

HPRU CHAIN OF CUSTODY WHAT CAN GO WRONG?

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BUILDING A HEALTHY NATION THROUGH RESEARCH





How Chain of custody works at on-site lab e.g. FBC sample?

- 1 The FBC sample is collected by the nurse-this is registered onto a specimen collection log in the blood draw/clinical exam room. The accompanying request form for that study specific kit used at this visit is completed with the ffg details. 

→ **LANCET/BARC
SA STUDY KIT**





How Chain of custody works at on-site lab e.g. FBC sample?

- 🚫 FBC is immediately taken to the on-site laboratory.
- 🚫 Once FBC tube is received at the on-site lab, The lab's internal chain of custody is initiated to track handling of specimen throughout testing and storage.
- 🚫 The FBC sample is registered onto the specimen tracking log which is the daily register of samples coming in to the lab. The sample is also registered onto the specimen shipping log. This info enables that site lab to track sample submission and receipt of information.





How Chain of custody works at off-site lab e.g. FBC sample?

- 1** The FBC sample is stored in the on-site fridge -until end of day where all samples to be shipped are QC. The sample info is QC ed against the request form, shipping log and specimen tracking to confirm all info is correct.
- 2** The FBC sample together with the original copy of the request form are packed according to IATA specifications and is then shipped with a copy of the shipping log.
- 3** This log is signed off by on-site Lab QC staff who has verified all samples and then by the off-site lab courier.



OFF-SITE TESTS

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How Chain of custody works at off-site lab e.g. FBC sample?

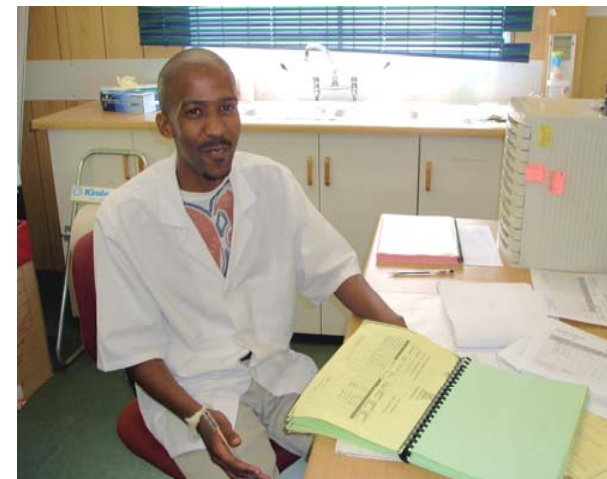
- ⚠ Upon receipt at the off-site lab- the MRC shipping log must be ticked and signed off for FBC tube received-this MRC shipping log is sent back to MRC together with all hard copies of results to enable results for all samples to be tracked.
- ⚠ The off-site lab chain of custody is initiated and the FBC sample is logged onto Meditech System, the request forms are signed, dated and time is inserted. The request form is also scanned to enable specimen audits to be done in the event of a problem.
- ⚠ The Meditech system automatically generates a shipping list which is sent with FBC sample to the Haematology department.






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Cases of what can go wrong with such a sample and test!




- ⚠ The Haematology department will test the sample and the result generated will be sent via e-version to the study specific staff who have been given access to e-version data within the agreed TAT [24-48hrs].
- ⚠ The on-site QA/QC Lab RA will QC the e-version and queries are only raised with the HPTN 035 lab co-ordinator if the on-site lab cant proceed or handle the query -at this point the ffg can go wrong:








Problem 	Investigate Cause of Event 	Solution and Documentation Required 
FBC Sample haemolysed	<ol style="list-style-type: none"> 1. Transportation condn 2. Specimen Draw 3. On-site lab or Off-site lab didn't request FBC test 4. Sample lost internally and when found-it is haemolysed 	<ol style="list-style-type: none"> 1. On-site lab-Check cooler boxes and gel ice packs/Fridge temp-QA event form 2. Speak to nurse about blood draw-expired tube, vacuum problem or speed of draw-re-train staff-training log 3. On-site QC and Off-site process failed-incident report 4. Off-site QC process failed-incident report



Problem 	Investigate Cause of Event 	Solution and Documentation Required 
FBC Normal Range	<ol style="list-style-type: none"> 1. Logged as male px 2. Normal range changed but data system not updated with info 3. Conversion of normal values into study specific SI unit is incorrect 	<ol style="list-style-type: none"> 1. Picked up during the QC of e-version results and off-site lab informed using DCF-amended report requested with comment detailing problem 2. Update data base with normal range change-inform the on-site lab-provide official letter of change over and incident reports of px affected. Amended report on px required. 3. Checked by HPTN 035 Lab Co-ordinator- request for amended report



Problem 	Investigate Cause of Event 	Solution and Documentation Required 
FBC Grading problem	<ol style="list-style-type: none"> 1. Clinician queried with HPTN 035 lab co-ordinator change from grade 1 to grade 4 neutrophil count in 2 weeks. 2. Co-ordinator requested repeat analysis of slide prepared. 	<ol style="list-style-type: none"> 1. Upon repeat analysis- Pathologist confirmed error on report-transcription error from raw data to data base. 2. Amended report to be placed on px file and incident report explaining the problem.

Always remember it is a fact finding mission not fault finding!!





Quiz Time!

- What is the name of the log used as a daily register for tracking of chain of custody at the SA sites?

**SPECIMEN TRACKING
LOG**





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Thank You From the Lab Team South Africa!!





SOUTH
AFRICAN
MEDICAL
RESEARCH
COUNCIL

Request form



Participant ID ---------------

Gender

Collection Date --

Collection Time :

Collectors Initials

Site **R K KHAN**

Dr Govinden a healthy nation through research

Medical Research Council
123 Jan Hofmeyr Rd, Westville
ct035
Container/Kit = 035R

4ml EDTA	_____
4.5 ml CTT	_____
5 ml SST	_____
URINE	_____



Dr = ct03500001
Dr. Govinden
R K KHAN - UNIT, CHATSWORTH
Ambulance parking, R K KHAN
Tel: (031) 401- 4150
Fax: (031) 401- 4563

KINDLY CROSS (X) APPLICABLE VISIT REQUIRED TO BE PERFORMED

SCREEN PART 1 PHASE II PHASE IIB

VISIT CODE

KINDLY CROSS (X) APPLICABLE TESTING REQUIRED TO BE PERFORMED

- 035F 1xUrine GC & CT - SDA
- 035A 1x 4ml EDTA FBC, PLATELETS, Diff
- 035B 1x 4.5 ml CITRATE COAGULATION (PI, PTT) LAB RECEIVES ALIQUOT FOR TESTING
- 035E 1x 5ml SST RPR reflex TPHA IF RPR POSITIVE
- 035C USE SST TUBE ALT, AST, ALK PHOS, GGT, T Bili
- 035D UREA, CREATININE

STORAGE

EDTA TUBE TO BE ALIQUOTED INTO 2X1ML PLASMA INTO CRYOVIALS AND KEPT FOR COLLECTION BY MRC LAB ALL STORAGE TO BE DONE AT MRC LAB

AUTHORIZATION REQUIRED FOR ADDITIONAL TESTING	
Additional Test:	
Comments:	
Internal use ONLY	

BARC CONTACT DETAILS:		COURIER DETAILS:	
Colin Moonsamy	Tel: 073-259-2940 Emergency 073 2592940	DURBAN:	Tel: 031-308-6516/12/02
Selvan Pillay	Tel: 082-095-4629 Emergency 082 0954629	BARC / Lancet Labs	Fax: 031-308-6503/6600