

Exhibit 3-41 G**Media fill test for Category 1 and Category 2 Compounding****Personnel Responsible: Designated Person**

The media fill test is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. This media fill is to encompass the most challenging conditions the compounding personnel will face. Use a microbial growth medium such as a Soybean-Casein Digest Medium. This test is to be performed every 6 months in an ISO Class 5 area after appropriate garbing and performing hand hygiene. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials. A gloved fingertip test must be completed after completing the media fill test with ≤ 3 Colony Forming Units (CFUs) totaled between each hand. Additionally, surface sampling of the direct compounding area must be performed according to facility SOPs and compared against published action levels. New personnel must pass this test before compounding any IV medications.

The following documentation is required: name of the person being evaluated; date and time of the media fill test; media and components used including the manufacturer; certificate of analysis; expiration dates and lot numbers; names of the evaluator and the person who reads and documents the results; interpretation of results and actions levels; and if needed, corrective action.

Incubation Directions: Incubate sample at 20 to 25°C and 30 to 35°C for at least 7 days at each temperature. Failure is indicated by visible turbidity on or before 14 days.

Name of personnel	Date/time completed	Media and components, manufacturer	Lot and expiration date	Name of person/date evaluating
		Starting temp of each incubation	Dates of incubation	Name of person reading results

Media fill test result: <input type="checkbox"/> Clear <input type="checkbox"/> Turbid/microbial growth	Gloved fingertip test result: <input type="checkbox"/> ≤ 3 CFUs total <input type="checkbox"/> ≥ 3 CFUs total
Was surface sample below action level? <input type="checkbox"/> No <input type="checkbox"/> Yes	Did personnel pass the test? <input type="checkbox"/> No <input type="checkbox"/> Yes

If no to any of the above, personnel must stop compounding. Personnel will be immediately instructed and re-evaluated by the designated person to ensure correction. There must be documentation of remediation and follow-up results.