IVQA INTRAVENOUS QUALITY ASSURANCE

CATEGORY 2 CSP MEDIA-FILL TEST KIT

Instructions for Use

KIT CONTENTS

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

INTENDED USE

The Category 2 CSP Media-Fill Test Kit validates compounding personnel's aseptic technique and sterile compounding proficiency. Intended for simulating Category 2 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
Staphylococcus aureus	6538	10-100	18-24 hours	Growth
Pseudomonas aeruginosa	9027	10-100	18-24 hours	Growth
Bacillus subtilis	6633	10-100	18-72 hours	Growth
Candida albicans	10231	10-100	18-72 hours	Growth
Aspergillus brasiliensis	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.

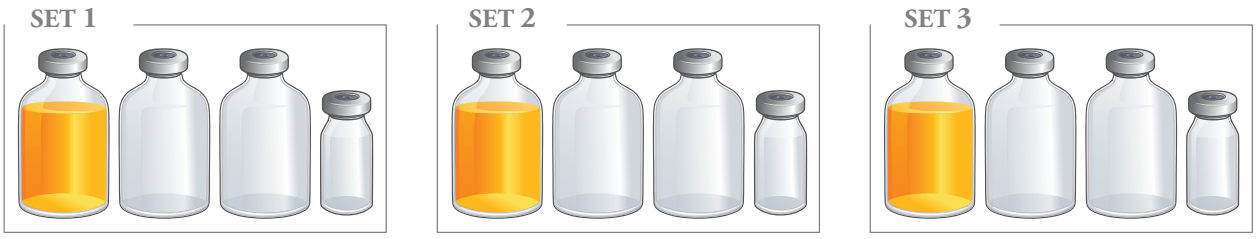
INTERPRETATION OF RESULTS

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

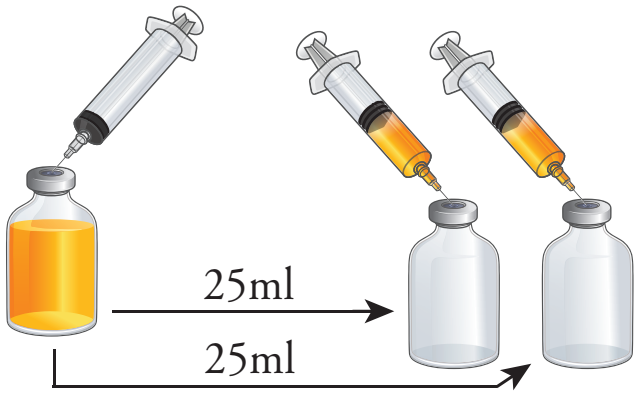
STEP 1:

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

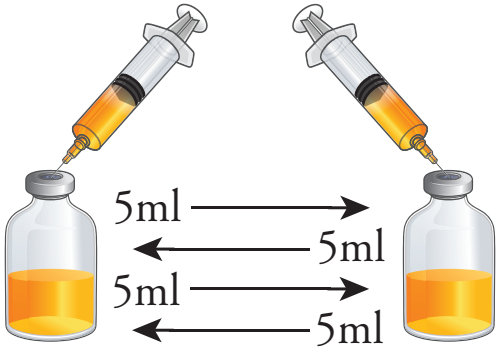


STEP 2:

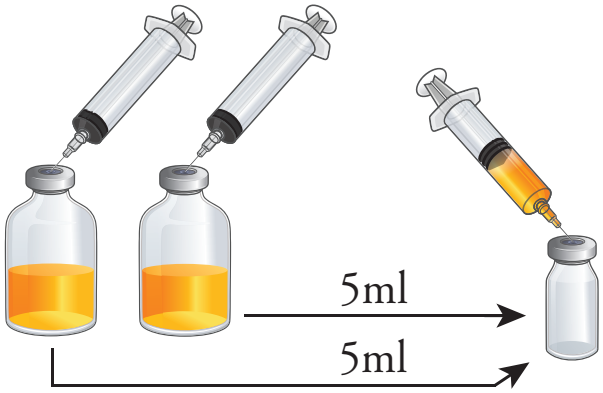
Using a syringe equipped with a vented needle, transfer 25ml from the 50ml test media vial into each empty 50ml serum vials. Repeat this process for the remaining sets of vials. If your standard practice involves using IV transfer tubing sets with vented needles or spikes, you should opt for this transfer method instead.



STEP 3:
With the two 50ml vials now containing 25ml of test media each, perform four aseptic transfers of 5ml test media between both vials. Repeat this process for the remaining sets of vials.



STEP 4:
Aseptically transfer 5ml from both 50ml vials into the empty 10ml serum vial. Repeat this process for the remaining sets of vials. When completed, you should have three 10ml vials filled with 10ml of test media, one from each set.



STEP 5:
Write your name and date of preparation on the three 10ml 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 6:
Incubate the three 10ml 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.