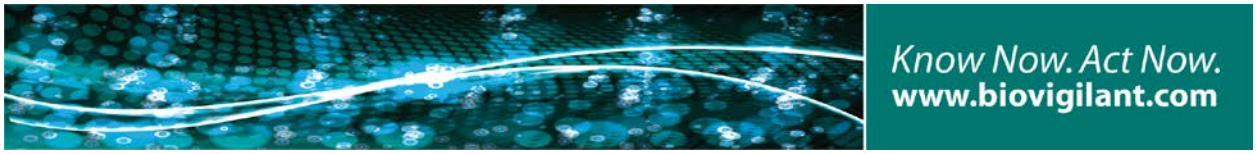

BioVigilant
Instantaneous Microbial Detection

Specificity Testing of IMD-A® 300/350 Systems

Introduction

This fact sheet provides a summary of test parameters and results for Specificity testing performed with BioVigilant's IMD-A 300 and IMD-A 350 systems. Specificity is one of the nine validation parameters listed in USP<1223> and one of the eight validation parameters listed in EP 5.1.6 for analysis toward the validation of an alternative microbiological method. The Specificity parameter in USP<1223> and EP 5.1.6 is composed of two distinct foci, true positive detection and false positive detection. True positive detection is based on the system's ability to detect a panel of microorganisms, while false positive detection requires that the alternative method be challenged in a worst-case manner that encourages "false positive" or interferent results on the system under test. Due to the two distinct aspects of USP<1223> and EP 5.1.6 Specificity testing, this parameter has been split into Specificity 1 true positive testing, and Specificity 2 interferent testing. Furthermore, Additional Specificity testing outside of the requirements set forth in USP<1223> and EP 5.1.6 has been completed in order to continue to rigorously characterize and assess the IMD-A system in a manner that will provide practical information for IMD-A users. This fact sheet reviews the Specificity 1, Specificity 2, and Additional Specificity testing performed on the IMD-A system.

Background

In the United States and Europe respectively, USP <1223> *Validation of Alternative Microbiological Methods* [A] and EP 5.1.6 *Alternative methods for control of microbiological quality* [B] guide the validation of alternative microbiological methods such as BioVigilant's IMD-A systems. Results from testing to these guidance documents are filed as part of BioVigilant's Drug Master File (DMF) submissions to the U.S. FDA, which supplement the testing drug makers may perform to validate IMD-A systems for use in their manufacturing areas. This DMF contains Specificity 1 and Specificity 2 test results.

Additional Specificity testing, outside of the scope of USP<1223> and EP 5.1.6 and not contained within the DMFs, has also been completed on the IMD-A system. This testing is designed to assess materials in a manner more similar to actual use in a customer environment in order to provide guidance on the selection and usage of cleanroom materials. A number of customers have performed similar testing in order to investigate and characterize their environments.

BioVigilant Tests	IMD-A User Tests
• Specificity 1 • Specificity 2 • Additional Specificity	• Environment-based Specificity

BioVigilant's DMF submissions contain information that the FDA can review when evaluating the use of the rapid microbiological method enabled by BioVigilant's systems for environmental monitoring in the manufacturing, processing, packaging or storage of drug products. Drug makers reference these filings during FDA review of IMD-A validation data. BioVigilant's DMF includes USP <1223> and EP 5.1.6 Specificity 1 and Specificity 2 test results.

Specificity Microbes and Materials

- USP<1223> and EP 5.1.6 Specificity 1
  - 5 organisms - *B. atrophaeus, E. coli, S. epidermidis, M. lylae, C. afermentans*
- USP<1223> and EP 5.1.6 Specificity 2
  - 6 materials – 70% IPA, silicone spray, cleanroom paper, cleanroom gown, tryptic soy broth, riboflavin
- Additional Specificity
  - 7 gloves – 4 latex and 3 nitrile
  - 6 wipes
  - 4 materials – 70% IPA, cleanroom paper, cleanroom gown, tryptic soy broth

[A] General Information Chapter <1223> Validation of Alternative Microbiological Methods. *United States Pharmacopeia 32 – National Formulary 27*: 2009.

