

# Basic information about microbial monitoring of cleanrooms



Viable particles of bacteria yeast and moulds living microscopic organisms present in the air and on surfaces of the environment.

Their analysis usually includes the monitoring of air, surfaces and staff and it is necessary to validate the quality of production environments.

## Viable air sampling

Settling Petri dishes or contact plates containing sterile growth media are used for microbiological environmental sampling.

**Petri dishes** can passively be exposed to the environment for 60 - 240 minutes. Viable microorganisms that settle on the medium surface grow when the plates are incubated. Settling plates can be used for a qualitative identification of viable particles, but they do not directly correlate to the microbial contamination of environment, because they do not provide a quantitative measurement of air contamination.



Figure 1. **Petri dishes with TSA for environmental control** (Cat. No. 131114ZI). The triple-irradiated wrapped packaging ensures that the package itself doesn't contaminate the cleanrooms where the dishes are used.

**Air samplers** - Active monitoring instrument such as SAS Super ISO or MAS-100 NT<sup>®</sup> measure an exact volume of air with a quantifiable number of viable microorganisms. Contamination can therefore be measured per cubic meter of air (1000 litres).



Figure 2. **SAS SUPER ISO microbiological air sampler** (Cat. No. 710-0869) is compliant with International Standards ISO 14698 and Pharmacopeia USP1116 chapter.

## Viable surface sampling

**Contact plates** - Similar to Petri dishes containing sterile growth medium. The agar protrudes above the sides of the plate. The convex contact plate is pressed against a flat, regular surface to be sampled. Any viable microorganism present on that surface will adhere to the agar and grow after incubation. The surface sampling technique is standardised using a 'Contact Weight' sampler to apply the same weight and the same contact time to the surface. Contact plates are not appropriate for irregular surfaces.



Figure 3. **TSA contact plates** (Cat. No. 271114ZI). The medium is pressed against the surface to take a sample of the environment. The special blister single packaging enables the use of a single plate at a time.



Swabs for environmental control in triple protection wrap for cleanrooms (Cat. No. 300-0228).



Figure 5. SANI-SPONGE, (Cat. No. 300-0230) sterile dry sponge in sterile bag used for sampling large surfaces.



Contact plate applicator to standardise the pressure of contact plates on surfaces (Cat. No. 710-0961).

**Swab** - Sterile swabs are used for sampling of uneven surface such as tubing, equipment, corner, etc. Swabbing can be a qualitative or quantitative technique. A known flat area (traditionally 10x10 cm) is swabbed using a back and forth technique that is repeated after 90° swab rotation. The same technique is used on uneven surfaces. The swab is then streaked onto the agar surface of a Petri dish for identification or transferred to stomacher for microbial population counting.

**Sponge** - Sterile sponges are used for sampling large surfaces. The sample site is pressed by the humidified sponge adopting aseptic technique to avoid hand contamination. The sponge is then treated in a bag by stomacher. The obtained dilution is then tested.

## Viable particles - staff monitoring

Personnel working in a controlled contamination environment should be monitored for germ contamination to evaluate gowning proficiency. Sampling sites are hands, gloves and gowns. Contact plates are used to dynamically monitor the staff's hands immediately before and after a critical process.

## Sampling locations

Sampling locations are selected based on potential product exposure areas, equipment design plus validation data and processing parameters. The frequency of sampling depends on product and quality requirements and based on trending results. A sampling plan, reported in a Standard Operating Procedure, should describe the procedure, the sampling sites, the sampling frequency plus the static and dynamic situation.

## Action/alert levels

Each company or laboratory should establish 'alert and action' levels based on previous environmental monitoring data. Exceeding the alert level should cause the increasing sampling intensity or frequency in the affected area. The consequent 'corrective actions' will have the goal to return a facility to acceptable limits of viable microorganisms as quickly as possible. These actions should include a determination of what caused the viable counts to be above acceptable limits and how that will be rectified in future.