



ENSURE SURFACE SAMPLING ACCURACY AND EFFICIENCY WITH APP¹ LOCKSURE3P™

In aseptic processing areas, even one single colony matters. This highlights the importance of having robust and sensitive culture media, while using reproducible and reliable sampling methods.

High variability of surface sampling methods can have a major impact on environmental monitoring control

Several standards exist to provide guidelines for surface sampling. These address surface sampling variability and decrease any associated risk of false negative results.

■ USP <1116> underlines the importance of standardization of surface sampling methods.

● SURFACE SAMPLING

Another component of the microbial-control program in controlled environments is surface sampling of equipment, facilities, and personnel. The standardization of surface sampling methods and procedures has not been as widely addressed in the pharmaceutical industry as has the standardization of air-sampling procedures. Surface sampling can be accomplished by the use of contact plates or by the swabbing method.

■ ISO 14698-1 highlights the importance of having uniform surface sampling.

● CONTACT SAMPLING DEVICES

The nutrient medium should be applied to the surface for a few seconds with a uniform and steady pressure to the whole area, without allowing any circular or linear movement.”

■ ISO 18593 claims that

“from the literature it is known that optimal results for contact plates are obtained with a contact time of 10 s and a pressure obtained with a mass of 500g”.



The APP LOCKSURE3P™ applicator ensures compliance with these standards thus reducing any associated risk of false negative results.



PIONEERING DIAGNOSTICS

STANDARDIZED AND EASY TO USE

When using Count-Tact culture media the APP LOCKSURE3P™ applicator standardizes surface monitoring by applying a uniform, reproducible and standardized steady pressure, during a defined lead time, on the analyzed surface.



Standardization

● APP LOCKSURE3P™ APPLICATOR

brings accuracy and efficiency to environmental monitoring by guaranteeing standardization of surface sampling.



Healthcare industries compatibility

● APP LOCKSURE3P™ APPLICATOR

design and validations provide full compatibility to the required pharmaceutical environments.



Efficiency

● APP LOCKSURE3P™ APPLICATOR

allows immediate visualization of the surface sampling status



Count-tact media inserted in the APP LOCKSURE3P™ applicator is ready to process surface sampling



The surface sampling is in process. A uniform pressure is applied on the surface to be sampled. A flashing red light indicates the sampling is on-going.



A green light indicates the end of the surface sampling. The Count-Tact media can then be removed from the applicator.

EFFICIENCY AND REPRODUCIBILITY



A detailed study shows the benefits of using the APP LOCKSURE3P™ applicator in the recovery of surface microorganisms. It also highlights the reduction of variability between operators, thus favoring the standardization of surface monitoring

➤ The use of the APP LOCKSURE3P™ applicator allows an 8% improvement in the recovery rate.

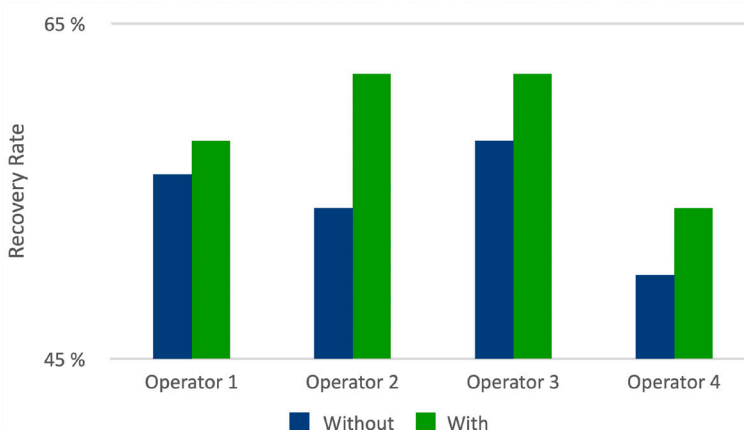


Figure 1: Recovery rate with and without APP LOCKSURE3P™ applicator for each operator.

Four operators used Count-Tact culture media with and without the APP LOCKSURE3P™ applicator for their surface monitoring. This graph shows the difference in recovery rates with and without the APP LOCKSURE3P™ applicator.

➤ The use of the APP LOCKSURE3P™ applicator results in a 9% decrease in variability between the four operators..

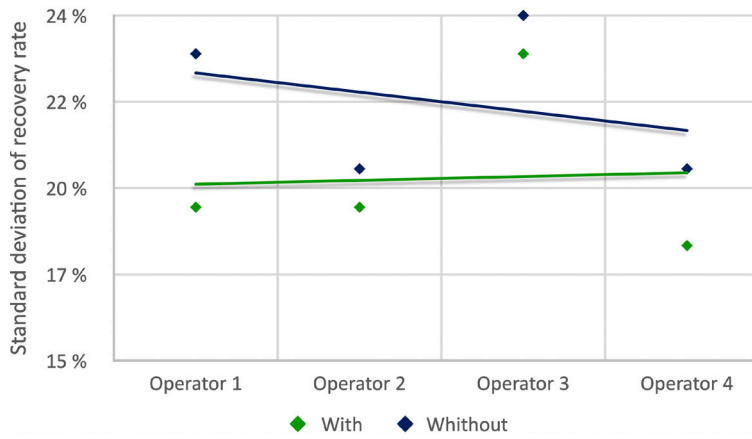


Figure 2: Standard deviation of recovery rate with and without the APP LOCKSURE3P™ applicator for each operator.

The use of the APP LOCKSURE3P™ applicator increases by 8% the chance of detecting a potential bacterial contamination in a clean room, which is critical in the manufacturing of sterile drugs to ensure patient safety.

The use of an applicator also reduces the variability between operators by 9%, which leads to better standardization of surface monitoring.



“Today, it is essential to guarantee the best recoveries we can for your Environmental Monitoring Strategy. During inspections or audits, it is important in the Pharmaceutical Industry to justify a practice allowing to collect the best information we can. In this way and especially for surface sampling, it is important to use an applicator systematically and for surfaces, hard to reach or for Barrier Technologies, it is essential to combine both contact plates and swabs.”

- Pierre DEVAUX, Scientific Director
THERAXEL

1: Reference 421160 - APPLockSure 3P

