## Exhibit 3-41 E

## Gloved Fingertip Sampling for Compounding Category 1 and Category 2

**Responsible Person: Designated Person** 

Initial qualification of all compounding personnel must have three samples (in succession but performed as three separate events) of gloved fingertip and thumb testing (GFT) with zero Colony Forming Units (CFUs) associated with hand hygiene and garbing evaluation. An additional GFT will be performed as part of the media-fill testing and requires  $\leq$ 3 CFUs totaled between hands. Subsequent GFTs will be done every six months and are required once for the garbing competency and once for media-fill testing. Action levels remain zero and  $\leq$ 3 CFUs for garbing and media fill, respectively.

**Procedure:** Gloves will <u>not</u> be disinfected with sIPA. Agar plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 will be used. Personnel will create a slight impression of all fingers from both hands. All plates will be inverted and the name of the individual, date, and the hands that coincide with the agar plates (left or right). Plates are to be incubated as detailed below. Plates may be incubated in the facility's lab, pharmacy, or may be outsourced dependent on the facility's policy.

The following personnel have completed the following:

| GFT related to garbing and hand hygiene competency:         | GFT post-media fill test: |
|---|---------------------------|
| ☐ Initial GFT (requires 3 successful samples in succession) | ☐ Initial competency      |
| ☐ Six-month re-evaluation (one sample)                      | ☐ Six-month re-evaluation |
|   |                           |

**Incubation Directions**: Incubate sample at 30-35°C for no less than 48 hours then at 20-25°C for no less than 5 additional days.

| Employee<br>Name | Time/Date<br>Completed          | Media<br>Manufacturer | Expiration<br>Date     | Lot<br>Number         | Name of Person/Date<br>Evaluating |
|------------------|---------------------------------|-----------------------|------------------------|-----------------------|-----------------------------------|
| Employee<br>Name | Temperature for each incubation | Dates of incubation   | # CFU<br>Right<br>Hand | # CFU<br>Left<br>Hand | Name of person reading results    |
|                  |                                 |                       |                        |                       |                                   |

## **Total CFU results:**

| Garbing and Hand Hygiene                          | Post-Media Fill Test          |  |
|---|-------------------------------|--|
| □ Zero CFU  | □ ≤ 3 CFU                     |  |
| $\Box \ge 1$ CFU for initial (remediation needed) | □ >3 CFU (remediation needed) |  |

| Did | personnel | nass the | threshold | for | CFUs? |
|-----|-----------|----------|-----------|-----|-------|
|     |           |          |           |     |       |

 $\square$  No

 $\Box$  Yes

If no, personnel will be reinstructed and re-evaluated by a designated person to ensure correction. There must be documentation of remediation and follow-up results.