# MTN 020 FBC CLOTTED TUBE – HOW TO PREVENT MISSING WINDOW PERIODS & PDs

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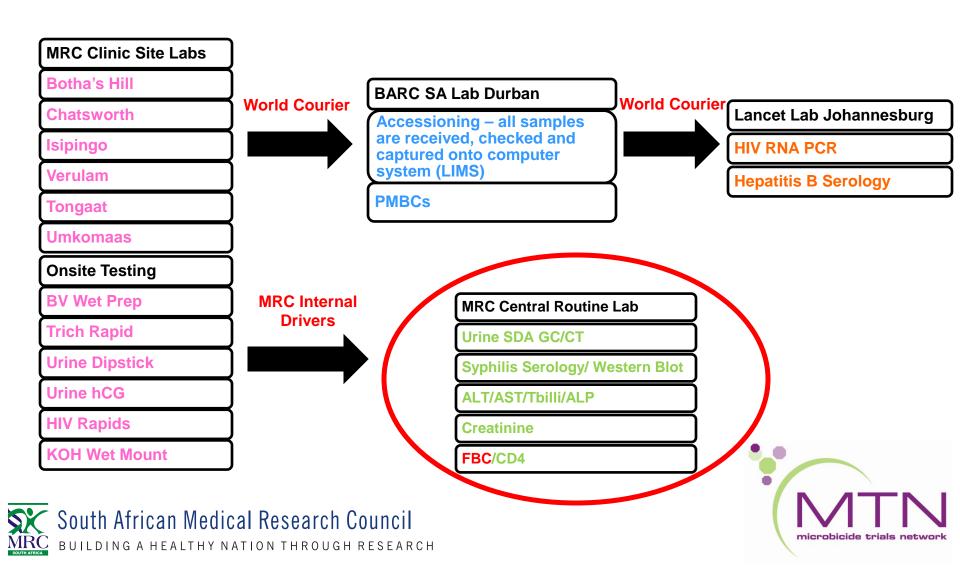
# HIV PREVENTION RESEARCH UNIT SOUTH AFRICAN MEDICAL RESEARCH COUNCIL DURBAN, SOUTH AFRICA

**MTN REGIONAL MEETING 2013** 



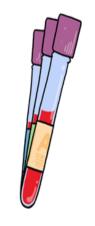


#### FLOW OF LAB WORK?



# WHAT HAPPENED AT HPRU CENTRAL ROUTINE LAB [CRL]?

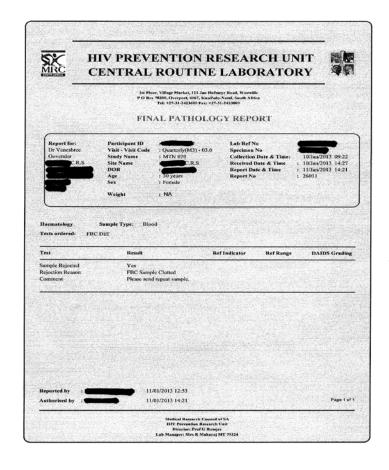
- FBC (EDTA tube) test was processed by a medical technologist
- The sample was clotted
- The med tech failed to notify the site involved on the day the incident occurred
- The COMMENT was entered, authorised and verified by Med Tech 1 BUT Med tech 2 didn't release the PTID so the result - pdf on email didn't go out within 24hours and a hard copy wasn't printed for the site



http://www.noc.nhs.uk



# WHAT HAPPENED AT HPRU CENTRAL ROUTINE LAB [CRL]?





#### LABORATORY MANAGEMENT REVIEW

MRC HPRU Laboratory follows Laboratory Management Review and troubleshooting using the RASPAE Model that the Lab Manager has presented at M2012



- ✓ R=Root Cause investigation;
- ✓ A=Analysis of the data,
- ✓ S=Solution identification, selection and implementation; Corrective Action
- ✓ P=Preventative Actions;
- ✓ A=Action plan; and
- ✓ E=Evaluate Solution



### **ROOT CAUSE INVESTIGATION**

#### At Clinic level-Laboratory site staff

- The medical technologist at site failed to track the e-version result within 24 hours (NB: The TAT for an e-version lab result is 24 hours and 48 hours for a hard copy lab report)
- The lab QA/QC RA failed to track the hard copy lab report within 48 hours

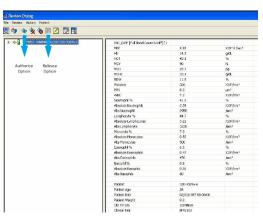
#### At MRC HPRU CRL

- Three working days later at the MRC HPRU CRL a LIMS incomplete specimen report was printed and it was noted that the PTID result had not been released on the system
- The e-version was then sent immediately to site HOWEVER the participants window period had closed on the day the LIMS incomplete specimen report was printed and therefore the participant couldn't be called in.

