



## Frequently-Asked Questions

### 1. What **viruses** and **bacteria** does the BioMask detect, trap and **kill**?

The BioMask detects and traps **most bacteria and viruses** and kills them within minutes. It particularly **targets and destroys** those that cause infectious **respiratory diseases**, such as:

- ▶ **Influenza Viruses** - which include seasonal and potential pandemic strains like **H5N1 (bird flu)**
- ▶ **Common cold viruses and other respiratory viruses** - which include Rhinovirus and SARS
- ▶ **Mycobacteria** - which include the agents causing tuberculosis and their drug-resistant forms
- ▶ **Bacteria-causing pneumonia** - which includes *Streptococcus pneumonia*
- ▶ **Measles virus**

It is also effective against the germs that cause **non-respiratory** diseases, such as **MRSA** (methicillin-resistant *Staphylococcus aureus*), a leading cause of hospital-acquired infections, and **Herpes Simplex Virus**. The active BioFriend™ textile is shown to kill most germs within minutes of contact. For further technical details, see Summary of Independent Laboratory Testing.

### 2. **How** does the BioMask **work**? What is the active ingredient?

In general, the BioFriend™ textile **CAPTURES** pathogens by mimicking the sites on human cells to which they normally attach, and **DESTROYS** them by **disrupting their surfaces (viruses) and cell walls (bacteria)**.

Many viruses, including influenza viruses, are known to bind to human cells through oligosaccharides attached to cell membrane glycolipids or glycoproteins, and, specifically, to a terminal sialic acid residue on a surface oligosaccharide of the cell membrane. The binding agent in the BioFriend™ textile mimics the binding action of sialic acid on influenza viruses. This technique is often called 'molecular mimicry.'

A safe component approved by the FDA functions as the binding agent. This component creates a negative charge at the molecular level, attracting microbes through electrostatic forces. Copper and zinc ions then kill the microbes. These metal ions kill pathogens by disrupting their viral envelope and bacterial walls, as well as by creating an ion imbalance in the bacteria or virus that inhibits normal metabolism.

### 3. **Can the microbe-killing mechanisms or ingredients harm me?** If the BioMask can kill germs so effectively, why doesn't it harm me?

**The BioMask is deemed safe when used as intended.** It has met or exceeded ISO standards for biocompatibility. See FAQ 4 (below). The anti-microbial **components**

**have been approved for biomedical use by the FDA** in sutures and contact lenses, for example. **Copper and zinc are essential to human health** and are an important part of a human being's daily nutritional intake, because they contribute to the function of numerous essential processes in the body, including wound healing.

Multi-cellular higher organisms, such as humans, possess mechanisms which bind or transport away copper and zinc ions. Single-cell organisms, such as bacteria and viruses, don't possess such efficient mechanisms and are easily killed by miniscule amounts of these compounds. Therefore, **copper and zinc are very toxic to bacteria and viruses, but not to humans.**

4. What **tests** have been conducted to ensure that the BioMask is **safe** for humans?

The BioMask achieved CE certification on 13 February 2009. **Filligent has met or exceeded the requirements of CE certification relating to human safety** for a device of this kind. Independent studies of the BioMask confirm that, when assessed in terms of all the major routes of exposure, oral, dermal and inhalation, the active ingredients used in the BioMask cause no harmful effects on isolated human cells.

Pursuant to CE requirements, the BioMask has been **tested** for dermal biocompatibility following **internationally recognized standards set out in ISO10933: Biological Evaluation of Medical Devices**. Tests were conducted to evaluate cytotoxicity to cells, skin irritation on contact, and skin sensitization after repeated contact. **No cytotoxicity, irritation or incidence of sensitization** was observed.

For further technical details, see Summary of Independent Laboratory Testing.

5. What is the **CE mark** and the significance of CE certification?

The **CE (Conformité Européenne) mark** is a conformity mark required to market certain products in the European Community. The CE mark is mandatory for certain product groups to indicate **conformity with the essential health and safety requirements set out in European Directives**. The BioMask has achieved certification pursuant to the European Community's Medical Devices Directive 93/42/EEC, meaning that Filligent has **met the stringent EU requirements for design, efficacy and safety** for this type of medical device.

