IVQA INTRAVENOUS QUALITY ASSURANCE

CATEGORY 3 CSP MEDIA-FILL TEST KIT

Instructions for Use

KIT CONTENTS

Quantity	Description
9	Sterile 10ml Empty Serum Vials
1	Container of Tryptic Soy Broth Non-Sterile Powder (3g)
1	Whirl-Pak® Bag
1	Log Sheet

INTENDED USE

The Category 3 CSP Media-Fill Test Kit validates compounding personnel's aseptic technique and sterile compounding proficiency. Intended for simulating Category 3 compounded sterile preparations, it evaluates the risk of microbial contamination and assesses competency in aseptic techniques. Suitable for the initial assessment and every 3-month revalidation of aseptic manipulation competency, in accordance with USP Chapter <797> guidelines.

TEST MEDIA SPECIFICATION

The 'Test Media' vial contains 3g of dehydrated 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, micron porosity filters, 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 not free flowing, appearance has changed from original pale / light beige, or if it is beyond its expiration date.

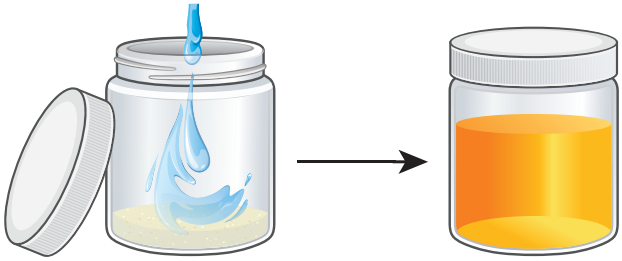
INTERPRETATION OF RESULTS

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:

Outside an ISO Class 5 air quality environment, dissolve the 3 grams of dehydrated Tryptic Soy Broth test media by adding 100ml of non-bacteriostatic water. Replace the lid and shake vigorously to ensure the powder has completely dissolved before proceeding.

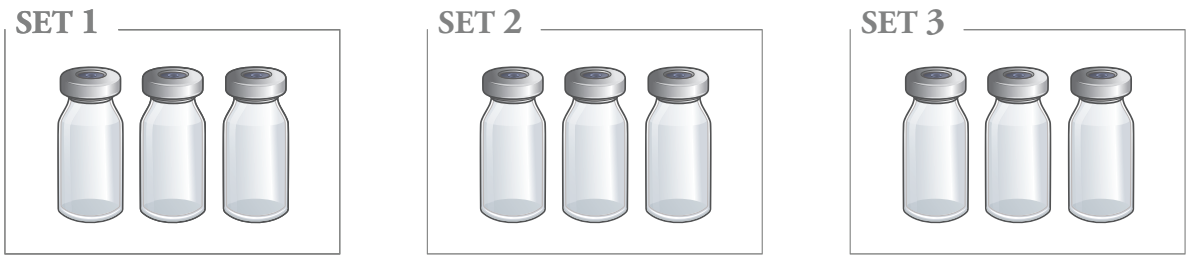


STEP 2:

Transport the prepared non-sterile test media to an ISO Class 5 air quality environment.

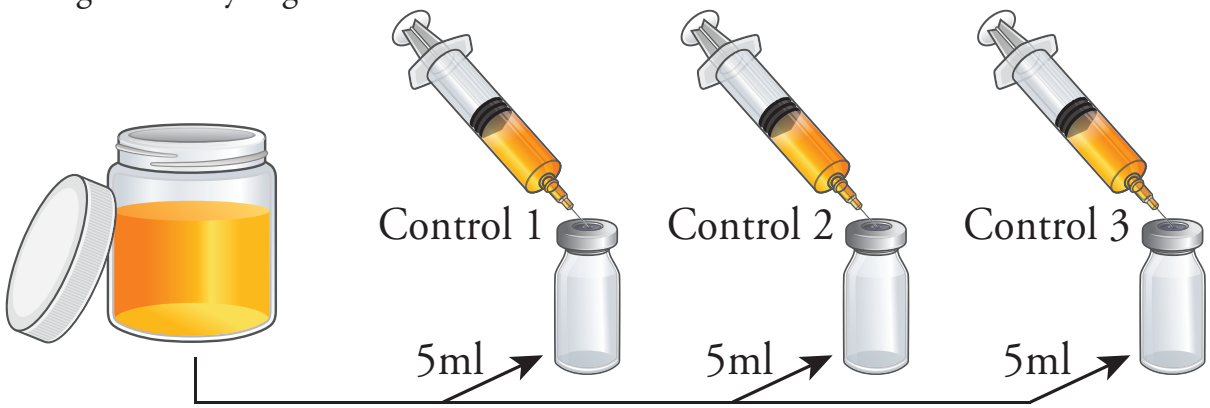
STEP 3:

Within an ISO Class 5 air quality environment, arrange the vials into three sets, each containing three empty 10ml serum vials. Label one vial from each set as ‘Control [set number]’.



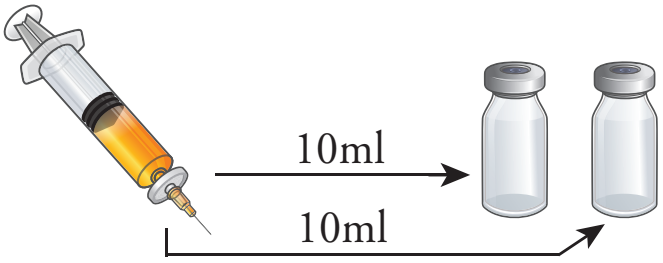
STEP 4:

Using three 30ml sterile syringes, withdraw 25ml of test media into each. Transfer 5ml of test media from set one's syringe into 10ml vial labeled 'Control 1'. Repeat this process for the other sets using their respective syringes, resulting in 5ml in each control vial and 20ml remaining in each syringe.



STEP 5:

Using aseptic techniques, affix a sterile 0.2 micron porosity filter and a 20-gauge needle to each syringe. Inject 10ml from set one's syringe into both empty 10ml vials in set one then set aside. Repeat this process for the other sets using their respective syringes and affixed filters.



STEP 6:

Write your name and date of preparation on all nine 10ml vial labels. 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 7:

Incubate the nine 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. For the vials not labeled as 'Control [set number]', 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.