World's Largest Microbial Surface Sampling Dataset Reveals Need for Each Person to be Qualified

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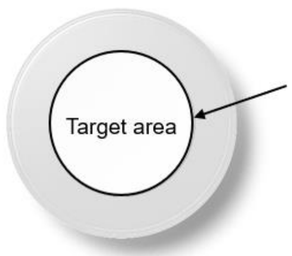
Introduction

Monitoring the level of bioburden on surfaces in cleanrooms is a critical component of an effective contamination control strategy. The recent revisions to Annex 1 underscore the importance of understanding recovery efficiency as it relates to your environmental monitoring program. However, in many cases, the microbial recovery efficiency of the personnel using their sample collection device is unknown. Here we present the results from the world's largest surface sampling performance dataset to date that includes >1,000 sampling events across more than 300 test sites.

This study was enabled by Enverify™ Test Surfaces. Enverify™ Test Surfaces are the first standardized microbial coated surfaces for evaluation of surface sampling performance. Each test surface has a precise quantity of viable microbes coated over the target area. They are stable at 2-8°C for >12 months and shippable anywhere in the world.



A precise quantity of viable microbes are coated and preserved onto the **target area** for sampling evaluation.

Purpose

The purpose of this study was to understand key contributors to surface sampling variation in the real world. This was accomplished by evaluating surface sampling performance, including microbial recovery efficiency and aseptic technique, of a large population of people in the field with standardized test surfaces.

Materials and Methods

The Enverify™ Surface Sampling Competency Kit included 3 microbial coated surfaces and 2 sterile blanks. Each microbial coated test surface contained <100 colony forming units (CFU) of *Escherichia coli* ATCC® 25922™. Each participant was instructed to receive the kit at their site, perform sampling using their sampling method and contact plates, and send the contact plates to a test lab for incubation and enumeration. The CFU results for each participant were then compared to the known quantity of CFU's on each Enverify™ Test Surface to determine the participants recovery efficiency and aseptic technique. The contact plate information (Cat #) for each participant was recorded throughout the study.

Step 1
Enverify™ Test Surfaces shipped to participant

Step 2
Participant performs sample collection on Enverify™

Step 3
Contact plates incubated and enumerated at lab

Results

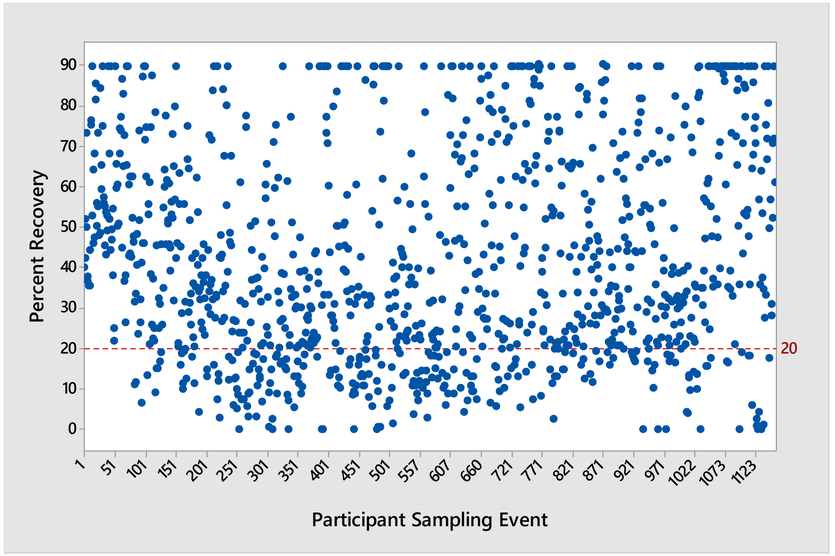


Figure 1: Contact Plate % Recovery by Participant Sampling Event

- **1,155** sampling events across >300 test sites
- **22%** of sampling events fell below 20% recovery
- **8.3% c**ontaminated the contact plates during sampling

Figure 1 shows the percent recoveries by 'participant sampling event' for this study (n = 1155). Each data point is the average of 3 microbial coated test surface replicates. The red line at 20% recovery indicates a recovery efficiency PASS/FAIL threshold that was established based on earlier datasets and contact plate literature.

Figure 2 shows the recovery efficiency of 16 different commercially available contact plates. These data were extracted from the larger surface sampling dataset. There was a high level of difference in the recovery efficiency of commercially available contact plates. These data underscore the need for a standardized method of qualifying contact plates for recovery of microbes from a surface.

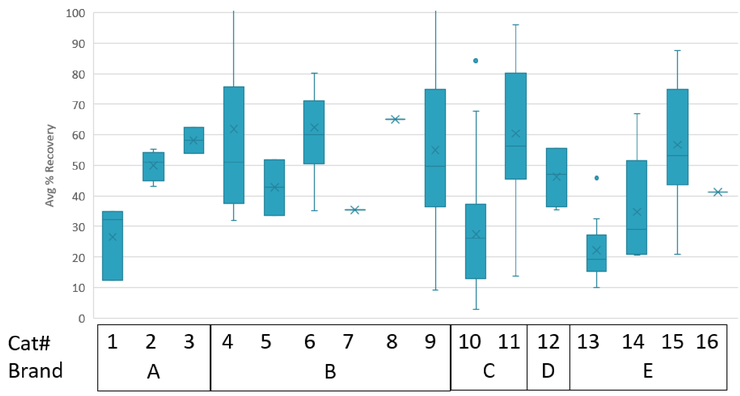


Figure 2: Recovery efficiency of different contact plate

Significance

This is the largest viable surface sampling dataset that has ever been generated. This dataset reveals important insights into the high level of impact that personnel surface sampling technique and contact plate devices have on environmental monitoring results.

There is a clear need for:

- Each person collecting surface samples to demonstrate competency in surface sampling as part of their annual training.
- Qualification of contact plates for use based on recovery efficiency of microbes from a surface.

These two actions will drive an improvement in surface sampling consistency and accuracy of EM data generated, and help with compliance with EU GMP Annex 1 revisions.

This study leveraged Enverify™ Test Surfaces, which are the first reference microbial coated surfaces for comparison of sampling performance of personnel and sample collection devices.

References

1. McIver, D., 2014. Validation of Environmental Monitoring Methods. [ebook] *Parenteral Drug Association (PDA).* Available at:
2. EU GMP Annex 1. Volume 4. Brussels, 22.8.2022. C(2022) 5938.