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PASS™ Aseptic Manipulation Competency Evaluation

Cat. # TBV120

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

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

PRODUCT INFO

Item: 20mL Multidose Vial	Component #: T-V020
Media Type: TSB, Sterile	Media Manufacture: Parasol Medical
Media Exp. Date: _____	Media Lot #: _____
Item: 100mL Mini-bag, underfilled	Component #: T-B100
Media Type: TSB, 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 #: _____

INTERVAL 1	INTERVAL 2
<small>The order of the incubation temperature must be described in the facility's SOPs.</small>	<small>Interval 2 temperature cannot be the same as interval 1</small>

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 - 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

PRODUCT INFO: LEFT HAND PRODUCT INFO: RIGHT HAND

Component #: _____	Component #: _____
Media Type: _____	Media Type: _____
Media Mfg: _____	Media Mfg: _____
Media Exp. Date: _____	Media Exp. Date: _____
Media Lot #: _____	Media Lot #: _____

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

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>¹

Gloved Fingertip and Thumb Sampling	Action Levels <small>(cfu, total from both hands)</small>
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

PRODUCT INFO

Component #: _____ Media Type: _____
Media Manufacture: _____
Media Exp. Date: _____ Media Lot #: _____

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

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: _____

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

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