Directions For Use

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

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Smarter, Cleaner, Convenient…Cultivate™

Cultivate
A PARASOL MEDICAL PRODUCT

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What is Cultivate?

Cultivate™ is a complete line of USP <797> and USP <800> pharmacy assurance testing products. Since its initial release to the market, Cultivate™ has been the industry leader in provided high-quality testing supplies to help facilities comply with USP guidelines. 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.

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The Cultivate™ Difference

Superior Packaging

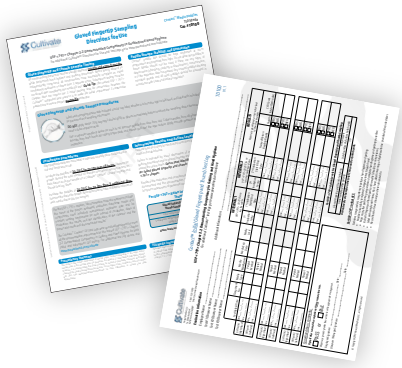
The cornerstone of each Cultivate™ product is its non-lint producing, recyclable packaging. Through the use of a customized tray design, each component is securely fastened and protected during shipment and storage. Unlike corrugate and open-cell foam packaging, the Cultivate™ trays can be wiped down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

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. Filling out the Cultivate™ log sheets will ensure all the required infomation is captured to help your facility pass state board inspection.



Unmatched Customer Service

Cultivate's™ team of engineers and experienced local 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 and can meet in person as needed.

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)

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Gloved Fingertip Sampling Directions for Use

Contact™ Media Paddles
TSA Media
Cat. # TD100

USP <797> Chapter 2.2 Demonstrating Competency in Garbing and Hand Hygiene
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Glove Fingertip and Thumb Sample Timing

"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."[1] ***Cultivate™ Best Practice:*** The revised USP <797> Chapter only requires that technicians past 3 sperate test. However, the Cultivate™ suggested best practice is to make the initial requirement 3 consecutive passing tests to ensure proper, ***repeatable*** technique.

Paddle Storage, Stability, and Destruction

Contact™ paddle kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. The media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Any unused paddles showing microbial growth and all used paddles should be discarded in accordance with State and Federal regulation.

Glove Fingertip and Thumb Sample Procedures

Before Use: It is possible that variation in temperature and pressure during shipping and storage may cause condensation in the vial. 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.*

Label each sampling device with included circular cap label, whether it is from the right or left hand, and label with included ID label for personnel and sampling information. DO NOT apply sterile 70% isopropyl alcohol (IPA) to gloves immediately before touching the sampling device because this could cause a false-negative result.

Use a separate sampling device for each hand. Remove the paddle from clear from the vial. Collect samples from all gloved fingers and thumbs from both hands by rolling finger pads and thumb pad over the agar surface. Apply enough pressure to make a slight impression.[1]

Incubation Procedures

After paddles have been inoculated or exposed, carefully place paddle back in the vial and firmly secure cap.

Incubate the paddles at **30–35°C for no less than 48 hours.** Examine for growth. Record the total number of discrete colonies of microorganisms on each device as cfu per sample on a Cultivate™ Contact™ Gloved Fingertip and Thumb Test Log Sheet.

Incubate the paddles at **20–25°C for no less than 5 additional days.** Examine the device for growth. Record the total number of discrete colonies on each media device (cfu per sample).

Per the USP <797> revision, "documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results."[1]

The Cultivate™ Contact™ GFT Test Logs were specifically designed to meet all the documentation requirements for the revised USP <797> Chapter 2.2 Demonstrating Competency in Garbing and Hand Hygiene for both initial and subsequent GFT testing. For additional test log sheets visit ***www.parasolmed.com/cultivate.***

Interpreting Results and Action Levels

Evaluate total cfu (colony forming units) count from both hands against action levels in the table below.

Failure is indicated by visual observation of improper hand hygiene and garbing procedures and/or gloved fingertip and thumb sampling results that exceed the action levels. ***Genus level identification is no longer required for failed gloved fingertip and thumb testing per the revised USP <797> chapter.***

Results of the evaluation and corrective actions, in the event of failure, must be documented, and the documentation maintained to provide a record and long-term assessment of personnel competency.

Per USP <797> Action Levels for Gloved Fingertip and Thumb Sampling[1]

Gloved Fingertip and Thumb Sampling	total number of cfu from both hands
Initial sampling after garbing	>0
Subsequent sampling after media-fill testing (every 6- months)	>3

Action levels are based on the total cfu count for both hands.

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSA Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, agar, lecithin, polysorbate 80 (Tween®).
Final pH 7.3 +/- 0.2 at 25°C.

- Lecithin – Inactivates quaternary ammonium compounds.
- Polysorbate 80 (Tween®) – Inactivates phenolics, hexachlorophenes, and formaldehyde.
- Lecithin & Polysorbate 80 (Tween®) – synergistic effect that inactivate ethanol.

[1] United States Pharmacopeial Convention; (2019); *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

DFU-TD100GFT v1.1

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Surface Sampling Directions for Use

Contact™ Media Paddles
TSA Media
Cat. # TD100

USP <797> Chapter 6.3 Monitoring Surfaces for Viable Particles

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Surface Sample Timing

"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"[1]:

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

Paddle Storage, Stability, and Destruction

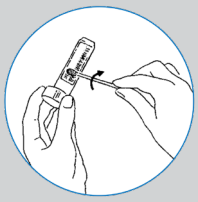
Contact™ paddle kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. The media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Any unused paddles showing microbial growth and all used paddles should be discarded in accordance with State and Federal regulation.

Surface Sample Procedures

Before Use: It is possible that variation in temperature and pressure during shipping and storage may cause condensation in the vial. 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.*

Contact Inoculation Procedure

Remove the vial, firmly press each side of the paddle onto the solid surface to be sampled. Complete contact with the surface is accomplished with the hinged design. **DO NOT** drag the agar across the surface. The surface sampling device will leave a residue of growth media on the sample site. After sampling, remove the residue from the surface using sterile 70% IPA.



Difficult to Reach Surfaces: Swab Sampling Procedure

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then firmly roll the swab on both agar surfaces.

Incubation Procedures

After paddles have been inoculated or exposed, carefully place paddle back in the vial and firmly secure cap. Incubate the paddles at **30–35°C for no less than 48 hours.** Examine for growth. Record the total number of discrete colonies of microorganisms on each device as cfu per sample on a Cultivate™ Contact™ Surface Sampling Test Log.

Incubate the paddles at **20°–25°C for no less than 5 additional days.** Examine the device for growth. Record the total number of discrete colonies on each media device (cfu per sample).

