**Microbicide Trials Network**

**CLARIFICATION MEMO #02 TO:**

**MTN-042**

**Phase 3b, Randomized, Open Label Safety Trial of Dapivirine Vaginal Ring and Oral TRUVADA® Use in Pregnancy**

**DAIDS Protocol #: 38544**

**IND#: 139,598**

**Version 1.0 / 16 April 2019**

**Clarification Memo Date: 11 December 2020**

*Section 1: Summary of Clarifications and Rationale*

The procedures clarified in this Clarification Memorandum (CM) have been approved by the NIAID Medical Officer and are to be implemented immediately upon issuance. IRB/IEC approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB/IEC overseeing the study at their site for information. This CM is official MTN-042 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-042. No change in informed consent is necessitated by or included in this CM.

This document clarifies that the MTN Laboratory Center can approve alternate STI testing methodologies to be used as backup in the event of laboratory supply chain disruptions.

*Section 2: Implementation*

With the exception of updates to the protocol team roster, text to be deleted is noted below with a ~~strikethrough~~, text to be added is in **bold**, and text in ***bold italics*** is not to be added, but to serve as a clarification of the implementation item in question. This information will be included in the protocol the next time the protocol is updated.

1.) The following clarification applies to the third bullet point of "Local Laboratory" sub-section in Section 7.12, *Laboratory Evaluations*:

- Pelvic
    - NAAT for GC/CT/Trich*****
    - Vaginal pH
    - Wet prep/KOH wet mount for candidiasis and/or BV

****In the event of laboratory supply chain disruptions, the MTN Laboratory Center can approve alternate methodologies to be used as backup.***

The above information will be incorporated into the next version of the protocol at a later time if it is amended.