

Biocompatibility - Safety

Description	International Test Standard	Laboratory Study #	Results	Comments
Cytotoxicity – Agar Overlay	ISO10993	Nelson # 430998	Average Score: 0 - no cytotoxicity	The BioFriend™ BioMask has no diffusible components that cause any harmful effects on isolated human cells.
Irritation – Primary Skin	ISO10993	Nelson # 431594	After 4 hours contact: Non-irritant - no skin irritation observed.	The BioFriend™ BioMask causes no irritation when worn against the skin.
Sensitisation- Buehler Method	ISO10993	Nelson # 431596	During Induction and Challenge phase at all time points: 0% incidence of sensitisation observed	The BioFriend™ BioMask causes no sensitisation when worn against the skin.
Extractables – Under Dynamic Flow	ISO10993-18	WuxiApptec #C7583A	Detected extractables released during dynamic flow conditions representative of inhalation are all well below levels of known toxicologic concern	No inhalation toxicity risk from a daily 8-hour wear of the BioFriend™ BioMask.

All of the above validation tests were conducted in compliance with Good Laboratory Practice (GLP) regulations and pursuant to International Standards by certified independent laboratories in the USA. All tests were conducted on the BF-200 BioMask. See Appendix for a description of Test Standards used.

Filtration of Micro-Organisms and Particulates

Description	International Test Standard	Laboratory Study #	Results	Comments
Bacterial Filtration	EN14683	Nelson # 431000	99.7% ± 0.1 % filtration efficiency	Filters 99.7% of airborne bacteria.
Viral Filtration	Modified ASTM F2101	Microbiotest # 639-110	>99.9% filtration efficiency	Filters >99.9% of airborne viruses.
0.1µm Latex Particulate Filtration	ASTM F2299	Nelson # 430996	98.0% ± 0.3% (average filtration efficiency)	Filters particulates ≥0.1 microns such as dust mites, pet dander, pollen and certain air pollutants.
Breathability (Differential Pressure)	EN14683	Nelson # 431000	Delta P of 2.22 ± 0.1(mm H ₂ O/cm ²)	Based on the FDA scale relating breathing resistance to comfort, a differential pressure drop of 2.0 - 3.0 is considered low and has a user perception of cool. ¹
Fluid Resistance	EN14683 (ASTM 1862)	Nelson # 430999	Pass @ 120 mmHg Pass @ 160 mmHg	Achieves resistance against fluid splashes equivalent to an arterial spurt at 120 mmHg systolic blood pressure.
Flammability	16 CFR 1610	Nelson # 430998	Class 1	Pass: Exhibits normal flammability.

All of the above validation tests were conducted in compliance with Good Laboratory Practice (GLP) regulations and pursuant to International Standards by certified independent laboratories in the USA. See Appendix for a description of Test Standards used.

¹ Source: FDA <http://www.fda.gov/cdrh/ode/guidance/094.pdf>

Microbial - **Contact Kill Rates** of Live Virus

Description	Test	Laboratory Study #	Results	Comments
<i>Virus</i>				
<i>Influenza A, H3N2 (A/Hong Kong /8/68)</i>	AATCC 100	Microbiotest # 639-119	99.96% ($3.50 \pm 0.45 \log_{10}$) @ 1 min 99.98% ($3.81 \pm 0.49 \log_{10}$) @ 5 min	Representative of the currently circulating influenza A subtype H3N2. An enveloped virus that binds to sialic acid receptors.
<i>Influenza A, H5N1 (NIBRG-14)</i>	AATCC 100	Microbiotest #639-136	99.99% ($3.95 \pm 0.43 \log_{10}$) @ 5 min	Avian influenza. High pandemic risk respiratory pathogen. An enveloped virus that binds to sialic acid receptors
<i>Influenza A, H1N1 (A/PR8/34)</i>	AATCC 100	Microbiotest #639-132	99.0% ($2.00 \pm 0.40 \log_{10}$) @ 1min 99.68% ($2.50 \pm 0.28 \log_{10}$) @ 5 min	Representative of the currently circulating influenza A subtype H1N1. An enveloped virus that binds to sialic acid receptors.
<i>Herpes Simplex Virus</i>	AATCC 100	Microbiotest # 639-108	99.35% ($2.19 \pm 0.32 \log_{10}$) @ 30 sec ≥99.41% ($\geq 2.23 \pm 0.19 \log_{10}$) @ 1 min *	An enveloped virus surrogate for all sialic acid receptor binding viruses.
<i>Rhinovirus</i>	AATCC 100	Microbiotest # 639-105	96.61% ($1.47 \pm 0.29 \log_{10}$) @ 1 min 97.76% ($1.65 \pm 0.23 \log_{10}$) @ 5 min	A cause of the common cold. Binds to ICAM-1 receptor and is representative of non-enveloped viruses.
<i>Coronavirus (229E)</i>	AATCC 100	Microbiotest # 639-106	≥99.99% ($\geq 4.86 \pm 0.14 \log_{10}$) @ 1 min * ≥99.99% ($\geq 4.86 \pm 0.20 \log_{10}$) @ 5 min *	Internationally used by researchers as a surrogate for the SARS causing <i>Coronavirus</i> .
<i>Measles</i>	AATCC100	Microbiotest # 639-107	≥99.999% ($\geq 5.00 \pm 0.27 \log_{10}$) @ 1 min * ≥99.99% ($\geq 4.95 \pm 0.26 \log_{10}$) @ 5 min *	Measles, a respiratory pathogen, also representative of enveloped viruses.

