



# MD2061 Test report

ASTM F2100-20 Level 3

Doc number - Version 1.0

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**Model #:** MD2061

**Lot #:** 32566

**Model name:** Procedural mask

**Manufacturer:** Nova Institute Inc.

**Manufacturer address:** 55 Village Centre Pl. Mississauga, ON L4Z 1V9, CANADA

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## ASTM F2100 Level 3 Test suite Summary

The ASTM F2100-20 standards require pass results of five tests: ASTM F2299 Submicron Particulate Filtration Efficiency (PFE), ASTM F2101 Bacterial Filtration Efficiency (BFE), EN14683:2019 Annex C Differential Pressure, F1862 Resistance to Blood Penetration, 16 CFAR Part 1610 Flammability. Table one shows a summary of the tests, standards, and requirements to meet ASTM F2100-20 Level 3. All test method acceptance criteria were met.

Test Standard	Test Description	Batch size	Requirement	Test result
ASTM F2299	Submicron Particulate Filtration Efficiency (PFE) Aerosol: Latex orb Particle size: 0.1um Flow rate: 28.3L/min Test area: 100cm <sup>2</sup>	5	> 98 %	Pass
ASTM F2101	Bacterial Filtration Efficiency (BFE) Particle size: 3.0um Aerosol: Staphylococcus Aureus Flow rate: 28.3L/min Test area: 100cm <sup>2</sup>	5	> 98%	Pass
EN14683:2019 Annex C	Differential pressure	5	< 49 Pa/cm <sup>2</sup> < 5 H <sub>2</sub> O/cm <sup>2</sup>	Pass
ASTM F1862	Resistance to penetration by artificial blood	32	160 mmHg	Pass
16 CFAR Part 1610	Flammability	14	Burn time > 3.5 sec	Pass

**TABLE 1: ASTM F2100 LEVEL 3 TEST SUITE SUMMARY**

## ASTM F2101 Bacterial Filtration Efficiency (BFE) and EN14683:2019 Annex C Differential Pressure

Test Side: Inside

BFE Test Area: ~40 cm<sup>2</sup>

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

Test Article Dimensions: ~175mmx~95mm

Positive Control Average: 2.5 x 10<sup>3</sup> CFU

Negative Monitor Count: <1 CFU

MPS: 2.8µm

Test article #	Percent BFE (%)	Delta P (mmH <sub>2</sub> O/cm <sup>2</sup> )	Delta P (Pa/cm <sup>2</sup> )
1	99.8	4.3	42.6
2	99.9	4.5	43.8
3	99.8	4.2	41.6
4	99.8	4.3	42.0
5	99.9	4.4	43.4

**TABLE 2: ASTM F2101 BACTERIAL FILTRATION EFFICIENCY (BFE) TEST RESULTS**

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## ASTM F2299 Submicron Particulate Filtration Efficiency

This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. All test method acceptance criteria were met.

Test Side: Inside  
Area Tested: 91.5 cm<sup>2</sup>  
Particle Size: 0.1µm  
Laboratory Conditions: 20°C, 32% relative humidity (RH) at 1001; 20°C, 32% RH at 1140  
Average Filtration Efficiency: 99.83%  
Standard Deviation: 0.083

Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Test article #	Test article counts	Average Control Counts	Filtration Efficiency %
1	10	11,312	99.912
2	21	10,947	99.81
3	16	10,804	99.85
4	33	11,137	99.70
5	12	11,257	99.98

**TABLE 3: ASTM F2299 SUBMICRON PARTICULATE FILTRATION EFFICIENCY (PFE) TEST RESULTS**

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## ASTM F1862 Resistance to penetration by artificial blood

This test complies with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO22609 requires testing to be performed in an environment with a temperature of  $21 \pm 5^{\circ}\text{C}$  and a relative humidity of  $85 \pm 10\%$ . Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters. All test method acceptance criteria were met.

Number of Test Articles Tested: 32

Number of Test Articles Passed: 29

Test Side: Outside

Pre-Conditioning: Minimum of 4 hours at  $21 \pm 5^{\circ}\text{C}$  and  $85 \pm 5\%$  relative humidity (RH)

Test Conditions:  $21.0^{\circ}\text{C}$  and 22% RH

Test Pressure: 160 mmHg

Per ASTM F1862 and ISO22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when >29 of 32 test articles show passing results.

Test article #	Synthetic Blood Penetration
1-10, 12-16, 18, 20-32	None Seen
11, 17, 19	Yes

**TABLE 4: ASTM F1862 RESISTANCE TO PENETRATION BY ARTIFICIAL BLOOD TEST RESULTS**

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## 16 CFAR Part 1610 Flammability

The Flammability test determines the time of flame spread for the given material. All fabrics of natural or regenerated cellulose, as well as certain types of finished and unfinished fabrics made from other natural or synthetic fibres, are combustible. Some combustible fabrics are potentially dangerous to the wearer because of the speed and intensity of flame with which these fabrics burn and their ease of ignition. Test was performed according to standard set out in 16 CFAR 1610. All test method acceptance criteria were met.

Test article size: 150mm x 150mm

Number of test articles: 14

All test articles passed had a burn time > 3.5 seconds.

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## Conclusion

All tests required by ASTM F2100-20 Level 3 were performed, and all test method acceptance criteria were met for each test. Average BFE of the tested samples was 99.84%, average PFE was 99.85%, and average differential pressure was 4.34 mmH<sub>2</sub>O/cm<sup>2</sup>. 29 of 32 samples passed synthetic blood penetration test at 160 mmHg, and all test articles passed Flammability class 1 according to 16CFAR Part 1610.



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Date