PHRU Lab Activities

The PHRU laboratory is a non-automated diagnostic laboratory offering rapid point-of-care testing including:

- Rapid HIV testing
- Rapid Trichomonas
- Rapid BV Blue
- Urine pregnancy and
- Urinalysis
- Syphilis Testing
- Wet mount- KOH and Saline
Other PHRU Lab Activities

- Coordination of samples to contracted labs
- Packaging and shipment of samples to international labs
- Sample storage and LDMS
- Offer technical support to studies at the unit
QC Programmes

Currently enrolled with EQA:

- WHO/NICD for: HIV Rapid testing, HIV Elisa testing
- CAP for: HIV Rapid, Clinical Microscopy and Syphilis, VS1
- PHRU Lab has IQC Programme: 1 pos and 1 neg previously tested samples are retested daily before testing for the day can resume.
Sample collection and Labeling

- Samples are collected using the BARC kits provided
- Request Forms are in Triplicate: 1 copy remains with clinic 2 copies sent to Lab
- Tubes and Request form are pre labeled with BARC barcode
- Clinic records PTID on samples and Request form
# Example of BARC Req Form

## Participant Demographics

<table>
<thead>
<tr>
<th>Initials</th>
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<table>
<thead>
<tr>
<th>Subject No</th>
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<table>
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<tr>
<th>DOB</th>
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<table>
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<tr>
<th>Gender</th>
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<table>
<thead>
<tr>
<th>Collection Date</th>
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<table>
<thead>
<tr>
<th>Collection Time</th>
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## Sponsor Details

- **Sponsor:** PHRU
- **Protocol:** MTN 003
- **TRIAL:** cMTN003S
- **Kit:** MT14

## Investigator Details

- **Investigator:** Dr B Mkhize

## Phlebotomist

- **Chris Hart Bara Hospital**

## Weight

- **Chris Hart Rd, Soweto**

## Visit Section

- **Visit:** Screening 1

## Clinical Trial

### Special Instructions

- **Received time and date:**
- **Entered by:**

### Type of tubes received

- **EDTA**
- **SST**
- **Other**

## SAMPLING SECTION

### Initial to confirm order, collection or receipt

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test</th>
<th>Init</th>
<th>Lab</th>
<th>Site</th>
<th>Send received</th>
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</thead>
<tbody>
<tr>
<td>SAGC</td>
<td>Test Charge</td>
<td></td>
<td></td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>MTH1</td>
<td>1x4ml EDTA</td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>MTH2</td>
<td>1x4ml SST</td>
<td>ALT AST CREAT + CC PO4</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>MTH4</td>
<td>1x5ml SST</td>
<td>HBsAg HBsAb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTH5</td>
<td>Universal Container</td>
<td>SDA for G6PD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTH6</td>
<td>Use HIV, Rapid EDTA</td>
<td>Western Blot</td>
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<td></td>
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</tr>
<tr>
<td>PHRU ONLY</td>
<td>1x4ml EDTA</td>
<td>HIV RAPID AND IF POS SEND TO BARC FOR WB</td>
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</tr>
<tr>
<td>PHRU ONLY</td>
<td>1x4ml SST</td>
<td>RPR AND IF POS DO TPHA</td>
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## MTN

- **Network:**
- **Protocol:** MTN 003
Delivering of samples at PHRU Lab

- When samples are delivered at the lab they are logged into the sample receiving book.
- Place BARC Bar code on the space provided in the book.
- Record time, date and name of staff delivering the samples
Samples are received according to SOP- LA 047

Request Form is checked and compared to number of samples collected.

Any Queries are communicated to Clinic

Samples collected are recorded on copy of Req Form

All samples to be tested at PHRU lab are assigned a Lab Accession Number

Prefix of Lab Number unique per study eg: LM 0000326 for MTN samples
Sample Processing

- Req Forms for Urine and Vaginal/ Pelvic samples are generated by PHRU Lab
- Urine samples for Pregnancy and Urinalysis are aliquoted into 5ml tubes and labeled with Lab Accession number before testing
- All other samples for testing at PHRU lab are tested per protocol requirements
Sample Testing

- PHRU Lab Accession number and PID is recorded on testing work sheet.
- Samples are tested and using appropriate test kits per protocol requirements and results recorded on Worksheet.
- For MTN studies: Start and End Times are recorded as well as time Checked/Reviewed.
- Protocol Specific Testing is separated from routine testing and the Test Kits are kept on separate benches.
Test Resulting

- Test Results are then entered on LIS and printed directly to clinic
- Reporting Computer is placed next to the testing bench. Allows Med Tech to recheck test strip before printing
- Result Reports are saved on the Lab Database which is backed up daily (Cibecs Continuity Agent)
- Testing Worksheets are reviewed by Lab Manager or Lab Supervisor Daily and filed
### Example of Test Worksheet

MTN Laboratory Operators manual
Protocol 003
Version 2, 09 September 2010
A Mofola

**Determine HIV 1/2 Rapid HIV Testing Worksheet**

**MTN-003**

<table>
<thead>
<tr>
<th>LAB NO</th>
<th>STUDY NO</th>
<th>DETERMINE RESULT</th>
<th>START TIME</th>
<th>END TIME</th>
<th>TESTER INITIALS</th>
<th>TIME CHECKED</th>
<th>CHECKED INITIALS</th>
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Reviewed by Supervisor: ___________________________  Date: ___________________________
Sample Coordination to Contracted Labs

- Samples that are not tested at PHRU lab are forwarded to Contracted labs
- A second copy of the Req Form remains at the lab
- Original is sent with the samples
- Samples are recorded on a shipping Log specific for each Lab
- The Courier has to check each kit against the barcodes on the Log
Example of Shipping Log

![Shipping Log Image]
## Challenges with MTN 003 Samples

<table>
<thead>
<tr>
<th>Challenge</th>
<th>Solution</th>
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<tbody>
<tr>
<td>SDA Urine samples at Visit 01.0 forgotten in the fridge</td>
<td>Created log to record MTN 003 samples requiring SDA per Req Form</td>
</tr>
<tr>
<td>Rapid HIV results not reviewed within the specified period</td>
<td>Separate Testing Worksheet for Determine and Unigold</td>
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</tbody>
</table>
Acknowledgement

The phru Lab Team
Acknowledgements

MTN is funded by NIAID (5U01AI068633), NICHD and NIMH, all of the U.S. National Institutes of Health