QA Processes That Work: Minimizing Errors During On-site Rapid HIV Testing

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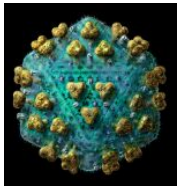
South African Medical Research Council

BUILDING A HEALTHY NATION THROUGH RESEARCH

HIV and Study Endpoints

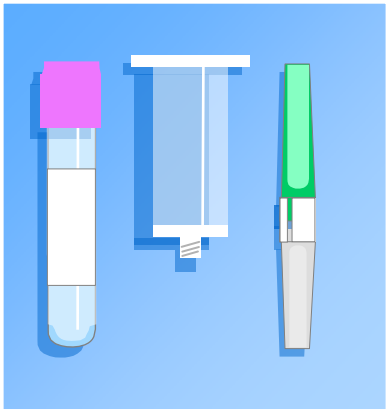
- In most cases, clinical trial data is largely laboratory in nature to include study endpoints e.g. HIV and participant safety data. Hence, if this laboratory data is called into question due to inconsistent practices, an entire trial effort could be deemed as a failure.
- In order for GCLP to be effective in the laboratory, the lab management or site lab co-ordinator must set the example-this has to be norm and culture for lab staff.
- QA checks and control measures at every point of the HIV pre-analytical to the post-analytical phase must be incorporated BUT follow-up of all aspects must be done to ensure compliance or the practice will fail.
- It is vital that lab staff are aware and have signed that they have read and understood what is required in the form of sops, cheat sheets and policies.

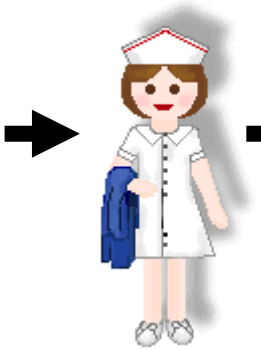


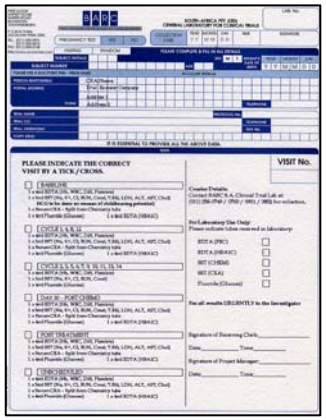
SOUTH AFRICAN MEDICAL RESEARCH COUNCIL

HIV Sample Collection at the On-Site Clinic- RKK and Hlabisa Site

Building a healthy nation through research



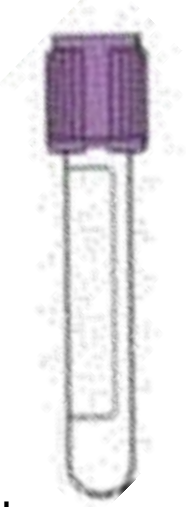




QC Procedures at the On-site Lab

- On arrival at the lab the Med. Tech. checks that the samples are correctly labeled and that the requisition form contains the identical information as written out on the EDTA tube for HIV testing.

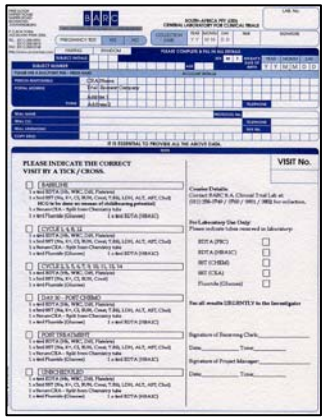
QA CHECK



➔ SEALED CAP

➔ PTID, VC, DOC, NURSE INITIALS

QA CHECK



- On the sample tracking log and indicates what samples were collected and who received them at the lab.
- If any discrepancies are noted it is immediately queried and resolved.

On-site HIV Rapid Testing

- QA CHECK A new HIV testing log is used each day to ensure HIV rapid tests lot control #, expiry date is captured on daily basis so no expired kits can be used.
- The participants PTID and visit code are captured onto the HIV testing log.
- QA CHECK Once the test is set up, the timer is started and the start time is recorded immediately onto this testing log.
- On completion of the test the end time is recorded on this testing log.
- The Med. Tech. performing the test is required to initial the log.
- QA CHECK E.g. If FDA-Approved Unigold rapid test is used, the test must be read at ten minutes and checker two and three must confirm the result within twelve minutes. This is time validity-any time out of this is INVALID
- QA CHECK The checkers are trained lab/clinical staff , project leader and/or the project manager.
- QA CHECK If there is any new clinic personal, training is to occur prior to this staff signing as checker 2/3- this must be documented and placed onto file-any tests signed by this staff member who wasn't trained is INVALID

On-site HIV Rapid Testing Documentation

QA CHECK
- The HIV Results transcription from the HIV testing log to the lab result forms and lab CRFs are QC'ed by the on-site Lab QA/QC Research Assistant to ensure the correct HIV results were transcribed and initials the QC column the result form before it is placed into the px files and revealed.

