Cultivate
A PARASOL MEDICAL PRODUCT

2023 Environmental Surface Sampling Directions for Use

Contact™ Media Paddles
Cat. # TD100 - TSA Media

2023 USP <797> Section 6.3 Monitoring Surfaces for Viable Particles
For additional Cultivate™ directions for use and test logs, go to www.parasolmed.com/cultivate/cultivate-resources

Storage, Stability, and Destruction

Contact™ paddle kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. The media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Paddles should be discarded in accordance with State and Federal regulation.

Testing Overview and Frequency

	Pass-through chambers and classified areas	Withing the PEC used to compound Cat. 3 CSPs	
		Not using a self-enclosed robotic device	Using a self-enclosed robotic device
Cat.1 & 2 CSPs	at least monthly	N/A	N/A
Cat. 3 CSPs	at least weekly* and must be completed prior to assigning a BUD longer than the limits established in Table 13 in USP <797> Section 14.3 Establishing a BUD for a CSP[1]	at the end of each batch prior to cleaning or disinfecting[1]	at least once daily at the end of compounding prior to cleaning or disinfecting[1]

Each classified area, including each room and the interior of each ISO Class 5 PEC and pass-through chambers connecting areas, must be sampled for microbial contamination using a risk-based approach. Samples should be taken from the following classified areas:[1]

- Equipment contained within the PEC
- Staging or work area(s) near the PEC
- Frequently touched surfaces

Gloved Fingertip and Thumb Sampling Procedures

BEFORE YOU BEGIN : *Inspect the media paddles carefully before starting to test. If the media agar is clear and free of contamination and particulate prior to testing, then any contamination or particulate observed after collecting the samples or incubating the samples will have been introduced by the testing personnel.*

Surface sampling should be preformed at the end of the compounding activities or shift, but before the area has been cleaned and disinfected. All sampling sites and procedures must be described in the facility's SOPs.[1] Download a copy of the media lot specific Certificate of Analysis (CoA) at www.parasolmed.com/cultivate/cultivate-resources.

Contact Inoculation Procedure

Remove the cover from the media paddle. Using a rolling motion, firmly press the media surface onto the surface to be sampled. Use both sides of the media paddle for each sample site. **DO NOT** drag the agar across the surface. After sampling, clean and disinfect the sampled area to remove the residue from the surface. After collecting the sample, carefully place the paddle back into the clear vial and secure firmly.

Swab Sampling Procedure for Difficult to Reach Surfaces

A sterile swab moistened with sterile water or a sterile neutralizer may be used to sample irregular or hard to reach surfaces.[1] Rotate the swab while moving it over the sample area to pick up as much sample as possible. Firmly roll the swab on both agar surfaces.

Incubation Procedures

- Handle with care and invert the paddles when incubating to avoid contamination and prevent condensate from dropping onto the agar during incubation and affecting the accuracy of the cfu reading.[1] **TIP:** You can cut the top of the TD100 plastic tray off and use it as a rack when incubating to prevent paddles from falling.
- The incubator must be placed in a location outside of the sterile compounding area and the temperature must be monitored either manually or by a continuous recording device.
- Incubate the paddle(s) at **30°–35° for no less than 48 h**. Examine for growth.[1] Record the total number of discrete colonies of microorganisms on each media device as cfu per media device on the *Cultivate™ Contact™ Surface Sampling Test Log* based on sample type (i.e., surface), sample location, and sample date.
- Incubate the paddle(s) at **20°–25° for no less than 5 additional days.** Examine for growth.[1] Record the total number of discrete colonies of microorganisms on each paddle (cfu per sample) on the *Cultivate™ Contact™ Surface Sampling Test Log* based on sample type (i.e., surface), sample location, and sample date.
- *Alternatively, to shorten the overall incubation period, two surface sampling paddles may be collected for each sample location and incubated concurrently. See Cutlivate 2023 Environmental Surface Sampling - Two Samples per Location DFU.*[1]

Interpreting Evaluation Results

Failure is indicated by cfu count(s) high than the action levels for the associated ISO Class. Evaluate cfu counts against the action levels, and examine counts in relation to previous data to identify adverse results or trends. If levels measured during surface sampling exceed the action levels for the ISO classified levels of the area sampled, the cause must be investigated and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. **The corrective action plan must be dependent on the cfu count and the microorganism recovered.** The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. If levels measured during surface sampling exceed the action levels, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a microbiologist.[1]

Action Levels for Surface Sampling, per 2023 USP <797>[1]

ISO Class	Surface Sampling Action Levels (cfu/device or swab)
5	>3
7	>5
8	>50

Action levels are based on the total cfu count for both sides of paddle

TSA Media Ingredient: Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, agar, lecithin, polysorbate 80 (Tween®). Final pH 7.3 +/- 0.2 at 25°C. Lecithin inactivates quaternary ammonium compounds Polysorbate 80 (Tween®) inactivates phenolics, hexachlorophenes, and formaldehyde. Lecithin & Polysorbate 80 (Tween®) together create a synergistic effect that inactivate ethanol.

[1] U.S. Pharmacopeia Convention. (2022). <797> Pharmaceutical Compounding–Sterile Preparations.