LAB BREAK-OUT SESSION:

LAB CHALLENGE : GRAM STAIN LABELLING

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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
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** - Mislabelled 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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