

Applications Concept:

Using the IMD-A® System for Cleanroom Materials Characterization

Major Benefit:

- Improved Awareness and Control of Cleanroom Environments

Purpose

The purpose of this document is to help guide material characterization testing which investigates the particulate shedding of commonly used cleanroom materials during typical use, to aid in their selection, and to gain a greater knowledge and control of one's cleanroom environment.

Introduction

Various materials are present in controlled environments, such as pharmaceutical or food and beverage manufacturing areas. These materials may be part of the manufacturing process, as is the case with a polystyrene bag for example, or may be used in critical environments, such as with gloves and wipes. Use of these materials can result in significant particle generation. Therefore, characterization of such materials is valuable in understanding a controlled environment and the particles therein.

Materials can vary widely in their particle shedding tendencies. Manufacturers may report material particulate levels, often in units of particles per square meter, which can be useful in selecting low particulate shedding cleanroom wipes and gowns. Such information is not provided for all materials; however, and when provided, may not supply an adequate measure of the likelihood or risk of the material to introduce particles into a controlled environment.

IMD-A Systems: Ideal Tools for Material Characterization Testing

The IMD-A 300 and IMD-A 350 systems are excellent tools for material characterization testing in cleanroom environments. Utilizing features such as synchronized data and video playback, it is possible to investigate the source of increased particulate counts in one's environment. Furthermore, with real-time reporting of inert and biologic counts, information on an activity or material can be obtained immediately.

Azbil BioVigilant's IMD-A systems detect the presence of airborne microbes continuously and in real-time, providing the following benefits:

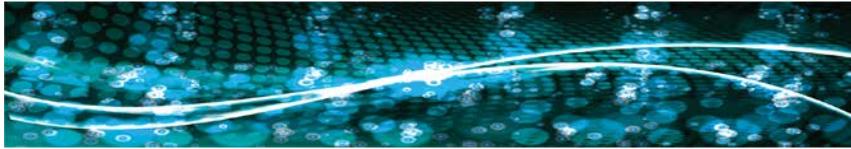
- Measure particle number, size and biologic status simultaneously
- Require no staining or reagents and minimal human intervention
- Report real-time results with the PharmaMaster® software interface
- Provide video camera and synchronized data playback function
- Offer increased sensitivity, as compared to traditional methods, with the ability to detect viable and viable but non-culturable microbes

Materials

As the IMD-A system is capable of providing real-time data on both inert and biologic particles, materials tested should be prepared according to typical use. If materials, such as cleanroom gowns, are purchased pre-packaged sterile and used as received, no additional sterilization may be required. If a material is typically sterilized before use, such as with cleanroom paper, the material should be sterilized using standard procedures. The goal of this study is to determine the potential of a material to introduce particles into a controlled environment. Please contact Azbil BioVigilant's Applications team or your sales executive for additional assistance with material testing studies.

Warnings and Precautions

1. Do not spray any liquids into the IMD-A inlet, or a sampling tube or isokinetic probe connected to the IMD-A inlet. Liquids inside the instrument can damage the optics and electronics. Please refer to the IMD-A System User Manual for a detailed list of warnings and precautions.
2. Ensure that any stainless steel tubing or probes are properly grounded to prevent the static electric buildup of particles on these surfaces. Upon release, such particles may inaccurately contribute to the particle levels measured for a material.
3. Perform testing in a clean and characterized environment such as an isolator or biological safety cabinet.



4. If testing is performed in a laminar flow environment utilize the IMD-A isokinetic probe with stand during testing.

Procedure

Many procedures are possible when performing material characterization testing in a given environment. Such procedures depend heavily on one's environment, the typical use of tested materials, and the equipment on hand. The following is a suggested procedure to provide guidance and initiate thought on such testing. Regardless of the procedure utilized, it is important to ensure that the IMD-A system and any accessories, such as tubing and an isokinetic probe, are clean before use so as not to introduce any unwanted particles during testing. Please refer to the IMD-A System/PharmaMaster User Manual and/or Customer Evaluation Protocols Section 10 for more detailed information on the use of the IMD-A and PharmaMaster software.

