Full Product Catalog

USP Chapter <797> & <800>
Validation Test Kits

Cultivate™
A PARASOL MEDICAL PRODUCT

The first aseptic products built to minimize risk—
starting with the packaging itself

Visit Us Online at:
WWW.PARASOLMED.COM/CULTIVATE

Smarter, Cleaner, Convenient...Cultivate™

Cultivate
A PARASOL MEDICAL PRODUCT

What is Cultivate?

Cultivate™ is a complete line of USP <797> and USP <800> pharmacy assurance testing products. From its inception, Cultivate™ has been the industry leader in provided high-quality testing supplies to help facilities comply with USP guidelines and standards. With the introduction of non-lint producing packaging to the market and the development of a complete line of comprehensive test logs and directions for use in compliance with the revised USP chapter, Cultivate™ continuously pushes the market forward with innovative solutions to make testing easier for our customers.

Revised USP <797> and Cultivate's Position

Cultivate™ has always provided our customers with the best testing supplies that meet all USP <797> requirements. The USP <797> chapter has been revised, but remains in the appeal process. Aiming to provide our customers with the most up to date products and increase patient safetly, Cultivate™ has taken the position of proactively changing our products and support material to address the changes to the chapter. Not all states are requiring facilities to make the changes until the chapter is approved, but all Cultivate™ products are supplied with Directions for Use, test log sheet, non-lint producing packaging that meet the proposed changes.

Important note: Although the chapter remains in appeal, the appeal request does not pretain to the sections associated with personnel and environmental testing. These sections will likely remain the same regardless of the appeal decision.

USP <797> Section	Current<USP> 797	Proposed Revision
Scetion 2.2: Gloved Fingertip and Thumb Sampling	Initally & Annually	Initally & Every 6-months
Sections 2.3: Aseptic Media Fill Technique Test	Initally & Annually	Initally & Every 6-months
Section 6.3: Environmental Surface Sampling	Periodically	Monthly

USP <800> Personnel Testing	Current<USP> 800
Hazardous Drug Handing and Spill Control	Initally & Annually

Superior Packaging

The cornerstone of each Cultivate™ product is its non-lint producing packaging. Through the use of a customized tray design, each component is securely fastened and protected during shipment and storage. Unlike corrugate and open-cell foam packaging, the Cultivate ™ trays can be wiped down and transported into classified and controlled environments without the need to repackage the products.

Product Variety

Cultivate™ has an extensive product portfolio, which includes products used for: gloved fingertip sampling, surface sampling, aseptic media fill test kits in pre-assembled and a la carte options, and hazardous drug handling validation. Cultivate™ will continue to grow the line of available products offered to meet our customers' needs and to address any change to industry standards.

Comprehensive Support Material

The revised USP <797> chapter increases the testing, documentation, and time burden of the individuals responsible for pharmacy assurance testing. Cultivate™ has preemptively developed a new line of support documentation to ease in the understanding of the changes made under the revised chapter. The new directions for use and log sheets were specifically designed to help you comply with the new documentation requirements for each type of testing, eliminating the need to cross-reference the standard.

Unmatched Customer Service

Cultivate's™ team of engineers, USP consultants, and experienced sales managers are available to guide you through the changes to USP <797>, the new USP <800> chapter, and to help develop a complete test plan to ensure compliance with the new standard. Cultivate™ maintains a specialty sales team with local sales reps throughout the country to provide hands-on assistance.

Contact™

Microbial Containment Monitoring System

Applicable USP <797>Sections

Section 2.2 Demonstrating Competency in Garbing and Hand Hygiene
Section 6.3 Monitoring Surfaces for Viable Particles

Aseptic Media Fill Overview

Contact™ flex paddles are designed with two rectangular sides to easily collect fingertip and thumb samples in one device without the need for swabbing. Contact™ flex paddles are designed with a flex hinge, which makes collecting samples from difficult surfaces like handles and tight spaces easy without the need for swabs. Supplemented with neutralizing additives (e.g., lecithin and polysorbate 80) to neutralize the effects of residual disinfecting agents on testing surfaces. Tight luer lock caps prevent agar from drying out during 7-day incubation, which is common with contact plates. Available with TSA and MEA growth media for a wide range of microbial testing. The USP revision allows for the use of TSA growth media as a broad spectrum media for the detection of both bacteria and fungi, reducing the need for fungi media (e.g., MEA or SDA). The raised, convex agar surface makes the Contact™ flex paddles fully compatible with the revised USP <797> section for surface sampling.

Designed to Help You Comply with USP <797>

- USP <797> approved sampling device for glove fingertip testing and surface testing
- Two-sided raised convex surface
- Supplemented with neutralizing additives, lecithin and polysorbate 80, to neutralize the effects of any residual disinfecting agents per USP <797> requirement
- USP <797> revised chapter allows for the use of tryptic soy agar (TSA) as a general growth media that supports the growth of both bacteria and fungi by incubation the paddles at two different temperature intervals
- Test logs specifically designed to meet the documentation requirements for USP <797>
  - Initial Gloved Fingertip Test Log
  - Subsequent Gloved Fingertip Test Log
  - Surfaces Sampling Test Log
  - Two Samples per Location Surface Sampling Test Log (reduces testing time)

TSA Flex Paddles

Cat. # TD100

Shelf Life* - 12 months

Double-sided TSA (trypticase soy agar) flex paddles. Supplemented with neutralizing additives. Lecithin inactivates quaternary ammonium on surfaces. Tween® (polysorbate 80) inactivates phenolics, hexachlorphenes, and formaldehyde. Together lecithin and Tween® together create a synergistic effect that inactivates ethanol.

