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

HazardTest 2™
Cat. # TVA5251 - TSB Media

2023 USP <797> Competency Testing in Aseptic Manipulation
For additional Cultivate™ Directions for Use and test logs go to www.parasolmed.com/cultivate/cultivate-resources

Testing Overview and Frequency

	Cat. 1 / Cat. 2 CSP Compounder	Cat. 3 CSP Compounder	Personnel who have direct oversight of compounding personnel
Initial Evaluation	Initially all personnel must successfully complete the aseptic manipulation competency evaluation consisting of a visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling of both hands, and surface sampling of the direct compounding area to assess aseptic technique and related practices.		
Subsequent Evaluations	At least once every 6 months	At least once every 3 months	At least once every 12 months*

USP <800> HD Handling Test Frequency: The effectiveness of training for HD handling competencies must be demonstrated by each employee. Personnel competency must be conducted initially and reassessed at least every 12 months.

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. 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 modifying, designing, 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. Download a copy of the media lot specific Certificate of Analysis (CoA) at **www.parasolmed.com/cultivate/cultivate-resources.**

When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media (Tryptic Soy Broth, TSB). The simulation must capture elements that could potentially affect the sterility of the CSP including but not limited to:[1]

- Factors associated with the length of the process that can pose contamination risk (e.g., operator fatigue, quality of equipment)
- Number of aseptic additions or transfers
- Number, type, and complexity of manipulations
- Number of personnel in the buffer room or SCA

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

Incubate the final container(s) **at 20°– 25°C** and **30°–35°C** for a minimum of 7 days at each temperature band to detect a broad spectrum of microorganisms. The order of the incubation temperature must be described in the facility's SOPs. The final container(s) must be incubated in an incubator.[1]

Interpreting Results

USP <797> Media-Fill Test: 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 the end of the incubation period. Microbial identification of the cfu is not required for media-fill testing.[1]

USP <797> Gloved Fingertip and Thumb Test: Successful completion of the gloved fingertip and thumb sampling after media-fill testing is defined as ≤ 3 cfu as a total from both hands. Microbial identification of the cfu is not required for gloved fingertip and thumb sampling.[1]

USP <797> Surface Sample Test: Failure is indicated by cfu count(s) high than the action levels for the associated ISO Class. Evaluate cfu counts against the action levels, and examine counts in relation to previous data to identify adverse results or trends. If levels measured during surface sampling exceed the levels for the ISO classified levels of the area sampled, the cause must be investigated and corrective action must be taken. 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]

A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulations competency. Results of the evaluation and corrective actions must be documented and the documentation maintained to provide a record and long- term assessment of personnel competency.[1]

USP <800> HD Handling & Containment Technique Test:
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.

Action Levels for Gloved Fingertip and Thumb Sampling, per 2023 USP <797>[1]

Gloved Fingertip and Thumb Sampling	Action Levels (cfu, total from both hands)
After media-fill testing	>3

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

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

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

Action levels are based on the total cfu count for both sides of paddle

TSB Media Ingredient: 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.

[1] U.S. Pharmacopeia Convention. (2022). <797> Pharmaceutical Compounding–Sterile Preparations.

BEFORE YOU BEGIN: Inspect the product and media carefully before starting to test. If the media fluid is clear and free of contamination and particulate prior to testing, then any contamination or particulate observed after collecting the samples or incubating the samples will have been introduced by the compounding personnel. If contamination or particulate is observed prior to opening or using the product, please contact your local sales rep.

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 manipulation. 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.[1]

HazardTest 2 Validation Kit Content per Test (2 tests per kit)

Included:

2 ea. 50 mL Vials (50 mL Fill), 2X TSB Media with Red Tracer (T2C-V050)
2 ea. 50 mL Vials (25 mL Fill), 2X TSB Media with Red Tracer (T2C-V5025)
2 ea. 10 mL Ampule, 2X TSB Media with Red Tracer (T2C-A010)
10 ea. Personnel ID labels (use for bag/bottles, syringes, bulk storage container)
1 ea. Pack of 10 tracer detection wipes

Additional Supplies Required per Test:

1 ea. 100 mL bag Normal Saline
1 ea. 150 mL (or larger) Empty Evacuated Container bottle/bag
1 ea. Administration Tubing Set
2 ea. Hydrophobic Dispensing Pin
2 ea. Sterile Empty Vials (≥ 10 mL capacity)
50 mL Sterile Water for Injections (SWFI)

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 using the provided wipes. See log sheet for suggested areas and surfaces.

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

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

Aseptic Manipulation Competency Gloved Fingertip and Thumb Sampling

Immediately following the media-fill test, gloved fingertip and thumb sampling must be performed on both hands and inside of an ISO Class 5 PEC. If conducting gloved fingertip and thumb sampling in a compounding aseptic isolator (CAI), compounding aseptic containment isolator (CACI), or a pharmaceutical isolator (CAI), samples must be taken from the sterile gloves placed over the gloves attached to the restricted-access barrier system (RABS) or pharmaceutical isolator sleeves.[1]

- Use Contact™ Media Paddles - Cat. No.: TD100
- Visit www.parasolmed.com/cultivate/cultivate-resources to download Cultivate™ 2023 Gloved Fingertip and Thumb Sampling Direction for Use for aseptic manipulation competency GFT sampling procedures, paddle incubation instructions, and how to interpret results.

Aseptic Manipulation Competency Surface Sampling

Media-fill testing must also be followed by surface sampling of the direct compounding area in accordance with the requirements of 2023 USP <797) 6.3 Monitoring Surfaces for Viable Particles.[1]

- Use Contact™ Media Paddles - Cat. No.: TD100
- Visit www.parasolmed.com/cultivate/cultivate-resources to download Cultivate™ 2023 Environmental Surface Sample Direction for Use for aseptic manipulation competency surface sampling procedures, paddle incubation instructions, and how to interpret results.

[1] U.S. Pharmacopeia Convention. (2022). <797> Pharmaceutical Compounding-Sterile Preparations.