



MEDICAL RESEARCH COUNCIL HIV PREVENTION RESEARCH UNIT TIMING VIOLATIONS



MTN REGIONAL MEETING 2011

**11 October 11
CAPE TOWN**

Presented by Juhina Bagwandeem & Thokozani Mkhize



The MRC HPRU 7 Clinical Research Sites (CRS's):

Botha's Hill

Tongaat

Umkomaas

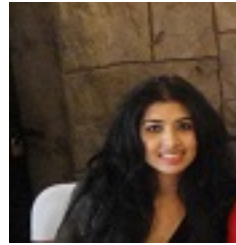
Overport

Chatsworth

Verulam

Isipingo

The on-site laboratories consist of a staff compliment of 2 med techs and a lab QA/QC RA - there are 36 lab staff at HPRU.



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MTN 003

CORRECT

HIV TESTING LOG

Kit Name: Unigold Recombigen

Site: MRC HPRU

Kit Lot No: 048501

Date: 05 Oct 11

Expiry Date: 31 Dec 11

	PTID	VISIT CODE	TEST TIME		HIV RESULT		INTERNAL CONTROL	CHECKER 1	CHECKER 2	CHECKER 3	Time	Time
			START	END	NEG	POS		SIGN LAB TECH.	SIGN MRC EMPLOYEE	SIGN MRC EMPLOYEE		
	123-123-0	10.0	10:40	10:50	✓	-	✓	ABC	DEF	-	10:51	-

ON SITE QC-CHECKED BY: XY 05 Oct 11
 OFF SITE QC-CHECKED BY: EZ 06 Oct 11

KEY NEXT TO PTID:
 * WESTERN BLOT DONE

INCORRECT

MTN 003

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		START	END	NEG	POS		SIGN LAB TECH.	SIGN MRC EMPLOYEE	SIGN MRC EMPLOYEE		
								Time	Time		
456-456-0	11.0	11:20	11:35	✓	-	✓	GH	IJ	11:36	-	-
		★	★					★	★		

ON SITE QC-CHECKED BY: XY 05 Oct 11
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KEY NEXT TO PTID:
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- **The quality control policies and procedures of an organization or laboratory forms the foundation on which accurate and precise results can be generated and reproduced.**
- **The HPRU Unit laboratory has stringent QA/QC polices and procedures to ensure that the testing, interpretation and documentation for all on-site lab procedures are accurate and valid.**



On-site lab – Timing of lab tests

- **Timing of lab tests are critical in producing accurate and valid results. Data quality is of utmost importance and inaccurate testing times and transcription compromises the quality of the data that the site produces, thus affecting study outcomes.**
- **As per GCLP all results are recorded onto all testing logs using a calibrated digital timer. E.g. Unigold HIV rapid is read at 10 minutes and verified by a checker 2 within 10-12 minutes as per package insert however, MRC HPRU policy dictates a checker 3 for all HIV positive results.**



- **At the internal monitoring in November 2010, a total of 70 timing violations across all 7 sites were picked up.**
- **This resulted in Protocol Deviations for each site.**
- **A Protocol Deviation form was completed detailing what had occurred, corrective action strategies and preventative measures.**





Corrective action

- **Staff and site management notified of errors at point of debriefing and at the weekly MTN meeting; in addition emails sent immediately upon pick-up by the MTN / MRC HPRU Laboratory Manager.**
- **MTN / MRC HPRU Laboratory Manager held meeting for all 7 sites to discuss solutions to problem + site management**



Corrective action.....continued

- Minutes taken – provided to all 7 sites (inclusive of lab staff and management)
- Meetings were held with staff involved with timing violations by MTN / MRC HPRU Lab manager
- Re-train of all MTN lab staff done by MTN / MRC HPRU Laboratory Manager
- Med Techs and Lab QA/QC RAs asked to be more vigilant and notify unit laboratory MTN / MRC HPRU Laboratory Manager upon these findings in real time
- Poor Performance letters given out to staff
- Competency was re-assessed and evaluated

Preventative Measures



- Placement of the clock above the work area where documentation and logs are used daily.



- Checker 2 and 3 + 3rd check by the onsite lab QA/QC RA done daily in real time re-iterated on vigilance and caution when QCing testing and QC logs, and all logs



Preventative Measures.....continued

- **Severity of the timing violations re-iterated**
- **Corrections to time can be made in real time of entry, initial date and comment with asterisk that it was corrected in real time and testing time is valid. However if the error is picked up at the end of the day by on site lab QA/QC RA or upon monitoring this is reportable protocol deviation to MTN protocol team.**



Additional measures for future findings

- Lab QA/QC RAs will need to fax MTN / MRC HPRU Laboratory Manager, Unit lab or Assistant Unit Lab Co-ordinator the following:
 - The testing or QC logs applicable where timing violation occurred,
 - QA event forms,
 - Proof that the test was run at next visit and result remained the same if applicable+ such logs involved with this proof,
 - Re-train logs of lab staff involved and checker 2/3,
 - Minutes of the training carried out with lab staff or scan and send to MTN / MRC HPRU Laboratory Manager in real time all such documents- that is same day this occurs



Additional measures for future findings....continued

- Meetings will be held with staff involved with timing violations by the MTN / MRC HPRU Laboratory Manager, if this is a 2nd or 3rd occasion HR Manager will be involved and this becomes a severe concern of performance and leads to disciplinary. Minutes will be placed on file of this with all such documents listed above.
- Poor Performance letters will be given out to staff- staff who have more than 3 PP letters will be handed over to HR in terms of performance and possible termination.



Conclusion

Together with the hard work and dedication of the MRC HPRU lab staff and Network Laboratory, uncompromised data quality/integrity is maintained.





THANK YOU



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