Approved Uses:

Section 2.2 Demonstrating Competency in Garbing and Hand Hygiene
Section 6.3 Monitoring Surfaces for Viable Particles

Kit Content:

- 10 x TSA (Trypticase Soy Agar) flex paddles
- 10 x personnel ID labels
- 10 x cap labels
- 1 x Surface Sampling Direction for Use & Test Log
- 1 x Gloved Fingertip Sampling Direction for Use & Test Log.

MEA Flex Paddles

Cat. # MD300

Shelf Life* - 12 months

Double-sided MEA (malt extract agar) flex paddles. Supplemented with neutralizing additives, lecithin, polysorbate 80 and chloramphenicol. Lecithin inactivates quaternary ammonium on surfaces. Tween® (polysorbate 80) inactivates phenolics, hexachlorphenes, and formaldehyde. Together lecithin and and Tween® create a synergistic effect that inactivates ethanol. Chloramphenicol inhibits bacterial overgorwth while permitting successful selective isolation of fungi and yeast

Aproved Uses:

Section 6.3 Monitoring Surfaces for Viable Particles
Only when with TSB media device for two samples per location to save time during incubation.

Kit Content:

- 10 x MEA (Malt Extract Agar) flex paddles
- 10 x personnel ID labels
- 10 x cap labels
- 1 xSurface Sampling Direction for Use & Test Log

PASS™

Personnel Aseptic Sampling System
Pre-assembled Media Fill Test Kit

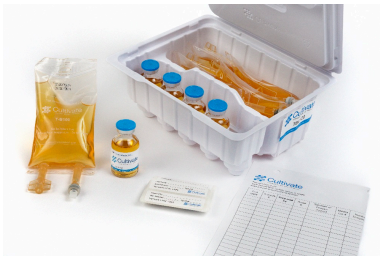
Applicable USP <797>Section
Section 2.3 Competency Testing in Aseptic Manipulation

Aseptic Media Fill Overview
Your aseptic media fill testing procedures should replicate the most difficult procedure used when compounding in your facility. Substitute actual components of dilutes and drugs with Cutlivate™ growth media compounds. The PASS™ line of pre-assembled media fill kits is a convenient option for Section 2.3 testing. The PASS™ kits are offered in low, medium, and high complexity (complexity risk levels for examples only). Select the kit that most closely mimics the compounding procedures used in your facility. Modify the test components or procedures as needed to better fit your needs. All PASS™ kits are packaged in durable thermal form trays to protect the components during shipping and handling and can easily be wiped down. If you need help selecting or modifying a PASS™ test kit, consult with your local sales representative.

PASS™

Cat. # TBV120 | 5 Test per Kit | Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application.



Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation

Kit Content

- 5 x 20mL vial with needle septa & tamper cap, TSB
- 5 x 100mL partically filled mini bag with needle & spike , TSB
- 10 personnel ID labels
- PASS Media Fill Direction for Use & Test Log

PASS 2™

Cat. # TBVA123 | 5 Test per Kit | Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Ideal for facilities manipulating ampules.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation

Kit Content

- 5 x 3mL ampule, red dyed TSB
- 5 x 20mL vial with needle septa & tamper cap, TSB
- 5 x 100mL partically filled mini bag with needle & spike , TSB
- 10 personnel ID labels
- PASS 2 Media Fill Direction for Use and Test Log

PASS 3™

Cat. # TVA3211 | 3 Test per Kit | Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Ideal for facilities manipulating ampules and reconstituting sterile powder.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation

Kit Content

- 3 x 10mL ampule, 2 x TSB
- 3 x 10mL vial with needle septa & tamper cap, 2 x TSB
- 3 x 20mL vial with needle septa & tamper cap, Sterile TSB Powder
- 3 x 30mL vial with needle septa & tamper cap, 2 x TSB
- 10 x personnel ID labels
- 1 x PASS 3 Media Fill Direction for Use & Test Log

HazardTest 2™

Cat. # TVA5251 | 2 Test per Kit | Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Ideal for facilities manipulating ampules. Simultaneously validates both the aseptic and containment techniques of personnel compounding hazardous sterile preparations.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation
USP <800> Section 9 Personnel Training

Kit Content

- 4 x 10mL ampule, 2 x TSB with red dye
- 4 x 50mL (25mL fill) vial with needle septa & tamper cap, 2 x TSB with red dye
- 4 x 50mL (50mL fill) vial with needle septa & tamper cap, 2 x TSB with red dye
- 10 x tracer detection wipes
- 20 x personnel ID labels
- 1 x HazardTest2 Direction for Use and Test Log