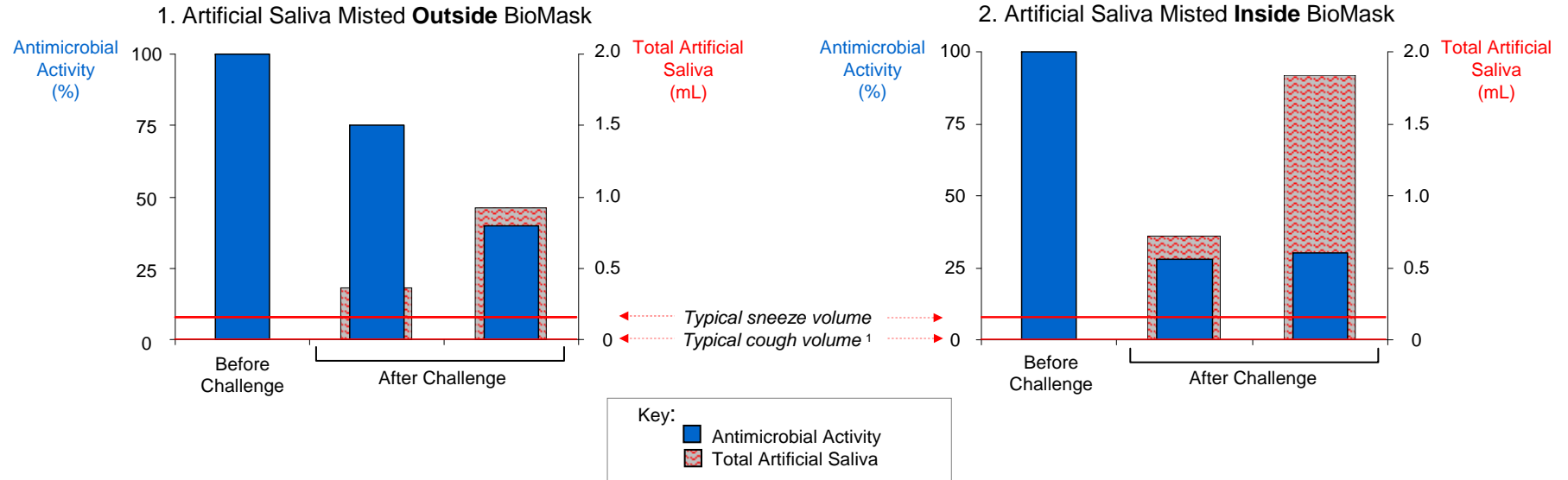
* No Virus Detected. "Amount of Pathogens Killed" calculated relative to the amount of microbes in the liquid control. Presented with 95% confidence interval. All of the above validation tests were conducted in compliance with Good Laboratory Practice (GLP) regulations and pursuant to International Standards by certified independent laboratories in the USA. See Appendix for a description of Test Standards used.

