



BioVigilant Systems Frequently Asked Questions

Pharmaceutical Manufacturing

Q: How do BioVigilant's Instantaneous Microbial Detection instruments detect microbes?

A: BioVigilant's instruments detect the presence of microbes (bacteria and fungi) by measuring the intrinsic fluorescence of each individual particle, while simultaneously measuring each particle's size. The instruments are able to use the fluorescence measurement to differentiate if a particle is of biological origin (e.g., a bacterium) or if it is inert (e.g., a speck of dust) because microbes possess certain organic compounds necessary for metabolism and, when excited by a light source at certain wavelengths, these compounds fluoresce, whereas inert particles do not fluoresce. Simultaneous with this, BioVigilant's instruments measure the size of each individual particle in order to further differentiate microbes from non-viable biological substances such as cigarette smoke (which is too small to be a microbe) and pollens (which are too large to be microbes).

Q: Many instruments detect the size of particles, many detect fluorescence, and some even do each sequentially. Why is it necessary that size and fluorescence be measured simultaneously, and for each particle individually?

A: If one knows only that some particles of varying sizes exist and that some of them are biological, but does not know which specific particle is biological, it is impossible to determine if the fluorescence came from smoke, pollens, or microbes.

Q: What is a fluorophor?

A: In the context of fluorescence spectroscopy and biochemistry, the term "fluorophor" is often used. Fluorophor is any molecule which is capable of fluorescence emission. In the field of microbial detection, some of the relevant fluorophors in a microbe are a reduced form of nicotinamide adenine dinucleotides (NADH), and riboflavin. These fluorophors will emit fluorescence under laser light illumination and are used by BioVigilant's IMD instruments to do microbial detection.

Q: What is fluorescence and why is fluorescence relevant to microbial detection?

A: Fluorescence is the emission of light at longer wavelengths by a substance after it absorbs the light at shorter wavelengths. Microbes such as bacteria and fungi consist of complex organic chemical compounds such as proteins and amino acids necessary for cellular metabolism, which are capable of fluorescence emission under the excitation of a suitable light source such as laser light illumination. BioVigilant's IMD instruments detect microbes by measuring this type of fluorescence signal.

Q: Are BioVigilant's IMD instruments different from fluorescent-antibody techniques?

A: Yes. BioVigilant's IMD instruments rely on intrinsic fluorescence (also called "auto-fluorescence") emanating from fluorophors inside microbial cells, so no sample preparation is needed to detect microbes. This is in contrast with fluorescent dye antibody based techniques, whereby, in order for the microbes to be detected, the sample needs to be treated with a reagent to give out a specific fluorescence signal.

Q: What mediums can BioVigilant's Instantaneous Microbial Detection instruments sample?

A: The IMD-A samples air and is available now.

Q: What types of microbes can BioVigilant's IMD instruments detect?

A: Bacteria, mold and fungi.

Q: What are the limitations of BioVigilant's IMD instruments?

A: BioVigilant's IMD instruments cannot unambiguously determine the genus or species of the microbes they detect and they cannot detect viruses.

Q: What is the chance that two or more separate microbes will pass through BioVigilant's IMD instruments so closely together that they may inaccurately be counted as one larger particulate?

A: While such a condition is theoretically possible, in operation, it is highly unlikely in any cleanroom environment. Because airborne particles are randomly distributed in the air and they pass through the interrogation area of the IMD-A instrument at a rate of approximately one per millisecond, the chance of two separate microbes being interrogated at the same time in a relatively clean environment is not statistically high. However, when the airborne particle concentration is high enough (estimated to be greater than 100,000 particles per liter of air, which does not occur in properly operating cleanrooms), the chance of two or more particles passing through the interrogation area at the same time increases to the point of statistical significance. In this case, the detector may give erroneous particle information. Such an error is termed "coincidence error."

Q: How fast can BioVigilant's IMD instruments detect the presence of microbes?

A: BioVigilant's IMD instruments detect the presence of microbes instantaneously as the environmental air passes through the device. The determination of the presence of microbes is done on an individual particle-by-particle basis at a time period equal to the time it takes for a particle to pass through the laser beam--about 1 millisecond. The length of time it takes to sample a particular volume of air is determined by the flow rate—for the IMD-A either 0.1 CFM or 1 CFM.

Q: Do BioVigilant's IMD instruments count spores as microbes?

A: Yes. IMD instruments will detect spores and count them as viable microbes.

Q: What human intervention and sample preparation is needed in order to operate BioVigilant's IMD instruments?

A: The IMD-A can be operated either continuously, or episodically. In continuous operation, the only human action required is to turn the instrument on. In episodic operation, the instrument will have to be transported, and turned on and off.

Q: Is it necessary to have a good idea in advance of testing what microbes one is trying to count in order to use BioVigilant's IMD instruments?

A: No.

Q: What reagents, dyes, growing medium, etc. is required in order to use BioVigilant's IMD instruments?

A: None.

Q: What are the advantages of continuous monitoring, as opposed to episodic monitoring?

A: (1) Continuous monitoring and real time detection of microbes enables clean room management to take corrective measures in a timely manner if a microbe excursion happens; (2) continuous monitoring can provide trending data useful in locating the root cause a contamination problem; and, (3) continuous and real time environmental monitoring facilitates the implementation of FDA's PAT initiative (Process Analytical Technology).

Q: Are there any recent technical advances that have made it possible for BioVigilant to create IMD instruments?

A: Extensive efforts in bio-agent sensor technology for military and homeland security applications provided valuable scientific data and technical materials for the development of IMD instruments. Additionally, BioVigilant was fortunate to be able to take advantage of recent advances in laser technology in the IMD design.

Q: Can BioVigilant's IMD instruments tell difference between live and freshly killed microbes?

A: The answer to this question depends on how much fluorescence remains in the killed microbe. If a significant amount of fluorophors is intact, the dead cell may continue to fluoresce sufficiently to be categorized as a microbe. If, however, the microbe has been dead for a while or was killed by a sanitizing technique that uses bleach or hydrogen peroxide that de-natures the fluorophors in the cell, the amount of fluorescence remaining will be below the threshold required for the IMD instrument to count the particulate as a microbe.

Q: In what ways are BioVigilant's IMD instruments preferred to conventional plate culturing methods and "rapid methods"?

A: The primary ways in which BioVigilant's IMD instruments are preferred to conventional plate culturing methods and rapid methods are: 1) time from measurement to results is virtually zero; 2) monitoring can be continuous as opposed to episodic; 3) in most cases, there is minimal or no time required to set up the sample; and, 4) there is minimal human intervention.

For more information, contact BioVigilant Systems at (520)292-2342 or info@biovigilant.com.

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