ClearCheck™

Microbial Contamination Tester Using Direct Transfer Method
a la carte Media Fill Test Component Kits

Applicable USP <797>Sections

Section 2.3 Competency Testing in Aseptic Manipulation

Aseptic Media Fill Overview

Your aseptic media fill testing procedures should replicate the most difficult procedure used when compounding in your facility. Substitute actual components of dilutes and drugs with Cutlivate™ growth media compounds. If one of the PASS™ kits does not closely match your compounding procedures or for those who want to create their own test, Cultivate™ offers the ClearCheck™ line of a la carte products. The ClearCheck™ components are offered in various container options (ampules, vials, bags, tube, pre-filled syringes, etc.) with several growth media options.

Trypicase Soy Broth (TSB) Products
24-month shelf-life

Cat. # TA003
- 20 x 3mL ampule, TSB with red dye
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # TV020
- 20 x 20mL vial with needle septa & tamper cap, TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # TV100
- 10 x 100mL vial with needle septa & tamper cap, TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # T2V020
- 20 x 20mL vial with needle septa & tamper cap, 2 x strength TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # TB100
- 10 x 100mL partially filled mini-bag with needle & spike port, TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # TB500
- 10 x 500mL partially filled bag with needle & spike port, TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # TS005
- 10 x 10cc (5cc fill) pre-filled syringe, TSB
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Fluid Thyglycolate (FTM) Products
12-month shelf-life

Cat. # FS005
- 10 x 10cc (5cc fill) pre-filled syringe, FTM
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction Use and Test Log

Cat. # FV020
- 20 x 20mL vial with needle septa & tamper cap, FTM
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # FV100
- 10 x 100mL vial with needle septa & tamper cap, FTM
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Empty, Sterile Products
24-month shelf-life

Cat. # EV020
- 20 x 20mL vial with needle septa & tamper cap, empty sterile
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

Cat. # EV100
- 10 x 100mL vial with needle septa & tamper cap, empty sterile
- 10 x personnel ID labels
- 1 x ClearCheck™ a la carte Direction for Use and Test Log

HazardTest™

USP <800> Hazardous Drug - Handling in a Healthcare Setting
Pre-assembled Media Fill Test Kit

Applicable USP <797>Section *(Cat. # TVA5251 only)*
Section 2.3 Competency Testing in Aseptic Manipulation

Applicable USP <800>Section
Section 9 Personnel Training
Section 16 Spill Control

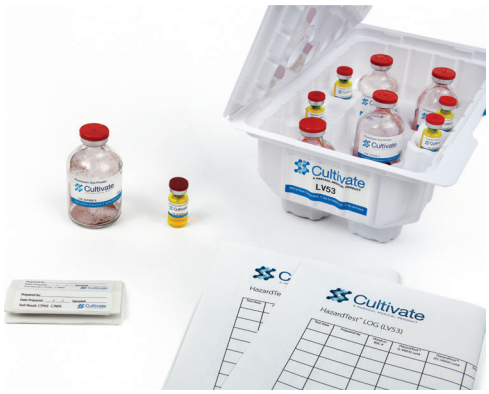
Aseptic Media Fill Overview
Assists in training for drug handling competency and verification. Can be used to simulate spills and subsequent clean-up protocol processes. Design a training method to reflect your most risk-associated process. After performing the determined manipulation us black light (LV53) or tracer wipes (TVA5251) on the working surface will reveal any spills and the need for technician retraining.

"The OSHA HCS and USP chapter <800> require employee training for the tasks that will be performed as part of the (hazardous drug compounding) safety program."

- ASHP Guidelines on Handling Hazardous Drugs

HazardTest™ Cat. # LV53 5 Test per Kit Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for low complexity levels within a sterile compounding pharmacy facility or other cleanroom application.



Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation

Kit Content
- 5 x 3mL vial with needle septa & tamper cap, fluorescein dye powder
- 5 x 100mL vial with needle septa & tamper cap, fluorescein dye fluid
- 10 personnel ID labels
- HazardTest Direction for Use & Test Log

HazardTest 2™ Cat. # TVA5251 2 Test per Kit Shelf Life* - 24 months

Recommended for verification of personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Ideal for facilities manipulating ampules. Simultaneously validates both the aseptic and containment techniques of personnel compounding hazardous sterile preparations.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation
USP <800> Section 9 Personnel Training

Kit Content
- 4 x 10mL ampule, 2 x TSB with red dye
- 4 x 50mL (25mL fill) vial with needle septa & tamper cap, 2 x TSB with red dye
- 4 x 50mL (50mL fill) vial with needle septa & tamper cap, 2 x TSB with red dye
- 10 x tracer detection wipes
- 20 x personnel ID labels
- 1 x HazardTest2 Direction for Use and Test Log

Featured Product - HazardTest 2 (Cat # TVA5251)

- Simultaneously validates USP <797> Sections 2.3 Competency Testing in Aseptic Manipulation & USP <800> Personnel Training / Spill Control in a single test.

