Nelson Labs.
A Sotera Health company

Sponsor:
Christopher Dobbing
Cambridge Environmental Solutions
Unit 179, 23 King Street
Cambridge, UK CB1 1AH
UNITED KINGDOM

Viral Filtration Efficiency (VFE) Final Report

Test Article:	Cambridge Mask Pro Admiral Size Large 5060437942118
Study Number:	1313390-S01
Study Received Date:	24 Jun 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:	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:	1.7 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.8 µm

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Alexa Sanders electronically approved for — 30 Jul 2020 20:09 (+00:00)
Study Director James Luskin — Study Completion Date and Time