NELSON LABORATORIES

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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article:	16-40348/201603200-100 16-40345/201603200-400 20130040-002/201603200-416A 20130040-005/201603200-416B
Purchase Order:	16-000533
Study Number:	889565-S01
Study Received Date:	28 Apr 2016
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 13 Protocol Detail Sheet (PDS) Number: 201601653 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7 - 2.7 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-14 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met.

BFE Area Tested:	Entire Test Article (Samples glued to plates)
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.
Negative Monitor Count:	<1 CFU

ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong
Study Director — Trang Truong, B.S.

26 May 2016
Study Completion Date

889565-S01

Results:

16-40348/201603200-100:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9	5.4[c]	53.2[c]
2	99.5	4.8[c]	47.5[c]
3	>99.9[ab] >99.9[b]	4.9[c]	47.9[c]
4	>99.9[b] >99.9[ab]	5.1[c]	50.5[c]
5	98.7	5.0[c]	49.6[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
Test Article Dimensions: ~120 mm x ~125 mm
Positive Control Average: 2.4×10^3 CFU, 2.1×10^3 CFU (3, 4)
MPS: 3.1 µm, 2.9 µm (3, 4)

16-40345/201603200-400:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9[a]	3.7[c]	36.1[c]
2	99.6	3.3[c]	32.0[c]
3	>99.9[b] >99.9[b]	3.3[c]	32.2[c]
4	>99.9	3.3[c]	32.7[c]
5	>99.9[a]	3.9[c]	37.9[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Outside
Test Article Dimensions: ~100 mm x ~100 mm
Positive Control Average: 2.4×10^3 CFU, 2.1×10^3 CFU (3)
MPS: 3.1 µm, 2.9 µm (3)

20130040-002/201603200-416A:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	7.7[b]	75.2[b]
		7.7[b]	75.2[b]
2	>99.9[a]	7.7[c]	75.7[c]
3	99.8	7.7[b]	75.2[b]
		7.8[b]	76.8[b]
4	>99.9	7.5[c]	73.7[c]
5	98.6	7.0[c]	68.8[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[b] The original result was unexpectedly different from its counterparts. Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be invalid. The valid results are reported in duplicate.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
Test Article Dimensions: ~135 mm x ~135 mm
Positive Control Average: 2.4×10^3 CFU
MPS: 3.1 µm

20130040-005/201603200-416B:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	>99.9[a]	3.2[c]	31.7[c]
2	>99.9[a]	3.3[c]	32.4[c]
3	>99.9[a]	2.9[c]	28.6[c]
4	>99.9	4.0[c]	39.0[c]
5	99.5	4.0[c]	39.1[c]

[a] There were no detected colonies on any of the Andersen sampler plates for this test article.
[c] Investigational testing was performed in duplicate to confirm the original result that was generated. Through an investigation and additional testing, the original result was determined to be valid. The valid results are reported as an average.

Test Side: Inside
Test Article Dimensions: ~105 mm x ~100 mm
Positive Control Average: 2.4×10^3 CFU
MPS: 3.1 µm

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