

Double sided TSA growth media paddles for surface or fingertip contamination sampling, formulated with polysorbate 80 and lecithin to inactivate antimicrobial compounds. Formulation: Tryptose, Yeast Extract, Dextrose Agar, Polysorbate 80, Lecithin

Storage, Stability, and Destruction:

EnviroTest[®] paddles should be stored unopened at room temperature and protected from light. The paddles must not be allowed to freeze. Any unused paddles showing microbial growth should be discarded. All used paddles should be discarded consistent with applicable State and Federal regulations.

Fingertip Log



Surface Log



Also available at:
www.qimedical.com

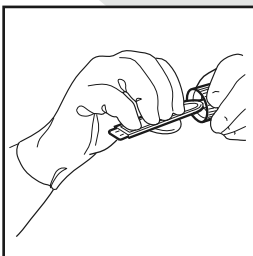
INSTRUCTIONS FOR USE

Glove Fingertip Sampling:

Per USP <797> test should be conducted immediately after completion of the hand hygiene and garbing procedure (e.g. donning sterile gloves before any disinfection with sterile 70% IPA)

1. Remove 2 EnviroTest[®] paddles (one for each hand being tested) and visually inspect for signs of contamination or dryness.
2. Properly note in the log sheet the necessary information (date, name of the individual, lot number, etc.)
3. Using an aseptic technique remove one EnviroTest[®] from the tube.
4. Place the four fingertips' pads on the device's upper side and the thumb pad on the underside (See Figure 1). Hold pads on the agar surface, pressing lightly (Do not squeeze) for 3-5 seconds.
5. Carefully replace the paddle into the tube and secure the lid.
6. Repeat the steps on the remaining gloved hand.
7. Fill out circular stickers in the EnviroTest[®] box to identify the individual and hand (i.e. Tech #1, left hand) and attach them to the appropriate tube
8. Incubate each media device, per USP <797> at 30°-35°C for no less than 48 hours, then incubate in the other incubator at 20°-25°C for no less than 5 additional days.

Figure 1



Surface Sampling:

Referring to the facility sampling plan, select a single EnviroTest[®] for each location to be tested.

1. Visually inspect each device for signs of contamination and dryness.
2. Properly note in the log sheet the necessary information (date, name of the individual, lot number, sample site, etc.)
3. At each sampling site, gently press the agar against the surface to be tested (Figure 2). Then flip the paddle over and press the agar directly next to the area so that you have sampled a square-shaped area (Figure 3)
4. Carefully replace the paddle into the tube and secure the lid.
5. Repeat the sampling process until all areas are completed.
6. Sampled surfaces should be cleaned to remove residual agar immediately after testing.
7. Fill out circular stickers in the EnviroTest[®] box to identify the sampling location and attach them to the tube.
8. Incubate each media device, per USP <797>, in a separate incubator. Incubate one device at 30°-35°C for no less than 48 hours, then incubate in the other incubator at 20°-25°C for no less than 5 additional days.

Figure 2

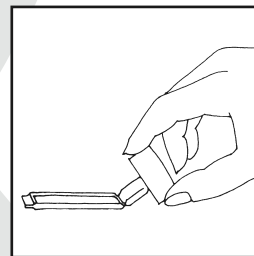
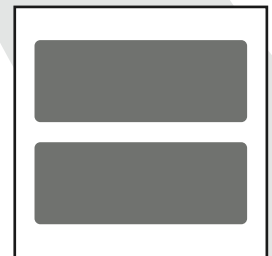


Figure 3



Interpretation of Results:

Carefully remove the paddle from the vial and visually examine it under good lighting. Count the number of discrete colonies present and report them as colony-forming units (cfus). Per <USP> 797, the results must be recorded on an environmental sampling form based on the sample type (i.e., surface), and include the sample location and name. Decide if action is necessary based upon USP <797> Recommended Action Levels as follows:

| ISO Class of Sampled Location | Fingertip Sample | Surface Sample |
|-------------------------------|------------------|----------------|
| 5 | >3* | >3 |
| 7 | Not Applicable | >5 |
| 8 | Not Applicable | >100 |

*CFU action level for gloved fingertips is based on the total CFU count on both gloves rather than per hand.