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## MTN 001 Data Communiqué #1

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June 18, 2008

This is official study documentation for MTN 001. Please circulate it among relevant staff for their review, print it, and place it in your MTN 001 SSP Manual in the Data Communiqués section. This document is considered part of the MTN 001 SSP manual.

### UPDATES

None.

### CLARIFICATIONS

**1. Safety Laboratory Results form, items 1b and 1c**

For urine leukocyte esterase (LE) and nitrites, results 1+ or greater are considered “positive”. Negative or trace results are considered “negative”.

**2. Enrollment form, instruction off of item 8**

Please note that the “*If not a replacement participant, go to item 10*” skip instruction applies to “yes” and “no” responses (and not just “no” responses for item 8).

**3. Enrollment Behavior Assessment form, item 9, and Study Product Adherence and Behavior Assessment form, item 15**

This question asks about items that women sometimes insert inside their vaginas. Mark the “yes” box only if the participant reports that she inserted the given item *inside* her vagina. If she used the given item for external genital washing *only* (e.g., “water”, “water with soap”, “fingers without anything else”), mark the “no” box.

### REMINDERS

None.