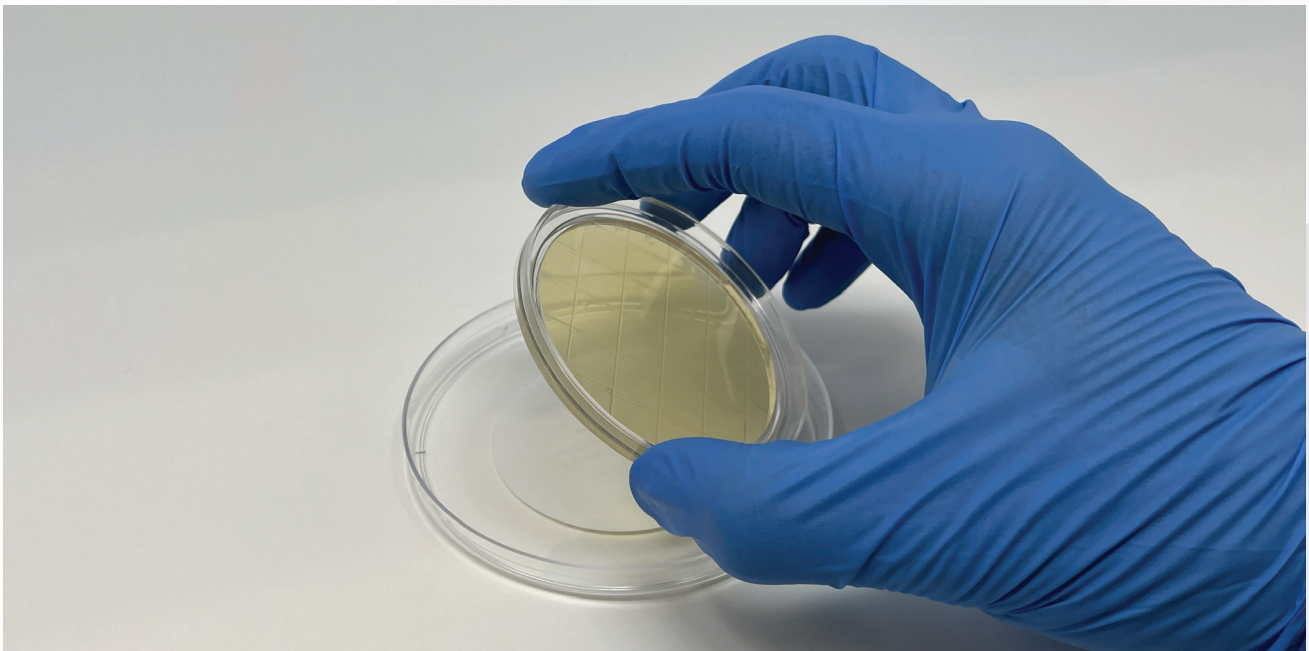


# Enverify™

Microbial-coated test surfaces for evaluating surface sampling competency



# Ensure the competency of your sampling personnel

Qualification of personnel who collect surface samples is a regulatory requirement and a crucial activity for an effective environmental monitoring program. Personnel sampling performance, including percent recovery, consistency, and aseptic technique, drives the quality of data that is generated and significantly impacts the integrity of an environmental monitoring program.



## Enverify™, the Industry Standard for Evaluating Surface Sampling Competency

Enverify™ Test Surfaces are the first standardized tool that enables you to evaluate and document surface sampling competency with quantitative data.

Each Enverify™ Test Surface contains a precise quantity of microorganisms, providing a benchmark for you to evaluate, verify, and compare performance. Enverify™ is designed for use with contact plates and swab sampling tools.



Determine Percent Recovery



Determine Sampling Consistency



Confirm Aseptic Technique



Document Personnel Competency



*The target area is located on the underside of the lid.*

Microorganisms are coated and preserved onto the **target area** for sampling.

Blinded blanks are included to confirm **aseptic technique**.

# Achieve compliance with industry standards and guidelines

## Applicable Industries

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- Pharmaceutical
- Compound pharmacy
- Medical device
- Cosmetics



## USP <797>

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New revisions to USP <797> are being implemented on November 1, 2023 and include the following requirements:

- Personnel must be trained and qualified by demonstrating knowledge and competency in collecting surface samples and using proper aseptic technique.
- Each compounding facility must have a process for evaluating the performance of individuals in key functions, including surface sample collection.
- Competency must be demonstrated at least every 12 months.
- Surface sampling must be conducted at least monthly and after media fill testing.

## Pharmaceutical Inspection Co-operation Scheme (PIC/S) & Annex 1

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New revisions to PIC/S and Annex 1 Good Manufacturing Practices are being implemented on August 25, 2023 and include the following requirements:

- Sampling methods and equipment should be fully understood and procedures should be in place for the correct operation and interpretation of results obtained. Support data for the recovery efficiency of the sampling methods chosen should be available.
- Personnel conducting surface sampling must be trained and qualified.

## Additional Standards and Guidelines

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Additional industry standards and guidelines describe the need and importance of qualification of personnel who collect samples, including:

- PDA Technical Report #13 Fundamentals of an Environmental Monitoring Program
- USP <1116>
- FDA Microbiology Manual



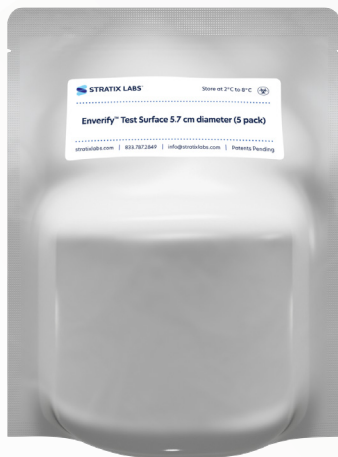
# Reduce risk in your production process using Enverify™

## Benefits for Surface Sampling Programs

- Demonstrate recovery efficiency and aseptic technique
- Document technician competency
- Identify training opportunities & improve sampling consistency
- Develop & validate sampling protocols
- Improve compliance with regulatory guidelines & best practices

## Available Products

Cat #	Product	Description
E25922C	Enverify™ Surface Sampling Competency Kit (5.7cm dia.)	Includes three (3) microbial-coated test surfaces and two (2) sterile blinded blank test surfaces. Compatible with contact plates and swab sampling tools.
E25922K	Enverify™ Surface Sampling Competency Kit (10cm x 10cm)	Includes three (3) microbial-coated test surfaces and two (2) sterile blinded blank test surfaces. Compatible with swab sampling tools.



**Contact us to purchase or learn more.**

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