Accuracy Verification Testing of BioVigilant's Instantaneous Microbial Detection Instrument: Comparison of Sampler Results for Five Aerosolized Bacteria at Varying Concentrations

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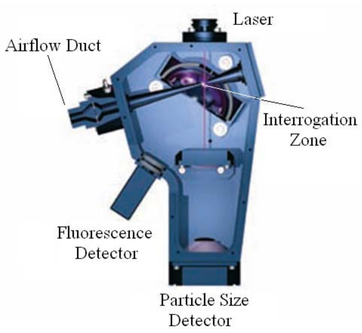
BioVigilant™
Instantaneous Microbial Detection

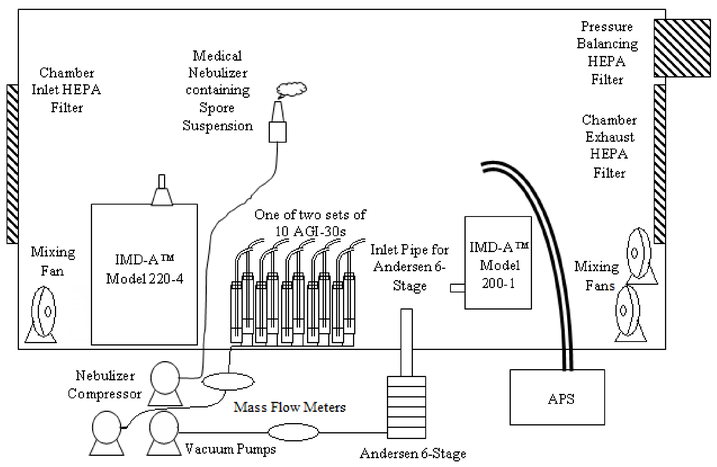
Introduction

The purpose of the testing was to confirm that the Instantaneous Microbial Detection-Air™ (IMD-A™) instruments produced results that are equivalent to or better than the reference method (conventional air samplers, as evaluated in comparison to the Andersen Six-Stage Viable Sampler and AGI-30s) for environmental monitoring. AlburtyLab, Inc. performed the study using FDA <1224> GLP procedures. The BioVigilant IMD-A instruments and the reference methods were exposed to a range of aerosol concentrations of the following biosafety level one bacterium—*Bacillus atrophaeus* (Bg), *Corynebacterium afermentans* (Ca), *Escherichia coli* (Ec), *Micrococcus lylae* (Ml), and *Staphylococcus epidermidis* (Se).

The BioVigilant™ IMD instruments for Instantaneous Microbial Detection sample air and utilize the same scientific principles in that they 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 whether a particle is of biological origin (e.g., a bacterium) or mineral origin (i.e., inert) 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.



Schematic of the Test Setup

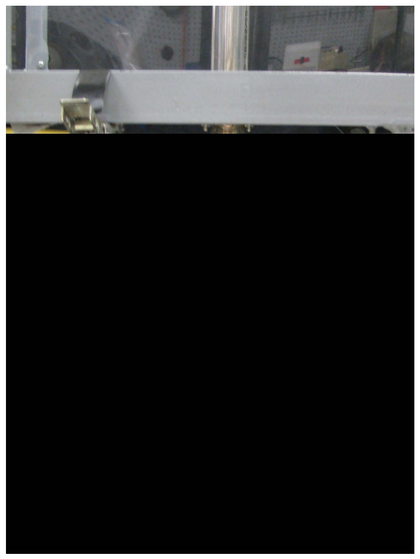


Methods

Testing consisted of ten replicate tests at five levels of aerosol concentrations for each of the five microorganisms of interest. Dissemination of the organism within the aerosol test chamber (ATC) was carried out using a medical nebulizer. The aerosol concentrations were increased in stepwise fashion for each test conditions by disseminating more concentrated nebulizer solutions. Levels were set by monitoring the particle size distribution and concentrations within the chamber using an Aerodynamic Particle Sizer.

AGI-30 Reference Samplers:

Aerosol concentrations were established during each run with two AGI−30s loaded with 20 mL of PBS and connected to a sampling manifold in the ATC.