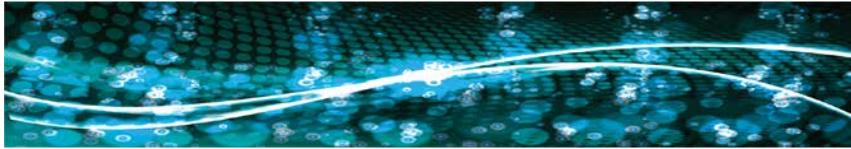
Important note: Materials should be tested in a manner most akin to common usage in your environment. In the tests performed by Azbil BioVigilant, materials were waved over the IMD-A isokinetic probe inlet for three minutes, three times each. Materials such as cleanroom gloves were removed from their packaging and waved over the probe inlet directly. However, when designing your material characterization study, keep common preparation/sterilization and usage of tested materials in mind. For example, if gloves are wiped down with IPA before any operations are performed, this preparation step should be maintained before testing.

1. It is important to perform materials testing in a clean environment, such as an isolator or biological safety cabinet, where background counts are low enough so as not to interfere with the results obtained.
2. If testing is performed in a laminar flow environment, place the IMD-A isokinetic probe with stand (**Figure 1**) into the isolator, biological safety cabinet, or other clean and controlled environment.



Figure 1: IMD-A 350 isokinetic probe with stand

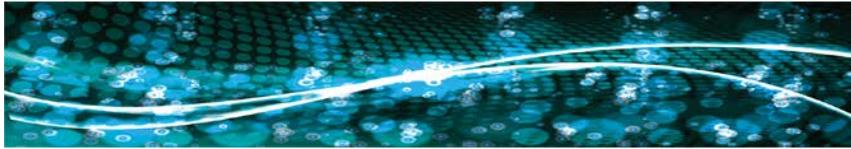
- a. Ensure that the isokinetic probe is clean and dry before use by cleaning with isopropyl alcohol or another appropriate agent.
- b. Note: If the IMD-A system can be placed directly into the sampling, non-laminar flow environment, an isokinetic probe or additional tubing may not be required.
3. If required, for example due to the use of the isokinetic probe, connect Bev-A-Line[®] tubing to the IMD-A inlet.
 - a. Ensure that the Bev-A-Line tubing is clean before use. Note: If liquid is introduced into the tubing during typical cleaning procedures, ensure that the tubing is completely dry before connecting to the IMD-A system.
4. Follow the IMD-A and PharmaMaster startup procedures described in the IMD-A/PharmaMaster User Manual to turn on the IMD-A system and open the PharmaMaster software.
5. Run the IMD-A cleaning process as detailed in the User Manual.
 - a. Note: If tubing is being used for sampling, attach a HEPA filter to the end of the tubing as opposed to the IMD-A inlet prior to running the cleaning process.
 - b. To verify that the tubing is clean and free of particles, run a short one- to two-minute sample on the IMD-A system with the HEPA filter still attached to the end of the tubing. No counts should be detected during this sample. If counts are obtained, replace the tubing with clean tubing and repeat the cleaning process and verification steps.
6. After the cleaning process has been completed and before removing the HEPA filter, turn off the IMD-A by clicking on the IMD Power button in the PharmaMaster interface.



