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MTN Lab Breakout Session
Background

- Early in 2016, the Wits RHI laboratory oversight group (LOG) embarked on an expansion initiative with the intention to build site capacity to conduct on-site testing for STIs.
- GeneXpert was identified as one of the technologies that would be relevant for set-up.
- An internal organizational inventory review lead to identification of 4 GeneXpert instruments in storage.
  - These were previously used for the TB program so no costs were incurred to purchase instruments.
- Cepheid - evaluated instruments and completed setup.
- Two adjacent clinical rooms were renovated to house the new equipment.
- Calibration and set up of 2 instruments were completed in June 2016.
Validation pathway

• Target Analytes:
  GC/CT, HIV Viral load, HPV and TV
• Thus far we have completed validation on
  - GC/CT (N=47)
  - HIV Viral Load (approved for MTN 025 testing).
• EQA - VQA for Viral load
  - CAP HC-7 Panel for GC/CT
Wits RHI GeneXpert Bench Team
Lessons learnt

• GC/CT: Sourcing validation samples was a challenge, we gained permission from the ECHO study to use residual sample.

• Very few positives this posed a challenge with the sample size.

• Sample size - 47 (10 GC positive, 22 CT positive).

• HIV Viral load – We acknowledge and are grateful for the assistance from the MTN Laboratory Centre with providing validation samples to complete this validation.

• Lab staff were all new to this technology, however with support and training from Cepheid we achieved competency.
Experience thus far

• Currently we are processing:
  - GC/CT: ≈ 60 Urine samples per month
  - HIV -1 Viral load: ≈ 20 samples per month

• CPU issue - The CPU required replacing. Issue was related to storage over a long period.

• We have had a few sample rejections for the VL assay (6 Invalid samples). Possibly due to poor pipetting.

• Outsourced lab experience: We had a number of our ECHO study GC/CT swab samples rejected on the BARC GeneXpert. BARC has indicated that this is related to mucoid vaginal swab samples. The ECHO study has requested repeating these samples on the Abbott.
## Wits RHI Studies

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*Note: Red Font - These studies are using the GeneXpert.*
Acknowledgment

• MTN LC for their continued support.
• ECHO Study for approving use of residual samples.
• Dr Thesla Palanee – Phillips
• WITS RHI laboratory team and Laboratory Oversight Group (LOG).
• BARC Laboratory.