[B] Chapter 5.1.6 Alternative methods for control of microbiological quality. *European Pharmacopoeia* Sixth Edition, Supplement 6.5: 2009.

Specificity 1 Test Parameters

Microbial Species Tested	
Spore, gram positive	*Bacillus atrophaeus*
Vegetative, gram positive	*Corynebacterium afermentans* *Micrococcus lylae* *Staphylococcus epidermidis*
Vegetative, gram negative	*Escherichia coli* 12 replicates tested at each of five concentrations
Facility	Azbil g-Lab, Fujisawa, Japan facility
Test Apparatus	2.9m^3 chamber specifically designed for aerosol studies Salter Laboratories nebulizer Kanomax 3900 particle counter
Systems Under Test	IMD-A 300 system (2 each) IMD-A 350 system (2 each)

Specificity 1 Purpose

The purpose of Specificity 1 is to assess and demonstrate the ability of the IMD-A system to suitably detect true positives through the testing of a panel of five microorganisms.

Test Microbes

Five microbes common to the pharmaceutical manufacturing environment were chosen including gram negative and gram positive, vegetative bacteria, and spore-state bacteria, as noted earlier.

Test Apparatus and Instruments

Aerosol Test Chamber

All USP <1223> and EP 5.1.6 biological challenge testing was performed in a purpose-built, state-of-the-art aerosol test chamber located in the Azbil g-Lab facility (**Figure 1**). This chamber contains a re-circulating HEPA filter with the ability to operate at 10m^3 per minute, which is equivalent to roughly three chamber air changes per minute. Sampling instruments are located outside of the chamber, with five ports on the chamber floor for the inlet sampling tubes of instrumentation (reference particle counters, IMD-A systems), and four ports located on the chamber sidewall with automated sanitary valves for air sampler interfacing.

Refer to the USP<1223> and EP 5.1.6 Validation Testing of IMD-A 300/350 Systems Fact Sheet for additional information.

Figure 1: Aerosol test chamber in the Azbil g-Lab facility

Nebulizer

A Salter Laboratories 8900-series nebulizer was located inside the test chamber and utilized to disseminate all bacterial suspensions during testing.

Particle Counter

An ISO 21501-4 compliant Kanomax 3900 particle counter was used as a reference instrument for microbial aerosol concentrations and to establish background particle count levels during testing.

Air Samplers (Compendial Method)

Three air samplers representing the traditional method were utilized during testing: the SAS Super 100, MAS 100NT, and SMA.

IMD-A 300 and IMD-A 350 Systems(Alternative Microbiological Method)

Testing was completed with two of each IMD-A model: IMDA-300 and IMD-350. The IMD-A 300 system operates at 1.15LPM, while the IMD-A 350 system operates at 28.3LPM. Both systems have a particle size detection range from 0.5µm to ≥ 10µm and operate based on a Mie scatter detection method for particle sizing and enumeration and intrinsic fluorescence detection for biologic classification.

Test Procedure

Four IMD-A systems, the particle counter and three air samplers were connected to the aerosol test chamber and sampled simultaneously. A Salter Laboratories nebulizer was utilized to disseminate the microbial suspensions, and twelve replicates were performed for each microbe at each of five concentrations. Although the air samplers were not required for quantitative data in Specificity 1, these instruments provided qualitative data as required in the acceptance criteria described on page 5.

