Biological Efficiency Testing of the bioMérieux *air IDEAL 3P* ® air sampler following the ISO 14698-1 standard versus the main commercially-available air samplers

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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° 988-05, (dated 9th December 2005) from the Health Protection Agency. The full version of the report is available during audits.

Abstract

The bioMérieux *air IDEAL 3P* microbial air sampler has been tested for biological efficiency following the ISO 14698-1 standard (ref. 1). The sampler was shown to be able to collect aerosols of *Staphylococcus epidermidis* with a high efficiency (92.1%) compared to the gold standard Casella slit sampler. The collection efficiency of *S. epidermidis* and *B. Subtilis* var. niger was also found to be higher to those of three main commercially-available air-samplers.

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. 2), 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: Casella slit sampler calibrated operating at 30 l/min. This non-portable sampler is known to collect bacteria with high efficiency and isused as standard for air-sampling evaluations.

Commercially-available air-sampler: three air-samplers based on the principle of impaction using irradiated Trypcase Soya Agar (TSA) recommended by the different instrument manufacturers.

- Instrument B: Merck MAS 100. Sampler operating at 100l/min and using TSA 90mm irradiated plates (ref AXO51146 from Merck).
- Instrument C: Biotest RCS Plus. Sampler operating at 50l/min and using TSA irradiated strip (ref 941115 from Biotest).
- Instrument D: PBI SAS Super 100. Sampler operating at 100l/min and using TSA 55 mm irradiated plates (ref 103070 from Redipor). In this case the instrument manufacturer has no special recommendation concerning the media

Spray suspension: mixed microbial suspension of *B. subtilis* var niger and *S. epidermitis*. The *B. subtilis* spores are recognized as aerostable microbial tracer and thus, used as indicator of the physical efficiency of the air-samplers. *S. epidermitidis* is a common contaminant of the air in Pharmaceutical clean-rooms derived from human skin cells. This strain was used as the test micro-organism for the biological efficiency testing.

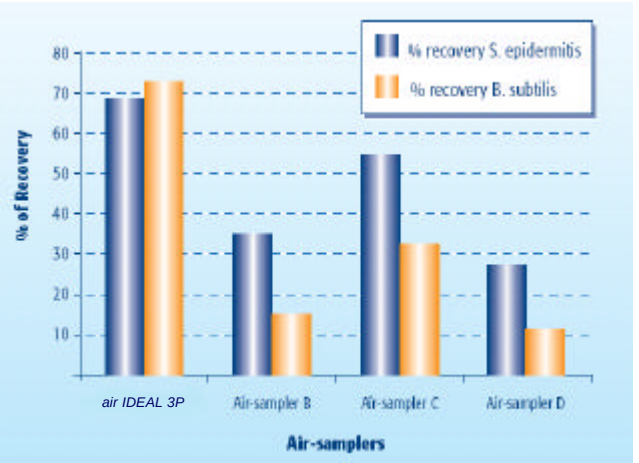
Aerosol generation: A three jet Collison nebuliser (ref. 3) operated at a pressure of 26 psi was used to generate the mixed microbial aerosol. This suspension was sprayed in a 18m^3 environmental chamber.

The contents of the room was sampled simultaneously by the *air IDEAL 3P*, the three commercially-available air samplers and the reference sampler. Each measure was taken 22 times. After incubation at 37°C the small white colonies of *S. epidermitis* (SE) and the larger orange colonies of *B. subtilis* (BS) were counted individually. The biological efficiency of *air IDEAL 3P* was calculated as follows:

$$\text{Biological efficiency} = \frac{\text{air IDEAL 3P's ratio SE/BS} \times 100}{\text{reference sampler's ratio SE/BS}}$$

In order to evaluate the physical and biological efficiency of air-IDEAL 3P versus the main commercially available air-samplers, for each of the 22 runs, a percentage of recovery of both strains was calculated using the Casella sampler as references. The figure 1 show the average percentage of each air-samplers obtained with *B. subtilis* and *S. epidermitis*.

Fig. 1 Collection efficiency of air IDEAL 3P vs main commercialy available air-samplers



Results and Discussion

The effectiveness of microbial air samplers can be split into two facets, physical and biological efficiency. Physical efficiency is the ability of the sampler to collect airborne particles from various sizes, while biological efficiency is the ability of the sampler to collect airborne micro-organisms without rendering them non-viable. The physical efficiency of the *air IDEAL 3P* has already been tested by the HPA (report number 970-05) and has demonstrated that *air IDEAL 3P* has a high level of collection for the particles of interest.

This study highlight that there is no significant difference between the biological efficiency of air IDEAL 3P to the gold standard Casella sampler in the 22 tests (p=0.234, paired Student t-test) with an overall comparative biological efficiency of 92.1%

In an other hand this study demonstrates the superior performances of this new instrument compared to the main commercially-available air samplers on both the strains of references tested: *B. subtilis* (indicator of physical efficiency) and *S. epidermitis* (indicator of biological efficiency). The low recovery observed in these experiments with some air-sampler, could potentially be linked to a low physical efficiency of these instruments. Another explanation that could play a role, is the quality of the media and its compatibility with each instrument.

1. NF EN ISO 14698-1 "Cleanrooms and associated controlled environments – Bioconamination control". (2004)
2. Andersen, A.A. "New sampler for the collection, sizing and enumeration of viable airborne particles." J. Bacteriology. (1976).
3. May, KR. "The Collison nebuliser: Description, performances and application". Aerosol Science. (1973).