



## MTN-034 Operational Guidance #02: Laboratory Updates: Microbiota Swab Update

The purpose of this operational guidance document is to update the current MTN-034 Study Specific Procedures (SSP) Manual guidance on laboratory procedures related to the collection of vaginal fluid for microbiota quantitative PCR.

MTN-034 SSP Manual Tables 9-1, 9-4, 9-5 and section 9.7.2, specifies the use of three flocked swabs for the collection of vaginal swabs for Microbiota at required visits. The MTN Laboratory Center (LC) supplied each participating REACH site with the specified flocked swabs prior to activation.

Due to COVID-19 related outages, the MTN LC is unable to provide additional flocked swabs to sites for use. Sites that anticipate shortages of the MTN LC-provided flocked swabs should contact the MTN LC for guidance. The MTN LC will provide written approval for sites to use an alternate swab for the collection of vaginal fluid for microbiota.

All Operational Guidance documents must be printed and filed with regulatory documentation. This guidance will be incorporated into the MTN-034 SSP Manual on next revision.

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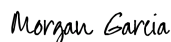
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