

Enverify™ Surface Sampling Competency Kit (5.7 cm dia.)

INSTRUCTIONS FOR USE

PRODUCT DESCRIPTION

Enverify™ Surface Sampling Competency Kit is a test kit for determining surface sampling competency and training verification. This includes the technician’s ability to adequately recover viable microorganisms from a surface as well as the technician’s aseptic technique while taking a surface sample. Each kit contains 5 total Enverify™ Test Surfaces. Three of the test surfaces are coated with a known quantity of the reference microorganism, and two of the test surfaces are sterile, blinded blank surfaces.



**Watch Enverify™
How-to Video**

The microorganisms contained in this product are nonpathogenic, BSL-1 microorganisms that are not known to pose a health risk to humans. Enverify™ Test Surface(s) are packaged in a sealed foil pouch and are disposable after use.

Enverify™ products are available in the following versions:

Cat #	Description
E25922	Enverify™ Test Surface (10cm x 10cm Test Surface)
E25922S	Enverify™ Test Surface (25cm x 36cm Test Surface)
E25922K	Enverify™ Surface Sampling Competency Kit (10cm x 10cm), Test Surface with microbes (Qty. 3) and Sterile Blank Test Surface, blinded (Qty. 2)
E25922C	Enverify™ Surface Sampling Competency Kit (5.7cm dia.), Test Surface with microbes (Qty. 3) and Sterile Blank Test Surface, blinded (Qty. 2)
CSTM	Custom Solutions: Contact us to submit a request for Enverify™ Test Surfaces with custom organisms, quantities, or surface materials.

INTENDED USE

The Enverify™ Surface Sampling Competency Kit (5.7 cm dia.) provides pre-inoculated test surfaces that are intended to be used to verify the environmental surface sampling competency of sampling personnel. This includes the personnel’s sampling technique to adequately recover a known quantity of microbes from a surface as well as proper aseptic technique during the operation of taking a surface sample. This product is compatible with most contact plates and swab sample collection devices. Applications may include environmental surface sampling in sterile pharmaceutical compounding facilities, pharmaceuticals, personal care production facilities, and healthcare environments.



WARNINGS AND PRECAUTIONS

- This product is not intended for human, animal, or pet consumption.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on our website at www.stratixlabs.com.
- The microorganisms contained in this product are nonpathogenic, BSL-1 microorganisms. Use appropriate precautions and aseptic handling.
- Wear protective gloves and protective clothing. When appropriate, wear eye and/or face protection. Wash hands after handling.

STORAGE

Store the foil pouch containing the Enverify™ Test Surface(s) at refrigeration temperature 2-8°C. This product will maintain the specified range of viable CFU counts when stored and used as directed. Do not open the foil pouch containing Enverify™ Test Surface(s) until you are ready to use the product. Use all test surfaces within 20 minutes of opening the foil pouch.

PRODUCT KIT COMPONENTS

- a) Foil pouch that includes five Enverify™ Test surfaces
- b) Clear, zipper bag with label (for shipping contact plates)
- c) Clear, zipper bag (no label, for used test surfaces)
- d) Adhesive dots strip(s), Qty. 2
- e) Convenience labels for contact plates
- f) Download Enverify Data Sheet: <https://stratixlabs.com/documents>

INSTRUCTIONS FOR USE

1. Download form F-071 Enverify Data Sheet at <https://stratixlabs.com/documents>
2. Prepare a clean working space using an appropriate surface cleaner.
3. Obtain five (5) contact plates and apply pre-printed labels to the contact plates (Sample #1-5). Write the identification of the sampling personnel (i.e., technician's initials) on every plate. Fill in Tables 1, 2, and 3 in F-071 Enverify Data Sheet.
4. Obtain the strip of adhesive dots. Remove one side of the protective backing and place the strip of adhesive dots on the work surface. To secure the dots on the surface, be sure to firmly press the edges of the dot to the work surface.
5. Remove the backing from the adhesive dots by pulling with a shear motion parallel to the working surface to maintain adhesion of the dots to the surface.
6. Tear open the foil pouch and remove the five (5) Enverify™ Test Surfaces.
Note: Once the foil pouch is opened, use all test surfaces within 20 minutes of opening.
7. Select one Enverify Test Surface. Place and press the Test Surface, label side down, on the adhesive dots adhered to the work surface. Remove the base of the test surface (non-labeled side of device).
Note: The microbial coating is on the inside of the device lid in the area outlined by the underside of the label. This is the area you sample with the contact plate or swab. Be sure not to inadvertently touch this surface during sampling.



8. Sample the white area of the Enverify™ Test Surface. **Ensure the sample number (Sample #1-5) on the contact plate used matches the sample number on the Enverify™ Test Surface.** Do not sample an individual test surface more than once.
9. Remove Enverify™ Test Surface from the adhesive dots and discard the used Enverify™ Test Surface into an appropriate waste stream.

Repeat steps 6-8 for the remaining test surfaces.

10. If sending contact plates to external lab for incubation and enumeration: obtain the labeled zipper bag and write your name and the Enverify™ lot number on the bag. Place your contact plates inside the bag and follow your test lab's instructions for shipping materials for CFU enumeration **AND** send your test lab F-071 Enverify Data Sheet.

If you are incubating and enumerating your contact plates in-house, proceed according to your laboratory's procedures. Fill out Table 4 on F-071 Enverify Data sheet and send to data@stratixlabs.com.

Note: If you do not have a biohazard waste stream, place the used Enverify™ Test Surfaces in the unlabeled zipper bag and send them to your test lab or to Stratix Labs for disposal.

Made in U.S.A by: **Stratix Labs Corporation**
1000 Westgate Drive, Suite 132
St. Paul, MN 55114
www.stratixlabs.com
info@stratixlabs.com

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