6. Can such an anti-microbial product **reduce my or my family's immunity**?

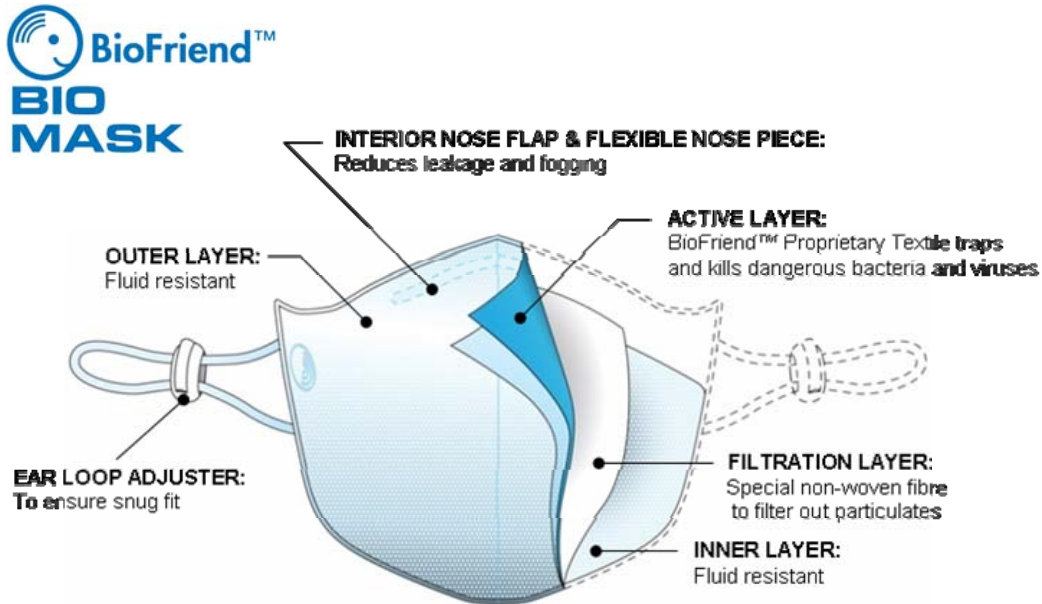
No. The immune system is inside the body and is activated only when pathogens enter **inside** the body. The BioMask keeps germs **outside** the body and kills germs **before** they enter the body. Therefore, it has **no effect on the body's immune system.**

7. Can the BioMask create **resistant germs**?

Germs can only develop defense mechanisms (i.e., resistance mutations) when proliferating **inside** the human body in the presence of a drug. The BioMask keeps the germs **outside** the body and kills microbes **before** they can enter the body. Therefore, use of the BioMask **does not result in microbes developing resistance** to either the BioMask or drugs.

8. How does the BioMask **compare** with ordinary face masks? With N95s?

Typical face masks (including **standard surgical masks and N95s**) **do not kill airborne pathogens**. They are **based on a passive mechanical filtration design**, where the live bacteria and viruses in droplets are drawn, by the breathing of the wearer, *on to* the surface of the mask. Sometimes live micro-organisms are also drawn *in to* the mask material layers, where the pathogens are captured by simple mechanical filtering. Many more are too small to be captured and are inhaled by the wearer. **The microbes on the surface of the mask and/or trapped inside the mask can stay alive for many hours**. These live pathogens can now be transmitted to the wearer and other people.



As part of the CE testing process, the BioMask was sprayed with live aerosolized Influenza A virus equivalent to 50 times the amount contained in a normal sneeze. (Bird flu is a strain of the Influenza A virus.) **The BioMask killed this massive viral load**, with more than 99.9% of the viruses killed after less than one minute. Tests were conducted on other key pathogens, with similar results. In a direct comparison between the BioMask and the leading N95, **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**. For further technical details, please consult our Summary of Independent Laboratory Testing.

In the case of a standard surgical or N95 mask, cross-contamination can easily occur by touching the microbe-laden mask. This is a particular risk for mask disposal. Ill-fitting, uncomfortable or poorly-ventilated masks exacerbate handling and cross-contamination.

Filligent's **BioMask** uses a special **"intelligent filtration" system**, designed specifically to **overcome these major drawbacks** and presents a significant level of increased protectiveness. The BioMask is fabricated from a **scientifically designed and tested** multilayer material which has in its internal structure a unique active layer which has highly targeted anti-microbial properties. This active layer aggressively detects, traps, and then rapidly kills pathogens without affecting airflow.

A high density non-woven textile layer behind the active layer also captures any pathogens that may happen to penetrate beyond the active layer. Any such pathogens are then held in close proximity to the BioFriend™ textile and killed rapidly.

When compared to the N95, the BioMask is far superior in terms of comfort, breathability AND efficacy: **The mechanical filtration of the BioMask is as effective as the N95's PLUS the BioMask kills microbes.** Testing with an aerosol challenge of influenza A virus showed the BioMask to have comparable mechanical filtration to the N95 with >99% of viruses filtered. Because N95s rely entirely on physical barrier and filtration design, they are very tight-fitting, uncomfortable and hard to breathe in.