The Cultivate™ Contact™ Surface Sampling Test Log was specifically designed to meet all of the documentation requirements for the revised USP <797> Chapter 6.2 Monitoring Surfaces of Viable Particles. For additional test log sheets visit ***www.parasolmed.com/cultivate.***

Alternatively, to shorten the overall incubation period, two samples may be collected for each sample location and incubated concurrently. (*See Contact™ Two Media Surface Sampling Test Log*)

- At least one samples must be TSA (Cat . #TD100).
- Incubate each sample in a separate incubator. Incubate one sample at 30–35°C for no less than 48 hours, and incubate the other sample at 20–25C° for no less than 5 days.
  - If fungal media are used as one of the samples, incubate the fungal media sample at 20–25°C for no less than 5 days.
- Count the total number of discrete colonies of microorganisms on each sample, and record these results as cfu per sample.

Interpreting Results and Action Levels

Evaluate cfu count against action levels in the table below. If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each device media.[1]

If levels measured during sampling exceed the action levels for the ISO classification level of the sampled area, the cause must be investigated, and corrective action must be taken. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Corrective action may include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. Once corrective action has been implemented, monitoring procedures must be repeated to evaluate the effectiveness of the changes.[1] If levels measured during surface sampling exceed the action levels, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a microbiologist.[1]

Environmental sampling methods have inherent variability. It is more useful to monitor contamination recovery trends over time rather than focus on a colony count of a single sample.

Per USP <797> Action Levels for Surface Sampling[1]

ISO Class	Surface Sampling Action Levels (cfu/device or swab)
5	>3
7	>5
8	>50

Action levels are based on the total CFU count for both hands.

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSA Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, agar, lecithin, polysorbate 80 (Tween®).
Final pH 7.3 +/- 0.2 at 25°C.

- Lecithin – Inactivates quaternary ammonium compounds.
- Polysorbate 80 (Tween®) – Inactivates phenolics, hexachlorophenes, and formaldehyde.
- Lecithin & Polysorbate 80 (Tween®) – synergistic effect that inactivate ethanol.

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

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Surface Sampling Directions for Use

Contact™ Media Paddles
MEA Media
Cat. # MD300

USP <797> Chapter 6.3 Monitoring Surfaces for Viable Particles

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Glove Fingertip and Thumb Sample Timing

"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"[1]:

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

Paddle Storage, Stability, and Destruction

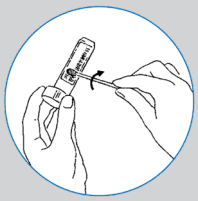
Contact™ paddle kits should be kept unopened at room temperature and protected from light. Do not allow the paddles to freeze. The media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Any unused paddles showing microbial growth and all used paddles should be discarded in accordance with State and Federal regulation.

Surface Sample Procedures

Before Use: It is possible that variation in temperature and pressure during shipping and storage may cause condensation in the vial. 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.*

Contact Inoculation Procedure

Remove the vial, firmly press each side of the paddle onto the solid surface to be sampled. Complete contact with the surface is accomplished with the hinged design. **DO NOT** drag the agar across the surface. The surface sampling device will leave a residue of growth media on the sample site. After sampling, remove the residue from the surface using sterile 70% IPA.



Difficult to Reach Surfaces: Swab Sampling Procedure

A sterile swab moistened with sterile water can be used to sample hard to reach surfaces. Rotate the swab while moving it over the sample area to pick up as much sample as possible. Then firmly roll the swab on both agar surfaces.

Incubation Procedures

After paddles have been inoculated or exposed, carefully place paddle back in the vial and firmly secure cap.

USP <797> provides an option for combination surface sampling with TSA and MEA growth media to shorten the overall incubation period. Two samples may be collected for each sample location and incubated concurrently.

- One media must be TSA (Cat #TD100) for bacteria and general growth, and the other can be MEA (Cat #MD300) for fungal growth.
- Incubate each sample in a separate incubator.
- Incubate the TSA media sample(s) at 30°–35°C for no less than 48 hrs.
- Incubate the MEA fungal media sample(s) at 20°–25°C for no less than 5 days.
- Count the total number of discrete colonies of microorganisms on each sample and record these results as cfu per sample.

The Cultivate™ Contact™ Two Samples per Location Surface Sampling Test Log was specifically designed to meet all of the documentation requirements for the revised USP <797> Chapter 6.2 Monitoring Surfaces of Viable Particles. For additional test log sheets visit www.parasolmed.com/cultivate.

MEA Media Ingredients:

Malt extract, dextrose, peptone, agar, chloramphenicol, lecithin, polysorbate 80 (Tween™).
Final pH 5.5 +/- 0.3 at 25°C.

- Chloramphenicol – Inhibit bacterial overgrowth while permitting successful selective isolation of fungi and yeasts.
- Lecithin – Inactivates quaternary ammonium compounds.
- Polysorbate 80 – Inactivates phenolics, hexachlorophenes, and formaldehyde.
- Lecithin & Polysorbate 80 – synergistic effect that inactivate ethanol.

Interpreting Results and Action Levels

Evaluate cfu count against action levels in the table below. If two devices were collected at a single location, all recovered growth on each must be documented and action levels are applied to each device media.[1]

If levels measured during sampling exceed the action levels for the ISO classification level of the sampled area, the cause must be investigated, and corrective action must be taken. The corrective action plan must be dependent on the cfu count and the microorganism recovered. Corrective action may include process or facility improvements, personnel training, cleaning and disinfecting, or HEPA filter replacement and/or repair. The extent of the investigation should be consistent with the deviation and should include an evaluation of trends. The corrective action plan must be documented. Once corrective action has been implemented, monitoring procedures must be repeated to evaluate the effectiveness of the changes.[1]

If levels measured during surface sampling exceed the action levels, an attempt must be made to identify any microorganism recovered to the genus level with the assistance of a microbiologist.[1]

Environmental sampling methods have inherent variability. It is more useful to monitor contamination recovery trends over time rather than focus on a colony count of a single sample.

Per USP <797> Action Levels for Surface Sampling[1]

ISO Class	Surface Sampling Action Levels (cfu/device or swab)
5	>3
7	>5
8	>50

Action levels are based on the total CFU count for both hands.

[1] United States Pharmacopeial Convention; (2019); USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Rockville, MD.

DFU-MD300SS v1.1

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.

Low Risk Media Fill Test Directions for Use

PASS™
Personal Aseptic Sampling System
Cat. # TBV120

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intended Use

Cultivate™ PASS™ pre-assembled media fill test kit (Cat. #TBV120) is recommended for verifying personnel aseptic technique for low complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for up to five technicians with general test procedures. Modify procedures to simulate actual compounding procedures better. Supplement test with ClearCheck™ a la carte components as needed. If you need assistance modifying, designing, or selecting the right Cultivate™ test kit or your facility, contact your local sales representative. This product is not intended to be used for the diagnosis of animal or human disease.

