Syphilis

investigation report (IR)

PRESENTED BY

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Outline

- Introduction
- Challenge(s)
- Root Cause Analysis
- Corrective Action
- Conclusion
Introduction

- Lab offers syphilis testing for following protocols: MTN-020, MTN-015 and HPTN 052.

- Training and Competence
  - Internal control
    - Kit controls
    - Lot to lot testing
    - Expired reagents not used
    - Equipment serviced bi-annually
  - EQA
    - College of American Pathologists (CAP)
Challenge(s)

- Lab had a challenge on Survey received and tested in April 2013. (CAP survey G-A panel)
- Score lower than expected result obtained.
- Investigation report (IR) required (SMILE) <100%.
- Root cause analysis was explored
Root Cause Analysis

- **Pre-analytical errors** - No issues
- **Analytical errors**
  - Instrument did not attain the required speed
  - Lack of adherence to SOP
- **Post analytical errors** - No issues
- Repeat testing on failed EQA material was done and intended results were obtained and reported.
Corrective Action

- Use of instrument immediately discontinued.
- A proper rotator with SOP specified speeds was obtained and put to use.
- Refresher training on SOP adherence was conducted.
- 233 negative samples repeated - all were negative.
- No participant results were affected.
- Data sent to Network lab for assessment and IR was closed.
Conclusion

Lessons learnt:

- We are ISO certified and participation in EQAs has helped us identify these challenges and successfully resolve them.

- There is always room for continual improvement especially when you are periodically monitored by external bodies like SMILE.
Thank you. (Siyabonga)