- Reduces annual personnel testing cost & time

- Eliminates one personnel test each year by testing both techniques. Rather than using two aseptic manipulation test and one hazardous drug handling test, validate aseptic technique and hazardous drug handling in a single test, leaving only the second aseptic manipulation test.

TT Micro System™

USP <800> Hazardous Drug - Handling in a Healthcare Setting
Pre-assembled Media Fill Test Kit

TT MicroSystem Overview
Validation tool for syringe to syringe or syringe to sterile container transfers. This is a destrucitve test.

TT Micro™ *TSB*
Cat. # TF7S005 | 10 Test per Kit | Shelf Life* - 24 months

Simultaneously validates both the aseptic and containment techniques of personnel compounding hazardous sterile preparations.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation
USP <800> Section 9 Personnel Training

Kit Content
- 10 x 10 cc, 5cc pre-fill syringe, TSB
- 10 x .22 micron filter with male luer lock connections
- 10 x personnel ID labels
- 1 x TT Micro (FTM) Direction for Use & Test Log

TT Micro™ *FTM*
Cat. # FF7S005 | 10 Test per Kit | Shelf Life* - 24 months

Simultaneously validates both the aseptic and containment techniques of personnel compounding hazardous sterile preparations.

Approved Uses:
Section 2.3 Competency Testing in Aseptic Manipulation
USP <800> Section 9 Personnel Training

Kit Content
- 10 x 10 cc, 5cc pre-fill syringe, TSB
- 10 x .22 micron filter with male luer lock connections
- 10 x personnel ID labels
- 1 x TT Micro (FTM) Direction for Use & Test Log

Cultivate Syringe Filters

Important Benefits

- High flow rate
- Filter more liquid befoe clogging
- Male and female luer lock fittings
- Non-leaching EtO residuals
- Protects valuable solutions
- Secure connections prevent leaking of hazardous or expensive drugs
- Custom color housing prevents using incorrect filter

Sterile High Performance Hydrophilic Filters

Specifications:

Housing material: Modified acrylic (blue)
Pore size: 0.2 micron
Effectve filtration area: 2.8 cm^2
Maximum pressure: 75 psi
Inlet connection: Female luer lock
Flow direction: Bidirectional

Membrane material: Polyethersulfone
Diameter: 25 mm
Fluid retention: <0.05 mL
Bubble Point (water): >45 psi
Outlet Connection: Male luer Lock
Packaging: Blister pack

0.22 Micron Syringe Filter

Cultivate™ Syringe filter 0.22 micron, double luer lock – designed for bacteria filtration and particulate retentive applications. Low protein binding. Incorporates Supor® membrane for higher flow rates.

Kit Content

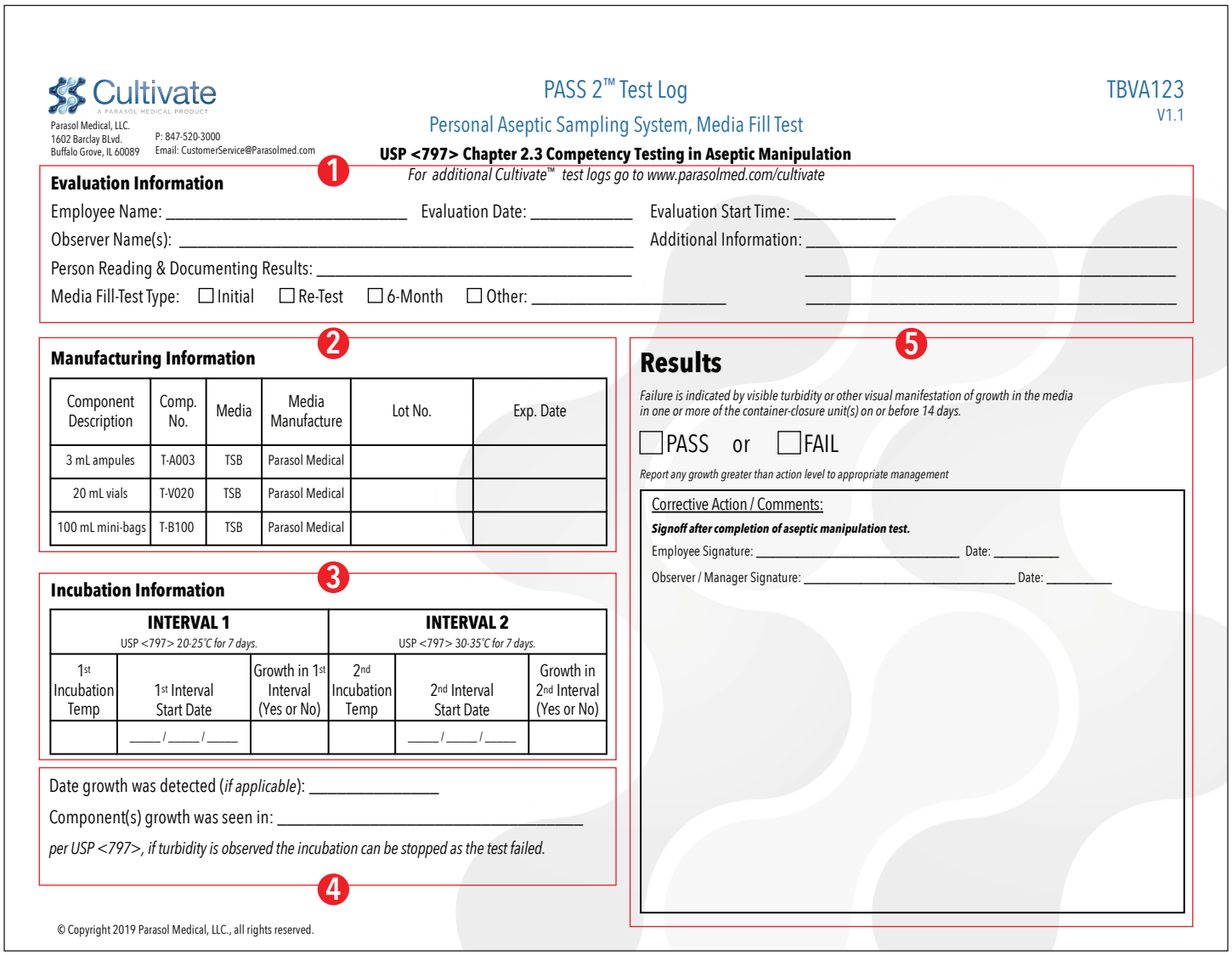
- 50 x Sterile 0.22 Micron Hydrophobic Syringe Filter