Aseptic Media Fill and Manipulation Timing

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 6 months thereafter.** When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean–casein digest (TSB) media.[1] ***Quick Tip:*** *Schedule staff testing on their birthdays to spread out testing throughout the year. Use half birthdays 6 month later for the second media test of the year. This spreads the testing out and makes remembering the dates easy for staff.*

Storage, Stability, and Destruction

Cultivate™ PASS™ kits should be kept unopened at room temperature and protected from light. Do not allow the components to freeze. The media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Any components showing microbial growth and all used components should be discarded in accordance with State and Federal regulation.

Incubation Procedure

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for **7 days at 20°– 25°C** followed by **7 days at 30°–35°C** to detect a broad spectrum of microorganisms.[1]

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.[1]

Per the USP <797> revision, "documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results."[1]

The Cultivate™ PASS™ Aseptic Media Fill Test Log was specifically designed for meet all of the documentation requirements for the revised USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation. For additional test log sheets visit www.parasolmed.com/cultivate.

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSB Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, dipotassium hydrogen phosphate, dextrose (glucose monohydrate) .
Final pH 7.3 +/- 0.2 at 25°C.

Tryptic Soy Broth is widely used for the cultivation of microorganisms from environmental sources; supporting the growth of the majority of bacteria and fungi.

- Digests of soybean meal and casein provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of microorganisms.
- Sodium chloride is added to maintain the osmotic equilibrium.
- Dextrose is incorporated as an energy source.
- The dipotassium hydrogen phosphate is included in the formulation as a buffer to maintain pH.

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

Low Risk Media Fill Test Directions for Use

PASS™
Personal Aseptic Sampling System
Cat. # TBV120

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

IMPORTANT NOTE:

Perform aseptic procedures in accordance with USP <797>. The procedures outlined are intended to provide general manipulation steps for using this product only. The procedures should be modified to simulate actual aseptic manipulations performed at the facility or by the technician. Per USP <797>, aseptic manipulation testing should replicate the technician's most complex manipulations.[1] Always use appropriate gowning techniques. Sanitize and disinfect surfaces and the outside of containers-including ampules, septa, vials, and bag-ports prior to use. Failure to perform gowning procedures or to adequately sanitize or disinfect surfaces or the outside of containers, including ampules, vial septa, and bag ports prior to use may result in growth during incubation or a failed test. Perform all manipulations inside the laminar air flow clean bench or similar environmentally controlled area using a validated process.

An assessment should be performed to determine if additional supplies or equipment are needed to validate the process when performing complex manipulations or in the verification of aseptic technique. Technicians should be re-certified at regular intervals as dictated by laboratory needs or determined by the complexity or risk level performed.

Aseptic Media Fill and Manipulation General Test Procedures

1. This test requires 1 Clear Check™ partially filled minibag and 1 Clear Check™ 20 mL vial, each containing TSB. The test involves adding 20 portions of the vial to the minibag and is one of the more complicated procedures the operator will perform.

2. Using standard procedures, sanitize the work area and swab the vial and bag ports.

3. If the test is to be performed within a laminar flow hood, protect the injection ports of the containers by placing them at least 6 inches within the work area. Take caution not to interrupt the clean air flow.

4. Select a sterile 3, 5, or 6cc disposable syringe. Remove the syringe from its packaging and place it in the workspace. Select 20 sterile needles (18G x 1" or smaller as appropriate).

5. Aseptically attach a needle to the syringe. Withdraw 1 mL of TSB from the vial and inject it into the minibag. Change the needle.

6. Repeat step (#5) 19 times, using 19 different needles with the same syringe and receiving minibag. After the final transfer there will be approximately 100 mL in the minibag. ***Personnel will modify compounding techniques when they know they are being tested, known as a test basis. After being asked to repeat procedure multiple times, they will often revert to normal compounding technique, providing more accurate testing.***

The complexity of the above procedure can be increased by transferring the contents of the minibag into another empty container at the end of step (#6). The receiving container should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

7. Immediately inspect the TSB in the final container for particulates, corings, and fibers. These particles should not be recorded as microbial growth. Label the final container with the included Cultivate™ ID label.

See reverse side for incubation procedures and how to interpreting results.

8. Following the test exercise, carefully and completely clear the compounding area of all testing supplies and equipment, thus preventing these materials from entering the institutional drug stream.

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

Medium Risk Media Fill Test Directions for Use

PASS 2™
Personal Aseptic Sampling System
Cat. # TBVA123

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intended Use

Cultivate™ PASS 2™ pre-assembled media fill test kit (Cat. #TBVA123) is recommended for verifying personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for up to five technicians with general procedures. Modify procedures to simulate actual compounding procedures better. Supplement test with ClearCheck™ a la carte components as needed. If you need assistance modifying, designing, or selecting the right Cultivate™ test kit or your facility, contact your local sales representative. This product is not intended to be used for the diagnosis of animal or human disease.

Aseptic Media Fill and Manipulation Timing

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 6 months thereafter.** When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean–casein digest (TSB) media. ***Quick Tip:*** *Schedule staff testing on their birthdays to spread out testing throughout the year. Use half birthdays 6 month later for the second media test of the year. This spreads the testing out and makes remembering the dates easy for staff.*

Storage, Stability, and Destruction

Cultivate™ PASS 2™ kits should be kept unopened at room temperature and protected from light. Do not allow the components to freeze. The media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Any components showing microbial growth and all used components should be discarded in accordance with State and Federal regulation.

Incubation Procedure

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for **7 days at 20°– 25°C** followed by **7 days at 30°–35°C** to detect a broad spectrum of microorganisms.[1]

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.[1]

Per the USP <797> revision, "documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results."[1]

The Cultivate™ PASS 2™ Aseptic Media Fill Test Log was specifically designed for meet all of the documentation requirements for the revised USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation. For additional test log sheets visit www.parasolmed.com/cultivate.

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSB Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, dipotassium hydrogen phosphate, dextrose (glucose monohydrate) .
Final pH 7.3 +/- 0.2 at 25°C.

Tryptic Soy Broth is widely used for the cultivation of microorganisms from environmental sources; supporting the growth of the majority of bacteria and fungi.

- Digests of soybean meal and casein provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of microorganisms.
- Sodium chloride is added to maintain the osmotic equilibrium.
- Dextrose is incorporated as an energy source.
- The dipotassium hydrogen phosphate is included in the formulation as a buffer to maintain pH.

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

Medium Risk Media Fill Test Directions for Use

PASS 2™
Personal Aseptic Sampling System
Cat. # TBVA123

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

IMPORTANT NOTE:

Perform aseptic procedures in accordance with USP <797>. The procedures outlined are intended to provide general manipulation steps for using this product only. The procedures should be modified to simulate actual aseptic manipulations performed at the facility or by the technician. Per USP <797>, aseptic manipulation testing should replicate the technician's most complex manipulations.[1] Always use appropriate gowning techniques. Sanitize and disinfect surfaces and the outside of containers-including ampules, septa, vials, and bag-ports prior to use. Failure to perform gowning procedures or to adequately sanitize or disinfect surfaces or the outside of containers, including ampules, vial septa, and bag ports prior to use may result in growth during incubation or a failed test. Perform all manipulations inside the laminar air flow clean bench or similar environmentally controlled area using a validated process.

