Nelson Labs
A Sotera Health company

Sponsor:
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Viral Filtration Efficiency (VFE) GLP Report

Test Article:	BTL Respirator C-FIT Healthcare Respirator
Study Number:	1346709-S01
Study Received Date:	28 Sep 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.

Test Side:	Inside
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:	1.4 x 10^3 PFU
Negative Monitor Count:	<1 PFU
MPS:	2.9 µm

Results:

Test Article Number	Percent VFE (%)
1	>99.9[a]
2	>99.9
3	>99.9
4	>99.9[a]
5	>99.9[a]

[a] There were no detected plaques on any of the Andersen sampler plates for this test article.

Leah Tiberius electronically approved — 25 Nov 2020 23:17 (+00:00)
Study Director Leah Tiberius — Study Completion Date and Time

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

Test Article Preparation: The VFE test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH), prior to testing.

Test Method Acceptance Criteria: The VFE positive control average shall be maintained at 1.1 - 3.3 x 10^3 PFU. The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

Procedure: The stock bacteriophage ΦX174 was diluted in peptone water (PEPW) to yield challenge level counts of 1.1 - 3.3 x 10^3 PFU per test article. The bacteriophage suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six agar plates containing *Escherichia coli* based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 12-24 hours. The plaques formed by each bacteriophage-laden aerosol droplet were counted and converted to probable hit values using the published conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of colonies for each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	08 Oct 2020
Phase Inspected by Quality Assurance: Challenge Procedure	10 Nov 2020
Audit Results Reported to Study Director	10 Nov 2020
Audit Results Reported to Management	11 Nov 2020

Scientists	Title
Adrianne Sandall	Supervisor
Leah Tiberius	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Nathan Tolman electronically approved
Quality Assurance

25 Nov 2020 23:11 (+00:00)
Date and Time