

## USP<797> Sampling Instructions – Surface Testing

*Surfaces of each ISO classified cleanroom area must be tested “periodically” (General Chapter USP<797>, 2008). The frequency of surface testing may change to a monthly requirement soon. The purpose of the testing includes evaluation of cleaning, disinfection, and handling procedures as well as competency of the compounding personnel.*

### **Perform sampling at the end of compounding activities but before the area has been cleaned or decontaminated!**

1. Determine surface sampling sites. Make sure that each ISO classified area is represented with at least one surface sample. Sampling sites include each direct compounding area, pass-through chambers, buffer room(s) and ante room(s).
2. When using triple-bagged contact plates, remove the plates from the shipping container. Remove the outer bag before entering the cleanroom area (buffer room). Discard the outer bag.
3. Visually inspect the plates for any signs of deterioration or contamination. Do not use damaged or contaminated plates for sampling.
4. Carry out the garbing procedure before crossing the demarcation line in the ante-room and prepare for sampling. Wipe the outside of the second bag with disinfectant (e.g. alcohol) and remove the final bag with contact plates. Store empty outer bag in the ante-room to be used again after the sampling is completed.
5. Remove individual contact plates from the last bag. When using plates from the same bag for different ISO classified areas remove plates in the cleanest area first.
6. Before taking the samples, disinfect your gloves and allow them to dry.
7. To take a sample, remove the lid, firmly press and roll the agar plate across the sampling site. When using lock-lid plates, twist the lid to close. For other contact plates use sterile flexible tape (Parafilm®) to seal each plate.
8. Label each plate with indelible ink using a unique identifier including the sample ID and sampling site. When using controls, label two unused plates for each media type.
9. When sampling is completed, disinfect the sampling site with iso-propanol or other disinfectant to remove any agar residue on the surface.
10. Place the used sealed and labeled sampling plates back into the sterile final bag. Close the bag with tape.
11. Transfer the bagged samples into the second (sterile) bag that has been store in the ante-room. Seal and tape the second bag.
12. Put sampling plates inverted in the shipping container. Protect the plates from physical damage with bubble wrap and add cold packs to the container.
13. Fill out the chain of custody (CoC) listing the same unique identifiers that is written on the contact plate. Remember to place the CoC into the container, tape the container shut and mark the top (“this side up”).
14. Use pre-printed shipping labels to overnight the samples to the laboratory.