An assessment should be performed to determine if additional supplies or equipment are needed to validate the process when performing complex manipulations or in the verification of aseptic technique. Technicians should be re-certified at regular intervals as dictated by laboratory needs or determined by the complexity or risk level performed.

Aseptic Media Fill and Manipulation General Test Procedures

1. This test requires 1 Clear Check™ ampule, 1 Clear Check™ partially filled minibag and 1 Clear Check™ 20 mL vial, each containing TSB. The test involves transferring the contents of an ampule to a vial and then adding 20 portions of the vial to the minibag. It is one of the more complicated procedures the operator will perform.

2. Using standard procedures, sanitize the work area and swab the vial and bag ports.

3. If the test is to be performed within a laminar flow hood, protect the injection ports of the containers by placing them at least 6 inches within the work area. Take caution not to interrupt the clean air flow.

4. Select a sterile 3, 5, or 6cc disposable syringe. Remove the syringe from its packaging and place it in the workspace. Select 20 sterile needles (18G x 1" or smaller as appropriate).

5. Aseptically attach a needle to the syringe.

6. Draw up contents of the ampule and inject into the vial. Shake to mix indicator dye.

7. Withdraw 1 mL of TSB from the vial and inject it into the minibag. Change the needle.

8. Repeat step (#5) 19 times, using 19 different needles with the same syringe and receiving minibag. After the final transfer there will be approximately 100 mL in the minibag. ***Personnel will modify compounding techniques when they know they are being tested, known as a test basis. After being asked to repeat procedure multiple times, they will often revert to normal compounding techniques, providing more accurate testing.***

The complexity of the above procedure can be increased by transferring the contents of the minibag into another empty container at the end of step (#6). The receiving container should be a frequently used size. The transfer is accomplished using gravity and a standard sterile pharmacy tubing set.

9. Immediately inspect the TSB in the final container for particulates, corings, and fibers. These particles should not be recorded as microbial growth. Label the final container with the included Cultivate™ ID label.

See reverse side for incubation procedures and how to interpreting results.

8. Following the test exercise, carefully and completely clear the compounding area of all testing supplies and equipment, thus preventing these materials from entering the institutional drug stream.

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations.* Rockville, MD.

Medium Risk Media Fill Test Directions for Use

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Aseptic Media Fill and Manipulation Timing

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices initially and every 6 months thereafter. When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean–casein digest (TSB) media. ***Quick Tip:*** Schedule staff testing on their birthdays to spread out testing throughout the year. Use half birthdays 6 month later for the second media test of the year. This spreads the testing out and makes remembering the dates easy for staff.

Storage, Stability, and Destruction

Cultivate™ PASS 3™ kits should be kept unopened at room temperature and protected from light. Do not allow the components to freeze. The media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Any components showing microbial growth and all used components should be discarded in accordance with State and Federal regulation.

Incubation Procedure

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for 7 days at 20°– 25°C followed by 7 days at 30°–35°C to detect a broad spectrum of microorganisms.

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.

Test Method 1: 6-manipulations, 3 test per TVA3211 kit

This exercise requires proper use of a dispensing pin, reconstituting and transfer of a large volume without a dispensing pin, use of a single-dose vial, and an ampule. Perform the following procedures, transferring all components to a 100mL capacity evacuated container or IV bag. Reconstitution of the PT-V020 is to be accomplished using 20mL sterile Water For Injection (WFI).

One test includes:

1 x T2-A010	1 x PT2-V020
1 x T2-V010	1 x T2-V030

Step 1: Using a dispensing pin, transfer 10mL from the T2-V030 vial to the final container.
Step 2: Without using a dispensing pin, reconstitute the PT2-V020 vial with 20mL WFI. Transfer 20mL to the final container.
Step 3: Withdraw an additional 10mL from the T2-V030 vial and transfer to the final container.
Step 4: Transfer 10mL from the T2-A010 ampule to final container.
Step 5: Without a dispensing pin, transfer 10mL from T2-V010 vial.
Step 6: Withdraw the final 10mL of the T2-V030 vial and transfer to the final container.

Test Method 2: 8-manipulations, 3 test per TVA3211 kit

This exercise requires proper transfer of sterile Water For Injection (WFI), using a compounder, gravity transfer set, or a 60mL syringe, whichever, is most representative of institutional procedures, in addition to the manipulation in TEST METHOD 1.

Step 1: Transfer 50mL of Water For Injection to a 100mL container via pump, gravity, or syringe.
Step 2: Using a dispensing pin, transfer 5mL from T2-V030 vial to final container.
Step 3: Without using a dispensing pin, reconstitute the PT2-V020 vial with 20mL WFI. Transfer 5mL to the final container.
Step 4: Without using a dispensing pin, transfer transfer 10mL
Step 5: Withdraw 5mL from T2-V030 vial and transfer to final container.
Step 6: Withdraw 5mL from PT2-V020 vial and transfer to final container.
Step 7: Transfer 10mL from the T2-A010 to the final container.
Step 8: Withdraw 5mL from T2-V030 vial and transfer to final container.
Step 9: Withdraw 5mL from PT2-V020 vial and transfer to final container.

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.

Cultivate
A PARASOL MEDICAL PRODUCT

Custom Media Fill Test Directions for Use

ClearCheck™
a la carte Media Fill Test Components

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intended Use

The ClearCheck™ line of a la carte products are recommended for verifying personnel aseptic technique within a sterile compounding pharmacy facility or other cleanroom application. Cultivate™ offers a variety of components that can be purchased separately to create an aseptic media fill test that simulates daily compounding procedures in your facility. Substitute actual components of dilutes and drugs with ClearCheck™ growth media compounds. For a convenient alternative, use PASS™ pre-assembled media fill test with general test procedures. If you need assistance designing a test or selecting the right Cultivate™ test kit for your facility, contact your local sales representative. This product is not intended to be used for the diagnosis of animal or human disease.

Aseptic Media Fill and Manipulation Timing and Procedures

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 6 months** thereafter. ***Quick Tip:*** *Schedule staff testing on their birthdays to spread out testing throughout the year. Use half birthdays 6-month later for the second media test of the year. This spreads the testing out and makes remembering the dates easy for staff.*

When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean–casein digest (TSB) media.[1] ***Personnel will modify compounding techniques when they know they are being tested, known as a test basis. After being asked to repeat procedure multiple times, they will often revert to normal compounding technique, providing more accurate testing. When developing a custom test procedure for your facility, select the most challenging compounding procedure for each technician, often with the most manipulation, and at a minimum triple the manipulations.***

IMPORTANT NOTE: Always use appropriate gowning techniques. Sanitize and disinfect surfaces and the outside of containers-including ampules, septa, vials, and bag-ports prior to use. Failure to perform gowning procedures or to adequately sanitize or disinfect surfaces or the outside of containers--including ampules, septa, and bag ports--prior to use may result in growth during the incubation window or a failed test. Perform all manipulations inside the laminar air flow clean bench or similar environmentally controlled area using a validated process. Immediately following the test exercise, carefully and completely clear the compounding area of all testing supplies and equipment, thus preventing these materials from entering the institutional drug stream.

