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# PASS 2™ Aseptic Manipulation Competency Evaluation

Cat. #: TBVA123

**2023 USP <797> Section 2.3 Competency Testing in Aseptic Manipulation**  
For additional Cultivate™ directions for use and test logs, go to [www.parasolmed.com/cultivate/cultivate-resources](http://www.parasolmed.com/cultivate/cultivate-resources)

**EMPLOYEE NAME:**

**ASEPTIC COMPETENCY - MEDIA-FILL TEST**

Test Observer Name: \_\_\_\_\_  
Test Date: \_\_\_\_\_ Test Time: \_\_\_\_\_  
 Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file. To download a copy, visit [www.parasolmed.com/cultivate/cultivate-resources](http://www.parasolmed.com/cultivate/cultivate-resources)

**PRODUCT INFO**

|  |   |
|--|---|
| <b>Item: 3mL Ampule</b><br>Media Type: TSB, Red Dye, Sterile<br>Media Exp. Date: _____<br><br><b>Item: 20mL Multidose Vial</b><br>Media Type: TSB, Sterile<br>Media Exp. Date: _____<br><br><b>Item: 100mL Mini-bag, underfilled</b><br>Media Type: TSB, Sterile<br>Media Exp. Date: _____ | Component #: T-A003<br>Media Manufacture: Parasol Medical<br>Media Lot #: _____<br><br>Component #: T-V020<br>Media Manufacture: Parasol Medical<br>Media Lot #: _____<br><br>Component #: T-B100<br>Media Manufacture: Parasol Medical<br>Media Lot #: _____ |
|--|---|

***Additional Components (optional)***

**Item:** \_\_\_\_\_ **Component #:** \_\_\_\_\_  
Media Type: \_\_\_\_\_ Media Manufacture: \_\_\_\_\_  
Media Exp. Date: \_\_\_\_\_ Media Lot #: \_\_\_\_\_

**Item:** \_\_\_\_\_ **Component #:** \_\_\_\_\_  
Media Type: \_\_\_\_\_ Media Manufacture: \_\_\_\_\_  
Media Exp. Date: \_\_\_\_\_ Media Lot #: \_\_\_\_\_

**INTERVAL 1**

The order of the incubation temperature must be described in the facility's SOPs.

Check One:  20-25°C for 7 day  
 30-35°C for 7 day

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

**INTERVAL 2**

Interval 2 temperature cannot be the same as interval 1

Check One:  20-25°C for 7 day  
 30-35°C for 7 day

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

**MEDIA-FILL TEST RESULTS**

Any growth / turbidity indicates a failed media-fill evaluation

Name of Person Reading the Results: \_\_\_\_\_  
Growth Results:  POSITIVE  NEGATIVE  
Media-fill Test Results:  PASS  FAIL

**ASEPTIC COMPETENCY - POST GFT TEST**

Test Observer Name: \_\_\_\_\_  
Test Date: \_\_\_\_\_ Test Time: \_\_\_\_\_  
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**PRODUCT INFO: LEFT HAND**

**PRODUCT INFO: RIGHT HAND**

|   |   |
|---|---|
| Component #: _____<br>Media Type: _____<br>Media Mfg: _____<br>Media Exp. Date: _____<br>Media Lot #: _____ | Component #: _____<br>Media Type: _____<br>Media Mfg: _____<br>Media Exp. Date: _____<br>Media Lot #: _____ |
|---|---|

**INTERVAL 1**  
2023 USP <797>  
30-35°C for no less than 48 hr

**INTERVAL 2**  
2023 USP <797>  
20-25°C for no less than 5 additional days

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

**POST GFT TEST RESULTS**

Report any growth greater than action levels to Pharmacy Manager

Name of Person Reading the Results: \_\_\_\_\_  
Visual Observation of Proper Garbing and Hand Hygiene  PASS  FAIL  
Growth Results (compare to action levels below):  POSITIVE  NEGATIVE  
Colony Forming Unit Count (total of both sides): \_\_\_\_\_  
GFT Test Results (must pass both visual and growth test):  PASS  FAIL

**GFT Sampling Action Levels, per 2023 USP <797><sup>1</sup>**

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

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

**ASEPTIC COMPETENCY - POST SURFACE SAMPLE TEST**

Test Observer Name: \_\_\_\_\_  
Test Date: \_\_\_\_\_ Test Time: \_\_\_\_\_  
 Check box to confirm you collected certificate of analysis (CoA) for growth media. Keep a copy of the CoA(s) on file. To download a copy, visit [www.parasolmed.com/cultivate/cultivate-resources](http://www.parasolmed.com/cultivate/cultivate-resources)

**PRODUCT INFO**

Component #: \_\_\_\_\_ Media Type: \_\_\_\_\_  
Media Manufacture: \_\_\_\_\_  
Media Exp. Date: \_\_\_\_\_ Media Lot #: \_\_\_\_\_

**INTERVAL 1**  
2023 USP <797>  
30-35°C for no less than 48 hr

**INTERVAL 2**  
2023 USP <797>  
20-25°C for no less than 5 additional days

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_  
End Date: \_\_\_\_\_

**POST SURFACE SAMPLE TEST RESULTS**

Report any growth greater than action levels to Pharmacy Manager

Name of Person Reading the Results: \_\_\_\_\_  
Growth Results:  POSITIVE  NEGATIVE  
Colony Forming Unit Count (total of both sides): \_\_\_\_\_  
Surface Sample Test Results:  PASS  FAIL  
If cfu count exceeds action levels, identify microorganism(s) to the genus level:

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**Surface Sampling Action Levels, per 2023 USP <797><sup>1</sup>**

| ISO Class | Surface Sampling Action Levels (cfu/device or swab) |
|-----------|---|
| 5         | >3  |

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

**EMPLOYEE ASEPTIC MANIPULATION COMPETENCY EVALUATION OVERVIEW**

**Sign-off after successful completion of all three test.**  
**Report any growth greater than action levels to appropriate management.**

PASS Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
 FAIL Manager Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**CORRECTIVE ACTION SUMMARY:**