

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

Training and Competency

SPIN Madagascar

RTV ZIKV/CHIKV/EBOLA NETWORK: MOSHI, TANZANIA, ETC.
CLINICAL LABORATORY EMPLOYEE COMPETENCY PROGRAM

TEST/PROCEDURE: Examination of blood for _____

EMPLOYEE: _____

QUALITY COMPETENCY TESTING

Specimen Identification	Employee Initial	Known Value	Result Accepted?
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>
			Yes <input type="checkbox"/> No <input type="checkbox"/>

20 Results: _____

Other competency testing results: _____

Signature of the assessor: Yes No

Signature: _____

Signature of the employee: _____

Date: _____

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Ongoing Monitoring

HPTN CLINICAL LABORATORY RESULTS
COMPREHENSIVE QUALITY ASSURANCE PROGRAM

Procedure: Determined HIV-1/2 Test

CLIA/CLIA 88
Information on form correct and complete? Yes No
If no, problem and corrective action:

MAWERS/STUDY CLINICAL LABORATORY RESULTS REGISTER
Information in register correct and complete? Yes No
Information agrees with results form? Yes No
If no, enter, problem and corrective action:

Lab numbers recorded? Yes No
Quality Control: yes/failed? Yes No
If no, enter, corrective action:

SERVICES REGISTER TO MAWERS/STUDY CLINICAL LABORATORY REGISTER
Information in register correct and complete? Yes No
Information on services with blood results register? Yes No
If no, enter, problem and corrective action:

1997-1998 HPTN CLINICAL LABORATORY RESULTS REGISTER

Ongoing Monitoring

1111 222 4444 555 IPTN 666 7777 8888 999

IPTN LABORATORY QUALITY ASSURANCE MONITORING

D A T E	PTID (If applicable)	Event Code*	Description of Event**	Corrective Action (Indicate if follow-up is required)	Initial	Review

*Specimen Management=SM, Results Reporting=RR, Technical Problems=TP, Compliance=C, Other=O
** Indicate location of event: Mousoni Gilbar, KCMC Clinical Lab, KCMC Research Lab, Binkach Building, Transit