

# Personal Protective Equipment Performance Testing



## Face Masks

Face masks protect against airborne bacteria and contaminants, with various levels of protection. Test results help manufacturers market their products at the right level of protection. Nelson Laboratories is a leading provider of superior testing solutions and consultative services for MedTech companies. With a strong belief that every test matters, we go beyond exceptional quality and rigorous testing standards to provide solutions that improve patient outcomes and minimize client risk. We set high standards, ensure accuracy, and work directly with clients to help solve complex issues.

**Testing services include test suites for China, USA, and Europe with the following standards:**

- China:** YY 0469-2011 Professional Standard of the People's Republic of China – Surgical Mask
- USA:** ASTM F2100 for Medical Face Masks
- Europe:** EN 14683 for Medical Face Masks

### Common Test Methods:

- Viral Filtration Efficiency (VFE) for Face Masks
- ASTM F2101 / EN 14683 – Bacterial Filtration Efficiency (BFE)
- BFE/VFE at Increased Challenge for results up to 99.9999% filtration efficiency
- 0.3 micron Sodium Chloride (NIOSH test 42 CFR part 84)
- ISO 10993 – Biocompatibility of Medical Devices
- ISO 11737-1 – Determination of a Population of Microorganisms on Products (Bioburden)
- Latex Particle Challenge (ASTM F2299) – Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres (particle size selection 0.1, 0.3, 0.5, 1 microns)
- ASTM F1862 / ISO 22609 – Resistance of Medical Face Masks to Penetration by Synthetic Blood
- MIL – M – 36954C / EN 14683 – Differential Pressure Air Permeability (Breathability)
- 16 CFR part 1610 – Flammability of Clothing Textiles



Surgeon with face mask



Bacterial Filtration Efficiency Testing

# Personal Protective Equipment Performance Testing



## Surgical Gowns & Drapes

Surgical protective apparel safeguards patients, staff, and equipment during operating procedures. Infection prevention within a healthcare setting is dependent on the level of protective apparel chosen for a given situation. Different levels of protection are better suited for specific tasks and include different testing requirements.

**Testing services include test suites for USA and Europe with the following standards:**

**USA:** ANSI/AAMI PB70 in accordance with ASTM F2407 for surgical gowns and drapes

**Europe:** EN13795 general requirements for surgical gowns and drapes used as medical devices. EN 14126 performance requirements for protective clothing against infective agents

### Common Test Methods:

- ASTM F1671 / ISO 16604 – Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174
- ASTM F1670 – Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood
- AATCC 127/ ISO 811 – Water Resistance: Hydrostatic Pressure (Hydro)
- AATCC 42 – Water Resistance: Impact Penetration (Spray)
- ISO 22610 – Resistance to Wet Bacterial Penetration
- ISO 22612 – Resistance to Dry Microbial Penetration
- ISO 9073-10 – Lint and Other Particles Generation in the Dry State (Gelbo)



ISO 22612 Testing



ASTM F1671 Testing

**Our goal at Nelson Laboratories is to help you achieve success.**

Before your next PPE performance test, contact your Nelson Labs sales rep or call **800-826-2088** to determine how our experts can help move your project forward.

**Industries** - Nelson Laboratories offers a broad range of regulatory compliance and product performance evaluations for:



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