# Viral Filtration Efficiency (VFE) Final Report

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|---|---|
| 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.

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| 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 |

Study Director _____ James W. Luskin

Study Completion Date 30 Apr 2020

**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