



Know Now. Act Now.  
[www.biovigilant.com](http://www.biovigilant.com)



## Real-Time Investigation Services Using Instantaneous Microbial Detection

### Introduction

In the pharmaceutical industry, product contamination poses a serious risk to manufacturing operations. If an out-of-specification event occurs, finding the root cause, taking remediation steps, and getting the manufacturing line back to full operational levels is critically important. Downtime on any manufacturing line can lead to a significant impact on the financial performance of the company.

Currently, the investigative tools and processes available to most pharmaceutical companies are slow, time consuming and often ineffective at shedding light on the source of contamination.

The IMD-A<sup>®</sup> 350 system is aptly designed for conducting investigations when out-of-specification findings occur. With the ability to detect inert and biologic aerosol particles simultaneously and in real time, the IMD-A system is an excellent assessment tool when conducting investigations. The instrument acts like an aerosol “sniffer” evaluating aseptic conditions in the impacted controlled environment, pointing investigators to possible causes so corrections can be made quickly.



### Background

Instantaneous Microbial Detection™ technology was invented by Azbil BioVigilant, Inc. and is utilized by the IMD-A 300 and IMD-A 350 systems to measure inert and biological particles present in an environment. The IMD-A system does not rely on microbial growth for detection, but leverages advanced optical detection technologies that are capable of detecting airborne microbes

instantaneously, displaying those results in real-time. The IMD-A system can detect bacteria, yeast, mold, vegetative cells and spores without the need to culture the microorganisms on media, thereby increasing the accuracy and speed of the results obtained. Currently, a number of manufacturing companies employ the IMD-A system as a real-time microbial monitor.

### How the Service Works

Azbil BioVigilant will provide your organization with one IMD-A system and up to 30 hours of application support for an emergency investigation.

Here's how it works:

- 1) Azbil BioVigilant sends an IMD-A instrument to the site of the investigation;
- 2) An Azbil BioVigilant Field Applications Scientist arrives for briefing on the event;
- 3) The Field Applications Scientist, accompanied by site sponsor, collects data in affected area;
- 4) Data sets are collected using the IMD-A system in conjunction with customers' existing processes;
- 5) An analysis of data sets is conducted to help determine root cause of event and determine where future risk may be present.

### Contact Us

Please contact your Azbil BioVigilant sales executive at 520-292-2342 to learn more or for investigation service pricing and availability.

IMD<sup>®</sup>, IMD-A<sup>®</sup>, PHARMAMASTER<sup>®</sup>, BIOVIGILANT<sup>®</sup>, the BioVigilant logo, and the term Instantaneous Microbial Detection™ are the trademarks or registered trademarks of BioVigilant Systems, Inc. in the United States and/or other countries. Other names or brands may be the property of others. Information in this document is subject to change without notice. While the information contained herein is believed to be accurate and reliable, BioVigilant Systems, Inc., assumes no responsibility for errors or omissions.

©2012 BioVigilant Systems, Inc. All rights reserved. Printed in U.S.A.