Microbial - **Contact Kill Rates** of Live Bacteria and Fungi/Yeast

Description	Test	Laboratory Study #	Results	Comments
Bacteria				
<i>Streptococcus pneumonia</i>	AATCC 100	Microbiotest # 639-111	63.17% ± 15.1% @ 10 min 81.25% ± 1.90% @ 60 min	A respiratory pathogen representative of 'Gram positive' bacteria.
<i>Haemophilus influenzae</i>	AATCC 100	Microbiotest # 639-112	65.9% ± 5.57% @ 10 min 86.47% ± 2.21% @ 60 min	A respiratory pathogen representative of 'Gram negative' bacteria.
MRSA	AATCC 100	Microbiotest # 639-113	99.9% ± 0.18% @ 30 min 99.94% ± 0.02% @ 60 min	Methicillin Resistant <i>Staphylococcus aureus</i> , a 'Gram positive' bacterium, is an important nosocomial pathogen.
<i>Mycobacterium terrae</i>	AATCC 100	Microbiotest # 639-114	88.97% ± 7.60% @ 10 min 85% ± 1.44% @ 60 min	Internationally used by researchers as a surrogate for <i>Mycobacterium tuberculosis</i> (TB).
<i>Staphylococcus epidermidis</i>	AATCC 100	Microbiotest # 639-126	99.84% ± 0.05 @ 4 hours 99.99% ± 0.01 @ 8 hours 99.93% ± 0.04 @ 24 hours	A 'gram-positive' bacterium responsible for human odour and specific skin infections.
Yeast & Fungi				
<i>Candida albicans</i>	AATCC 100	Microbiotest # 639-115	79.78% ± 5.03% @ 180 min	Diploid fungus, a form of yeast. Used as a representative yeast in standard tests to evaluate anti-microbial agents.
<i>Aspergillus niger</i>	AATCC 100	Microbiotest #639-116	92.63% ± 1.04% @ 60 min 84.42% ± 1.31% @ 180 min	A fungus. Used as a representative fungus in standard tests to evaluate anti-microbial agents.
<i>Trichophyton rubrum</i>	AATCC 100	Microbiotest # 639-127	94.58% ± 3.34 @ 4 hours 99.96% ± 0.04 @ 8 hours 99.99% ± 0.00% @ 24 hours	A dermatophyte which is the most common cause of Athletes Foot (tinea pedis) and other fungal skin infections

"Amount of Pathogens Killed" calculated relative to the amount of microbes in the liquid control. Presented with 95% confidence interval. All of the above validation tests were conducted in compliance with Good Laboratory Practice (GLP) regulations and pursuant to International Standards by certified independent laboratories in the USA. See Appendix for a description of Test Standards used.

BioFriend™ BioMask Maintains Antimicrobial Activity under Increasing Saturation with Artificial Saliva
 Activity against Influenza A (Relative to Non-Active Control)



Artificial saliva was applied to the outside or the inside of the BioFriend™ BioMask to simulate two situations: 1- A healthy person wearing the mask while being exposed to coughs and sneezes from the environment, and 2- An infected person coughing and/or sneezing while wearing the mask. The volumes of artificial saliva applied in this study are beyond what is expected to be faced during normal use. Following application of artificial saliva the BioMask was exposed to a single high dose of Influenza A H3N2 virus – equivalent to approximately 3.5-70x the amount of viruses in a normal sneeze. After 15 minutes of contact surviving infectious virus was extracted and measured.

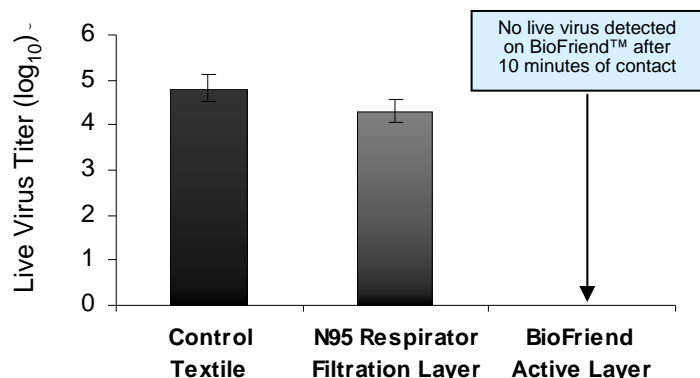
The BioFriend™ BioMask™ is active even under high saturation with artificial saliva. Antimicrobial activity was maintained after being challenged with the equivalent of 5-10 full sneezes at point-blank range.