Revised USP<797> Test Specific Test Logs

The revised USP <797> chapeter has put an emphasis on documentation of testing. Cultivate has developed a custom line of test log sheets specifically designed to meet all of the documentation requirements of the revised USP <797> chapter. Custom test log sheets are organized for efficient and complete compliance with the revised chapter. Makes maintaining personnel files simple for stateboard inspections. All Cultivate test log sheets are available for download at www.parasolmed.com/cultivate/resources and can be filled out electronically.

USP <797> Documentation must at a minimum include:

1. "The name of the person evaluated, evaluation date/time, the identification of the observer, and the person who reads and documents the results."
2. "The media and components used including manufacturer, expiration date and lot number"
3. "The starting temperature for each interval of incubation, dates of incubation", no need to cross reference the standard.
4. Growth Results
5. Pass / Fail Results, area for additional comments, notes, and corrective action.



Cultivate
A PARASOL MEDICAL PRODUCT

Parasol Medical, LLC.
1602 Barclay BLvd.
Buffalo Grove, IL 60089

P: 847-520-3000
Email: CustomerService@Parasolmed.com

PASS 2™ Test Log

Personal Aseptic Sampling System, Media Fill Test

TBVA123
V1.1

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

For additional Cultivate™ test logs go to www.parasolmed.com/cultivate

1

Evaluation Information

Employee Name: _____ Evaluation Date: _____ Evaluation Start Time: _____

Observer Name(s): _____ Additional Information: _____

Person Reading & Documenting Results: _____ _____

Media Fill-Test Type: ☐ Initial ☐ Re-Test ☐ 6-Month ☐ Other: _____ _____

2

Manufacturing Information

Component Description	Comp. No.	Media	Media Manufacture	Lot No.	Exp. Date
3 mL ampules	T-A003	TSB	Parasol Medical		
20 mL vials	T-V020	TSB	Parasol Medical		
100 mL mini-bags	T-B100	TSB	Parasol Medical		

3

Incubation Information

INTERVAL 1 USP <797> 20-25°C for 7 days.			INTERVAL 2 USP <797> 30-35°C for 7 days.		
1st Incubation Temp	1st Interval Start Date	Growth in 1st Interval (Yes or No)	2nd Incubation Temp	2nd Interval Start Date	Growth in 2nd Interval (Yes or No)
	____/____/____			____/____/____	

Date growth was detected (*if applicable*): _____

Component(s) growth was seen in: _____

per USP <797>, if turbidity is observed the incubation can be stopped as the test failed.

4

5

Results

Failure is indicated by visible turbidity or other visual manifestation of growth in the media in one or more of the container-closure unit(s) on or before 14 days.

☐ PASS or ☐ FAIL

Report any growth greater than action level to appropriate management

Corrective Action / Comments:

Signoff after completion of aseptic manipulation test.

Employee Signature: _____ Date: _____

Observer / Manager Signature: _____ Date: _____

Contact™ Media Flex-Paddle FAQs

Moisture and water droplets occasionally appear on the inside of Contact™ housing. Does this have any effect on performance or shelf life?

Variations in temperature and pressure during shipping and storage may cause condensation in the vial. Moisture on the inside of the housing does not harm Contact™ products. Agar is mostly water, and the atmosphere inside the housing stabilizes the 100% humidity sometimes causing condensation. If condensation does occur, remove the paddles from the vial in a sterile environment and allow them to dry (inverted on cap) for 10-15 minutes immediately before use. Make a note of this on the log sheet as it is a possible source of contamination.

How should a pharmacist purposely contaminate a Contact™ product if they want to demonstrate microbial growth?

