


# Syphilis

## investigation report (IR)



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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)

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- ❑ 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)**