QA CHECK
- At the end of each day-the HIV testing log is QC for an on-site QC to ensure all participants who came in for a visit that required HIV, was done, verifies the kit lot no, expiry date, the participants details and timing of the test.

QA CHECK
- The QA/QC Lab RA will sign on the On-site QC row daily, whilst monthly off-site QC is performed by the Unit or Asst Unit lab co-ordinator or lab manager.

Onsite HIV Rapid Testing And Quality Control Documentation

- **QA CHECK** Should a new HIV kit lot # be used, the QA/QC Lab RA will verify that lot control QC was performed before usage-CHECKING THE HIV QC LOG.
- **QA CHECK** The QA/QC Lab RA will also ensure that the lot # was indicated on the HIV testing log, at the PTID where this new lot # was being used.
- If this is not picked-up by the on-site QC, the OFF-SITE QC WILL ALWAYS PICK-UP SUCH A EVENT!!
- **QA CHECK** In the event, a test time was noted as being out of the valid time, in most cases the med tech have read the test correctly but recorded the incorrect time, P.S. THE TIME OR RESULT CANNOT BE CORRECTED ON THE LOG!!!
- **QA CHECK** The ffg procedure is used: A QA event form is used to correct any errors that are identified on the testing log i.e. Incorrect result or timing of test.
- The med tech states refer to QA event form on the HIV testing log at the row of the affected PTID and initials and dates the entry.

On-site HIV Rapid Testing and Confirmatory HIV testing

- All discordant or positive HIV results are confirmed using the Biorad Genetics HIV-1 Western Blot technique.

QA CHECK

- The western blots are run at HPRU laboratory at Overport. Samples are QC against request forms, then processed. Raw data is then QC via a triple check- performer, approver and authorizer who reads protein bands and verifies correct final HIV result, lot # and expiry date of the testing kit.

QA CHECK

- The results are transcribed from the raw data worksheet to the results report, The report is QC by second lab person ti verify transcription and request form details captured.

QA CHECK

- HIV Rapid tests-Discordant rates-a log has been generated centrally by the 035 laboratory co-ordinator-to ensure lab QA/QC RA notifies her of any discordant tests AS THIS OCCURS and she will troubleshoot and assess what can be done at site level. Any troubleshooting has to be documented on a QA event form.

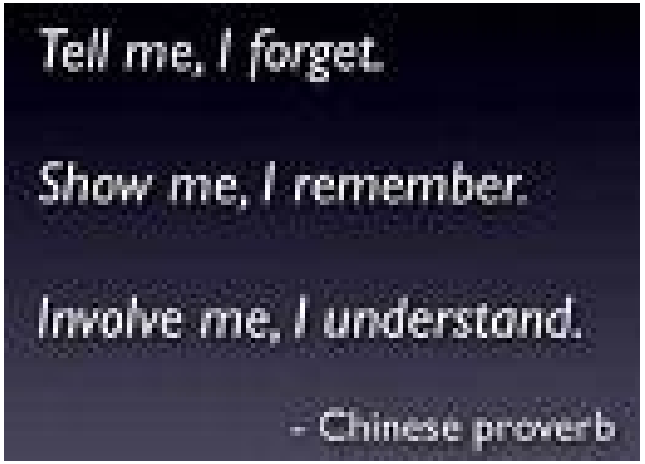
QA CHECK

- When in doubt-ALWAYS CONTACT HPTN NL OR MTN PNL.

Lessons Learnt with HIV testing

- **Errors will occur-but QA check must be in place at each stage.**
- **QA processes have to be verified by an external QC-such as Off-site QC to prevent a bias QC. All logs should have off-site QC-so 100% of logs are reviewed.**
- **Correction of time or result should not occur-QA process must be in place.**

THANK YOU FROM SA TEAM!!