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Specificity 2 Test Parameters

Materials Tested	70% IPA *(Vai, Decon-Ahol)* Silicone spray *(Vai, Steri-silicon)* Cleanroom paper *(ITW Texwipe, TexWrite 22)* Cleanroom gown *(Dupont, Tyvek IsoClean)* Tryptic soy broth *(BD, double wrapped)* Riboflavin *(Fisher Scientific, 98%)* 10 replicates performed for each material & background
Facility	Azbil BioVigilant Applications Lab, Tucson, AZ
Test Apparatus	Custom stainless steel nebulization stand designed for aerosol studies Lovelace nebulizer SMA air sampler
Systems Under Test	IMD-A 300 system IMD-A 350 system

Specificity 2 Purpose

The purpose of Specificity 2 is to test commonly used cleanroom materials on the IMD-A system, in a worst-case scenario fashion so that they are likely to elicit a fluorescent response, and determine if they are at risk of being system interferents. This test represents a worst-case scenario as the materials are being nebulized directly into the IMD-A systems; a testing technique that is not recommended.

Test Materials

Six materials common to the pharmaceutical manufacturing environment were chosen for analysis. Riboflavin was added as a positive control, and all materials came sterile, were autoclaved (paper), or 0.1µm filtered (riboflavin) before use.

Test Apparatus and Instruments

Nebulization Stand

All USP <1223> and EP 5.1.6 Specificity 2 testing was performed in a custom nebulization stand (**Figure 2**). This stand is fabricated out of stainless steel and grounded to prevent deposition of test particles and permit easy cleaning of the system. The system flow rate is highly tunable. An increase in system flow allows system clean out in only a few minutes. This stand permits simultaneous sampling with up to four systems at one time.

Figure 2: Nebulization stand in the Azbil BioVigilant Applications Laboratory

Nebulizer

An In-Tox Products Lovelace nebulizer was utilized to disseminate all background and material suspensions.

SMA Air Sampler

An SMA air sampler was utilized as a reference instrument to confirm the nebulization stand cleanliness during testing.

IMD-A 300 and IMD-A 350 Systems

Testing was completed with one IMD-A 300 and one IMD-A 350 system as described previously.

Test Procedure

Sterile TSB, gown, paper and riboflavin samples were placed into 10mL of 0.1µm filtered DIUF water and then hard vortexed. Three TSA spread plates were made for each material and water background, and 5mL were placed in a Lovelace nebulizer cup for nebulization. IPA and silicone were plated and placed directly into the nebulizer cup undiluted as filtered air was utilized as the background for these materials. Three systems, an IMD-A 300, IMD-A 350 and an SMA were connected to three sampling ports on the nebulization stand and sampled simultaneously. A Lovelace nebulizer was utilized to disseminate suspensions, and a twelve minute sample was performed for each test material and background. **Note: Nebulization of these or any other materials directly into the IMD-A systems is NOT recommended at any time.**

Negative Controls

Settle plates, spread plates and SMA air sampler plates were all utilized as negative controls. TSA

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settle plates were placed within the biological safety cabinet during all sample preparation. TSA spread plates, in triplicate, were prepared for all water backgrounds and material suspensions. An SMA air sampler was utilized during all background and material nebulizations. All TSA plates were incubated at 20-25°C for 3 days followed by 30-35°C for 2 days.

Additional Specificity Test Parameters

Materials Tested	
Gloves	4 latex, 3 nitrile
Wipes	6 wipes
Specificity 2 Materials	70% IPA (Vai, Decon-Ahol) Cleanroom paper (ITW Texwipe, TexWrite 22) Cleanroom gown (Dupont, Tyvek IsoClean) Tryptic soy broth (BD, double wrapped) Three 3-minute replicates performed for each glove & wipe, and one 3-minute sample performed for USP <1223> Specificity materials
Facility	Azbil BioVigilant Applications Lab, Tucson, AZ
Test Apparatus	Class II, Type A2 biological safety cabinet (BSC) IMD-A 350 isokinetic probe Lasair II particle counter
System Under Test	IMD-A 350 system

Additional Specificity Purpose

The purpose of the additional specificity tests were to assess commonly used cleanroom materials on the IMD-A system in a manner more typical of common usage, and to provide guidance on the use of such materials.

Additional Specificity Test Materials

Multiple gloves and wipes, and other materials commonly used in a cleanroom environment previously tested in Specificity 2 testing were tested. Additional information on the gloves and wipes is provided at the end of the document in **Table 5** and **Table 6**.

