Quality Assurance of 035 In-Clinic Testing

The University of Pennsylvania
& The Children’s Hospital of Philadelphia
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• 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)
In-Clinic Testing

- Wet mount
  - Result log kept
  - Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement
In-Clinic Testing

- pH
  - Result log kept
  - Perform sendout from American Proficiency Institute every four months to fulfill CLIA certification requirement
In-Clinic Testing

- **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
In-Clinic Testing

- 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
In-Clinic Testing

- **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.
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