



## Bacterial Filtration Efficiency (BFE) Final Report

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| <b>Test Article:</b> Filti Mask Material | <b>Testing Facility:</b> Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A. |
| <b>Study Number:</b> 1292279-S01         | <b>Test Procedure(s):</b> Standard Test Protocol (STP) Number: STP0004 Rev 18                         |
| <b>Study Received Date:</b> 23 Apr 2020  | <b>Deviation(s):</b> 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<sup>3</sup> 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.

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| <b>Test Side:</b> Inside                                   | <b>Conditioning Parameters:</b> 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours |
| <b>BFE Test Area:</b> ~40 cm <sup>2</sup>                  | <b>Negative Monitor Count:</b> <1 CFU  |
| <b>BFE Flow Rate:</b> 28.3 Liters per minute (L/min)       | <b>MPS:</b> 2.6 µm   |
| <b>Positive Control Average:</b> 3.3 x 10 <sup>3</sup> CFU |  |

### Results

| Test Article Number | Percent BFE (%) |
|---------------------|-----------------|
| 1                   | 99.6            |
| 2                   | 99.5            |
| 3                   | 99.6            |
| 4                   | 99.3            |
| 5                   | 99.4            |

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