9. Is the BioMask **breathable** and **comfortable** to wear for long periods?

**Yes, it provides all-day comfort and use.** The intelligent filtration system in Filligent's BioMask allows for a mask design where pressure drop across the face mask layers is kept low, making the mask **highly breathable. Heat and moisture do not build up**, allowing for comfortable wear over long periods. By contrast, N95 masks are noted for causing hypoxia (oxygen deprivation) in wearers as there is a high pressure drop across the mask layers. These masks easily become hot and saturated with moisture which further reduces breathability.

10. **How long** can the BioMask be worn?

The BioMask is effective for **all-day wear**. Due to its ability to kill pathogens, the BioMask is **self-sanitizing** and can be worn, without replacement, for an entire day, unless excessively soiled. Other masks are not self-sanitizing and are therefore easily prone to contamination when handled or wet, meaning they must be replaced 6-8 times a day, on average.

11. Is the BioMask **effective when wet**? Can I wash and reuse it?

**Wetting the BioMask will not affect its safety or efficacy.** Do not wash and reuse the BioMask. See packaging for intended use.

12. Does the BioMask come in **child** sizes?

In non-E.U. markets, we sell a child-size BioMask.

Children play a key role in disease transmission. Almost everyone has close contact with a child, while most children are in close contact with each other. Halting disease transmission among children is a critical component of disease containment.

13. Can the BioMask provide **protection** during an influenza pandemic, such as bird flu?

The BioMask is **effective against influenza viruses, including bird flu and potential pandemic strains.** It can be considered a vital tool in any pandemic toolbox. It should be used in conjunction with good hygienic practices, such as thorough and frequent hand sanitization.

14. What **hospitals** have adopted or bought it? Where can I **buy** it?

The BioMask will be available for consumer retail purchase at leading drugstore chains in China and Hong Kong during the first half of 2009. The BioMask will also be available through established medical device distributors in Asia and Europe in the same period. Otherwise, please [contact.us@filligent.com](mailto:contact.us@filligent.com) if you are interested in purchasing the BioMask.

15. How can the BioMask help **humanitarian efforts**?

The BioMask can provide advanced **protection** during man-made and natural disasters, **where there is a high risk of infection**.

It is the only commercially available mask that detects, traps and then rapidly **kills bacteria and viruses** on contact, while retaining high levels of breathability and comfort. Its anti-microbial properties also **reduce** the (i) **cross-contamination** of disease between people and (ii) **re-contamination** of the wearer, caused by ordinary face masks.

The BioMask also provides a high level of protection from the **inhalation of fine particulates** (greater than 0.1 microns in size) such as dust and aerosolized debris.

Please contact Filligent at [contact.us@filligent.com](mailto:contact.us@filligent.com) with any other questions or comments.

**Biocompatibility - Safety**

Description	International Test Standard	Laboratory Study #	Results	Comments
1 Cytotoxicity – Agar Overlay	ISO19033	Nelson # 430998	Average Score: 0 - no cytotoxicity	The BioFriend™ BioMask has no diffusible components that cause any harmful effects on isolated human cells.
2 Irritation – Primary Skin	ISO19033	Nelson # 431594	After 4 hours contact: Non-irritant - no skin irritation observed.	The BioFriend™ BioMask causes no irritation when worn against the skin.
3 Sensitisation- Buehler Method	ISO19033	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.

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 FM-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
4 Bacterial Filtration	EN14683	Nelson # 431000	99.7% ± 0.1 % filtration efficiency	Filters >99.9% of airborne bacteria.
5 Viral Filtration	Modified ASTM F2101	Microbiotest # 639-110	>99.9% filtration efficiency	Filters >99.9% of airborne viruses.
6 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.
7 Breathability (Differential Pressure)	EN14683	Nelson # 431000	Delta P of 2.22 ± 0.1(mm H <sub>2</sub> O/cm <sup>2</sup> )	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. <sup>1</sup>
8 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.
9 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. All tests were conducted on the FM-200 BioMask. See Appendix for a description of Test Standards used.