Storage, Stability, and Destruction

Cultivate™ PASS™ kits should be kept unopened at room temperature and protected from light. Do not allow the components to freeze. The media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Any components showing microbial growth and all used components should be discarded in accordance with State and Federal regulation.

Incubation Procedure

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for **7 days at 20°– 25°C** followed by **7 days at 30°–35°C** to detect a broad spectrum of microorganisms.[1]

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.

Per the USP <797> revision, "documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results."[1]

The Cultivate™ ClearCheck™ Media Fill Test Log was specifically designed for meet all of the documentation requirements for the revised USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation. For additional test log sheets visit ***www.parasolmed.com/cultivate.***

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSB Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, dipotassium hydrogen phosphate, dextrose (glucose monohydrate) .
Final pH 7.3 +/- 0.2 at 25°C.

- Digests of soybean meal and casein provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of microorganisms.
- Sodium chloride is added to maintain the osmotic equilibrium.
- Dextrose is incorporated as an energy source.
- The dipotassium hydrogen phosphate is included in the formulation as a buffer to maintain pH.

[1] United States Pharmacopeial Convention; (2019); USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. Rockville, MD.

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

Cultivate
A PARASOL MEDICAL PRODUCT

Hazardous Containment Test Direction for Use

HazardTest™
Cat. # LV53

USP <800> Hazardous Drug Compounding and Handing

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intended Use

The HazardTest™ (Cat. # LV53) is intended to validate the technique of health care workers who manipulate hazardous drugs. The directions for use are designed to simulate frequently performed procedures where antineoplastic and other hazardous drugs are compounded, sterilized, reconstituted, mixed, transferred, and prepared for administration. The LV53 HazardTest™ is NOT intended to validate aseptic technique. Caution: Ultraviolet light may be harmful to eyes and unprotected skin. Do not shine the UV light into eyes or for prolonged periods onto skin. TURN OFF ambient lights in the work area when using the UV Light.

Hazardous Containment Test Timing

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 12 months thereafter.**[1]

Quick Tip: *Schedule staff testing on their birthdays to spread out testing throughout the year. This spreads the testing out and makes remembering the dates easy for staff.*

Storage, Stability, and Destruction

Cultivate™ HazardTest™ kits should be kept unopened at room temperature and protected from light. The media should not be used if the expiration date has passed.

Materials Supplied in HazardTest™ Kit

5 x 50 mL vial with powdered fluorescein dye, non-sterile
5 x 3 mL vial with fluorescein dye solution, non-sterile

Materials Supplied by User

UV Light
Empty flexible container (Minibag), 50-250mL capacity
Diluent (NS, D5W, OR SWI)
Luer lock syringes
Appropriately sized needles
Gloves, mates, gowns, disinfectants, waste containers, other protective supplies

Optional
Closed-system drug transfer device
Needle-less system
IV Administration set

Interpreting Results

Failure of the hazardous compounding containment is indicated by the presence of fluorescein dye on the inspected surfaces under the UV light.

Test Procedures:

You should modify the test instructions below to replicate your facilities training, written procedures, equipment, supplies and housekeeping policies.

The LV53 test procedure is designed to test one of the more complex procedures the operator will be expected to perform. It consists of:

a. Reconstituting a powder in a 50 mL vial and transferring the liquid contents to a small flexible container,

b. Transferring the contents of a 3 mL vial to a flexible container, and

c. Priming a typical IV administration set.

1. Prepare and arrange all supplies in the Biological Safety Cabinet (BSC) or area used for manipulating hazardous drugs.

2. Sanitize work area using standard procedures. Swab vials, bag, and ports according to standard procedures.

3. Before proceeding, the test supervisor should carefully shine the UV light on all work surfaces, supplies, mats, gloves, and gown. Any materials or spots that exhibit fluorescence should be removed or noted in the test log. This is to prevent them from being counted later as accidental spills or aerosolization of the fluorescein dye.

4. Using standard procedures and supplies, reconstitute the fluorescein dye powder in the 50 mL vial.

5. Transfer the fluorescein solution to the flexible container. Retain the flexible container. Transfer the fluorescein dye solution in the 3 mL vial to the flexible container.

6. Optional - Spike the flexible container with the IV administration set. Using standard procedures, prime the set.

7. At this point, the test supervisor carefully shines the UV light on the work surfaces and sides of the BSC, mat, used containers, IV administration set, gloves, and gown. Record the number and size of fluorescein spots in the log.

Hazmat Cleanup Testing:

Save the bag of fluorescein dye solution for future hazardous material cleanup testing. Create a hole in the bag and "Spill" the solution in the work area to simulate a hazardous material accident. After the appropriate cleanup procedures are completed, shine the UV light on the spill area to evaluate effectiveness of the cleanup.

[1] United States Pharmacopeial Convention; (2019). <800> Hazardous Drugs–Handling in Healthcare Settings (p. 8). Rockville, MD.

Simultaneous USP <797> Aseptic Manipulation & USP <800> Hazardous Containment Technique Test

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation / USP <800> Hazardous Drug Compounding and Handing

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intended Use

Cultivate™ HazardTest 2™ (Cat. #TVA5251) simultaneously validates USP <797> Chapter 2.3 aseptic manipulation and USP <800> hazardous containment techniques in a single test. The HazardTest 2™ is recommended for verifying personnel aseptic technique for medium complexity levels within a sterile compounding pharmacy facility or other cleanroom application. Each kit contains enough media to perform aseptic technique verification for up to two technicians with general procedures. Modify procedures to simulate actual compounding procedures better. Supplement test with ClearCheck™ a la carte components as needed. If you need assistance designing a test or selecting the right Cultivate™ test kit or your facility, contact your local sales representative. This product is not intended to be used for the diagnosis of animal or human disease.

Test Timing

USP <797> Aseptic Media Fill and Manipulation Technique

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 6 months thereafter.** When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean–casein digest media.

USP <800> Hazardous Containment Technique

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices **initially and every 12 months thereafter.**[2]

Quick Tip: *Schedule staff testing on their birthdays to spread out testing throughout the year. Use half birthdays 6 month later for the second media test of the year. This spreads the testing out and makes remembering the dates easy for staff.*

Storage, Stability, and Destruction

Cultivate™ HazardTest 2™ kits should be kept unopened at room temperature and protected from light. Do not allow the components to freeze. The media should not be used if there are any signs of deterioration, contamination, or if the expiration date has passed. Any components showing microbial growth and all used components should be discarded in accordance with State and Federal regulation.

