Cultivate
A PARASOL MEDICAL PRODUCT

# 2023 Gloved Fingertip and Thumb Sampling Directions for Use

Contact™ Media Paddles
**Cat. # TD100 -** TSA Media

**2023 USP <797> Section 2.2 Demonstrating Competency in Garbing and Hand Hygiene**
For additional Cultivate™ directions for use and test logs, go to www.parasolmed.com/cultivate/cultivate-resources

## Testing Overview and Frequency

| | Cat. 1/Cat. 2 CSP Compounder | Cat. 3 CSP Compounder | Personnel who have direct oversight of compounding personnel |
|---|---|---|---|
| **Initial Evaluation** | All personnel must successfully complete an initial garbing competency evaluation **no fewer than 3 separate times. The 3 successful completions must be in succession**–failure of any of the 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row. Each of the 3 initial competency evaluations must occur after preforming a seperate and complete hand hygiene and full garbing procedure and also includes a visual documented audit of proper garbing and hand hygiene procedures.[1] | | |
| **Subsequent Evaluations** | At least once every 6 months | At least once every 3 months | At least once every 12 months* |

## Storage, Stability, and Destruction

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

## Gloved Fingertip and Thumb Sampling Procedures

**BEFORE YOU BEGIN:** Inspect the media paddles carefully before starting the test. If the media agar is clear and free of contamination and particulate matter prior to testing, any contamination or particulate matter observed after collecting or incubating the samples must have been introduced by the compounding personnel. If you observe contamination or particulate matter prior to opening media paddles, contact your local sales rep.

In accordance with 2023 USP <797> section requirements, Cultivate™ TSA growth media is supplemented with neutralizing additives such as lecithin and polysorbate 80.

Download a copy of the media lot specific Certificate of Analysis (CoA) at www.parasolmed.com/cultivate/cultivate-resources.

**Procedures**[1]

- GFT sampling must be preformed on donned sterile gloves on both hands in a classified are or segregated compounding area (SCA) after garbing.
- **DO NOT** apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the media device because this could cause a false-negative result.
- Use one Contact™ TSA media paddle per hand. Label each media device with one of the personnel ID label provided, personnel name, right or left hand, and the date and time of sampling.
- Using a separate media paddle for each hand, collect samples from all gloved fingertips and thumbs from both hands by rolling fingertip pads and thumb pads over the agar surface. Use both side of the paddles to collect samples.
- After collecting the sample, carefully place the paddle back into the clear vial and secure firmly.

## Incubation Procedures

- Incubate the paddles at **30°–35°C for no less than 48 hours, and then at 20°–25°C for no less than an additional 5 days**. Samples must be placed in an incubator for this process. Handle paddles with care and invert them during incubation to avoid contamination and to prevent condensate from dropping onto the agar, which could affect the accuracy of the colony-forming unit (cfu) reading.[1] **TIP:** For added stability, you can cut off the top of the TD100 plastic tray and use it as a rack during incubation to prevent the paddles from falling over.

## Interpreting Evaluation Results

- Record the number of cfu per hand (left hand, right hand) after the incubation periods are complete.[1]
- Action levels for gloved fingertip and thumb sampling are for the total cfu for both hands. Determine whether the cfu action level is exceeded by counting the total number of cfu from both hands.[1]

### Action Levels for Gloved Fingertip and Thumb Sampling, per 2023 USP <797>[1]

| Gloved Fingertip and Thumb Sampling | Action Levels *(cfu, total from both hands)* |
|---|---|
| After garbing | >0 |
| After media-fill | >3 |

***Action levels are based on the total cfu count on both hands***

**Failure is indicated by any one of the following:**[1]

- Visual observation of improper hand hygiene and garbing procedures, regardless of growth after incubation.
- Gloved fingertip and thumb sampling results that exceed the action levels

***IMPORTANT: Microbial identification of colony forming units (cfu) is NOT required for gloved fingertip and thumb sampling even if the cfu count exceeds the action levels.***

Results of the evaluation and corrective action, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.[1]

*The Cultivate™ Contact™ GFT Test Logs were specifically designed to meet all the documentation requirements for the revised USP <797> Chapter 2.2 Demonstrating Competency in Garbing and Hand Hygiene for both initial and subsequent GFT testing. For additional test log sheets visit* ***www.parasolmed.com/cultivate/cultivate-resources.***

**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.