¹ Note. The study was conducted on representative test samples cut from the BioMask (~10% of total breathable area). The actual typical volume of a sneeze is 1.75 ml and cough 0.044 ml. Study conducted with Microbiotest. Report Number 639-129

Comparative Contact Kill Rates

BioFriend™ vs Leading N95

Live Influenza A (H3N2) after 10 Minutes of Contact



Laboratory Study: Microbiotest # 639-121
 Test Method: (modified) AATCC100
 Challenge: Influenza A A/Hong Kong/8/68 (H3N2)
 Titer: 7.15 log₁₀ TCID₅₀/ml
 Volume: 0.5 ml
 Contact Time: 10 min

No surviving virus was recovered from the BioFriend™ active layer after 10 minutes of contact with live Influenza A viruses, whereas 50,000 viruses remained alive within the layers of the leading N95 mask at the end of the same period.

Appendix – Description of Test Methods

Biocompatibility

Tested pursuant to *ISO10993: Biological Evaluation of Medical Devices*:

Cytotoxicity

The agar overlay test is used to evaluate the cytotoxicity of diffusible components from materials on cell culture monolayers to provide evidence of biocompatibility. This test was conducted pursuant to *ISO 10993-Part 5: Tests for Cytotoxicity – In Vitro Methods*. For this test, samples of test material are applied directly to cell culture monolayers covered with an agar overlay. After incubation for a set period the cell monolayers are evaluated for cytopathic effects.

Irritation

The primary skin irritation test is designed to determine the dermal irritation potential of the test materials on the skin and was conducted pursuant to *ISO 10993-Part 10: Tests for Irritation – In vivo*. The procedure involves applying pre-wetted test and control materials to the shaved skin of rabbits. After a set exposure period, patches are removed, and observations for skin irritation are made at varying time points.

Sensitization

The *Repeated Patch Dermal Sensitization Test - Buehler Method* is used to evaluate the allergenic potential or sensitizing capacity of test materials and was conducted pursuant to *ISO 10993-Part 10: Tests for Irritation – In vivo*. The procedure involves guinea pigs being repeatedly applied with patches of the test or control materials over a set period, followed by an extended rest period, after which animals are re-patched. Any irritation response observed indicates a delayed dermal sensitization has occurred.

Extractables

Release of substances from BioMask under dynamic flow conditions, representative of air flow during use was assessed in a custom study in accordance with the principles of *ISO 10993-Part 18: Chemical Characterisation of Materials*. Humidified air of a known flow-rate was passed through test materials held in a fixture and exiting air sampled at discrete time-points for metals and organics. Released substances were identified and quantified against known standards.

Appendix – Description of Test Methods

Bacterial Filtration Efficiency

Tested pursuant to *European Norm EN 14683: 2005 Surgical Masks - Requirements and Test Methods*. This test evaluates the percentage efficiency by which facemask materials restrict bacteria from passing through. Mask materials are subjected to an aerosol challenge of live *Staphylococcus aureus* bacteria at a constant flowrate of 28.3 L/min. Aerosol particles are in the size range of 1 to 5 microns with an average diameter of 3 micron. Bacteria is collected with a sieve sampler with and without mask materials in place and percentage efficiency calculated.

Virus Filtration Efficiency

Tested pursuant to *ASTM F2101: Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus*, with standard modifications for virus. This test evaluates the percentage efficiency by which facemask materials restrict virus from passing through. Mask materials are subjected to an aerosol challenge of virus at a constant flowrate of 28.3 L/min. Aerosol particles are in the size range of 0.78 to 9.0 microns with an average diameter of 1.8 micron. Viruses that pass through are collected with a single stage sampler and recovered virus assayed by inoculation into host cells. Percentage filtration efficiency is then calculated.

Sub-micron (0.1 μm) Particulate Filtration Efficiency

Tested pursuant to *ASTM F2299: Standard Test Method for Determining the Initial Efficiency of Materials Used in Medical Face Masks to Penetration by Particulates Using Latex Spheres*. Mask materials are subjected to an aerosolized challenge of a solution of water and latex spheres with a mean diameter of 0.1 micron at a constant flowrate of 28.3 L/min. Particles are counted using a laser particle counter from the upstream and downstream flows and percentage efficiency calculated.

Breathability (Differential Pressure)

Tested pursuant to *European Norm EN 14683: 2005 Surgical Masks - Requirements and Test Methods*. Differential pressure is measured using a device which measures the pressure differential to draw air through a measured surface area at a constant air flowrate. Mask materials are placed in a special test fixture and the pressure on both the inlet and exit sides of the mask is measured when air is forced through at a flowrate of 8 L/min. The differential pressure drop across the mask material is then measured.

