HIV PREVENTION RESEARCH UNIT

HPRU CHAIN OF CUSTODY
WHAT CAN GO WRONG?

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DURBAN
SOUTH AFRICA

South African Medical Research Council
BUILDING A HEALTHY NATION THROUGH RESEARCH
How Chain of custody works at on-site lab e.g. FBC sample?

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.
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?

- 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.
- 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.
- This log is signed off by on-site Lab QC staff who has verified all samples and then by the off-site lab courier.
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 Haemotology department.
Cases of what can go wrong with such a sample and test!

- The Haemotology 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 can't proceed or handle the query - at this point the ffg can go wrong:
<table>
<thead>
<tr>
<th>Problem</th>
<th>Investigate Cause of Event</th>
<th>Solution and Documentation Required</th>
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<tbody>
<tr>
<td>FBC Sample haemolysed</td>
<td>1. Transportation condn</td>
<td>1. On-site lab-Check cooler boxes and gel ice packs/Fridge temp-QA event form</td>
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<td></td>
<td>2. Specimen Draw</td>
<td>2. Speak to nurse about blood draw-expired tube, vacuum problem or speed of draw-re-train staff-training log</td>
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<tr>
<td></td>
<td>3. On-site lab or Off-site lab didn’t request FBC test</td>
<td>3. On-site QC and Off-site process failed-incident report</td>
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<td>4. Sample lost internally and when found-it is haemolysed</td>
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| FBC Normal Range             | 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 | 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 |
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| FBC Grading problem     | 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. | 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. |
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
Thank You From the Lab Team South Africa!!
Dr. G Ramjee
Medical Research Council
123 Jan Hofmeyr Rd, Westville
ct035
Container / Kit = 035R

Participant ID - - - - -
Gender FEMALE
Collection Date
Collection Time
Collectors Initials R K KHAN
Site 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

KINDLY CROSS (X) APPLICABLE TESTING REQUIRED TO BE PERFORMED

035F 1x Urine   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 Bilir
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

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