Andersen Six-Stage Viable Sampler:

The Andersen Six-Stage Viable Sampler was connected to a valved inlet tube that extended into the ATC. This facilitated the recovery and reloading of impactor plates at the conclusion of each test run without opening the chamber.

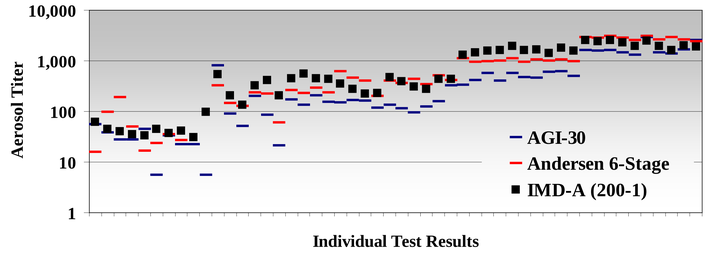
Conclusions

The current USP expectations are that the new microbial detection method provide an estimate of the aerosol concentration not less than 70% of the traditional method, or that it count as many as the traditional method using an appropriate statistical analysis. The plots to the right indicate that the IMD-A met this criteria for all of the organisms included in this testing program. The organisms selected for testing were based upon the following criteria: common environmental isolates, common human-borne micro-organisms, and cultures that are likely to form or exist in a viable but not culturable (VBNC) state.

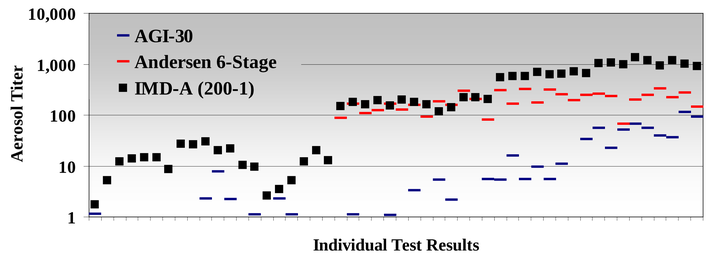
Results

Bacillus atrophaeus

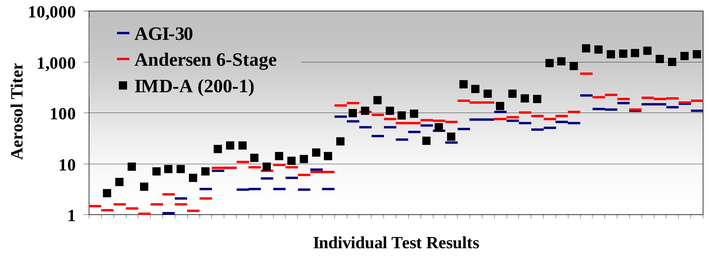
(Disseminated dry using a Small Scale Powder Disperser.)



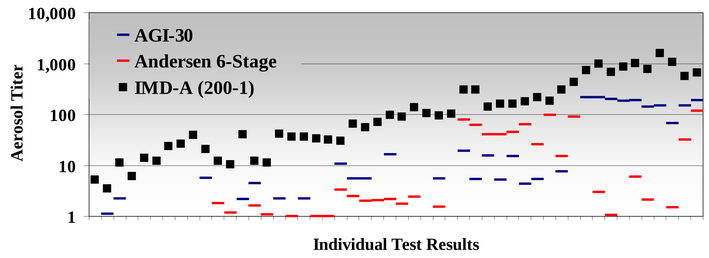
Corynebacterium afermentans



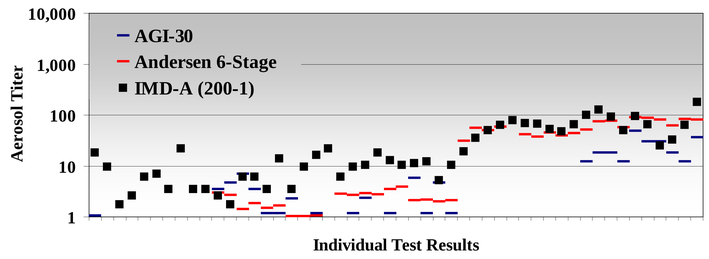
Escherichia coli



Micrococcus lylae



Staphylococcus epidermidis



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