Fluid Resistance

Tested pursuant to *ASTM F1862: Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)*, as referenced in EN14683. This test method involves conditioning mask in high humidity before testing to simulate actual use. Mask materials are then placed in a special holder and are subjected to a 2 ml horizontal shot of synthetic blood from a distance of 30 cm. The inside of the mask is then visually inspected to check for penetration into the inside of the mask. Surgical masks are tested at three velocities corresponding to the range of human blood pressure 80, 120, and 160 mmHg. Fluid resistance is achieved when no liquid penetration is detected on the inside of the mask at 120 mmHg.

Flammability

Tested pursuant to *US Code of Federal Regulations 16 CFR Part 1610: Standard for the Flammability of Clothing Textiles*. The test method specified by this standard is a 45° angle flammability test that calls for ignition of the face of the fabric and then measures the time required to burn a specified distance of 5 inches. Longer burn times indicate lower flammability characteristics. Class 1 fabrics take longer than 4 seconds to burn the specified distance and are considered to exhibit normal textile flammability.

Microbial Contact Kill -- Antimicrobial Activity Testing

Tested pursuant to *AATCC Test Method 100-2004 Assessment of Antibacterial Finishes on Textile Materials*. This test evaluates the effectiveness of the BioFriend™ antimicrobial textile to inactivate microorganisms on direct contact. The procedure involves challenging pieces of textile with a mist of the test microorganism and holding for specified contact times. After completion of the holding periods, surviving microorganisms are extracted, assayed for, and reduction of microorganism relative to the titer of the challenge calculated.

Appendix – Independent Laboratories

Microbiotest

<http://www.microbiotest.com/>

Microbiotest is one of the leading airborne microorganism research facilities in the world, with the most technologically advanced aerobiology laboratory in the private sector. A combination of their staff's expertise in regulatory compliance and their proficiency in performing GLP antimicrobial efficacy studies comprise the foundation of Microbiotest's outstanding testing services that has earned client trust and respect for over 20 years. Microbiotest is recognised by the FDA as an independent contract laboratory for performing Agency-required testing, and is experienced in testing to regulatory requirements set by the US EPA, FDA, and agencies within the European Community, Canada and Australia. Microbiotest is based in Washington, DC, USA.

Nelson Laboratories

<http://www.nelsonlabs.com/>

Nelson Laboratories provide extensive high quality GLP test services to manufacturers in the medical device, pharmaceutical and nutraceutical industries. Nelson Laboratories has been serving the medical device and pharmaceutical industries since 1985 and employ more than 320 scientists and staff, among which are more than 130+ degreed scientists are 50+ registered and specialist microbiologists (National Registry of Microbiologists). The laboratory is FDA registered and third-party certified to ISO 9001:2000 and ISO 17025. Nelson Laboratories is based in Salt Lake City, Utah, USA.

Wuxi AppTec

<http://www.wuxiapptec.com/>

Established in December 2000, WuXi AppTec is a leading global pharmaceutical, biotechnology and medical device R&D outsourcing company with operations in both China and the United States. WuXi AppTec provides broad laboratory and manufacturing services, including comprehensive GLP/GMP-compliant testing, contract research and development, and specialized cGMP manufacturing services. Wuxi AppTec facilities are FDA registered; additional qualifications include ISO certification and AAAALAC accreditation.

Important Information – BioMask Summary of Independent Test Results

Please contact us directly for copies of the studies described herein. For more information on the BioMask and its intended use in your jurisdiction, please see packaging details or visit the Filligent website at www.filligent.com. Nothing in this document should be construed as expanding the intended use of the BioMask beyond that permitted by the regulatory certifications and / or approvals that apply to the BioMask in your jurisdiction.

Although every effort has been made to ensure their accuracy and completeness, these test results may contain technical inaccuracies or typographical errors, and Filligent or its Representatives may revise them without notice. Filligent or its Representatives may make improvements and/or changes to the BioMask at any time without notice.

These results are provided "as is", without any representation or warranty, express or implied, of any kind including warranties of accuracy, completeness of information, merchantability, noninfringement or fitness for any particular purpose. Some jurisdictions do not allow for the exclusion of implied representations or warranties, so those exclusions may not apply to you. Reliance on any of these results shall be at your sole risk. In no event will Filligent or its Representatives be liable to any party for any direct, indirect, incidental, special or consequential damages resulting from the use of or reliance upon any of these results.

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