IVQA

High Risk Level Compounded Sterile Preparations

The **High Risk Media fill** Test Kit is designed to document correct personal technique and effective environmental control for the preparation of high risk compounded sterile products (CSPs). The annual completion of this test will satisfy the requirements for staff members who are involved in high risk CSP preparation.

Test Materials

Test Kit includes:

- 1 each -- 3 gram vial test media
- 9 each -- 10ml empty sterile vials

Other required materials (not included)

- 100 ml non-bacteriostatic water
- 3 30-mL syringes
- 3 Sterile syringes
- 3 0.22 micron sterile filters
- 3 or more adhesive seals

Test Procedure

Note: Once the test is initiated:

1. The test must be carried out to completion without interruptions.

2. Test performance conditions should mimic the usual work environment.

Step 1. : Outside an ISO class 5 air quality environment, dissolve 3 gm of nonsterile commercially available Soybean-Casein Digest Medium in 100 ml of non-bacteriostatic water to make a 3% solution

Add 100 mL Water

Securly replace cap on vial and shake vigorously until powder has completly dissolved

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Step 2:
Withdraw 25 ml of the medium into each of three 30-ml sterile syringes.

Step 3:
Transfer 5 ml from each syringe into separate sterile 10-ml vials. Label these vials as controls. These vials will generate exponential microbial growth, indicated by visible turbidity upon incubation.

Step 4:
Under aseptic conditions (in an ISO class 5 air quality environment), and using aseptic techniques, affix a sterile 0.2-μm porosity filter unit and a 20-gauge needle to each syringe. Inject 10 ml from each syringe into each of two, 10 ml sterile vials. Repeat the process with each of the three syringes, injecting 10 ml aliquots into each of two, 10 ml sterile vials. On all 6 vials, write the name and date of person taking this test.

Step 5:
Affix sterile adhesive seals to the closure of the nine vials, and incubated them at 25° to 35°C. Inspect for microbial growth over 14 days. Sterile vials will remain clear and without bubbles, precipitate, cloudiness or changes in turbidity. Cloudiness, turbidity, bubbles or a precipitate on the bottom of any of the vials indicates bacterial contamination. All 6 vials must be sterile to constitute a passed test. The 3 control vials should become turbid or develop a precipitate demonstrating bacterial growth.