

NVBOP – Media Fill Testing Reference

- Performed prior to performing sterile compounding for all new staff members.
- Performed annually for low or medium risk level compounding.
- Performed semi-annually for high risk level compounding.
- Must be performed under conditions that closely simulate the most challenging or stressful conditions encountered during normal compounding.
- Testing must be performed per manufacturer’s guidelines.
- The completed product is incubated either at 20 – 25 C or at 30 to 35 C for a minimum of 14 days. Refer to the manufacturer’s guidelines for specific incubation temperatures.
- Person interpreting and documenting the results should be trained on how to properly read the results and what to look for in the incubated samples (i.e. turbidity).
- Proposed USP 797 guidelines state that if a compounding personnel fails a media fill test then they must successfully pass 3 additional tests prior to compounding.
- Recommend using the manufacturer’s documentation form to accurately document all items required.
- Facility should have a SOP in place to document what steps are taken if an employee fails a media fill test.

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.