

Specimen Management

PHRU LAB

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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		SPONSOR DETAILS	
Initials	<input type="text"/>	Sponsor:	PHRU
Subject No	<input type="text"/>	Protocol:	MTN 003
DOB	<input type="text"/>	TRIAL:	ctMTN003S
Gender	<input type="text"/>	Kit:	MT1A
Collection Date	<input type="text"/>	INVESTIGATOR DETAILS	
Collection Time	<input type="text"/>	ctMT003S01 Dr B Mkhize	
Phlebotomist	<input type="text"/>	Ground Flr, Nurses Home	
Weight	<input type="text"/>	Chris Hani Bara Hospital	
		Chris Hani Rd, Soweto	
		Tel: 011 989 9705	

VISIT SECTION Indicate visit code in writing

VISIT Screening 1 visit code -

CLINICAL TRIAL:	Lab Use Only:
Special Instructions:	RECEIVED TIME AND DATE
	RECEIVED BY
	ENTERED BY
	TYPE OF TUBES RECEIVED
	EDTA
	SST
	OTHER
	MRI NUMBER
	DEMO CHECKED BY

SAMPLING SECTION Initial to confirm order, collection or receipt

TEST CODE	Test	tube	taken	Barc received
BARC	Barc Charge	X	X	X
MTN1	1x4ml EDTA FBC and Diff	X		
MTN2	1x5ml SST ALT AST CREAT + CC PO4	X		
MTN4	1x5ml SST HBSAG HBSAB	X		
MTN5	Universal Container SDA for GC/CT	X		
MTN6	Use HIV Rapid EDTA Western Blot			
PHRU ONLY	1x4ml EDTA HIV RAPID AND IF POS SEND TO BARC FOR WB			
PHRU ONLY	1x5ml SST RPR AND IF POS DO TPHA			

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

Sample Receiving

- ❑ **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 Mohlala

DETERMINE HIV 1/2 RAPID HIV TESTING WORKSHEET
MTN- 003

DATE: _____

DETERMINE LOT NO: _____

DETERMINE EXPIRY DATE: _____

LAB NO	STUDY NO	DETERMINE RESULT	START TIME	END TIME	TESTER INITIALS	TIME CHECKED	CHECKED INITIALS

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

29 SEP '10 10:25



**PERINATAL
HIV
RESEARCH
UNIT**

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BARC SPECIMEN LOG FORM

BARC BARCODE	COURIER (Please Tick)	BARC LAB (Please Tick)	Comments:
 3304-94112-SF BARC-J	✓		
 3304-83290-SF BARC-J	✓		
 3304-83888-SF BARC-J	✓		
 3304-85543-SF BARC-J	✓		
 3304-89598-SF BARC-J	✓		
 3304-89586-SF BARC-J	✓		
 3304-83448-SF BARC-J	✓		
 3304-83485-SF BARC-J	✓		
Total number of samples: Collected by (Print Name):		8 PCUNSON	Received by (Print Name):
Date collected:		11-30	Date Received: 29 Sep 10
Time Collected:		29 09:10	Time Received: 10:25

Challenges with MTN 003 Samples

Challenge	Solution
SDA Urine samples at Visit 01.0 forgotten in the fridge	Created log to record MTN 003 samples requiring SDA per Req Form
Rapid HIV results not reviewed within the specified period	Separate Testing Worksheet for Determine and Unigold

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