Minimizing touch contamination is a primary goal of aseptic technique testing. Pressing intentionally contaminated gloved fingertips on the Contact™ agar is an excellent way to inoculate the media. It also demonstrates how easily contamination can occur during a lapse in aseptic technique.

This product contains components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious and handle observing the usual universal blood precautions to be abundantly cautious. Do not ingest, inhale, or allow to come into contact with skin.

Can the Contact™ media paddle be used for testing sterile gloved fingertips for microbial contamination?

The Contact™ media paddle is an excellent choice for fingertip testing. You can easily hold the cap and will have distance between the agar and the cap which should help prevent accidental contamination whereas with plates, the media is poured all the way to the edge and may come into contact with gloves. Paddles provide more room to properly roll your fingers on the media. Also allows you to test the pads of your fingers and not the tips as you would using a circular plate.

Why does the incubation instructions require me to incubate the samples at two different temperatures?

The revised USP <797> standard emphasizes using TSA (Trypticase soy agar) as a general growth media for cultivating bacteria, fungi, and yeast. In order to grow the different organisms, the standard requires that the agar for gloved fingertip samples and surface samples be incubated at 30–35°C for 48 hours for the cultivation of bacteria and then no less than and then 20–25°C for the cultivation of bacteria for no less than 5 additional days. Periodically examine the samples. If at any point the number of cfu (colony forming units) exceed the action levels, there is no need to continue to incubate as the test has failed.

How often is gloved fingertip required under the revised USP <797> section 2.2 standard?

"All compounding personnel must be visually observed initially and every 6 months while performing hand hygiene and garbing procedures. Before being allowed to independently compound, all compounders must successfully complete an initial competency evaluation no fewer than 3 separate times. Subsequent testing must be conducted after completing the media-fill test." ***Cultivate™ Best Practice:*** *The revised USP <797> Chapter only requires that technicians past 3 separate test. However, the Cultivate™ suggested best practice extends beyond the requirement to make the initial requirement 3 consecutive passing tests to ensure proper, repeatable technique (suggested best practice only).*

How often is environmental surface sampling required under the revised USP <797> section 2.2 standard?

"Surface sampling of all classified areas and pass-through chambers connecting to classified areas for microbial contamination must be conducted at least monthly. When conducted, surface sampling must be performed at the end of compounding activity or shift, but before the area has been cleaned and disinfected. Each classified area must be sampled, including the following":

- *The interior of the PEC and the equipment contained in it*
- *Staging or work area(s) near the PEC*
- *Frequently touched surfaces*

The flex hinged paddle makes it easier to make complete contact with the surface. It is also easier and better than plates at reaching hard to reach areas such as behind door handle where a plate cannot reach. Air circulation within hoods often deposits particles in the edges and corners of the hood where a circular plate cannot reach.

Each lot of Cultivate™ products go through a rigorous quality test using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CoA). Cultivate™ CoA's can be obtained directly from www.parasolmed.com/cultivate/ using the lot number found on each component.

PASS™ Pre-assembled Media Fill Test FAQs

When should I use the PASS™ pre-assembled test kits? How do I choose the right PASS™ kit?

The PASS™ pre-assembled test kits are a convenient, ready to use, test kit with general test procedures. Per the revised USP <797> section 2.3, aseptic media fill test must simulate the most difficult and challenging compounding procedures and processing conditions encountered by pharmasist or pharmacy technician. Choose the PASS™ kit that closely replicates daily compounding procedures. Supplement the PASS™ kits with the ClearCheck™ components as needed to more closely replicate daily procedures.

Why does the incubation instructions require me to incubate the samples at two different temperatures?

The revised USP <797> standard emphasizes using TSB (Trypticase soy broth) for the detection of a broad spectrum of microorganisms. To grow the different organisms, the standard requires that the media be incubated for 7 days at 20°– 25°C followed by 7 days at 30°–35°C. Periodically examine the samples. If contamination or turbidity is examined in the broth at any point, there is no need to continue to incubate as the test has failed.

Do the components need to be wiped down prior to bringing into a controlled environment?

Although the components and growth media is sterile, the kit itself is not sterile. The components must be wiped down to avoid bringing contaminates into a controlled environment. The packaging developed by Cultivate™ is non-lint producing. The custom kit trays can be wiped down and brought into the controlled environment without the need to repackage components.

How important is it to stictly follow the Directions for Use that come with each box of PASS™ and PASS2™ kits?

The DFUs are written as general procedures and are suggestions only. They can and should be modified to more closely mimic the most difficult aseptic manipulations performed by a particular operator or pharmacy.

Why did the revised USP <797> section 2.3 remove the arbitrary examples of low, medium, and high risk levels on media fill test

USP provided arbitrary examples of compounding risk levels in the previous revision, low, medium, and high complexity. These examples have been removed in the revision because facilities were using these examples literally and not modifying the procedures to mimic actual compounding procedures in their facility. Cultivate has downloadable documents at www.parasolmed.com/cultivate/ to help you determine the correct kit for your testing. Please reference this document or reach out to customer service for assistance. Cultivate™ offers a complete line of a la carte components (ClearCheck™) to substitute for actual components of dilutes and drugs, to help you replicate exact processes in your facility. Cultivate™ will continue to provide the PASS™ line of pre-assembled test kit as a convenient starting point for creating a medial fill test.

