

## Viral Filtration Efficiency (VFE) Final Report

Test Article: AntiMicrobe Web R  
Study Number: 1272273-S01  
Study Received Date: 28 Feb 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  $\Phi$ X174 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  $1.1 - 3.3 \times 10^3$  plaque forming units (PFU) with a mean particle size (MPS) of  $3.0 \mu\text{m} \pm 0.3 \mu\text{m}$ . 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: Either  
Test Area:  $\sim 40 \text{ cm}^2$   
VFE Flow Rate: 28.3 Liters per minute (L/min)  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Positive Control Average:  $1.3 \times 10^3$  PFU  
Negative Monitor Count:  $< 1$  PFU  
MPS:  $3.1 \mu\text{m}$



Curtis Low For 16 Mar 2020  
Study Director James W. Luskin Study Completion Date



1272273-S01

**results:**

Test Article Number	Percent VFE (%)
1	>99.9 <sup>a</sup>
2	>99.9 <sup>a</sup>
3	>99.9 <sup>a</sup>
4	>99.9 <sup>a</sup>
5	>99.9 <sup>a</sup>

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:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request

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

Test Article: AntiMicrobe Web R  
Study Number: 1272274-S01  
Study Received Date: 28 Feb 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  $1.7 - 3.0 \times 10^3$  colony forming units (CFU) with a mean particle size (MPS) of  $3.0 \pm 0.3 \mu\text{m}$ . 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: Either  
BFE Test Area:  $\sim 40 \text{ cm}^2$   
BFE Flow Rate: 28.3 Liters per minute (L/min)  
Delta P Flow Rate: 8 L/min  
Conditioning Parameters:  $85 \pm 5\%$  relative humidity (RH) and  $21 \pm 5^\circ\text{C}$  for a minimum of 4 hours  
Positive Control Average:  $2.1 \times 10^3$  CFU  
Negative Monitor Count:  $< 1$  CFU  
MPS:  $3.2 \mu\text{m}$

Study Director

  
James W. Luskin

  
Study Completion Date



1272274-S01

801-290-7500

[nelsonlabs.com](http://nelsonlabs.com)

[sales@nelsonlabs.com](mailto:sales@nelsonlabs.com)

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FRT0004-0001 Rev 22

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**results:**

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

Test Article Number	Delta P (mm H <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	5.4	53.4
2	6.1	59.8
3	5.9	58.0
4	5.9	57.8
5	5.8	57.3

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request



## Latex Particle Challenge Final Report

Test Article: AntiMicrobe Web R  
Study Number: 1272275-S01  
Study Received Date: 28 Feb 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): 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.

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: Either Side  
Area Tested: 91.5 cm<sup>2</sup>  
Particle Size: 0.1 µm  
Laboratory Conditions: 21°C, 24% relative humidity (RH) at 0854; 21°C, 23% RH at 1200  
Average Filtration Efficiency: 99.79%  
Standard Deviation: 0.042



  
Study Director

Curtis Gerow, B.S.

  
Study Completion Date



1272275-S01

801-290-7500 | [nelsonlabs.com](http://nelsonlabs.com) | [sales@nelsonlabs.com](mailto:sales@nelsonlabs.com)

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**Results:**

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	20	12,610	99.84
2	23	13,655	99.83
3	31	12,495	99.75
4	31	13,291	99.77
5	33	14,085	99.77