Test Apparatus and Instruments

Class II, Type A2 Biological Safety Cabinet

All Additional Specificity testing was performed in an Esco Labculture Reliant Class II, Type A2 BSC (**Figure 3**).

Particle Counter

A Lasair II particle counter was used as a reference instrument to establish background particle count levels in the BSC.

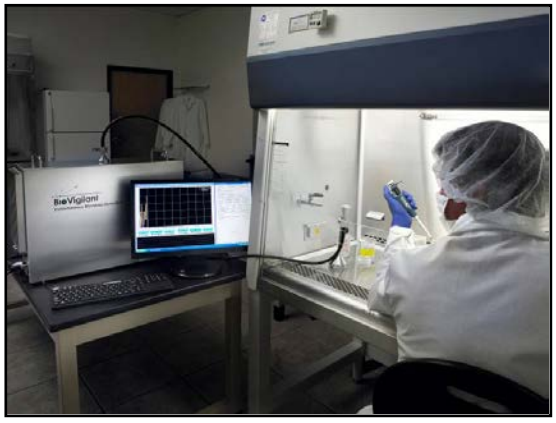

Figure 3: Class II Type A2 BSC in Azbil BioVigilant Applications Laboratory

IMD-A 350 Isokinetic Probe

An IMD-A 350 isokinetic probe (**Figure 4**) was utilized to perform sampling within the BSC.

Figure 4: IMD-A 350 isokinetic probe with stand

IMD-A 350 System

Testing was completed with one IMD-A 350 system, as described in more detail previously.

Test Procedure

An IMD-A 350 system was placed outside of the BSC with an IMD-A 350 isokinetic probe and stand placed within the BSC for sampling. For the seven gloves and six wipes, each material was opened within the BSC and then shaken over the probe for three minutes with three replicates performed. For the Specificity 2 materials, one three-minute sample

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was performed for each material. The IPA was sprayed over and near the probe, the paper and gown were shaken over the probe, and the TSB bottle was opened over the probe and then the bottle was moved vigorously back and forth.

Negative Controls

Settle plates and Lasair II and IMD-A background runs were all utilized as negative controls. TSA settle plates were placed within the BSC during all sample preparation and manipulation. The 34 TSA settle plates were incubated at 20-25°C for three days followed by 30-35°C for two days.

Test Acceptance Criteria

Different acceptance criteria were necessary for the three aspects of Specificity testing. In an effort to rigorously validate the IMD-A series as per USP <1223> and EP 5.1.6 guidelines, BioVigilant actively communicated with a biostatistician throughout the development of the test acceptance criteria for Specificity 1 and Specificity 2. The Additional Specificity testing was designed to provide guidance on the selection and usage of materials. As this additional testing was not part of the IMD-A validation to USP<1223> and EP 5.1.6 and due to the focus of the testing, materials were compared on a relative basis.

Specificity 1

As stated in USP <1223>, and similarly stated in EP 5.1.6, the qualitative Specificity 1 metric assesses the ability of a quantitative microbiological method "to detect a range of microorganisms that may be present in the test article." Consequently, five microbes common to the pharmaceutical manufacturing environment were chosen for testing. The Specificity 1 metric was assessed based on the following acceptance criteria:

1. The IMD-A systems produce quantitative (> 50% detectability of replicates) results for each of the five concentrations tested for each microbe, which is corroborated by some level of positive growth for each reference method (i.e., air sampler).

Specificity 2

The quantitative Specificity 2 test is utilized to "challenge the alternative technology in a manner that would encourage false positive results." The IMD-A systems were thus challenged with five common pharmaceutical cleanroom materials with the potential to elicit a fluorescence response on the IMD-A system and thus be considered interferents. The Specificity 2 metric was assessed based on the following acceptance criteria:

1. Evaluate the statistical significance between the mean biological counts observed during material testing and the biological counts observed during background testing using a t-test with a 95% level of significance.

