

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

Test Article: Company Name: Xiantao Yongli Medical Products Co,ltd
 Product Name: Surgical Facemask
 Model: 17.5*9.5cm
 Study Number: 1277673-S01
 Study Received Date: 16 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 $1.7 - 3.0 \times 10^3$ colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. 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.

The Delta P test is performed to determine the breathability of test articles 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

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: $\sim 40 \text{ cm}^2$
 BFE Flow Rate: 28.3 Liters per minute (L/min)
 Delta P Flow Rate: 8 L/min
 Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
 Test Article Dimensions: $\sim 174 \text{ mm} \times \sim 154 \text{ mm}$
 Positive Control Average: 2.2×10^3 CFU
 Negative Monitor Count: < 1 CFU
 MPS: $3.2 \mu\text{m}$

Results:

5.1.2e



27 Mar 2020

Study Completion Date



1277673-S01

 801-290-7500 | nelsonlabs.com | 5.1.2e@nelsonlabs.com

ks

FRT0004-0001 Rev 22

Page 1 of 2

Results:

| Test Article Number | Percent BFE (%) |
|---------------------|-----------------|
| 1 | 99.8 |
| 2 | >99.9 |
| 3 | 99.9 |
| 4 | >99.9 |
| 5 | >99.9 |

| Test Article Number | Delta P (mm H ₂ O/cm ²) | Delta P (Pa/cm ²) |
|---------------------|--|-------------------------------|
| 1 | 4.1 | 39.7 |
| 2 | 4.0 | 39.4 |
| 3 | 4.1 | 40.0 |
| 4 | 4.2 | 41.5 |
| 5 | 3.9 | 38.4 |

The filtration efficiency percentages were calculated using the following equation:

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

C = Positive control average

T = Plate count total recovered downstream of the test article

Note: The plate count total is available upon request