Incubation Procedure

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for **7 days at 20°– 25°C** followed by **7 days at 30°–35°C** to detect a broad spectrum of microorganisms.[1]

Interpreting Results

USP <797> Aseptic Media Fill and Manipulation Technique

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.[1]

USP <800> Hazardous Containment Technique

The presence of red dye on the trace wipes from the inspected surfaces indicates the failure of the hazardous compounding containment. Failure demonstrates a breach of proper containment technique and indicates the need for additional training in containment manipulation.

Per the USP <797> revision, "documentation must at a minimum include the name of the person evaluated, evaluation date/time, media and components used including manufacturer, expiration date and lot number, starting temperature for each interval of incubation, dates of incubation, the results, and the identification of the observer and the person who reads and documents the results."[1]

The Cultivate™ HazardTest 2™ Simultaneous Hazardous Compounding & Aseptic Technique Test Log was specifically designed for meet all of the documentation requirements for the revised USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation. For additional test log sheets visit ***www.parasolmed.com/cultivate.***

Precautionary Statement

This product may contain 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. Do not ingest, inhale, or allow to come into contact with skin. Visit www.parasolmed.com/cultivate for more information or consult your sales representative.

TSB Media Ingredients:

Pancreatic digest of casein, peptic digest of soybean meal, sodium chloride, dipotassium hydrogen phosphate, dextrose (glucose monohydrate) .
Final pH 7.3 +/- 0.2 at 25°C.

- Digests of soybean meal and casein provide amino acids and other nitrogenous substances, making it a highly nutritious medium for a variety of microorganisms.
- Sodium chloride is added to maintain the osmotic equilibrium.
- Dextrose is incorporated as an energy source.
- The dipotassium hydrogen phosphate is included in the formulation as a buffer to maintain pH.

DFU-TVA5251F v1.1

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations*. Rockville, MD.
[2] United States Pharmacopeial Convention; (2019). <800> Hazardous Drugs–Handling in Healthcare Settings (p. 8). Rockville, MD.

USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation / USP <800> Hazardous Drug Compounding and Handing

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Test Kit Contents Per Test (two test per kit)

2 x T2C-V5025 50 mL Vials with 25mL 2x TSB Media
2 x T2C-V050 50 mL Vial, 2x TSB Media
2 x T2C-A010 10mL Ampule, 2x TSB Media
20 x Gloss ID labels
1 x HazardTest 2 Log Sheet
5 x Tracer Detection Wipes

Test Kit Contents Per Test (two test per kit)

1 x 100 mL Bag Normal Saline
1 x 150 mL (or Larger) Empty Evacuated Container Bottle
1 x Administrative Tubing Set
2 x Hydrophobic (Chemo) Dispensing Pins
2 x Sterile Empty Vials (≥ 10 mL Capacity)
1 x 50 mL Sterile Water for Injection (SWFI)
1 x Sterile Gauze for Ampule Opening
2 x Hazardous Waste Containers
10 x 19Ga Needles
2 x Filter Needles
8 x 20mL Syringes
2 x 30mL Syringes
3 x 60mL Syringes
6 x Syringe Caps
6 x Vial Seals

IMPORTANT NOTE:

Perform aseptic procedures in accordance with USP <797>. The procedures outlined are intended to provide general manipulation steps for using this product only. The procedures should be modified to simulate actual aseptic manipulations performed at the facility or by the technician. Per USP <797>, aseptic manipulation testing should replicate the technician's most complex manipulations.[1] Always use appropriate gowning techniques. Sanitize and disinfect surfaces and the outside of containers-including ampules, septa, vials, and bag-ports prior to use. Failure to perform gowning procedures or to adequately sanitize or disinfect surfaces or the outside of containers, including ampules, vial septa, and bag ports prior to use may result in growth during incubation or a failed test. Perform all manipulations inside the laminar air flow clean bench or similar environmentally controlled area using a validated process.

An assessment should be performed to determine if additional supplies or equipment are needed to validate the process when performing complex manipulations or in the verification of aseptic technique. Technicians should be re-certified at regular intervals as dictated by laboratory needs or determined by the complexity or risk level performed.

Aseptic Media Fill and Manipulation General Test Procedures

The below directions for use are written for mixing with standard needles and dispensing pins. When using a closed system transfer device, modify these directions for use by substituting the CSTD adapters and connectors as appropriate.

1. Transfer 50 mL from the bag of normal saline to the empty evacuated container.
2. Attach administration set to the bag of normal saline, prime the tubing, and secure to prevent leakage.
3. Using a dispensing pin, remove 50 mL of media from one of the T2-V050 vial, and transfer to the evacuated container.
4. Without using a dispensing pin, remove 50 mL media from the other T2-V050 vial, transfer to the bag of normal saline.
5. Transfer 10 mL from one of the T2-A010 ampule to the evacuated container. Make final adjustments in an empty vial.
6. Transfer 10 mL from the other T2-A010 ampule to the evacuated container. Make final adjustments in an empty vial.
7. Without using a dispensing pin, add 25 mL SWFI to one of the T2-V5025 vials.
8. Using a dispensing pin, add 25 mL SWFI to the other T2-V5025 vial.
9. Without using a dispensing pin, prepare 3 each 10 mL syringes from the T2-V5025 vial diluted in step 7.
10. Using a dispensing pin, prepare 3 each 10 mL syringes from the T2-V5025 vial diluted in step 8.
11. Properly prepare and label the vials diluted in steps 7 and 8 as well as all final containers and syringes prepared.
12. Immediately following the test, recovery of compounding residue may be accomplished by systematic swabbing of a representative surface. See log sheet for suggested areas and surfaces.
13. Following the test exercise, carefully and completely clear the compounding area of all testing supplies and equipment, thus preventing these materials from entering the institutional drug stream.

See reverse side for incubation procedures and how to interpreting results.

13. Following the test exercise, carefully and completely clear the compounding area of all testing supplies and equipment, thus preventing these materials from entering the institutional drug stream.

