



Nelson Labs®

A Sotera Health company

CORONAVIRUS & BARRIER MATERIAL TESTS

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RESPIRATORS AND BARRIER MATERIALS

Coronavirus

The new strain of coronavirus originating in Wuhan, Hubei Province, China has raised new concerns. This virus is similar to the SARS coronavirus and can cause mild to severe respiratory illness. The virus spreads through droplet transmission. An article issued by the U.S. National Library of Medicine and National Institutes of Health states, "Corona virions are spherical with diameters of approximately 125 nm." This class of virion has a feature called spike projections.

For those who may come in contact with the virus or with infected patients, the following contact precautions are recommended:

- Use a fit-tested respirator, at least as protective as a National Institute of Occupational Safety and Health (NIOSH) approved N-95 filtering facepiece (i.e., disposable) respirator.
- Infected patients should use medical face masks to contain droplets generated from sneezing or coughing.
- Face mask use and good hand hygiene reduce the risk of respiratory infection.
- Use gloves and gowns for all patient contact.

For more information, visit the CDC web site:

<https://www.cdc.gov/coronavirus/index.html> and <https://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm>

Nelson Laboratories offers test services to help manufacturers assess their products regulatory compliance and barrier performance for viruses.

42 CFR Part 84 – Approval of Respiratory Protective Devices

According to the CDC and OSHA, when there is possible contact with the corona virus, the minimum recommended protection is an N95 disposable respirator. N-series filters are evaluated using a sub-micron 0.3µm Sodium Chloride aerosol applied at a flow rate of 85 L/min. Nelson Labs can pre-qualify your product for certification by NIOSH and perform routine testing following certification to verify manufacturers maintain quality levels as required by NIOSH. The required tests for pre-qualification are: 1) filtration efficiency, 2) inhalation resistance, 3) exhalation resistance, and 4) exhalation valve leak (when applicable). There are additional respiratory protective standards required in other countries, including CSA Z94.4-01 in Canada, HSE 282/28 in the United Kingdom, AS/NZS 1715:1994 in Australia and EN529:2005 in Europe.

ASTM F1671/ISO16604 – Viral Penetration Tests

A procedure commonly used to test the barrier properties of gowns in the U.S. is ASTM F1671 "Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using phi-X174 Bacteriophage Penetration as a Test System." This procedure uses a liquid challenge containing the phi-X174 bacteriophage virus to simulate contaminated body fluids. The International analog, ISO 16604 "Clothing for protection against contact with blood and body fluids. Determination of resistance of protective clothing materials to penetration by blood-borne pathogens. Test method using Phi-X174 Bacteriophage" is used internationally to test this property of protective clothing.

This test is required for ANSI/AAMI PB70 highest barrier level gowns (level 4) for high exposure settings and is commonly used in surgical settings. The lower barrier levels (1-3) use water as the challenge fluid which is less stringent.

The ASTM F1671 method is an excellent surrogate test for how barriers might perform against harmful or infectious viruses (e.g. HIV, Hepatitis B and Hepatitis C). Although the coronavirus route of transmission is respiratory, to reduce the possibility of coronavirus from contacting the wearer in high exposure situations, level 4 gowns would provide the highest level of protection.

The Case for phi-X174 Bacteriophage:

The ideal properties of a suitable surrogate virus include small size, spherical or polyhedral morphology, environmental stability, low or non-human infectivity, high assay sensitivity, rapid growth, and high titer. The phi-X174 bacteriophage was selected as the most appropriate surrogate because it satisfies all of these criteria. The phi-X174 bacteriophage is one of the smallest known viruses (25-27nm) and is nonenveloped, with icosahedral (nearly spherical) morphology. It has excellent environmental stability, is non-infectious to humans, and has a limit of detection, which approaches a single virus particle. It grows rapidly and can be cultivated to reach high titers.

ASTM F2100, EN 14683 – Performance Requirements for Medical Face Masks

According to the CDC, a surgical facemask should be provided to patients that are suspected of respiratory illness identified by symptoms such as coughing and sneezing to control the spread of the virus droplets. Face masks are evaluated for bacterial filtration efficiency using 3µm mean particle-size droplets containing Staphylococcus aureus and also tested for particulate filtration efficiency using non-neutralized, 0.1 µm latex spheres. Both tests are conducted at a flow rate of 28.3 L/min. Required testing varies according to the standard being used. ASTM F2100 requires testing of 1) filtration efficiency (viable and non-viable particles), 2) breathability (delta P), 3) synthetic blood penetration, 4) flammability. EN14683 testing requirements include 1) filtration efficiency (viable particles only), 2) breathability (delta P), 3) synthetic blood penetration, and 4) microbial cleanliness. Biocompatibility testing is required in all cases. Nelson Labs can perform all required testing on medical face masks.

Viral filtration efficiency testing can also be evaluated at Nelson Labs using phi-X174 Bacteriophage with a test method similar to the bacterial filtration testing required for medical face masks.

Nelson Labs can help with shelf life validation testing and evaluating performance after sterilization.

Request More Information

We are committed to helping our clients improve the quality of life by providing the highest quality viral and bacterial barrier testing available. Call today or email our Sales group to receive a quote.

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