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

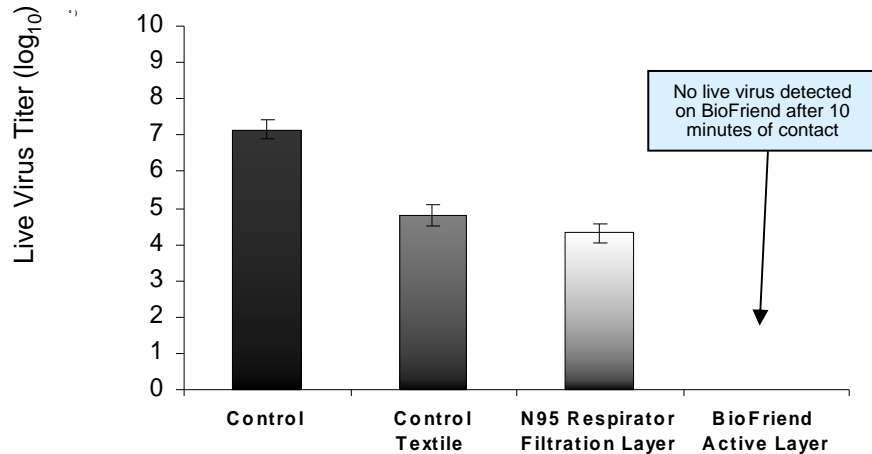
Microbial - **Contact Kill Rates** of Live Pathogens

Description	Test	Laboratory Study #	Results	Comments
<b>Virus</b>				
10	<i>Influenza A</i>	AATCC 100	Microbiotest # 639-119 99.96% (3.50 ± 0.45 log <sub>10</sub> ) @ 1 min 99.98% (3.81 ± 0.49 log <sub>10</sub> ) @ 5 min	Highest pandemic risk respiratory pathogen. An enveloped virus that binds to sialic acid receptors. H3N2 is used as a surrogate for all influenza A viruses, including H5N1(Bird Flu).
11	<i>Herpes Simplex Virus</i>	AATCC 100	Microbiotest # 639-108 99.35% (2.19 ± 0.32 log <sub>10</sub> ) @ 30 sec ≥99.41% (≥2.23 ± 0.19 log <sub>10</sub> ) @ 1 min *	An enveloped virus surrogate for all sialic acid receptor binding viruses.
12	<i>Rhinovirus</i>	AATCC 100	Microbiotest # 639-105 96.61% (1.47 ± 0.29 log <sub>10</sub> ) @ 1 min 97.76% (1.65 ± 0.23 log <sub>10</sub> ) @ 5 min	A cause of the common cold. Binds to ICAM-1 receptor and is representative of non-enveloped viruses.
13	<i>Coronavirus (229E)</i>	AATCC 100	Microbiotest # 639-106 ≥99.99% (≥ 4.86 ± 0.14 log <sub>10</sub> ) @ 1 min * ≥99.99% (≥ 4.86 ± 0.20 log <sub>10</sub> ) @ 5 min *	Internationally used by researchers as a surrogate for the SARS causing <i>Coronavirus</i> .
14	<i>Measles</i>	AATCC100	Microbiotest # 639-107 ≥99.999% (≥ 5.00 ± 0.27 log <sub>10</sub> ) @ 1 min * ≥99.999% (≥ 4.95 ± 0.26 log <sub>10</sub> ) @ 5 min *	Measles, a respiratory pathogen, also representative of enveloped viruses.
* No virus detected				
<b>Bacteria</b>				
15	<i>Streptococcus pneumonia</i>	AATCC 100	Microbiotest # 639-111 63.17% ± 15.1% @ 10 min 81.25% ± 1.90% @ 60 min	<i>Streptococcus pneumonia</i> , a respiratory pathogen, is representative of 'Gram positive' bacteria.
16	<i>Haemophilus influenzae</i>	AATCC 100	Microbiotest # 639-112 65.9% ± 5.57% @ 10 min 86.47% ± 2.21% @ 60 min	<i>Haemophilus influenzae</i> , a respiratory pathogen, is representative of 'Gram negative' bacteria.
17	<i>MRSA</i>	AATCC 100	Microbiotest # 639-113 99.9% ± 0.18% @30 min 99.94% ± 0.02% @ 60 min	<i>MRSA</i> , a 'Gram positive' bacteria, is an important nosocomial pathogen.
18	<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).
<b>Other</b>				
19	<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.
20	<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.

"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. All tests were conducted on the FM-200 BioMask. See Appendix for a description of Test Standards used.

## Comparative Contact Kill Rates

**BioFriend™ vs Leading N95**  
Live Influenza A (H3N2) after 10 Minutes of Contact



Laboratory Study: Microbiotest # 639-121  
 Test Method: AATCC100  
 Challenge: Influenza A A/Hong Kong/8/68 (H3N2)  
 Titer: 7.15 log<sub>10</sub> TCID<sub>50</sub>/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 *ISO19033: 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*.

### 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*.

### 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.

## Appendix – Description of Test Methods

### 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 – Frequently-Asked Questions and 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](http://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.

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End. February 2009.