10^3 plaque forming units (PFU) with a mean particle size (MPS) of 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. The VFE test procedure was adapted from ASTM F2101.

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:	Smooth Side
Test Area:	~40 cm^2
VFE 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
Positive Control Average:	2.9 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

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Study Director James W. Luskin

30 Apr 2020
Study Completion Date

1286322-S01

Results:

Test Article Number	Percent VFE (%)
1	>99.9
2	>99.9
3	>99.9
4	>99.9[a]
5	>99.9

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request