

Understanding ASTM Levels for Facemasks

What is ASTM?

[ASTM International](#) is an organization that defines and sets standards for a variety of products, materials, systems, and services used by people performing their jobs every day. These standards are created to enhance performance of these work tools and improve lives by promoting quality and safety. ASTM International is a global organization that is open to anyone who wants to help subject matter experts create or update standards; this collaborative nature helps keep standards as up-to-date as the industries who use them. They have over 12,800 standards operating throughout the world, including those that cover personal protective equipment such as medical facemasks (e.g., [ASTM F2100](#)). The U.S. Food and Drug Administration (FDA) maintains a list of recognized standards, in which ASTM standards are included.

ASTM F2100

The standard that covers the performance requirements and test methods for materials used to construct medical facemasks used in providing healthcare such as surgical services and patient care. However, this specification does not evaluate all aspects of medical facemask design such as barrier properties, breathability, and respiratory protection regulations. ASTM levels are addressed in this standard and are assigned based on material performance in five tested areas.

The 5 Performance Tests of ASTM F2100[†]

(current terminology and definitions below are from Section 9)

- Bacterial Filtration Efficiency – Determine the bacterial filtration efficiency as directed in Test Method [F2101](#).
- Differential Pressure – Determine the breathing resistance or differential pressure as directed in [EN 14683:2019, Annex C](#). Note: this test method provides a measurement of pressure per unit area of material specimen tested.
- Sub-Micron Particulate Filtration – Determine particulate filtration efficiency as direct in Test Method [F2299](#).
- Resistance to Penetration by Synthetic Blood – Determine synthetic blood penetration resistance as specified in Test Method [F1862](#).
- Flammability – Determine flammability as specified in [16 CFR Part 1610](#).

	ASTM Level 1	ASTM Level 2	ASTM Level 3
Bacterial Filtration Efficiency @ 3 µm	≥ 95%	≥ 98%	≥ 98%
Differential Pressure (mm H ₂ O/cm ²)	< 4.0	< 5.0	< 5.0
Sub-Micron Particulate Filtration @ 0.1 µm	≥ 95%	≥ 98%	≥ 98%
Resistance to Penetration by Synthetic Blood (mmHg)	80	120	160
Flammability	Class 1	Class 1	Class 1

ASTM Levels

- **ASTM Level 1:** Ideal for procedures in which there is low risk of fluid exposure (no splashes or sprays expected).
- **ASTM Level 2:** Ideal for procedures in which there is moderate risk of fluid exposure (splashes or sprays can be produced).
- **ASTM Level 3:** Ideal for procedures in which there is high risk of fluid exposure (splashes or sprays will be produced).



Protection Provided

Wearing a facemask that has been ASTM-rated will ensure that your nose and mouth (breathing area) are protected against fluids, microorganisms, and particulates at the level to which the mask is rated (i.e., 1, 2, or 3 specifications). However, these masks do not provide protection against airborne diseases.

Facilities should provide N95 or higher-level respirators, and fit-testing (passing a fit-test is needed for the respirator to be protective to airborne diseases), to their staff. For information about how respirators are approved and help with selecting respirators for use, please follow the provided links:

[42 CFR Part 84](#)

[NIOSH Guide to the Selection and Use of Particulate Respirators](#)

References:

<https://www.astm.org/Standards/F2100.htm>