Cultivate
A PARASOL MEDICAL PRODUCT

ClearCheck™ Aseptic Manipulation Competency Evaluation Directions for Use

ClearCheck™ a la carte Media-fill Kits

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*

Intended Use

Cultivate™ ClearCheck™ a la carte kit are recommended when designing a custom aseptic media-fill evaluation. They can also be used to supplement a PASS™ pre-assembled test kits to more closely mimic daily compounding procedures. 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.

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™ ClearCheck™ 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

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]

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]

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.[1]

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]

The Cultivate™ ClearCheck™ Aseptic Media Fill Test Log was specifically designed for meet all of the documentation requirements for the 2023 USP <797> Chapter 2.3 Competency Testing in Aseptic Manipulation. For additional test log sheets visit ***www.parasolmed.com/cultivate/cultivate-resources.***

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>. 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. Technicians should be re-certified at regular intervals as dictated by laboratory needs or determined by the complexity or risk level performed.[1]

Aseptic Media Fill and Manipulation General Test Procedures

If all of the starting components are sterile to begin with, manipulate them in a manner that simulates sterile-to-sterile compounding activities, and transfer to sterile soybean-casein digest (TSB) media into the same type of container closure systems commonly used at your facility. Do not further dilute the media unless specified by the manufacturer.

If some of the starting components are non-sterile to begin with, dissolve a commercially available non-sterile soybean-casein digest powder in non-bacteriostatic water to make a 3% non-sterile solution. Manipulate it in a manner that simulates non-sterile-to-sterile compounding activities. Prepare at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visual turbidity upon incubation.

An assessment should be performed to determine appropriate supplies or equipment are needed to validate the process when performing complex manipulations or in the verification of aseptic technique.

The procedures should to simulate actual aseptic manipulations performed at the facility or by the technician. Each compounder should be tested based on the most difficult compounding procedure they preform. Per USP <797>, aseptic manipulation testing should replicate the technician's most complex manipulation.

Personnel may 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. When designing a custom aseptic media-fill procedure, it is recommended to include repetitive compounding procedures to minimize test basis.
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.

If you need assistance modifying, designing, or selecting the right Cultivate™ test kit or your facility, contact your local sales representative.

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.