

Media-Fill Testing

Documentation of competence is required initially and again every 12 months.

Personnel who have not compounded an allergenic extract prescription set in more than 6 months must be evaluated in all core competencies before resuming compounding duties.

1. Clean

Perform USP 797-mandated hand hygiene and your clinic's garbing procedures.

Apply sterile 70% isopropyl alcohol to the horizontal work surface and allow to air dry.

If you are using sterile materials, such as those included in a commercially-sold media-fill kit, do not further dilute the media unless specified by the manufacturer.

2. Prepare

If your clinic mixes its own soybean-casein solution, dissolve nonsterile commercially available soybean-casein medium in nonbacteriostatic water to make a 3% nonsterile solution.

Using a sterile syringe, draw up the soybean-casein solution. Transfer the solution in the container-closure system used for serial dilution.

3. Transfer

Prepare at least 1 container as the positive control to demonstrate growth promotion.

Incubate the container(s) filled with test media solution in an incubator for two week-long periods to detect a broad spectrum of microorganisms:

Week 1 (7 days): 20°- 25°C/68°-77°F

Week 2 (7 days): 30°-35°C/86-95°F

4. Incubate

Look for visible turbidity (cloudiness) or other manifestations of growth in the media in one or more container-closure units on or before 14 days.

5. Evaluate

Pass: No visible turbidity indicates sterile transfer & competence in the procedure.

Fail: Any visible turbidity indicates failure. Personnel must re-do the procedure.

