Applied Microbiology Laboratory

Environmental Monitoring

Villa Cella, Milan, Italy

APPLICATION NOTE N° 130

"DAILY-SHIFT" ASPIRATING HEAD USE IN CLEANROOM

STANDARD OPERATING PROCEDURE (POS)

INTRODUCTION

Use of DAILY SHIFT aspirating head for TRIO.BAS air samplers

GLP (Good Laboratory Practice), GSP (Good Sterilization Pratice), GAP (Good Aseptic Pratice), "GAMP" (Good Air-Monitoring Practice) request that all the material used for the microbiological monitoring of the environment is sterile and the inspector authorities ask to document the sterilization compliance. Such notes request a written certification on what you are doing. The "Daily Shift" aspirating head of TRIO.BAS microbial air samplers includes a certification of sterilization by gamma irradiation

OBJECT

Procedure for the correct use of microbial air sampler, in combination with the "Daily Shift" aspirating head, in Cleanroom, Isolator, RABS

PURPOSE

Reduction of the risk of microbial contamination during air sampler handling

RESPONSIBILITY

It is the responsibility of Quality Control Staff to ensure proper operation, maintenance and calibration of Air Sampler per this procedure.
It is the responsibility of Quality Control/Quality Assurance to ensure that all personnel performing this procedure is properly trained.
It is the responsibility of Quality Control Personnel to update and revise this procedure as appropriate.

GLOSSARY

Agar, Autoclave, Contact Plate, Cleanroom, 55 mm Contact Plate, CFU: Colony Forming Units, Disinfection, Disinfectant, Impact, Medium,90 mm Petri dish, POS, RABS, Risk, RODAC, SDA: Sabouraud Dextrose Agar, Sterilization, Total Bacterial Count, TSA: Tryptic Soy Agar

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STANDARD REFERENCE

ISO 14698-1:2003 - Cleanrooms and associated controlled environments - Biocontamination control - Part 1: General principles and methods

MATERIAL

-TRIO.BAS microbial air samplers DUO, TRIO models, TRIO.BAS Isolator (100 or 200 litres per minute) for 90 mm Petri dish or 55 mm Contact plate



-Charging battery by induction
-Daily Shift plastic, sterile aspirating head for 90 mm Petri dish or 55 mm Contact plate (double bagged)
Sterile disinfectant 70%
Fresh prepared double bagged identified Petri dish or Contact plate with Tryptic Soy Agar (TSA)

PROTOCOL

THE "DAILY SHIFT" ASPIRATING HEAD USE IN CLEANROOM



"Daily Shift" head is used in the same cleanroom for several sampling cycles during the same shift. Before starting a new cycle, the "Daily Shift" is screwed to the sampler.

TRIO.BAS AIR SAMPLER

A. TRIO.BAS AIR SAMPLER - The air sampler should be used according the Instruction Manual and programmed according the company instructions. The suggested volume of air to be aspirated for each cycle is 1000 litres (1 cubic metre). This volume may be aspirated continuously on the same plate or progressively in separate cycles (e.g.: at ten minute intervals).

B. TRIO.BAS ISOLATOR

B1. The Satellite aspirating chamber should be positioned inside the isolator as close as possible to the more critical area and to avoid any interference to the operating activity and any disruption of the air flow. Several sampling chambers may be positioned in different critical points of the isolator.

B2. The control unit of the TRIO.BAS Isolator should be positioned outside of the isolator in a place to facilitate the sampling command. The induction battery charger should positioned near the command unit.

B3. The sterile Petri dish or Contact plates are transferred inside the isolator in their sterile package.

B4. The sterile DAILY SHIFT aspirating head are transferred inside the isolator in their sterile package.

B5. The Petri dish or Contact plate is inserted into the aspirating chamber of the air sampler; the lid of the plate removed and the sterile DAILY SHIFT aspirating head applied.

B6. The test should be repeated every hour or at rest, in operation and at the end of operation.

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C. The plate should be removed at the end of each aspirating cycle. It will then be transferred out of isolator to the incubator (32°C or 37°C).

D. The sampling data should be printed connecting the air sampler to a printer or a P.C.

E. The Colony Forming Units (CFU) of each plate are counted at the end of incubation time and reported on the final report.

NON CONFORMITY

1.Broken packaging of the plates /aspirating head.
2.Expired date of the plates / aspirating head.
3.Contaminated plates before their use.

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