Nelson Labs
A Sotera Health company

Sponsor:
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Bacterial Filtration Efficiency (BFE) GLP Report

Test Article:	BTL Respirator FLAT-FIT Healthcare Respirator
Study Number:	1324374-S01
Study Received Date:	24 Jul 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: STP0004 Rev 18
Deviation(s):	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 10^3 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.

Test Side:	Inside
BFE Test Area:	~40 cm^2
BFE 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
Test Article Dimensions:	~245 mm x ~186 mm
Positive Control Average:	2.6 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

Adam Brigham electronically approved — 28 Sep 2020 14:41 (+00:00)
Study Director Adam Brigham — Study Completion Date and Time

Results:

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

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

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

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 test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE testing.

Test Method Acceptance Criteria: The BFE positive control average shall be maintained at 1.7 – 3.0 x 10^3 CFU.

The MPS control average of the challenge aerosol shall be maintained at 3.0 ± 0.3 µm.

Procedure:

BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to yield challenge level counts of 1.7 – 3.0 x 10^3 CFU per test article. The bacterial culture 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 soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by the bacteria laden aerosol droplets were then counted and converted to probable hit values using the positive hole 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 the colonies on 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	04 Sep 2020
Phase Inspected by Quality Assurance: Sample Preparation	10 Sep 2020
Audit Results Reported to Study Director	11 Sep 2020
Audit Results Reported to Management	14 Sep 2020

Scientists	Title
Adrianne Sandall	Supervisor
Adam Brigham	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.

Loxane Konesavanh electronically approved
Quality Assurance

25 Sep 2020 17:38 (+00:00)
Date and Time