

Validation of the use of the bioMérieux air IDEAL®3P™ air sampler in isolators

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The use of the air IDEAL®3P™ in isolators was third party validated by SKAN A.G and LCB. This document summarizes and discusses the report "air IDEAL®3P™ use in Isolators" (dated 15th December 2005).

Abstract:

The isolator environment is highly restrictive for the instruments that have to work in there. The air IDEAL®3P™ engine, electronic components and seals have been totally re-designed to meet the strict constraints of isolator use.

The ability of air IDEAL®3P™ to be used in isolators has been evaluated by the SKAN's Center of Competence for Isolator Technology. The ability of air IDEAL®3P™ to resist repeated standard cycles of decontamination in isolators has been tested. These studies highlight that air IDEAL®3P™ performances are not affected by sequences of isolator decontamination.

Material and methods:

Air sampler: The air IDEAL®3P™ from bioMérieux is 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 265 calibrated holes. The resulting air streams containing microbial particles are directed onto the agar surface in a bioMérieux irradiated Trypcase Soy Agar plate. Two air samplers have been used in this study: air IDEAL®3P™ n°09P09 and n°09P10.

Isolator: ARIS-Isolator from SKAN A.G. (CH) is a barrier isolator that can be operated in negative or positive pressure for both product protection and safety of the environment. ARIS isolators are provided with a completely integrated H₂O₂ decontamination system: SIS 700. The decontamination cycle used (see fig. 1) guarantees a SAL of 10⁻⁶ in the enclosure (ref. 2).

Process simulation. Two air IDEAL®3P™ air samplers were placed in the isolator. 30 decontamination cycles were applied using a 35% hydrogen peroxide solution (H₂O₂). The first sampler (n° 09P09) was running during the maximum H₂O₂ concentration step in each of the cycles (air sampling duration of 10 min for 1000L). The other sampler (n°09P10) was at rest during the cycles.

air IDEAL®3P™ performances. After decontamination, the two air samplers were tested, disassembled and all parts were visually examined. The following point were checked:

- **Functionality:** all the functions must be operated in compliance with standard specification described in the air IDEAL®3P™ user's manual.
- **Air flow rate:** the air flow was controlled using an F.R.M.B.(flow rate measuring bench). This testing bench is an air flow meter using the "transit time difference" ultrasonic method for the measurement of fluid velocity. The calibration of the bench was carried out by the CETIAT, an independent national laboratory. The air IDEAL®3P™ air flow rate standard specification is 100L/min ± 6.5L /min.
- **Visual aspect:** all potential damages of the different components were tracked: change in the material color or aspect, oxidation traces...

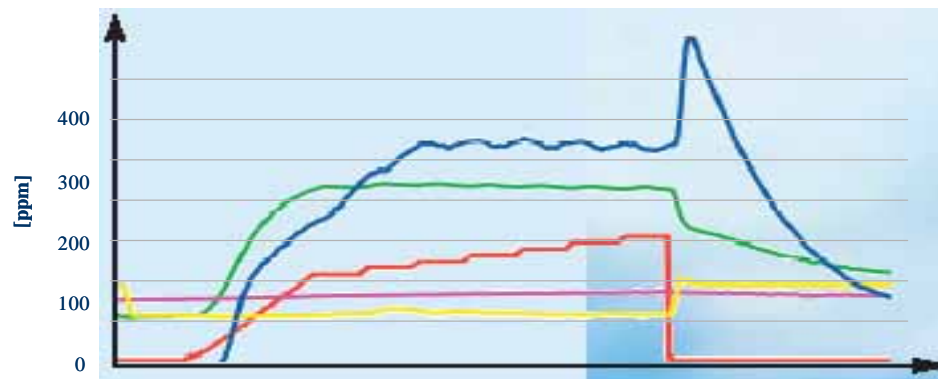


Fig. 1: H₂O₂ decontamination cycle

Curves legend:

Blue: H₂O₂ ppm rate, Green: humidity %, Red: quantity of H₂O₂ in grams, Pink: temperature in °C, Yellow: flow speed in meters/second

Results and Discussion:

Functionality: All the menus, including "After Sales Service" menus were available and operating.

Air flow rate: Compliant with the specifications for the two air samplers tested: 99.5L/min for the equipment n°09P09 and 97.4L/min for the equipment n°09P10.

Visual aspect: None of the 14 components of air IDEAL®3P™ showed defective function. Only the stainless steel strip for Petri dishes presented few visible traces of oxidation. This minor change does not affect the performance of the sampler.

This study guarantees that the performances of air IDEAL®3P™ are not affected by sequences of isolator decontamination.

Furthermore, different studies performed by the SKAN's Center of Competence for Isolator Technology (ref. 2 and 3) demonstrated that a standard decontamination cycle in a SKAN isolator allowed the reduction by 10⁶ logs of spores of *B. stearotherophilus* on the raw materials used in air IDEAL®3P™ instrument.

In conclusion these studies confirm that air IDEAL®3P™ is perfectly designed to be used in isolators.

1. Andersen, A.A. "New sampler for the collection, sizing and enumeration of viable airborne particles." J. Bacteriology. (1976).
2. Sigwarth V., Moirandat C. "Development and qualification of H₂O₂ decontamination cycles" PDA Journal (2000).
3. Sigwarth V. "Effect of Carrier Materials on the Resistance of Spores of *Bacillus stearotherophilus* to gaseous Hydrogen Peroxide" PDA Journal (2000).