UZ-UCSF Laboratory
Rapid HIV Testing QC plan for HPTN 035

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Purpose

- Ensure that sites are adhering to written procedures when performing rapid HIV testing and that the results are accurate.

Procedure

- All specimens tested with Rapid HIV tests at the site lab, will be sent to UZ-UCSF Central Lab

- UZ-UCSF Central Lab will retest every 10th serum/plasma specimen, depending on the type of sample collected for the particular visit.

- Test used will be FDA approved ELISA (BIO-RAD HIV 1/2 O plus)

Reporting QC checks

- Results from QC checks will be available for review at both the sites and UZ-UCSF central laboratory.

- Where there are discordant results between site and central lab – the rapid HIV algorithm (Oraquick and Determine) will be repeated.

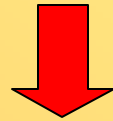- If still discordant, an ELISA, then a Western Blot test will be performed.

e.g. Site Results

HIV +ve (both rapid tests +ve)

Central Lab
ELISA HIV –ve

Repeat Oraquick and Determine

If both +ve /discordant

Western Blot

QA Checks

- Site supervisor will perform monthly spot checks (using a check–list) to observe adherence to SOP's and QA procedures.

Check list questions (testing done by Med Lab scientist)

- Testing algorithm used

- Presence of SOP

- Procedure followed

- Expiration date of kit recorded on worksheet

- Test devices labelled correctly

- Kits logged and stored correctly

- Safety procedures and waste disposal procedures being followed

Any Questions or Comments?