Nelson Labs.
A Sotera Health company

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# Viral Filtration Efficiency (VFE) Final Report

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|---|---|
| Test Article: | Patito Face Mask Ag+ Tech |
| Study Number: | 1288960-S01 |
| Study Received Date: | 15 Apr 2020 |
| Testing Facility: | Nelson Laboratories, LLC<br>6280 S. Redwood Rd.<br>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 $3.9 \times 10^3$ 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: | Inside |
| Test Area: | ~7.1 $cm^2$ |
| 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: | $3.9 \times 10^3$ PFU |
| Negative Monitor Count: | <1 PFU |
| MPS: | 2.8 µm |

The positive control average was out of specification per STP0007 Rev 16 section 6.1 which states, "The VFE positive control average shall be maintained at 1.1-3.3 x $10^3$ PFU." Testing with a more severe challenge to the test articles represents a worse case. The sponsor accepted the use of the higher challenge; therefore, the results are considered valid at the testing conditions that occurred.

**Results:**

| Test Article Number | Percent VFE (%) |
|---|---|
| 1 | 98.7 |

Alyssa Sendera for James W. Luskin
Study Director

01 May 2020
Study Completion Date

1288960-S01

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