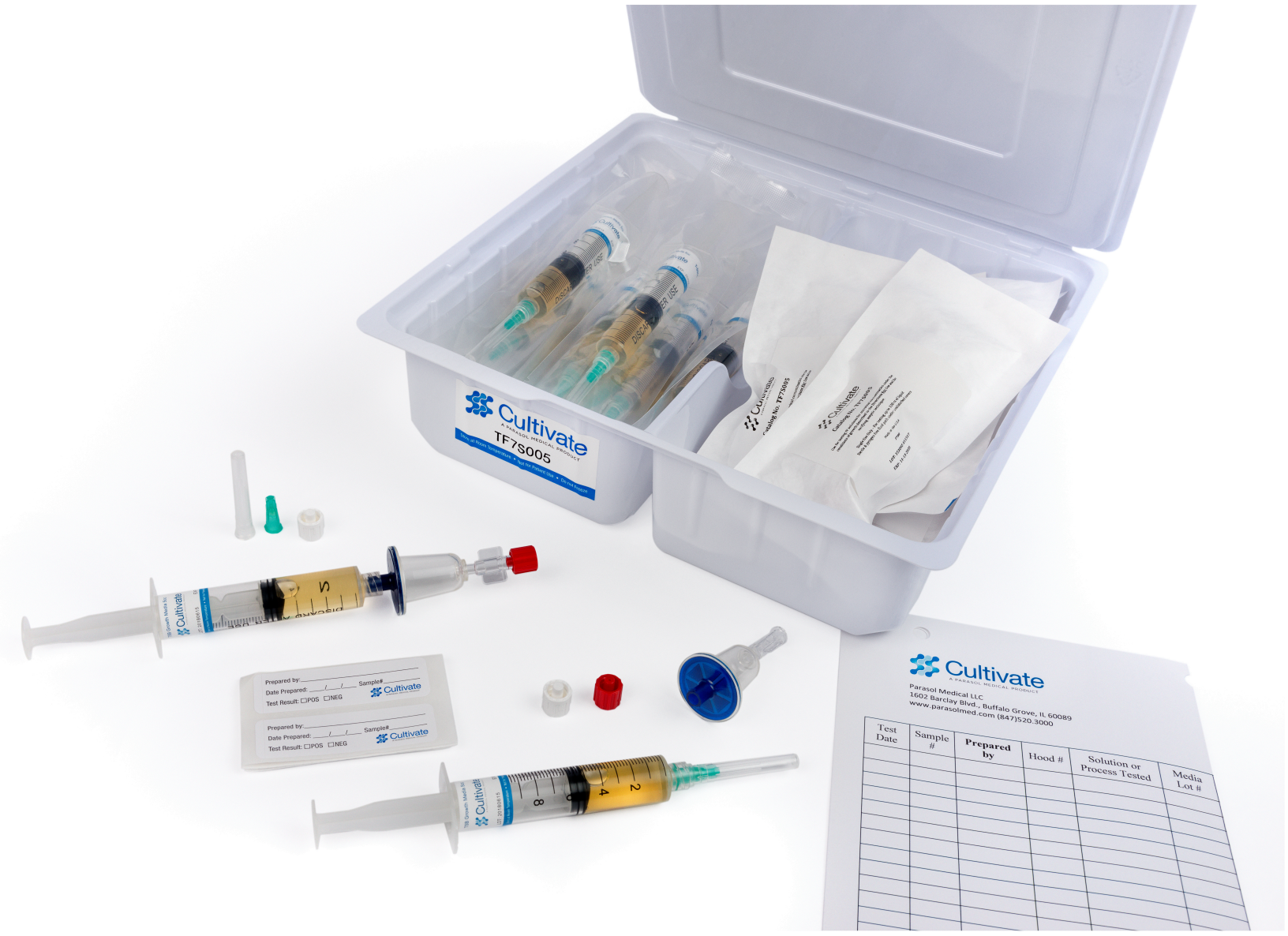
Pharmacy staff should employ all personal hygiene and barrier controls, engineering controls, preparation, aseptic manipulation, clean-up, waste disposal, logging, and other procedures in accordance with policies

[1] United States Pharmacopeial Convention; (2019). *USP General Chapter <797> Pharmaceutical Compounding – Sterile Preparations*. Rockville, MD.

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.



Full Filtration Microbial Contamination Test System Direction for Use

TT Micro System™
Cat. # TF7S005

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intented Use

Validation tool for syringe to syringe or syringe to sterile container transfers. Full filtration microbial contamination test system for small volume compounded sterile products. This is a destrucitve test.

Storage, Stability, and Destruction

Cultivate™ TT Micro System™ kits should be kept unopened at room temperature and protected from light. The media should not be used if the expiration date has passed.

Incubation Proceudres

Once the compounding simulation is completed and the final containers are filled with the test media and labeled, incubate them in an incubator for **7 days at 20°– 25°C** followed by **7 days at 30°–35°C** to detect a broad spectrum of microorganisms.[1]

Materials Supplied in TT Micro System™ Kit

- 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 (TSB) Direction for Use & Test Log

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.

Directions for Use

1. Remove and discard RED Vented Male Luer cap on INLET Female Luer Lock fitting on F700 Micro Filter

2. Attach syringe containing solution to be tested to the INLET Female Luer Lock fitting.

3. Remove and save WHITE Nonvented Male Luer cap from OUTLET Female Luer Lock fitting. Carefully position in laminar air flow to avoid contamination of inner surface of Male Luer cap.

4. Firmly attach a sterile, empty (receiving) syringe to the OUTLET Female Luer Lock. The empty syringe must have a capacity equal to or greater than the volume of solution in the syringe being tested.

5. Press plunger on syringe containing solution to be tested to transfer solution through F700 Micro Filter into the receiving syringe. Pull back syringe plunger slightly and press again to transfer any solution remaining in the filter housing.

6. Carefully remove and cap receiving syringe.

NOTE: F700 Micro Filter is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients.

7. Replace WHITE cap on OUTLET Female Luer Lock fitting.

8. Remove empty syringe from INLET Female Luer Lock fitting.

9. Attach syringe containing TSB growth media to the INLET Female Luer Lock fitting.

10. Press plunger on growth media syringe to fill chamber on F700 Micro Filter.

NOTE: Point syringe DOWN while pressing plunger. This will remove air from filter chamber

11. Leave growth media syringe attached to the TT Micro™.

12. Complete, then attach gummed label to the Cultivate™ syringe.

13. Incubation, USP Chapter Sterility Test Method

If the test is positive before 14 days of incubation, further incubation is not necessary.

14. Remove "piggy back" gummed label from TT Micro™ and record results in F700 Micro Filter log sheet.

15. Discard used F700 Micro filters in a safe manner.

IMPORTANT:
Do not use to test blood, blood products, or emulsions.
Do not use if protective covers are missing or not in place.
Do not use for direct infusion into patient.
Do not resterilize or reuse, discard after use.

[1] United States Pharmacopeial Convention; (2019). <800> Hazardous Drugs–Handling in Healthcare Settings (p. 8). Rockville, MD.

Full Filtration Microbial Contamination Test System Direction for Use

TT Micro System™
Cat. # FF7S005

For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate

Intented Use

Validation tool for syringe to syringe or syringe to sterile container transfers. Full filtration microbial contamination test system for small volume compounded sterile products. This is a destrucitve test.

Storage, Stability, and Destruction

Cultivate™ TT Micro System™ kits should be kept unopened at room temperature and protected from light. The media should not be used if the expiration date has passed.

