

CATEGORY 1 CSP MEDIA-FILL TEST KIT

Instructions for Use

KIT CONTENTS

Quantity	Description
12	Sterile (Tryptic Soy Broth) Test Media 10ml Vials, 5ml Fill
3	Sterile 50ml Empty Serum Vials
1	Whirl-Pak® Bag
1	Log Sheet

INTENDED USE

The Category 1 CSP Media-Fill Test Kit validates compounding personnel's aseptic technique and sterile compounding proficiency. Intended for simulating Category 1 compounded sterile preparations, it evaluates the risk of microbial contamination and assesses competency in aseptic techniques. Suitable for the initial assessment and every 6-month revalidation of aseptic manipulation competency, in accordance with USP Chapter <797> guidelines.

TEST MEDIA SPECIFICATION

The 'Test Media' vials contain Tryptic Soy Broth (TSB), a comprehensive medium for culturing a broad spectrum of environmental microorganisms. TSB promotes the growth of a wide variety of bacteria and fungi, in compliance with United States Pharmacopeia standards.

PRECAUTIONS

This product is For Laboratory Use only and is not intended for diagnostic purposes.

ADDITIONAL REQUIRED MATERIALS

To complete the media-fill test procedure, some materials not included in the kit are necessary including syringes, vented needles, adhesive seals, incubators, etc.

QUALITY CONTROL

Each lot of prepared media undergoes quality control testing and is inoculated with the microorganisms specified below. Detailed results are documented in the included Certificate of Analysis.

Microorganism	ATCC®	Approx. Inoculum (CFU)	Incubation Period	Results
<i>Staphylococcus aureus</i>	6538	10-100	18-24 hours	Growth
<i>Pseudomonas aeruginosa</i>	9027	10-100	18-24 hours	Growth
<i>Bacillus subtilis</i>	6633	10-100	18-72 hours	Growth
<i>Candida albicans</i>	10231	10-100	18-72 hours	Growth
<i>Aspergillus brasiliensis</i>	16404	10-100	Within 5 days	Growth

STORAGE AND SHELF LIFE

Store between 2°–30°C. Do not use test media if there are signs of turbidity, deterioration, or if it is beyond its expiration date.

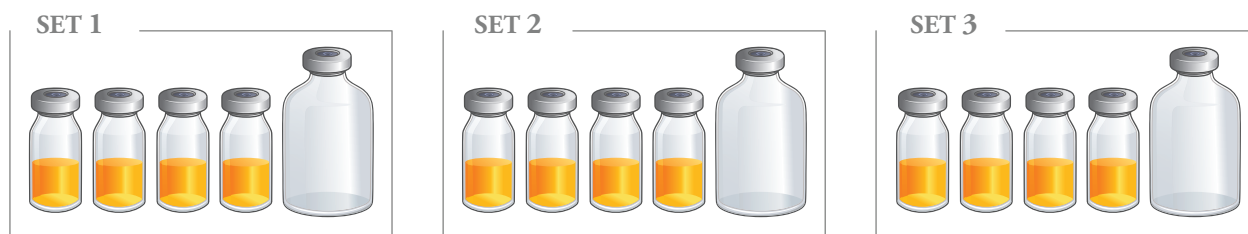
INTERPRETATION OF RESULTS

The outcome of the media-fill test is determined by observing the media for up to 14 days. Visible growth or turbidity within this period, suggests bacterial contamination and denotes a failure in maintaining aseptic conditions during the test. Conversely, the absence of such growth or turbidity signifies a successful execution of the test, demonstrating adherence to aseptic techniques.

TEST PROCEDURE

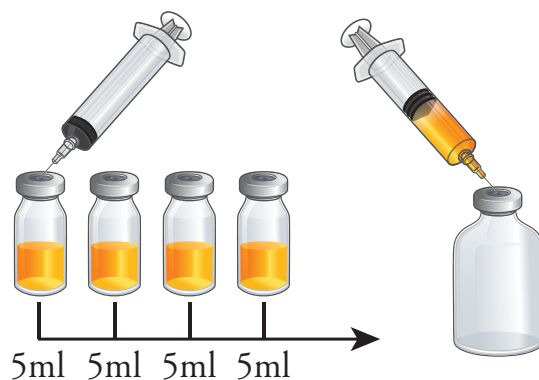
STEP 1:

Within an ISO Class 5 air quality environment, arrange the vials into three sets, each containing four 10ml vials filled with 5ml test media, along with one empty 50ml serum vial.



STEP 2:

Using a syringe equipped with a vented needle, aseptically transfer 5ml of Tryptic Soy Broth test media from each 10ml vial into one empty 50ml serum vial, ensuring a total volume of 20ml per 50ml vial. Repeat this process for the remaining sets of vials.



STEP 3:

Write your name and date of preparation on the three 50ml vial labels, one from each set. Then, aseptically apply a sterile adhesive seal to the rubber closures and place the sealed vials inside the provided Whirl-Pak® bag for transfer to the incubator.



STEP 4:

Incubate the three 50ml vials at 20°–25°C (68°– 77°F) and 30°–35°C (86°– 95°F) for a minimum of 7 days at each temperature range to detect a broad spectrum of microorganisms. A total incubation period of at least 14 days is recommended to confirm the absence of microbial growth. Any signs of microbial growth, such as turbidity or precipitation, at any point during the incubation period, indicates a failure in the sterility test.

REFERENCES

- ATCC® is a registered trademark of the American Type Culture Collection.
- Whirl-Pak® is a registered trademark of Nasco International, Inc.
- USP Chapter <797> guidelines can be found in the current version of the United States Pharmacopeia and National Formulary (USP–NF), which outlines the standards for sterile compounding procedures and quality assurance practices.