

Barrier Face Covering Evaluation Test Final Report

Test Article: AGI-3502-21APR22
Study Number: 1515615-S01
Study Received Date: 13 May 2022
Test Started Date: 18 May 2022
Test Finished Date: 27 May 2022
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: STP0014 Rev 10
Deviation(s): None

Summary: This procedure was performed to evaluate the particle penetration and airflow resistance properties of barrier face coverings as specified in ASTM F3502-21. This method is in compliance with 42 CFR Part 84 and is a modified version of the NIOSH method TEB-APR-STP-0059.

A neutralized, poly-dispersed aerosol of sodium chloride (NaCl) was generated and passed through the test article. The performance of the test article was assessed by measuring the concentration of salt particles penetrating the test article compared to the challenge concentration entering the test article. The filtration performance of each test article was calculated. The airflow resistance was measured using the same method.

The filter tester used in testing was a TSI® CERTITEST® Model 8130 Automated Filter Tester that is capable of efficiency measurements of up to 99.999%. It produced a particle size distribution with a count median diameter of 0.075 ± 0.020 microns (μm) and a geometric standard deviation not exceeding 1.86 μm . The mass median diameter was approximately 0.26 μm , which is generally accepted as the most penetrating aerosol size.

Testing was performed on samples as they were received. If refurbishing is needed, it is up to the sponsor to provide appropriate samples for testing before and after refurbishing.

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.

Area Tested: Entire Face Covering
Airflow Rate: 85 ± 4 liters per minute (L/min)
Test Side: Outside
Test Set-Up: Sealed onto a metal plate and mounted in a chamber placed within the filter holder
Conditioning Parameters: $38 \pm 2.5^\circ\text{C}$, $85 \pm 5\%$ relative humidity (RH) for 25 ± 1 hour



Lisa Bonner electronically approved
Study Director

Lisa Bonner

31 May 2022 16:31 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Initial Airflow Resistance (mm H ₂ O)	Initial Particle Penetration (%)	Filtration Efficiency (%)
1	1.0	44.4	55.6
2	1.1	47.3	52.7
3	1.3	50.3	49.7

Barrier Face Covering Minimum Performance Requirements per ASTM F3502 Table 2:

Performance Property	Level 1 (Lower Performance)	Level 2 (Higher Performance)
Sub-Micron Particulate Filtration Efficiency	≥20 %	≥50 %
Airflow Resistance, Inhalation	≤15 mm H ₂ O	≤5 mm H ₂ O

Each Performance Property is Classified Separately; there are four possible sets of classifications. A barrier face covering can have:

- (1) Level 1 performance for both properties,
- (2) Level 1 performance in sub-micron particulate filtration efficiency and Level 2 performance in airflow resistance,
- (3) Level 2 performance in sub-micron particulate efficiency and Level 1 performance in airflow resistance, and
- (4) Level 2 performance for both properties.