

Initial and Ongoing Gloved Fingertip and Thumb Sampling (GFT) Competency

1. Sampler and Samplee both perform hand hygiene and garbing, but *Samplee does NOT sanitize gloves with sterile IPA.*
2. Sampler brings sterile 100 mm TSApl (with neutralizers) into buffer room or across perimeter line if SCA.
3. Sampler sanitizes hands with sterile IPA immediately before removing 2 plates from sterile pack and recloses sterile pack.
4. Using cleanroom permanent marker, Sampler labels plates, agar side up, around perimeter with Samplee's first initial and last name, date, indicate # GFT (such as "#1 IGFT"), and L or R hand designation.
5. When Samplee is ready, Sampler removes lid without contaminating and holds plate vertically.
6. Samplee rolls finger pads and thumb of first hand one at a time, each in a discrete space.
7. Sampler replaces lid of sampled plate and repeats previous steps with second plate.
8. Samplee doffs gloves; applies alcohol-based surgical rub; and when dry, dons new pair sterile gloves; and sanitizes with sterile IPA.
9. Sampler leaves SCA or buffer/anteroom, secures plates, and places them agar side up in incubator set to and that maintains a temperature of 30 to 35 °C.
10. Ongoing GFT competency is performed at the required frequency according to USP compounding categories.

GFT and Surface Sampling in DCA during Media-Fill Testing

1. Sampler and Samplee both perform hand hygiene and garbing.
2. Transfer MFU supplies and sterile 100 mm TSApl and 55 mm contact plates (with neutralizers) into buffer room or across perimeter line if SCA.
3. Samplee follows organization SOPs for MFUs while Sampler sanitizes hands with sterile IPA and removes plates from sterile package, reclosing package.
4. Sampler labels plates around perimeter with cleanroom marker noting Samplee's first initial and last name, date, designation of SS (55 mm) or GFT (100 mm), and left or right hand for GFT plates.
5. As the Samplee concludes MFU preparation (or randomly at the end of the compounding day), the Sampler asks the Samplee to stop activity.
6. After sanitizing gloves with sterile IPA, the Sampler moves the two 100 mm and one 55 mm plate inside the PEC.
7. Sampler removes lid of 55 mm contact plate, samples the deck below the DCA, replaces the lid, and sets it down inside the PEC but outside the DCA.
8. Sampler places both 100 mm plates in front of Samplee and removes lid from plate farthest from the Sampler first; proceed per steps 6 and 7 of Initial and Ongoing GFT.
9. Sampler removes sampled plates and follows step 9 under Initial and Ongoing GFT.
10. Samplee must leave the PEC, follow step 8 under Initial and Ongoing GFT, then reenter PEC to transfer supplies out of PEC. Clean and disinfect deck using sterile agents. May resume compounding activity if random sampling.

