

MTN-020 (ASPIRE) Operational Guidance 6: Further Revisions to Ring Storage for Residual Drug Analysis

The purpose of this communication is to update ring storage procedures based on updated information from the testing lab. These procedures replace those issued in SSP version 1.2 31JUL13

13.8.8 Intra-Vaginal Ring Storage

Once your site has full regulatory approval, all returned used rings will be stored in the laboratory.

The key outcome of this process is storing a dry ring to prevent microbial growth on the ring.

Procedure:

1. Retrieve the ring from the participant.
 - a. The participant may submit the ring in a bag.
 - b. The ring may be placed in a temporary bag if not being rinsed immediately.
 - c. In any situation, the bag must be labeled with PTID and date. Care must be taken to not misidentify rings during processing.
 - d. If a participant returns 2 rings at 1 study visit
 - i. Store both rings
 - ii. Note this in specimen comments in LDMS. The comments will appear on the shipping manifest.
 - iii. If possible, the clinic label the specimens to indicate which was more recently used and this can be indicated in the specimen comments in LDMS.
 - e. Transport the ring at room temperature.
2. Rinse the ring in water.
 - a. If not processing in a biological safety hood the person should wear protective eye wear, lab coat or gown, and gloves when rinsing. Do not rinse in a sink because the ring is covered with potentially infectious material.
 - b. To prevent aerosols place the ring in a disposable container with tap water, swirl the ring gently, remove and blot dry with disposable paper towels.
 - c. Discard the towels with other biohazardous material. Decontaminate the water used for rinsing before discarding per local guidelines for biohazard waste disposal. Decontaminate the area used to process the ring.
 - d. Do not use any soaps, cleaners or chemicals to rinse the ring. Use only tap water.
3. Place the ring in a new unused bag.
4. Affix a SCHARP label to the bag with PTID, visit code and date.
5. Enter the ring in LDMS using the codes in Appendix 13-3.
6. Store the ring at room temperature.
7. The NL will provide shipping instructions at the time of shipping request.

All Operational Guidance documents must be printed and filed with regulatory documentation