HIV RAPID TEST CONTROL ISSUE
AT BLANTYRE SITE, MALAWI

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INTRODUCTION

- MTN 020 Study was activated at our site on 22 May 2013.
- First screening was on 29 May 2013.
- Research nurses on our site are trained and competency is assessed regularly.
- Tests done:
  - Oraquick HIV 1/2
  - Determine HIV 1/2
  - QuickVue HCG serum / urine
The clinic does weekly controls for the above tests

Roughly, the clinic is doing 40 HIV and HCG tests a month

Lab checks

- The QA/QC officer does weekly checks and monthly reviews of the lab tests and QCs done at the clinic
It was noted by our QA/QC officer during his monthly review of the clinic logs that:

- The clinic used expired Oraquick controls from 1\textsuperscript{st} June 13 – 26 June 13.
INVESTIGATIONS

- Our International QA/QC Officer was notified
- She notified the MTN network lab (NL) and asked for guidance on the way forward.
The NL needed to check with regulatory department.

- New guidelines had been released and they wanted to find out if this was a protocol deviation or not.
- They requested the site to send the following info:
  - Wanted to know if the problem was corrected.
  - Our response: The clinic was given a new lot of QC on 3-July-13 and they ran the new QC lot the same date.
Investigation Con’t

- How many MTN 020 HIV rapids had been run while using expired controls?
  - Our response 13.

- How many clients were enrolled while the expired controls were in use?
  - Our response 4

- We were notified that it was not a critical protocol deviation
Corrective action

- We were told to do corrective actions as follows:
- A refresher training with all the clinic staff and the lab staff on reviewing all the necessary elements when doing the QCs and test was conducted.
- A note to file was written and a copy was sent to the NL.
As a lab we put in place following measures:

- Returning of all the QC material to the lab every Fridays
- Signing and recording expiry date when giving the QC and testing materials to the clinic
- Expiry date verification column added on QC and testing logs
QUESTIONS??
THANK YOU FOR YOUR ATTENTION