Quality Assurance of 035 In-Clinic Testing

The University of Pennsylvania & The Children's Hospital of Philadelphia The University of Pennsylvania & The Children's Hospital of Philadelphia

- HPTU Principal Investigator: David Metzger
- Principal Investigator: Lisa Maslankowski
- Study Coordinator: Johnnita Prince
- Study Nurse: Cynthia Bayer
- Laboratory Manager: Nancy B. Tustin

In-Clinic Testing Performed by a Nurse, Nurse Practitioner, or Doctor

- Wet mount
- pH
- Urine dipstick (if indicated)
- Pregnancy test
- Rapid HIV (OraQuick)

 Wet mount

 Result log kept
 Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement



- Result log kept

 Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement

- Urine dipstick (if indicated)
 Result log kept
 - High and normal controls will be run weekly if there is a participant that week
 - Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement

Pregnancy test

- Result log kept
- High and normal controls will be run weekly if there is a participant that week

 Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement

- Rapid HIV (OraQuick)
 - Result log kept
 - Positive and Negative controls will be run daily if there is a participant that day and in parallel with new lots of test kits or new lots of controls
 - Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement

Monitoring to be Done by CHOP Laboratory

- Assist in form preparation for result logs and temperature logs
- Perform monthly review of all result logs
- Perform monthly review of room and 4C temperature log

Monitoring to be Done by CHOP Laboratory

 Perform QA for urine dipstick, pregnancy testing and rapid HIV testing using commercial controls once a month for the first three months and quarterly thereafter

Acknowledgements



- Ginnene DiStefano-Middleton
- Kristina Go
- Nancy Raftery
- Richard Tustin
- UPenn Site Staff