Incubation Proceudres

Once the compounding simulation is completed and the final containers are filled with the FTM test media and labeled, incubate them in an incubator **30-35˚C for not less than 14 days.**

Materials Supplied in TT Micro System™ Kit

- 10 x 10 cc, 5cc pre-fill syringe, FTM
- 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

Interpreting Results

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container–closure unit(s) on or before 14 days. Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency.

Directions for Use

1. Remove and discard RED Vented Male Luer cap on INLET Female Luer Lock fitting on F700 Micro Filter

2. Attach syringe containing solution to be tested to the INLET Female Luer Lock fitting.

3. Remove and save WHITE Nonvented Male Luer cap from OUTLET Female Luer Lock fitting. Carefully position in laminar air flow to avoid contamination of inner surface of Male Luer cap.

4. Firmly attach a sterile, empty (receiving) syringe to the OUTLET Female Luer Lock. The empty syringe must have a capacity equal to or greater than the volume of solution in the syringe being tested.

5. Press plunger on syringe containing solution to be tested to transfer solution through F700 Micro Filter into the receiving syringe. Pull back syringe plunger slightly and press again to transfer any solution remaining in the filter housing.

6. Carefully remove and cap receiving syringe.

NOTE: F700 Micro Filter is not intended to filter-sterilize (cold sterilize) contaminated solutions or admixtures made from non-sterile ingredients.

7. Replace WHITE cap on OUTLET Female Luer Lock fitting.

8. Remove empty syringe from INLET Female Luer Lock fitting.

9. Attach syringe containing FTM growth media to the INLET Female Luer Lock fitting.

10. Press plunger on growth media syringe to fill chamber on F700 Micro Filter.

NOTE: Point syringe DOWN while pressing plunger. This will remove air from filter chamber

11. Leave growth media syringe attached to the TT Micro™.

12. Complete, then attach gummed label to the Cultivate™ syringe.

13. Incubation, USP Chapter Sterility Test Method

If the test is positive before 14 days of incubation, further incubation is not necessary.

14. Remove "piggy back" gummed label from TT Micro™ and record results in F700 Micro Filter log sheet.

15. Discard used F700 Micro filters in a safe manner.

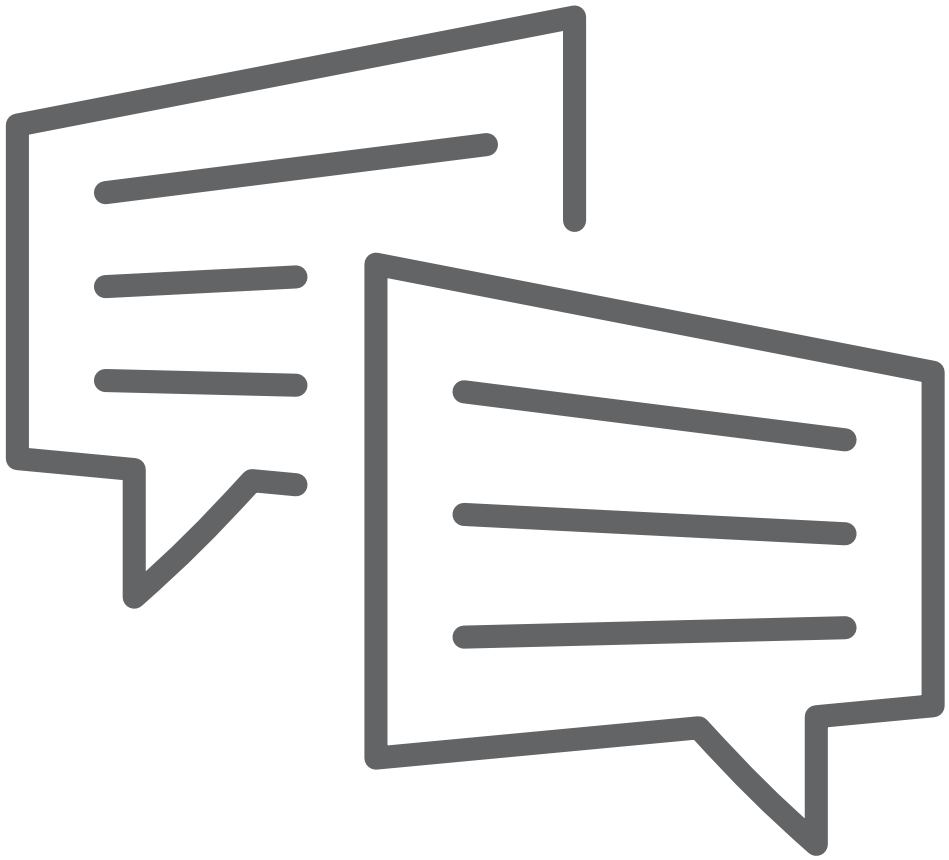
IMPORTANT:
Do not use to test blood, blood products, or emulsions.
Do not use if protective covers are missing or not in place.
Do not use for direct infusion into patient.
Do not resterilize or reuse, discard after use.

[1] United States Pharmacopeial Convention; (2019). <800> Hazardous Drugs–Handling in Healthcare Settings (p. 8). Rockville, MD.

FAQ's

Quality Assurance

Frequently Asked Questions



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.

Key Product Solutions

USP <797> Section 2.2: Demonstrating Competency in Garbing and Hand Hygiene

Required initially and every 6-months thereafter. Initial testing requires 3 successful test before being allowed to compound

USP <797> Section 6.3: Monitoring Surfaces for Viable Particles

Required at least monthly

Contact™ Flex paddle,
TSA w Lecithin & Polysorbate 80
Cat. # TD100

One Product - Two Uses

Use for both gloved fingertip ans surfaces sampling

Cultivate™ Best Practice: *The revised USP <797> Chapter requires the 3 initial passing tests be no fewer than 3 separate times. Cultivate's™ suggested best practice is to make the requirement 3 consecutive passing test to ensure proper, repeatable technique.*

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

Required initially and every 6-months thereafter

PASS - Pre-assembled Aseptic Media Fill Test Kits

PASS™ Low Risk
Cat. # TBV120

PASS 2™ Medium Risk
Cat. # TBVA123

PASS 3™ Medium Risk
Cat. # TVA3211

HazardTest 2™ Medium Risk
Cat. # TVA5251 **

ClearCheck - a la carte Kits

If one of the PASS pre-assembled media fill test kits does not closely resemble your facilities or personnel compounding procedure, use the ClearCheck a la carte line of products to build a custom test kit. You can also use the ClearCheck components to enhance the Pass kits. For a complete list of ClearCheck kits visit www.parasolmed.com/cultivate/

Cat. # TV020

Cat. # TB100

Cat. # TS005

Cat. # TA003

USP <800> Hazardous Drugs – Handling in Healthcare Settings: Chapter 9

Required every 12-months

HazardTest 2™ Medium Risk
Cat. # TVA5251 **

*** Simultaneously validates aseptic manipulation (USP <797> section 2.3) and hazardous containment (USP <800> chapter 9) techniques.*

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.