#### **ANALYSIS OF DATA**

#### **At Clinic level-Laboratory site staff**

- There was no eversion result at site
- There was no hard copy result at site
- No emails of request to the MRC HPRU CRL within the 24-48hours period
- The participant schedule database showed Window period was near end, if repeat was requested this would be out of window period and a PD



#### At MRC HPRU CRL

- LIMS incomplete specimen report was printed 3 days later
- LIMS illustrated that Med tech 2 failed to press release icon to release the result

# SOLUTION IDENTIFICATION, SELECTION AND IMPLEMENTATION, CORRECTIVE ACTION

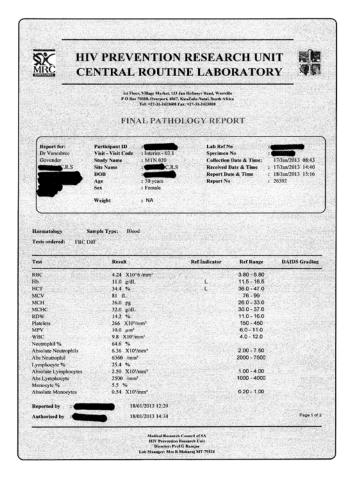
- The site med tech and lab qa qc ra failed to follow up on the result as per JD
- The CRL med tech failed to notify site about the clotted FBC tube within 24hrs
- CRL did not print the report as the results were released and the PTID was not verified with the lab report

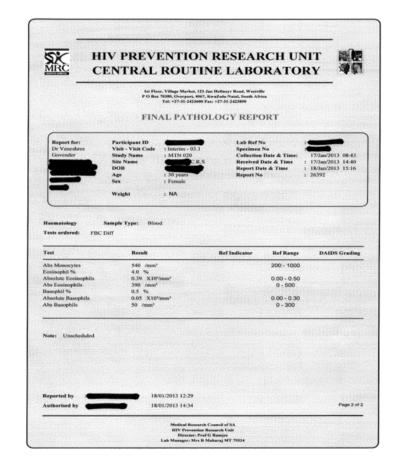
# SOLUTION IDENTIFICATION, SELECTION AND IMPLEMENTATION, CORRECTIVE ACTION

#### **Corrective action**

- Investigation with supporting documents reviewed
- Minuted meeting with the lab manager and staff members involved
- CRL completed Laboratory incident report and sample rejection log
- Site completed a laboratory note to file [LN2F] explaining the incident to place with the lab report
- Lab manager reviewed and approved the incident report & LN2F
- Site contacted the participant to visit the clinic for a repeat FBC blood draw
- Participant returned to site for the repeat blood draw but her month 3 window was closed therefore this is regarded as a protocol deviation as a missed test under code 15 on PD CRF

# SOLUTION IDENTIFICATION, SELECTION AND IMPLEMENTATION, CORRECTIVE ACTION









#### **At Clinic level-Laboratory site staff**

- Ensure the draw order of tubes are maintained to prevent cross contamination
- Ensure a full EDTA tube of blood is collected (NB: If the incorrect volume of blood: anticoagulant ratio is collected, this will result in a clot formation)

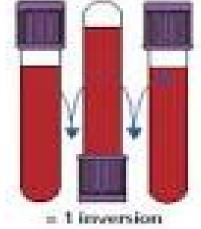






- Draw the participants blood using an EDTA tube then gently invert tube at least 8 times after specimen collection to ensure adequate mixing with the anticoagulant
- The site medical technologist and lab QA/QC RA to check the FBC tube once the nurse has delivered the specimen.
- Ship the FBC samples at an ambient temperature in appropriately labelled cooler boxes to HPRU Central Routine laboratory.



