

Medium Risk Level Compounded Sterile Preparations

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

Test Materials

Test Kit includes:

- 3 each -- 50ml vials containing test media
- 6 each -- 50ml empty sterile vials
- 3 each -- 10ml empty sterile vials

Other required materials (not included)

- 3 sets IV transfer tubing with needle or spike
- 3 Sterile 10-mL syringes
- 3 Sterile vented needles
- 3 Sterile 5-mL syringes
- 3 Sterile non-vented needles
- 3 or more adhesive seals

Test Procedure

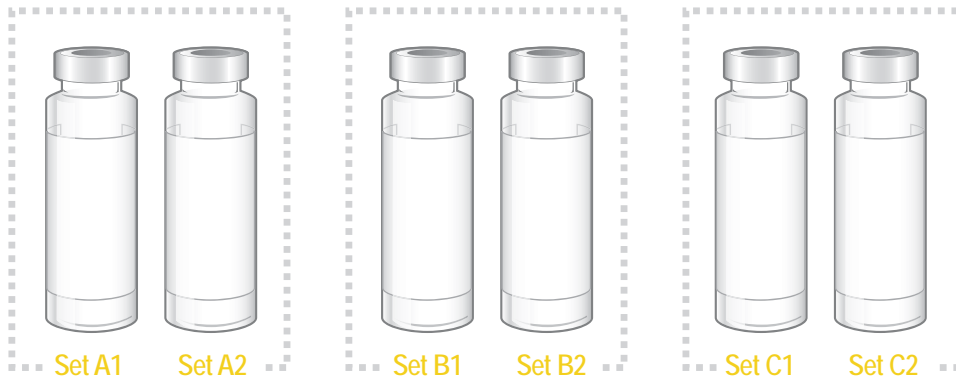
Note: Once the test is initiated:

1. *The test must be carried out to completion without interruptions.*
2. *Test performance conditions should mimic the usual work environment.*

Step 1. : In an ISO class 5 air quality environment, set up 3 50-mL vials containing test media (total of 3 vials).



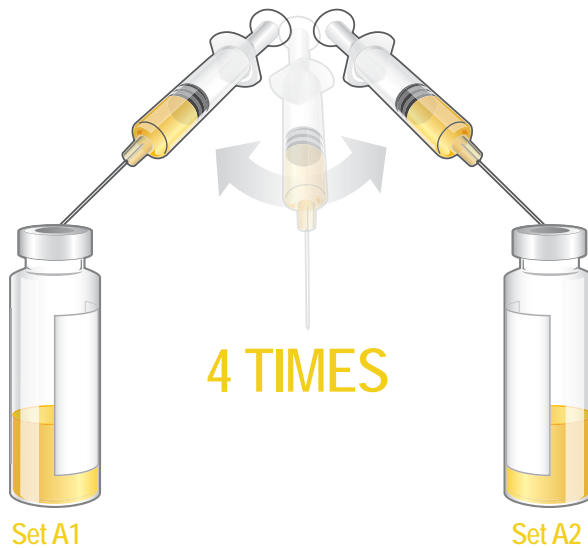
Step 2. Set up 3 sets of two each, empty 50-mL sterile capped vials (total of 6 vials).



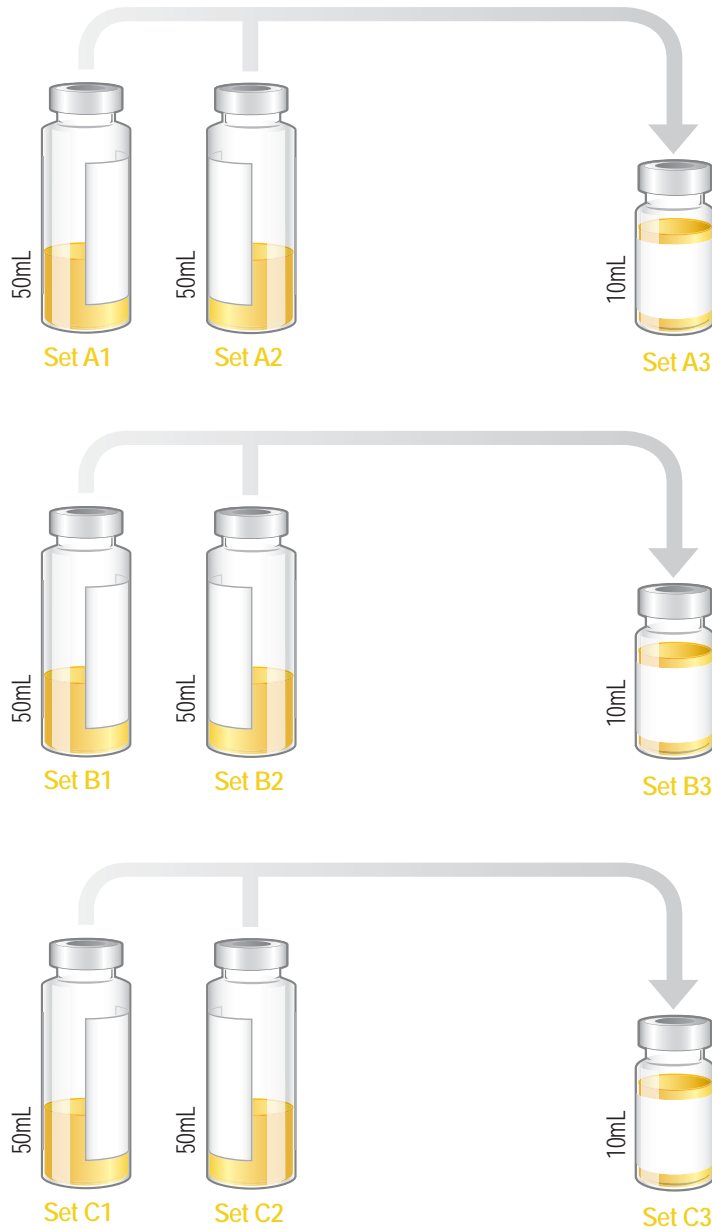
Step 3. Now, by use of IV transfer tubing sets and vented needles or spikes, transfer approximately 25 ml into each of the 6 empty 50-mL vials from the 3 test media vials provided.

Step 4. Perform 4 aseptic transfers of 5 ml aliquots between each set of 2 vials with a syringe and needle. Perform these 4 transfers for each of the 3 pairs.

Example:



Step 5. Aseptically transfer 5 ml from each of the 2 vial sets into a 10 ml sterile vial. When you have done this for each set you will have three 10-ml vials filled with media. Cover each 10 ml vial with a sterile adhesive seal



Step 6. Incubate the three 10 ml vials at 25 to 35 degrees for 14 days. If at the end of this time the solution is clear this denotes a pass, if it is turbid or has a precipitate this indicates a failure. In most cases, a vial that fails to pass will become turbid or develop precipitate within 7 days.