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?