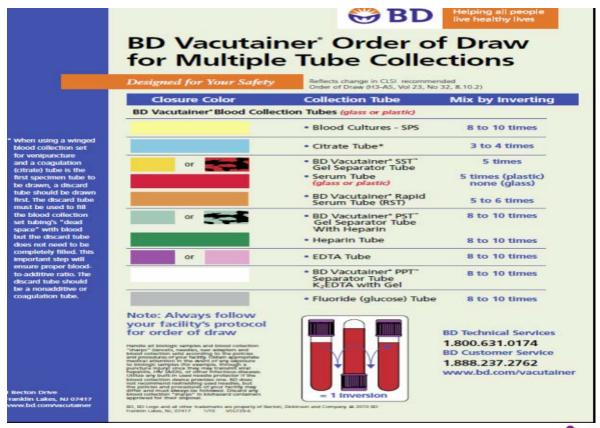




#### **HPRU CRL**

- Documented retrain of staff by the LIMS administration personnel to be conducted on the verifying and release of the PTID and not the test
- All sites to be notified immediately if a sample is unsuitable so a repeat sample can be taken
- LIMS sample unreleased reports to be done daily as OSR







#### At Clinic level-Laboratory site staff

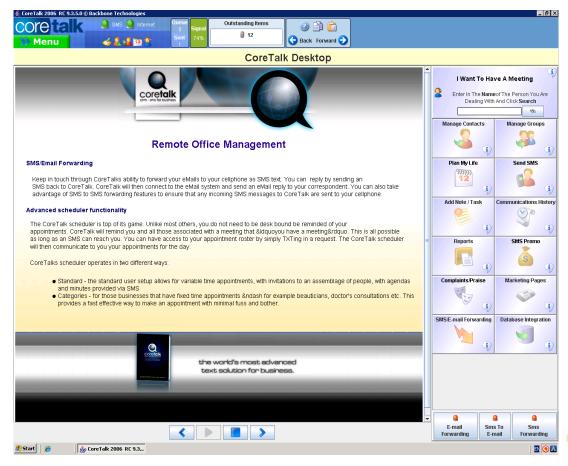
- Clinic requested to ensure long window periods between safety/STI testing requests - to allow repeats and remain within windows
- Extra vigilance of site staff to follow-up on outstanding eversions and hard copy results within TAT - any deviations will be reported to the lab manager
- Poor Performance letter to staff responsible for the error
- Assessment of measures in 1 month proved the action plan works - No PDs to date in such events



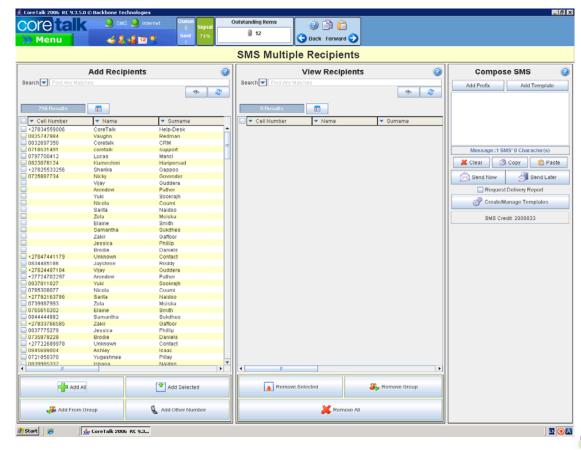
#### **HPRU CRL**

- A communication book was put in place to notify staff of urgent messages to follow up
- Unsuitable sample messages are sent out via core talk SMS to site clinician, med tech, CRS management
- LIMS administration will create instant messaging for any urgent messages that need to be addressed
- LIMS administrator will try to implement a system to prevent the test from being authorized instead of the PTID
- Poor Performance letter to staff responsible for error
- Assessment of measures in 1 month proved action plan works - No PDs to date in such events