HPTN 035
LOG FOR COLLECTION OF BLOOD SPECIMENS

Date: _____

ATIENT ID	VISIT CODE	TIME	BLOOD TUBES	COMMENTS	SIGNATURE OF NURSE

HPTN-035 STUDY

SPECIMEN TRACKING LOG

DATE: _____ **SITE:**

_____

PID No.	Visit Code	Serum		Plasma				EDTA Tube	Urine	Swab Dacron	Slides			Comments	Sign Lab Tech
		SST Tube Lancet	1ml serum aliquot LDMS Westville	Coag aliquot Lancet	1ml Coag aliquot LDMS Westville	4X1ml+1 X 0.5ml plasma aliquots LDMS Westville	4 X 0.5ml plasma aliquots LDMS Westville	FBC Tube Lancet	Probe Tec Lancet	GUD PCR LDMS Westville	Pap X1 slide Lancet	Gram X 2 slides LDMS Westville	W B		

ON SITE QC-CHECKED BY: _____

OFF SITE QC-CHECKED BY: _____

KEY: WB- Refers to Western Blot and is applicable to EDTA tube sent for Western Blot to Lancet in the ffg e.g. after the site has aliquoted the 4X0.5ml plasma aliquots for sample 1 and sample 2, or at screening when a discordant HIV result is obtained!!!

HPTN-035 STUDY

HIV TESTING LOG

Kit Name: _____ **Site:** _____

Kit Lot No: _____ **Date:** _____

Expiry Date: _____

PID.NUMBER	VISIT CODE	TEST TIME		HIV RESULT		INTERNAL CONTROL	CHECKER 1 SIGN LAB TECH.	CHECKER 2 SIGN MRC EMPLOYEE	CHECKER 3 SIGN MRC EMPLOYEE
		START	END	NEG	POS				

ON SITE QC-CHECKED BY: _____

OFF SITE QC-CHECKED BY: _____

KEY NEXT TO PID:

* WESTERN BLOT DONE

MEDICAL RESEARCH COUNCIL
HPTN-035 Study
Laboratory Result Form

PID No.: _____ **Date of Visit:** _____

Visit Code: _____

TEST	VALUES	POS	NEG	QC signature
Pregnancy test				
Urine dipstick	**Leucocytes Esterase** ☐ **Nitrites** ☐			
HIV Rapid test 1				
HIV Rapid test 2				
Western Blot				
Vaginal pH level				
Whiff test				
Trichomonas vaginalis				
Candida yeast	**Symptomatic** ☐ **Asymptomatic** ☐			
Clue cells >20%				

Lab Tech: _____ **Date:** _____

MRC Employee: _____ **Date:** _____

***Clinician:** _____ **Date:** _____

*Clinician to sign only if participant is HIV positive

ELIGIBLE:
YES ☐ NO ☐ N/A ☐

QC LOG FOR HIV TESTING

HIV KIT NAME: _____ **SITE:** _____

Date	Test Kit			QC Kit			QC Results		Comments	Sign. Lab Tech	Sign. MRC Employee
	Lot #	Exp. Date	Open Date	Lot #	Exp. Date	Open Date	Neg Control	Pos Control			

Corrective Action Taken:

ON SITE QC-CHECKED BY: _____

OFF SITE QC-CHECKED BY: _____

QA EVENT CONTROL FORM

Date of Event: _____

Project Name: _____

Site: _____

Specimen ID (*if Applicable*): _____

Specimen Type(*if Applicable*): _____

**Visit Code((*if Applicable) :* _____

Quality Control/Equipment involved (*if Applicable)* : _____

Date and Time: _____

Reported by: _____

Nature of Problem:

_____
__
_____
_____
_____
_____
_____
_____
_____
_____
__
_____
__
_____
__

Person Notified: _____

At (Place): _____

Date/Time:_____

Resolution:_____
_____
_____
_____
_____

HPTN-035 STUDY

HIV TESTING LOG

Kit Name: Recombigen Unigold **Site: RKK Site**

Kit Lot No: R143008 **Date: 09 Sep 2008**

Expiry Date: 30 Oct 2008

PID.NUMBER	VISIT CODE	TEST TIME		HIV RESULT		INTERNAL CONTROL	CHECKER 1 SIGN LAB TECH.	CHECKER 2 SIGN MRC EMPLOYEE	CHECKER 3 SIGN MRC EMPLOYEE
		START	END	NEG	POS				
XXXX	YY	10:20	10:35	X	-	X	10:30	10:32	REFER TO QA EVENT FORM-RM 09 SEP 08

VALID TIME 10-12 MIN