Physical Efficiency Testing of the bioMérieux *air IDEAL 3P* ® air sampler following the ISO 14698-1 standard

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air IDEAL 3P was third party validated by the Health Protection Agency (UK) to meet the requirements of ISO 14698-1 for the control of clean rooms. This document summarises and discusses the report N° 975-05, (dated 5th October 2005) from the Health Protection Agency. The full version of the report is available during audits.

Abstract

The Physical efficiency of the bioMérieux *air IDEAL 3P* microbial air sampler for collecting bacteria-laden particles of various sizes have been compared with membrane filter samplers following the ISO 14698-1 standard (2004). The samplers were operated simultaneously in a controlled room and challenged with uniform sized particles of different diameters containing bacterial spores. The result showed that *air IDEAL 3P* is efficient (85 – 139%) for collecting bacterial spores in the range 2.1 microns and above These values fully meet the requirements set by the ISO 14698 standard.

Material and methods

Test sampler: The *air IDEAL 3P* air sampler. It's an impactor type of instrument based on the principle described by Andersen *et al*. (ref. 1), in which air is aspirated through a grid perforated with a pattern of 286 calibrated holes. The resulting air streams containing microbial particles are directed onto the agar surface in a bioMérieux irradiated Trypcase Soya Agar plate.

Reference sampler: A Membrane filter sampler consisting of a holder incorporating a filter linked to a vacuum system to provide a flow rate of 80 litres.min $^{-1}$. After sampling, the membrane filter is placed on a bioMérieux irradiated Trypcase Soya Agar plate. This non-portable sampler is known to collect bacterial spores with high efficiency and is used as standard for air-sampling evaluations.

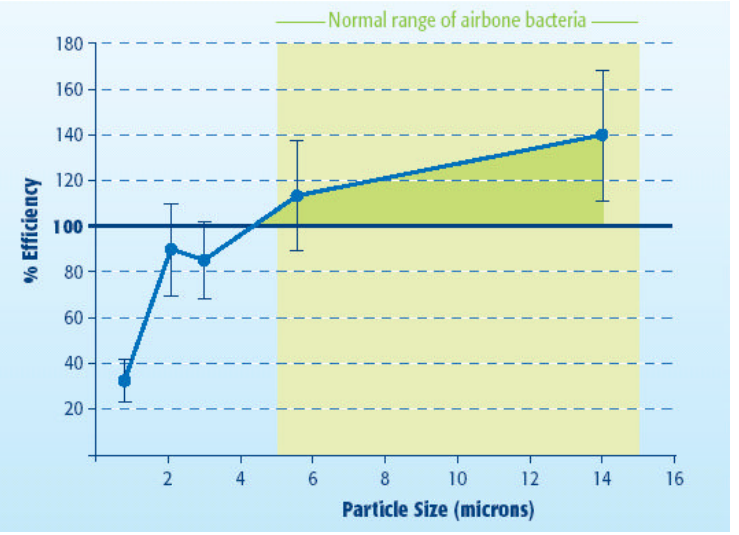
Bacteria-laden particles: Aqueous suspensions of washed *Bacillus subtilis* var *niger* NCTC 10073 spores in 80% ethanol with the following concentrations of potassium iodide (KI), 0%, 0.007%, 0.07%, 0.7% and 7%. The higher the concentration of potassium iodide, the higher the aerodynamic particle size. A spinning top aerosol generator (STAG Mark 2) was used to produce an aerosol of controlled particle size containing bacterial spores into the controlled room. The KI suspensions of spores were injected into the STAG, operating at 48,000 rpm, using a peristaltic pump

Controlled room: A room of 28m^3 in volume and fitted with computer controlled aerosol sampling and generation equipment. Microbial aerosols were generated by the Spinning Top Aerosol Generator in still air in the chamber.

System determining the mass mean diameter of particles: A Four Stage Cascade system operating at 17.5l/min. This sampler was used to collect airborne micro-organisms on a series of four glass slides depending on the aerodynamic particle size.

The contents of the room was sampled by both the test and reference samplers. Each measure was taken ten times for each concentration of potassium iodide. Results were expressed as mean and standard deviation.

Figure 1. Physical Efficiency of the bioMérieux *air IDEAL 3P* air sampler



Results and Discussion

Thirty years of investigation on environmental airborne particles containing bacteria have demonstrated that the range of particle sizes is from 5 to 15µm, with a median size of particles at 13µm (ref. 2 – 6).

The result of the physical evaluation of *air IDEAL 3P* following the ISO 14698-1 standard, demonstrated that the bioMérieux air sampler is highly efficient for collecting particles containing bacterial cells in the range 2.1 – 14 microns. Indeed, in this range of particle size, air Ideal 3P collects from 85% to 139% of the particles versus the non-portable Gold Standard air sampler.

This study confirmed that *air IDEAL 3P* has a high level of collection of the particles of interest (above 5µm). For these significant particle sizes, *air IDEAL 3P* was shown to have an efficiency of collection, superior to 100% set by the reference air-sampling method.

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