Additional Specificity

The Additional Specificity testing was designed as a comparative study to assess commonly used cleanroom materials on the IMD-A system in a manner more typical of common usage. As a result, the IMD-A system was challenged with four latex gloves, three nitrile gloves, six different wipes, and four other common pharmaceutical cleanroom materials by shaking, opening or spraying these materials over the IMD-A isokinetic probe inlet. The Additional Specificity metric was assessed based on the following acceptance criteria:

1. Relatively compare the biologic and particle counts obtained due to shaking, opening or spraying of materials over the isokinetic probe inlet, and provide guidance to customers on the use of such materials.

Test Results Summary

Specificity 1

The Specificity 1 validation test results are shown in the Summary Test Matrix result table (**Table 1**) below. Four IMD-A systems and three air samplers were challenged at five distinct concentrations (T1-T5), for five different organisms. All systems sampled air from the test chamber concurrently in order to provide the most accurate comparison possible. The IMD-A systems were found to meet the Specificity 1 acceptance criteria in all cases as shown by the table composed of only green squares.

Legend:	Met/exceeded acceptance criteria	Summary Test Matrix for USP <1223> & EP 5.1.6 Specificity 1 Test														
	Did not meet acceptance criteria for one IMD-A system tested	IMD-A Comparison to Three Air Samplers Over Five Conentrations														
	Did not meet acceptance criteria for both (2) IMD-A systems tested	SAS Super 100 (100LPM)					MAS 100NT (100LPM)					SMA (28.4LPM)				
Test Function	Microbe	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5	T1	T2	T3	T4	T5
IMD-A 300	*Bacillus atrophaeus*															
	Escherichia coli															
	Staphylococcus epidermidis															
	Micrococcus lylae															
	Corynebacterium afermentans															
IMD-A 350	*Bacillus atrophaeus*															
	Escherichia coli															
	Staphylococcus epidermidis															
	Micrococcus lylae															
	Corynebacterium afermentans															

Table 1: Specificity 1 test results

Specificity 2

The Specificity 2 validation test results are shown in the two result tables below (**Tables 2 and 3**), which contain particle counts per liter, biologic counts per liter, percent biologic and potential interferent risk for each material. Upon directly nebulizing these

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materials into the IMD-A systems, in a test designed to ensure evaluation of the materials tested in a worst-case scenario fashion, all materials tested except for silicone spray were found to pose a potential interferent risk to the IMD-A system. However, **as seen in the Additional Specificity results the potential interferent risk of many of these materials is removed or diminished when tested in a manner more akin to real-world usage.**

Silicone Spray

Direct nebulization of silicone spray resulted in the introduction of a large number of particles directly into the IMD-A systems. As can be seen in **Table 2,** more than 40,000 particles per liter of air were detected by the IMD-A 300 system. With the higher flow IMD-A 350 system an even larger number of silicone particles flooded the system during sampling, and consequently, the result for silicone spray on the IMD-A 350 system is listed as N/A. Silicone spray was found not to pose an interferent risk to the IMD-A system. Out of over 40,000 particles per liter sampled on the IMD-A 300 system, only 23 counts per liter were found to be biologic.

Cleanroom Gown

Although the Specificity 2 test was designed to create as many test material particles as possible for nebulization and sampling, very few particles per liter were obtained for the Tyvek gown. However, of the 4.4 particles per liter detected by the IMD-A 300 system, 0.5 counts per liter were biologic. The resulting 11.76% biologic counts indicate that the material poses a potential interferent risk. However, the low risk of particles being shed from this material during typical usage is not factored into this result.

IPA, Cleanroom Paper, TSB and Riboflavin

Based on percent biologic results, 70% IPA, cleanroom paper, TSB and riboflavin were also found to pose some level of potential interferent risk when directly nebulized into the system and tested in a worst-case scenario. Note that riboflavin was tested as the positive control, as this is one of the metabolic fluorophores detected by the IMD-A system. The Additional Specificity results provide a risk assessment of these materials after testing in more of a real-world fashion.

