HPTN 035
Moshi Tanzania
Quality Assurance for Rapid Tests
RAPID TESTS

- Performed at satellite laboratory at Mawenzi Clinic
  - Reduces turnaround time
  - Simplifies logistics
  - Preserves specimen integrity
RAPID TESTS

- **Urine Pregnancy Testing**
  - Quidel QuickVue One Step hCG Urine Test

- **Urine Macroscopic Examination**
  - Quidel QuickVue UrinChek (Nitrite and Leucocytes)

- **Wet Mount for Bacterial Vaginosis**
RAPID TESTS

HIV Testing

- Abbott Laboratories Determine HIV-1/2
- Orasure Technologies OraQuick Rapid HIV-1 Antibody Test
QUALITY ASSURANCE

- Quality Control
- Training and Competency Testing
- Ongoing Monitoring
Quality Control

- Urine Pregnancy
  - Quidel Positive and Negative Control
  - Once per Box (Every 25 tests)
  - Documentation on Lot log sheet and Urine Results Register
Quality Control

- Urine Macroscopic
  - QC only recorded for Nitrites and Leucocytes
  - Sentry Normal and Abnormal
  - Monthly
  - Documentation in the Urine Results Register and Lot Log Sheets
Quality Control

- Wet Mount for Bacterial Vaginosis
  - Commercial QC materials not available
  - Rely on competency of technologists
  - May implement random review of slides
Quality Control

- OraQuick HIV
  - Orasure Positive and Negative controls
  - Every 100 kits
  - Documentation in Blood results register and Lot Log Sheets
Quality Control

- Determine HIV
  - Known Positive and Negative frozen sera
  - Every 100 kits
  - Documentation in Blood results register and Lot Log Sheets
Quality Control
# Training and Competency

## Table:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Frequency</th>
<th>Keynote Note</th>
<th>Date Completed</th>
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<tbody>
<tr>
<td>Activity 1</td>
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<td>Activity 2</td>
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<td>Activity 4</td>
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**Memos**
Ongoing Monitoring
Ongoing Monitoring

<table>
<thead>
<tr>
<th>DATY (If applicable)</th>
<th>PTID</th>
<th>Event Code</th>
<th>Description of Event**</th>
<th>Corrective Action (Indicate if follow-up is required)</th>
<th>Initial</th>
<th>Review</th>
</tr>
</thead>
</table>

*Spotsman Management: SM, Results Expeditious: RE, Technical Problems: TP, Complaint: C, Others: O*

**Indicate Importance of event: Minor: C, No Action: K, KCMC Clinical Lab, KCMC Research Lab, Network Building, Trimeter