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# PASS 3™ Aseptic Manipulation Competency Evaluation

Cat. #: TVA3211

**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**

<p><b>Item: 10mL Ampule</b>                      Component #: T2-A010 Media Type: 2x Strength TSB, Sterile      Media Manufacture: Parasol Medical Media Exp. Date: _____      Media Lot #: _____</p> <p><b>Item: 20mL Multidose Vial</b>                      Component #: T2-V010 Media Type: 2x Strength TSB, Sterile      Media Manufacture: Parasol Medical Media Exp. Date: _____      Media Lot #: _____</p> <p><b>Item: 20mL Multidose Vial</b>                      Component #: PT2-V020 Media Type: 2x Strength TSB Powder, Sterile      Media Manufacture: Parasol Medical Media Exp. Date: _____      Media Lot #: _____</p> <p><b>Item: 30mL Multidose Vial</b>                      Component #: T2-V030 Media Type: 2x Strength TSB, Sterile      Media Manufacture: Parasol Medical Media Exp. Date: _____      Media Lot #: _____</p> <p><i>Additional Components (optional)</i></p> <p><b>Item:</b> _____ Component #: _____ Media Type: _____ Media Manufacture: _____ Media Exp. Date: _____ Media Lot #: _____</p>	
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**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: \_\_\_\_\_  
 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: LEFT HAND	PRODUCT INFO: RIGHT HAND
Component #: _____ Media Type: _____ Media Mfg: _____ Media Exp. Date: _____ Media Lot #: _____	Component #: _____ Media Type: _____ Media Mfg: _____ Media Exp. Date: _____ Media Lot #: _____

INTERVAL 1	INTERVAL 2
2023 USP <797> 30-35°C for no less than 48 hr	2023 USP <797> 20-25°C for no less than 5 additional days

Actual Temp. Reading: \_\_\_\_\_      Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_      Start Date: \_\_\_\_\_  
End 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	INTERVAL 2
2023 USP <797> 30-35°C for no less than 48 hr	2023 USP <797> 20-25°C for no less than 5 additional days

Actual Temp. Reading: \_\_\_\_\_      Actual Temp. Reading: \_\_\_\_\_  
Start Date: \_\_\_\_\_      Start Date: \_\_\_\_\_  
End 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 (compare to action levels below):  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:**