	IMD-A 300			
Material	**Particles (Counts/L)**	**Biologics (Counts/L)**	**% Biologic**	**Interferent Risk**
70% Isopropyl Alcohol	1458	34	2.31	**Yes**
Silicone Spray	41,123	23	0.06	**No**
Cleanroom Paper	609	49	8.08	**Yes**
Cleanroom Gown	4.4	0.5	11.76	**Yes**
Tryptic Soy Broth	2278	981	43.06	**Yes**
Riboflavin	34	33	96.68	**Yes**

Table 2: Specificity 2 IMD-A 300 test results

	IMD-A 350			
Material	**Particles (Counts/L)**	**Biologics (Counts/L)**	**% Biologic**	**Interferent Risk**
70% Isopropyl Alcohol	366	11	3.11	**Yes**
Silicone Spray	N/A	N/A	N/A	**N/A**
Cleanroom Paper	134	10	7.21	**Yes**
Cleanroom Gown	0.9	0.1	14.62	**Yes**
Tryptic Soy Broth	560	187	33.48	**Yes**
Riboflavin	17	16	94.46	**Yes**

Table 3: Specificity 2 IMD-A 350 test results

Additional Specificity

The results of the three different aspects of Additional Specificity testing are shown. **Figures 5** and **6** display the results of the cleanroom glove and cleanroom wipe testing. Average IMD-A 350 raw counts are reported for biologic, particles ≥ 0.5µm, and particles ≥ 5.0µm. **Table 4** contains results for the subset of Specificity 2 materials tested.

Cleanroom Gloves

In general, with regards to both particle and biologic counts and in the manner tested, nitrile gloves were typically found to shed fewer particles than latex gloves. Moreover, the three replicates for Nitrile 1 gloves all resulted in zero biologic and particle counts during 3 minutes of shaking over the probe inlet for each glove tested. For both the latex and nitrile gloves it was found that the gloves packaged in bulk shed the fewest number of particles, whereas individually packaged and folded gloves shed the highest number of particles. Furthermore, as can be seen in the large error bars in **Figure 5,** there was a significant level of variability in counts between the latex glove replicates.

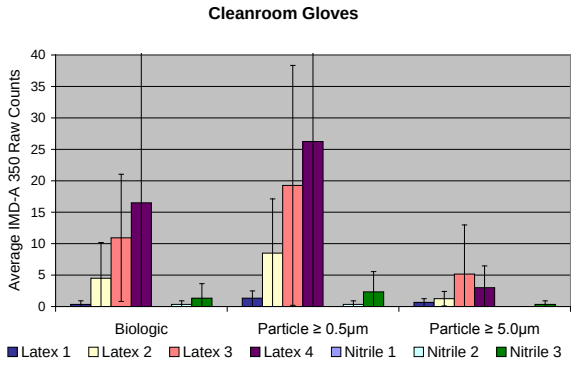

Figure 5: Additional Specificity cleanroom glove comparative results

Cleanroom Wipes

For a majority of the cleanroom wipes (**Figure 6**) less variability was observed between the replicates tested. Aside from Wipe 1, the particle count results for Wipes 2 through 6 followed the trend expected from the particle counts reported by the manufacturers (**Table 6**), with Wipe 2 shedding the fewest particles and Wipe 6 shedding the highest number of particles. Further testing is planned for both gloves and wipes in an effort to understand the

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nature of fluorescent particles detected by the IMD-A system (e.g., dead microbes, live microbes, fibers, other inert particles, etc.).