- a. When the IMD Power button is clicked on in the PharmaMaster interface, air is drawn through the system even when the system is not sampling. Clicking the IMD Power off will thus prevent potentially dirty air from entering the IMD-A system upon removal of the HEPA filter and, if necessary, attachment of tubing to the isokinetic probe.
7. If utilizing an isokinetic probe, connect the Bev-A-Line tubing from the IMD-A inlet to the isokinetic probe.
8. Turn on the IMD-A system by clicking on the IMD Power button in the PharmaMaster interface.
9. Take a **background sample** of the biological safety cabinet/isolator for the desired time/volume of air by clicking on the Sample button in the PharmaMaster interface.
 - a. The background run will provide information on the level of counts present in the testing environment.
 - b. A background sample equivalent in time/volume to sample runs is recommended.
 - c. Select the desired mode of sampling using either Point Manager or Continuous Manager. The use of Point Manager may simplify testing and data analysis as samples will stop automatically after reaching the set time/volume of air. If using Continuous Manager, the sample must be stopped manually by clicking on the Sample button in the PharmaMaster interface when the desired time/volume of air has been collected.
 - i. It may be useful to create a materials testing sampling profile with a set sampling time/volume for use with all background, control and material samples.
 - d. Repeat the background run if replicates are desired.
10. Obtain a **control sample** by performing sampling steps without a test material.
 - a. Perform this test for the same sample time/volume as that to be utilized during material testing.
 - b. Begin a sample by clicking on the Sample button in the PharmaMaster interface.
 - c. Using a gloved hand inserted into the biological safety cabinet or a gloved isolator hand, mimic the waving motion to be utilized during material testing.
 - d. Repeat the control sample if replicates are desired.
11. Obtain a **material sample** by performing sampling steps with a test material.
 - a. Begin a sample by clicking on the Sample button in the PharmaMaster interface.
 - b. Open the test material within the clean environment (i.e. within the biological safety cabinet or isolator).
 - c. Immediately begin waving the test material (i.e. cleanroom wipe, gown, etc.) over the isokinetic probe without touching the probe with the test material.
 - i. Materials were waved over the isokinetic probe in the testing performed by Azbil BioVigilant. This step should reflect the common use of your materials as best as possible. Waving or shaking, however, may be desired if testing is designed to characterize the potential of materials to shed particles during use.
 - d. Continuously wave the test material over the probe for the testing duration. Three-minute test replicates were performed in the Azbil BioVigilant testing.
 - e. Repeat the material test with a new material sample if replicates are desired.
12. Once testing of the first material is complete, apply a HEPA filter to the IMD-A inlet or the end of the Bev-A-Line tubing and run the IMD-A cleaning process.
13. Remove the HEPA filter and repeat material sample testing (procedural step 11) for the next test material.

Test Results

Azbil BioVigilant performed material testing on a number of cleanroom gloves, wipes and other cleanroom materials. **Figure 2** shows the results from testing six different cleanroom wipes, placed in order of manufacturer reported particulate levels. Three separate three-minute replicates were performed for each material. The average IMD-A biologic counts, particles $\geq 0.5\mu\text{m}$, and particles $\geq 5.0\mu\text{m}$ were then calculated for each test material by taking an average



of these counts across each of the three replicates performed. Through such analysis it was evident that Wipe 2 showed the lowest level of particulate shedding under the conditions tested. For additional information on the material testing performed or for assistance with data analysis, please contact Azbil BioVigilant.

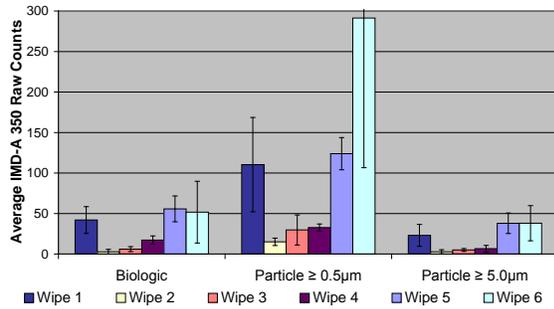


Figure 2: Cleanroom wipe comparative results

Support

Please contact Azbil BioVigilant's Applications team or your sales executive for additional assistance.

We can assist with:

- On-site and remote support by our Field Applications Scientist team
- Complete evaluation protocols and data analysis tools
- Custom protocol development including a sample training protocol

References

1. Azbil BioVigilant IMD-A Series Rapid Biologic Detection System for Air Product Specifications Sheet LI-005
2. Azbil BioVigilant USP<1223> & EP 5.1.6 Validation Testing of IMD-A 300/350 Systems Fact Sheet LI-007
3. Azbil BioVigilant IMD-A System/PharmaMaster User Manual Models IMD-A 300 and 350 UM-IMD0009
4. Azbil BioVigilant IMD-A Series Isokinetic Probe with Stand Specification Sheet LI-006
5. Azbil BioVigilant Customer Evaluation Protocols for IMD-A 300 and IMD-A 350 Systems CP-IMD0003

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