Microbicide Trials Network

CLARIFICATION MEMO #03 TO:

MTN-015
An Observational Cohort Study of Women following HIV-1 Seroconversion in Microbicide Trials, Version 1.0, 19 June 2007

DAIDS Document ID 10529

Date of Clarification Memorandum: 20 February 2009

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 approval of this CM is not required by the sponsor; however, investigators may submit the CM to the IRB overseeing the study at their site for information. This CM is official MTN-015 documentation and is effective immediately. A copy of this CM must be retained in each study site's Essential Documents file for MTN-015. No change in informed consent is necessitated by or included in this CM.

The primary goal for this CM is to omit references to wet mount to allow for consistency with newer testing methods employed by study sites. Additionally, the Protocol Team Roster is updated.

Section 2: Implementation

Text to be deleted is noted by ~~strikethrough~~ and text to be added is noted below in **bold.**

1. The following update is made to the Protocol Team Roster that appeared in MTN-015, CM #02, dated 21 August 2008:

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2. Reference to wet mount is replaced with **testing** in the following tables and sections:

Table 1: Screening and Enrollment Visit, Pelvic Samples.

Pelvic Samples	Vaginal pH ~~Wet Mount~~ **Testing** for bacterial vaginosis (BV), Candida, and Trichomonas †Pap Smear at Selected Sites

Table 2: Month 1 and Month 3 Post-Seroconversion Visits

Pelvic Samples	*Vaginal pH *~~Wet Mount~~ **Testing** for BV, Candida, and Trichomonas */† Pap Smear at Selected Sites

Table 3: Month 6 and Q6 Months Post-Seroconversion Visits

Pelvic Samples	*/**Vaginal pH */**~~Wet Mount~~ **Testing** for BV, Candida and Trichomonas */† Pap Smear at Selected Sites (annually)

*If indicated; */**Urine SDA for Chlamydia and Gonorrhea, Syphilis Serology, Vaginal pH, and ~~Wet Mount~~ **testing for BV, Candida, and Trichomonas** should be performed at visits annually, with performance of these measures at additional scheduled visits as clinically indicated; †PAP smears should be done at 6 month intervals in the first year after seroconversion, and then annually if the initial tests are negative.

Table 4: Week 2, Month 1, and Month 3 after Initiation of ART

Pelvic Samples	*Vaginal pH *~~Wet Mount~~ **Testing** for BV, Candida, and Trichomonas */† Pap Smear at Selected Sites

Table 5: Month 6 and Q6 Months Visits After Initiation of ART

Pelvic Samples	*/**Vaginal pH */**~~Wet Mount~~ **Testing** for BV, Candida and Trichomonas */† Pap Smear at Selected Sites

*If indicated; */**Urine SDA for Chlamydia and Gonorrhea, Syphilis Serology, Vaginal pH, and ~~Wet Mount~~ **testing for BV, Candida, and Trichomonas** should be performed at visits annually, with performance of these measures at other scheduled visits as clinically indicated; †PAP smears should be done at 6 month intervals in the first year after seroconversion, and then annually if the initial tests are negative.

Table 6: Final Visit

Pelvic Samples	Vaginal pH ~~Wet Mount~~ **Testing** for BV, Candida and Trichomonas */† Pap Smear at Selected Sites

Section 7.5.1, Local Laboratory Specimens, Pelvic Samples, first paragraph:

Vaginal pH testing and ~~wet mount~~ testing for bacterial vaginosis, candidiasis and trichomoniasis will be conducted at the sites by clinical and/or laboratory staff who have established proficiency in these procedures per MTN policies and procedures.

Appendix I: Schedule of Study Visits and Evaluations

~~Wet Mount~~ **Testing** for BV, Candida, Trichomonas	X	▲	▲	▲ (Annual)	▲	▲ (Annual)	X