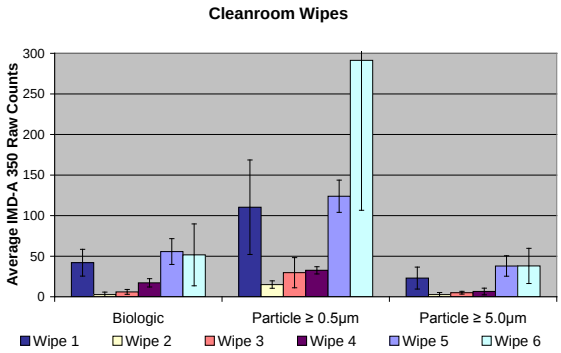

Figure 6: Additional Specificity cleanroom wipe comparative results

IPA, Cleanroom Paper, Cleanroom Gown, TSB

The Additional Specificity results for the subset of Specificity 2 materials are shown in **Table 4**. Unlike results from the Specificity 2 worst-case scenario testing, **when these materials are shaken, sprayed or opened over the IMD-A isokinetic probe inlet the resulting biologic counts are minimal.** For TSB, the bottle was opened over the probe and then moved back and forth for three minutes. Only one particle count, a biologic particle, was observed during this time when the bottle was vigorously swirled over the probe inlet. This is an indication that although TSB is likely to elicit a fluorescent response on the IMD-A system if detected, we found that the likelihood of TSB particles being detected by the IMD-A system during opening and vigorous movement of the bottle near the inlet posed no or very low interferent risk. Particle counts were observed when 70% IPA was sprayed directly over and very close to the probe inlet. However, of the 50 particles detected, none of these particles were biologic indicating that the specific IPA evaluated has no detectable interferent risk when tested in more of a real world fashion. When cleanroom paper was shaken over the probe inlet for three minutes, zero biologic particles and zero total particles were detected. These results indicate that an autoclaved version of this paper does not pose an interferent risk to the system when shaken over the inlet. Lastly, both particle counts and biologic counts were observed when shaking a cleanroom gown over the isokinetic probe inlet. The cleanroom gown was thus again found to pose some level of interferent risk to the system. As with the cleanroom gloves and wipes, further investigation is planned in order to characterize these fluorescent particles.

Material	Particles (Counts/L)	Biologics (Counts/L)	Sample Time	Detected Interferent Risk
70% Isopropyl Alcohol	50	0	2min 27sec	**No**
Cleanroom Paper	0	0	3min	**No**
Cleanroom Gown	13	7	3min	**Yes**
Tryptic Soy Broth	1	1	3min	**Low**

Table 4: Additional Specificity test results for a subset of the materials tested in Specificity 2 testing

Observations and Recommendations

Throughout the Specificity and other IMD-A testing a number of useful lessons have been learned:

1. Accessories used for sampling (e.g., tubing, isokinetic probe) and surrounding work surfaces may be contaminated with particles from previous testing. These particles have the potential to affect future results through re-aerosolization. For example, if IPA is sprayed over a contaminated probe or tubing, particles may be dislodged by the IPA droplets coming into contact with these surfaces, potentially resulting in the detection of particle and biologic counts. With regard to a contaminated work surface, items placed on this surface and then moved near an instrument inlet may lead to detected counts due to particle transfer. These counts may not typically be noticed in a static environment or an environment where the disruption of particles on a surface is infrequent.
2. Cleanroom garments such as gloves and gowns may be laden with particles not removed during the cleaning and/or packaging process (Videos of particles generated from cleanroom wipes, gowns and paper can be found at the following Shin Nippon website. The site may be translated into English with many web browsers http:// www.snk.co.jp/particle/example03.html).
3. Other instruments (e.g., air sampler, particle counter) operating in a clean environment (e.g., isolator) may exhaust particles or stir up particles that are then detected by the IMD-A system.
4. It is important to characterize your testing environment to gain a better understanding of how the materials and protocols used affect background particulate levels.