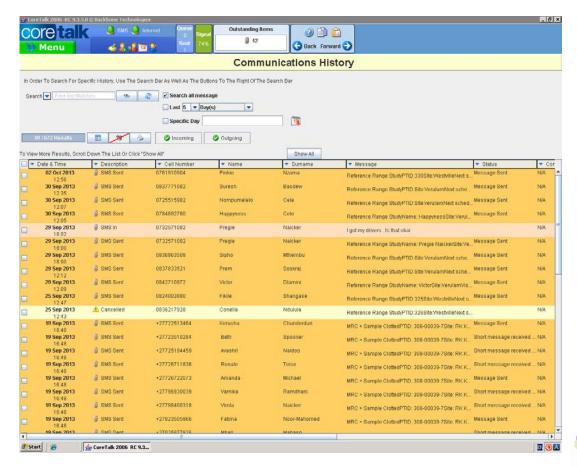




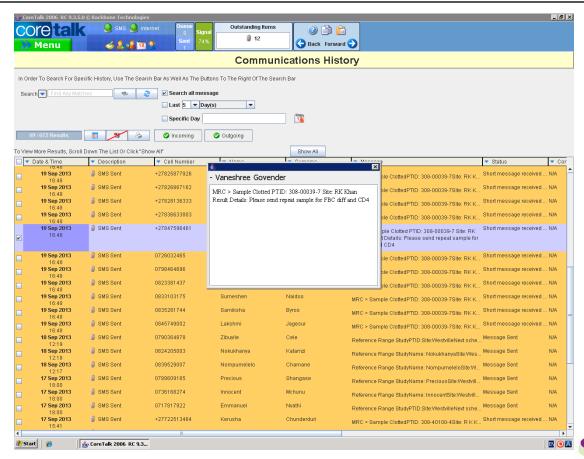














#### **EVALUATE SOLUTION**

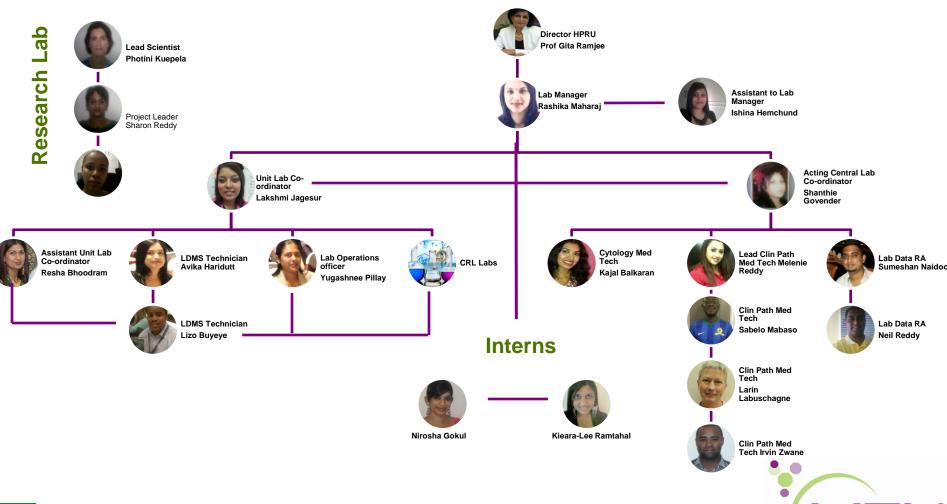
- Monthly laboratory management review showed no occurrence of any window period missed for clotted FBC. All sample rejections can occur at site level via SOP available on benches and upon arrival at CRL
- A monthly review illustrates that from this one incident, these preventative measures have been working well





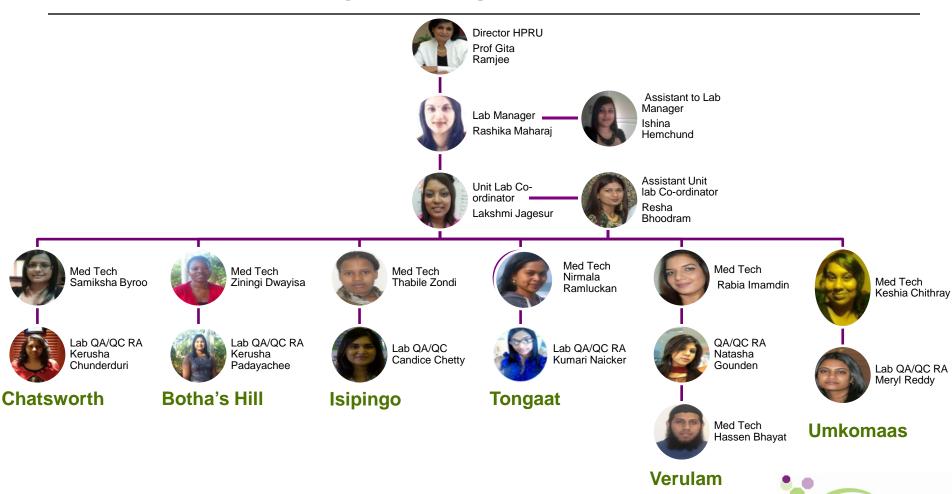


### MRC HPRU LAB FAMILY



microbicide trials network

# MRC HPRU LAB FAMILY



microbicide trials network



#### REFERENCES

- MTN 020 Lab note to file 05
- HPRU Central lab Laboratory incident investigation form
- BD vacutainer order of draw for multiple tube collection





#### **ACKNOWLEDGEMENTS**

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