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# HazardTest 2™ Aseptic Manipulation Competency Evaluation

Cat. #: TVA5211

**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: 10mL Ampule</b>	Component #: T2C-A010
Media Type: TSB, Red Dye, Sterile	Media Manufacture: Parasol Medical
Media Exp. Date: _____	Media Lot #: _____
<b>Item: 50mL Multidose Vial, 25mL Fill</b>	Component #: T2C-V5025
Media Type: TSB, Red Dye, Sterile	Media Manufacture: Parasol Medical
Media Exp. Date: _____	Media Lot #: _____
<b>Item: 50mL Multidose Vial, 50mL Fill</b>	Component #: T2C-V050
Media Type: TSB, Red Dye, Sterile	Media Manufacture: Parasol Medical
Media Exp. Date: _____	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 #: \_\_\_\_\_

<b>INTERVAL 1</b> The order of the incubation temperature must be described in the facility's SOPs.	<b>INTERVAL 2</b> Interval 2 temperature cannot be the same as interval 1
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Check One: <input type="checkbox"/> 20-25°C for 7 day <input type="checkbox"/> 30-35°C for 7 day	Check One: <input type="checkbox"/> 20-25°C for 7 day <input type="checkbox"/> 30-35°C for 7 day
Actual Temp. Reading: _____	Actual Temp. Reading: _____
Start Date: _____	Start Date: _____
End 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 - PSOT 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)

<b>PRODUCT INFO: LEFT HAND</b>	<b>PRODUCT INFO: RIGHT HAND</b>
Component #: _____	Component #: _____
Media Type: _____	Media Type: _____
Media Mfg: _____	Media Mfg: _____
Media Exp. Date: _____	Media Exp. Date: _____
Media Lot #: _____	Media Lot #: _____

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

<b>Gloved Fingertip and Thumb Sampling</b>	<b>Action Levels</b> <i>(cfu, total from both hands)</i>
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 #: \_\_\_\_\_

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

<b>ISO Class</b>	<b>Surface Sampling Action Levels</b> <i>(cfu/device or swab)</i>
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:**



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# HazardTest 2™ Hazardous Drug Containment Evaluation

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**2023 USP <800> Hazardous Drug Compounding and Handling**  
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:**

HAZARDOUS DRUG COMPOUNDING CONTAINMENT TEST	
Test Observer Name: _____	
Test Date: _____ Test Time: _____	
PRODUCT INFO	
<i>See reverse side for product info details.</i>	
HAZARDOUS DRUG COMPOUNDING CONTAINMENT EVALUATION	
Location	Check if red dye is observed on tracer wipe(s)
14" x 14" section of critical aseptic work surface	<input type="checkbox"/>
Vial Septa, syringe barrels, bags and bottle exteriors, and additive ports	<input type="checkbox"/>
Gloved hands, gown cuffs, and sleeves of the candidate	<input type="checkbox"/>
Front grille and lower threshold (lip) of the BSC	<input type="checkbox"/>
14" x 14" section of the floor immediately adjacent to the BSC	<input type="checkbox"/>
Countertop or work surface where product is placed following removal from the hood	<input type="checkbox"/>
Disposal area / containment exterior	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>
Other (describe);	<input type="checkbox"/>

EMPLOYEE HAZARDOUS DRUG CONTAINMENT EVALUATION OVERVIEW	
Failure is indicated by the presence of red dye on any of the inspected surfaces. Failure demonstrates a breach of proper compounding and containment technique and indicates the need for additional training in containment.	
<input type="checkbox"/> PASS	Employee Signature: _____ Date: _____
<input type="checkbox"/> FAIL	Manager Signature: _____ Date: _____

CORRECTIVE ACTION SUMMARY: