



LAB BREAK-OUT SESSION:

LAB CHALLENGE : GRAM STAIN LABELLING

**Lindelwa N. Nkangane (Medical Technologist)
Wits Reproductive Health and HIV Institute (Wits RHI)**

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PRESENTATION OUTLINE

Laboratory
Challenge

Corrective
Action

Preventative
Action



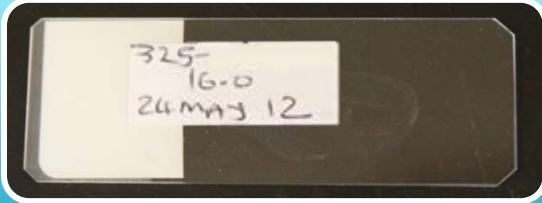
CHALLENGE: GRAM STAIN LABELLING

Occurred in January 2013

MTN NL notification: 20 VOICE gram stain slides incorrectly labelled



Incorrect labels used & labels placed directly on top of specimens



Incorrect labels used & labels on the underside of slides obscuring smear



Correct SCHARP label used but on wrong end of the slide

CORRECTIVE ACTION

- A two pronged investigation was conducted to determine the cause:

ON- SITE

Observation: Incorrect labels used or SCHARP labels incorrectly placed

Investigation: Review of gram stain labelling procedures by clinical staff

Outcome: Clinical staff reported correct labelling
Verified by med tech prior to shipment

OFF- SITE

Observation: Labels appeared to be peeled off and re-stuck

Investigation: Consultation with outsourced lab (LDMS logging & storage procedures)

Outcome: Outsourced lab reported no deviation from labelling procedures

Conclusion: Exact cause could not be determined

- The Wits RHI Medical technologists visited the outsourced lab
- Rectified the incorrectly labelled back-up gram stain slides as outlined in MTN 003 SSP section 13.7.5.
- Protocol Deviation Form was completed – Site took responsibility



PREVENTATIVE ACTION

1

- This violation was discussed with the clinical & lab teams at Wits RHI to increase awareness

2

- Wits RHI clinical & lab staff were retrained on gram stain labelling procedures (SSP section 13.8.4 of the MTN 020 SSP Manual)

3

- Outsourced lab was advised to re-train the LDMS team on correct Gram slides labelling procedures & submit DCFs to site when incorrect labelling is observed



CONCLUSION

- Correct specimen labelling is **VITAL**- Mislabeled specimens can obscure data & objectives of the study
- Both on-site staff & outsourced lab staff must be appropriately trained on labelling instructions as per relevant SSP
- Effective communication must occur between site & outsourced labs to avoid challenges like this



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