Bacterial Filtration Efficiency with Increased Delivery Challenge (BFE) in ASTM F2101 and EN14683

Proven that OOH SHIELD technology can effectively filter increased challenge of bacteria (99.8%)

Nelson Labs.
A Sotera Health company

Sponsor:
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Bacterial Filtration Efficiency (BFE) Final Report

Test Article:	HKMSLMASK000
Purchase Order:	HKMSLPO20200326
Study Number:	1282265-S01
Study Received Date:	28 Mar 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 3.5×10^3 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; with the exception of the higher challenge level, which may represent a more severe test.

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
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:	~176 mm x ~160 mm
Positive Control Average:	3.5×10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

The positive control average was out of specification per STP0004 Rev 18 section 6.1 which states, "The BFE positive control average shall be maintained at $1.7\text{-}3.0 \times 10^3$ CFU." 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.

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Alyssa Sanders — Study Director
for James W. Luskin
20 Apr 2020 — Study Completion Date

1282265-S01

Results:

Test Article Number	Percent BFE (%)
1	99.8
2	99.8
3	99.8
4	99.8
5	99.8

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