BioVigilant References

1. Azbil BioVigilant, USP<1223> and EP 5.1.6 Validation Testing of IMD-A 300/350 Systems, LI-007
2. Azbil BioVigilant, IMD-A Series Isokinetic Probe with Stand Specifications, LI-006

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Specificity Test Highlights

Specificity 1

- All Specificity 1 tests passed and met the USP<1223> & EP 5.1.6 acceptance criteria
  - 75 comparison tests performed for each IMD-A system tested

Specificity 2

- All Specificity 2 tests passed and met the USP<1223> & EP 5.1.6 acceptance criteria
- When tested in a worst-case scenario fashion all materials except for silicone spray were found to pose a potential interferent risk to the IMD-A system

Additional Specificity

- All Additional Specificity testing met the set acceptance criteria
  - Nitrile gloves were found to shed fewer particles than latex gloves
  - Keep manufacturer reported particulate shedding level in mind when purchasing wipes
  - When tested in a more real world fashion, three out of four Specificity 2 materials posed no or very low interferent risk to the system
- **When tested in a manner more akin to real-world use, most cleanroom materials, when carefully selected, applied and used, should not generate interferent results on the IMD-A system**
- Careful selection and characterization of materials and operating protocols can aid in limiting particle generation in your cleanroom environment

	Latex #1	Latex #2	Latex #3	Latex #4	Nitrile #1	Nitrile #2	Nitrile #3
Product Name	Kimberly-Clark KIMTECH PURE G3	Fisherbrand Powder Free Latex Surgical Gloves	Cti Clean-Class SGPF Series	Ansell AccuTech 870	Kimberly-Clark KIMTECH PURE G3	VWR CertiClean	Kimberly-Clark KIMTECH PURE G3
Packaging & Treatment	Bulk, packaged in ISO 5 cleanroom, washed in ultrapure DI water	Individually wrapped, gamma irradiated	Individually wrapped, gamma irradiated, double bagged	Individually wrapped, gamma irradiated	Bulk, packaged in ISO 5 cleanroom	Bulk, packaged in ISO 5 cleanroom	Individually wrapped, packaged in ISO 5 cleanroom, gamma irradiated
Recommend For Use In	ISO 3 or higher cleanrooms	Medical, Laboratory and Industrial	Class 5 Cleanrooms	Pharmaceutical, medical device, & biotech	ISO 3 or higher cleanrooms	Cleanroom environments	ISO 3 or higher cleanrooms
Sterile?	No	Yes	Yes	Yes	No	No	Yes
Folded?	No	No	Yes	Yes	No	No	Yes

Table 5: Description of cleanroom gloves tested in the additional Specificity testing. Gloves have been separated into latex and nitrile, and then placed in order based on packaging. Gloves packaged in bulk are listed first and move toward individually wrapped and then individually wrapped and sterile, followed by individually wrapped, sterile and folded.

	Wipe #1	Wipe #2	Wipe #3	Wipe #4	Wipe #5	Wipe #6
Product Name	Berkshire Value-Seal 1500	ITW TexWipe TexTra10	Berkshire Gamma Wipe CapSure VP	VWR Spec-Wipe 7 Wipers	ITW TexWipe MiracleWipe Wiper	VWR Spec-Wipe 3 Wipers
Material	100% continuous fiber polyester knit	100% Continuous filament double-knit polyester	100% Continuous filament polyester knit	100% No-run interlock polyester knit	100% Continuous filament nylon	45% Polyester/55% Cellulose
Packaging & Treatment	Laundered & packaged in ISO 4 cleanroom	Cleanroom laundered & packaged	Gamma irradiated, sterile, laundered & packaged in ISO4 cleanroom	Laundered in ISO 4 cleanroom	Cleanroom-laundered & packaged	Gamma irradiated & sterile
Edge Description	Laser sealed edge	Full sealed border	Sealed Edge	Sealed Edge	Cut edge	Cut edge
Particulate Levels (particles/m²)	0.14×10^6	2.0×10^6	4.7×10^6	4.8×10^6	15×10^6	21.5×10^6

* Particulate level (particles/m^2) is a value reported by the manufacturer for each wipe

Table 6: Description of cleanroom wipes tested in the additional Specificity testing. The six wipes have been placed in order based on particulate levels reported by the manufacturer, from low reported particulate shedding to high. Also of note is the edge description. Four out six wipes had a sealed edge versus a cut edge. Wipe #2 had a full sealed border with a quality resembling that of a napkin or handkerchief.

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