

MEDIA FILL CHALLENGE FOR STERILE COMPOUNDING

Documentation of all compounding personnel passing a Media Fill Challenge, which tests aseptic technique, is required. The media fill is to encompass the most challenging conditions the compounding personnel will face. There are Media Fill Challenge kits commercially available, however, these kits may not simulate the sterile compounding occurring at a particular facility. In these cases, it is recommended the facility purchase media and construct a Media Fill Challenge that actually replicates the most challenging sterile compounding process performed. This Media Fill Challenge must be performed initially before compounding begins and then annually for low and medium risk compounding and semi-annually for high risk compounding. Media fill testing is to be performed at the end of the day to simulate worst case conditions.

The following documentation is required:

1. Media selection
2. Fill volume
3. Incubation time
4. Incubation temperature
5. Inspection of filled units
6. Interpretation of results
7. Actions levels
8. Corrective action if needed