



## MTN-042 Operational Guidance #02: Laboratory Updates: Microbiota Swab type and DBS Storage Temperature

This operational guidance document changes or clarifies current SSP guidance on laboratory procedures.

### *1] Vaginal Swab collection for Microbiota*

Guidance for collection of vaginal swabs for Microbiota is found in SSP section 7.12.5, 10.8.3, Appendix 10-1 and Appendix 10-2.

Because of COVID-19 related outages, vaginal swabs for microbiota swab type is changed from Flocced Swab to Dacron Swabs. Additionally, the number of swabs collected at each required timepoint is changed from 1 swab to 2 swabs. The following study tools have been updated to reflect this change:

- MTN-042 Swab Order Collection Guide
- MTN-042 Pelvic Exam Checklist
- MTN-042 Visit Checklists for: Bi-weekly Visits, 6-week PPO/SEV, and Early Termination Visits
- LDMS Tracking Sheet: The LDMS Aliquot Derivative Code is changed from FLS to SWB.

Sites should update any site-specific study materials to reflect these changes and send to FHI 360 and MTN LC. Please work with MTN LC and FHI 360 to set an implementation date for these changes at your site, no later than 16OCT2020

### *2] Storage Temperature for Dried Blood Spots*

Dried Blood Spots are to be stored at  $\leq -70^{\circ}\text{C}$ . SSP Section 10.7.8 will be corrected to harmonize this with the LDMS Tracking sheets.

All Operational Guidance documents must be printed and filed with regulatory documentation. This guidance will be incorporated into the SSP on next revision.

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