How are Cultivate™ products validated?

Each lot of Cultivate™ products go through a rigorous quality test using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CoA). Cultivate™ CoA's can be obtained directly from www.parasolmed.com/cultivate/ using the lot number found on each component.

ClearCheck™ a la carte Media Fill Test FAQs

When should I use ClearCheck™ a la carte products? Why use a la carte products over the PASS™ pre-assembled test kits?

The PASS™ pre-assembled test kits are a convenient, ready to use, test kit with general test procedures. Per the revised USP <797> section 2.3, aseptic media test should simulate the most difficult and challenging compounding procedures and processing conditions encountered by the pharmasist or pharmacy technician. If one of the PASS™ kits does not closely replicate your daily procedures or components, the ClearCheck™ kits can be used to create a custom test. The ClearCheck™ components can also be used to supplement the PASS™ kits to add components.

How should I develop a test procedure if using the ClearCheck™ kits to make a custom media fill test?

Per the revised USP <797> section 2.3, aseptic media test should simulate the most difficult and challenging compounding procedures and processing conditions encountered by the pharmasist or pharmacy technician. When developing a custom test procedure, a good starting point is to take the manipulations and, at a minimum, multiply the manipulations by three. When technicians know they are being tested, they will change their technique, known as a test bias. After being asked to repeat a manipulation many times, they will often revert to their normal compounding technique due to boredom, providing more accurate testing results.

Why is ClearCheck™ media offered in a variety of vials and bags?

Media transfer validations should simulate the actual manipulations encountered in a particular pharmacy. Examples include syringe transfers from vials to minibags, multiple additive procedures, syringe filling, and use of automated compounders. Multiple repetitive transfers from ClearCheck™ vials to Clear Check™ minibags is an excellent example of a simulation of an actual procedure.

Why does the incubation instructions require me to incubate the samples at two different temperatures?

The revised USP <797> standard emphasizes using TSB (Trypticase soy broth) for the detection of a broad spectrum of microorganisms. To grow the different organisms, the standard requires that the media be incubated for 7 days at 20°– 25°C followed by 7 days at 30°–35°C. Periodically examine the samples. If contamination or turbidity is examined in the broth at any point, there is no need to continue to incubate as the test has failed.

Do the components need to be wiped down prior to bringing into a controlled environment?

Although the components and growth media is sterile, the kit itself is not sterile. The components must be wiped down to avoid bringing contaminates into a controlled environment. The packaging developed by Cultivate™ is non-lint producing. The custom kit trays can be wiped down and brought into the controlled environment without the need to repackage components.

How are Cultivate™ products validated?

Each lot of Cultivate™ products go through a rigorous quality test using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CoA). Cultivate™ CoA's can be obtained directly from www.parasolmed.com/cultivate/ using the lot number found on each component.

HazardTest™ Hazardous Drug Handling Test FAQs

How often is hazardous drug handling testing required?

The OSHA HCS and USP chapter <800> require employee training for the tasks that will be performed as part of the (hazardous drug compounding) safety program, including spills and subsequent clean-up protocol processes, initially and every 12 months thereafter.

What is the difference between the HazardTest™ (Cat. # LV53) and HazardTest 2™ (Cat. # TVA5251)?

The HazardTest™ (Cat. # LV53) kit uses a fluorescein dye to indicate a spill or breach of proper technique. When using an ultraviolet light, the fluorescein dye will illuminate. The HazardTest 2™ (Cat. # TVA5251) uses TSB (trypticase soy broth) with red indicator dye. Immediately following the test, wipe the surfaces with the included tracer wipes, which will absorb any spilled liquid. Since the HazardTest 2™ kit uses TSB, it simultaneously validates USP <797> Chapter 2.3 aseptic manipulation and USP <800> hazardous containment techniques in a single test. This reduces the number of tests required per technician per year.

Can I use the HazardTest 2™ (TVA5251) kit if using a closed chemo system?

Yes, you can use the HazardTest 2™ kit when using a closed chemo system by only using the vials and not the ampule.

How do the Cultivate HazardTest™ kits differ from other hazard test kits?

The Cultivate™ HazardTest™ kits (LV53 and TVA5251) kits are personnel technique test kits. The HazardTest 2™ kit also tests for microbial contamination. However, neither of the Cultivate™ HazardTest™ kits test for residual hazardous drugs on surfaces.

Why does the incubation instructions require me to incubate the samples at two different temperatures?

The revised USP <797> standard emphasizes using TSB (Trypticase soy broth) for the detection of a broad spectrum of microorganisms. To grow the different organisms, the standard requires that the media be incubated for 7 days at 20°– 25°C followed by 7 days at 30°–35°C. Periodically examine the samples. If contamination or turbidity is examined in the broth at any point, there is no need to continue to incubate as the test has failed.

