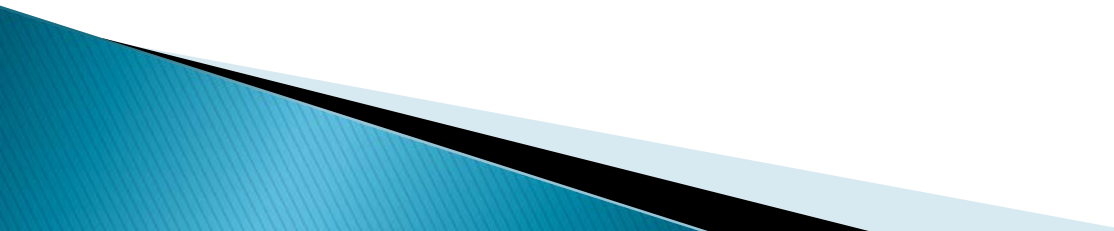


# **HIV RAPID TEST CONTROL ISSUE AT BLANTYRE SITE, MALAWI**

MADALITSO KAMALIZA  
POINT LAB TECH  
COM-JHU LAB, MALAWI

# 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
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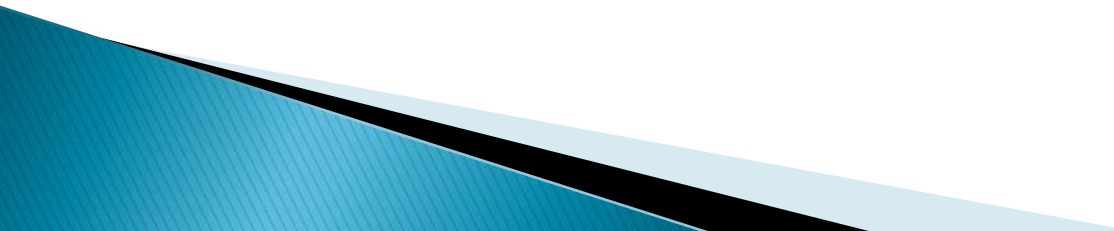
# INTRODUCTION con't

- ▶ 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

# PROBLEM NOTED

- ▶ 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<sup>st</sup> 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.
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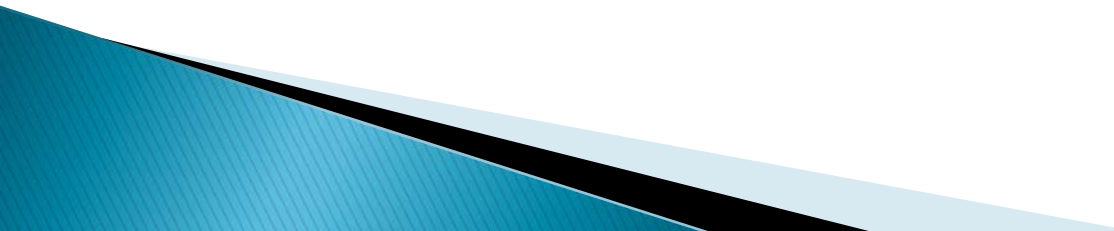
# Investigation Con't

- ▶ 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

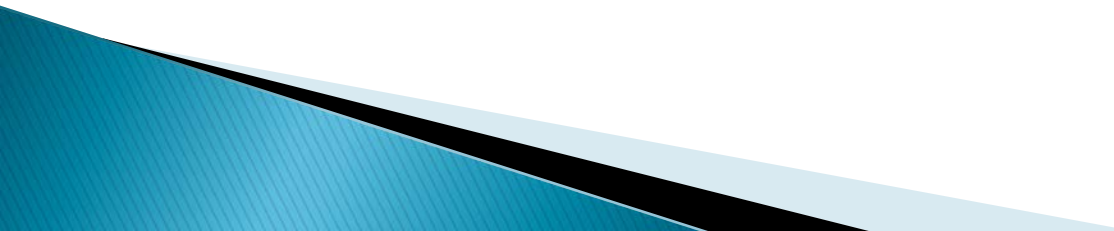
# Corrective action

- ▶ 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.
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# WAY FORWARD

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
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QUESTIONS??

**THANK YOU FOR YOUR ATTENTION**