Do the components need to be wiped down prior to bringing into a controlled environment?

Although the components and growth media is sterile, the kit itself is not sterile. The components must be wiped down to avoid bringing contaminates into a controlled environment. The included tracer wipes are non-sterile, disinfect after testing. The packaging developed by Cultivate™ is non-lint producing. The custom kit trays can be wiped down and brought into the controlled environment without the need to repackage components.

How important is it to strictly follow the Directions for Use that come with each box HazardTest and HazardTest 2™ kits?

The DFUs are written as general procedures and are suggestions only. They can and should be modified to more closely replicate the most difficult aseptic manipulations performed by the pharmacist / pharmacy technician.

How are Cultivate™ products validated?

Each lot of Cultivate™ products go through a rigorous quality test using appropriate quality control microorganisms and quality specifications as outlined on the Certificates of Analysis (CoA). Cultivate™ CoA's can be obtained directly from www.parasolmed.com/cultivate/ using the lot number found on each component.

Selecting the right aseptic media fill test kit for your facility

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

Do you want to start with a pre-assembled media fill testing kit with general test procedures?

YES

PASS™
Personnel Aseptic Sampling System

Choose from one of the pre-assembled kits below. Select the kit that most closely replicates the compounding procedure of the personnel.

PASS™ (Cat. # TBV120) - Low Risk
One test includes:
1 x 20mL vial with needle septa & tamper cap, TSB
1 x 100mL partically filled mini bag with needle & spike , TSB

PASS 2™ (Cat. # TBVA123) - Medium Risk
One test includes:
1 x 3mL ampule, red dyed TSB
1 x 20mL vial with needle septa & tamper cap, TSB
1 x 100mL partically filled mini bag with needle & spike , TSB

PASS 3™ (Cat. # TVA3211) - Medium Risk
One test includes:
1 x 10mL ampule, 2 x TSB
1 x 10mL vial with needle septa & tamper cap, 2 x TSB
1 x 20mL vial with needle septa & tamper cap, Sterile TSB Powder
1 x 30mL vial with needle septa & tamper cap, 2 x TSB

HazardTest 2™ (Cat. # TVA5251)
One test includes:
4 x 10mL ampule, 2 x TSB with red dye
4 x 50mL (25mL fill) vial with needle septa & tamper cap, 2 x TSB with red dye
4 x 50mL (50mL fill) vial with needle septa & tamper cap 2 x TSB with red dye
10 tracer detection wipes

** The HazardTest 2 test kit simultaneously validates USP <797> Chapter 2.3 aseptic manipulation and USP <800> hazardous containment techniques in a single test.*

Does one of these kits resemble the compounding procedures in your facility?

NO

YES

Do you need to supplement the kit with additional components to more closely resemble compounding procedures?

YES

NO

Do you need help modifying the test procedure?

YES

ClearCheck™
a la carte kits

Build your own aseptic media fill test using the ClearCheck™ a la carte kits. Replace CSPs (drugs and diluents) with the same container components with TSB growth media.

Cat. #	Description	Quantity/Kit
TA003	3mL ampule,TSB	20
TV020	20mL vial with neddle septa & tamper cap, TSB	20
T2V020	20mL vial with neddle septa & tamper cap, 2 x TSB	20
FV020	20mL vial with neddle septa & tamper cap, FTM	20
EV020	20mL vial with neddle septa & tamper cap, empty sterile	20
TV100	100mL vial with neddle septa & tamper cap, TSB	10
FV100	100mL vial with neddle septa & tamper cap, FTM	10
EV100	100mL vial with neddle septa & tamper cap, empty sterile	10
TB100	100mL partially filled mini-bag with needle & spike port, TSB	10
TB500	500mL partially filled bag with needle & spike port, TSB	10
TS005	10cc, 5cc fill pre-filled syringe, TSB	10
FS005	10cc, 5cc fill pre-filled syringe, FTM	10

Design a test procedure: The test procedure should replicate the most complex compounding procedure for each personnel. When developing a test procedure, best practice is to take the manipulations and at a minimum, multiply the manipulations by three. When technicians know they are being tested, they will change their technique, known as a test bias. After being asked to repeat a manipulation many times, they will often revert to their normal compounding technique, providing more accurate testing results.

Cultivate's™ team of engineers and local sales managers can help you design a custom test kit and procedure for your facility either starting with a PASS™ kit or using ClearCheck™ a la carte kits.

About Parasol Medical

Parasol Medical™ is a premier developer of specialty medical devices designed to serve the growing and ever-changing healthcare industry. Our direct relationship with clinical end-users allows us to develop and quickly implement suggestions and changes to product designs that make the lives of healthcare workers easier and improve patient outcomes.

At the forefront of new and emerging technologies, Parasol Medical™ is rapidly expanding its footprint throughout the Healthcare market. Parasol Medical™ is FDA registered, complies with Good Manufacturing Practices cGMP, and maintains an ISO 13485 quality system.

PARASOL MEDICAL LLC

1602 Barclay Blvd.
Buffalo Grove, IL 60089

parasolmed.com
847.520.3000