



GC/CT testing with Cepheid GeneXpert

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Background for GC/CT testing for MTN

- 2004 ProbeTec was chosen for HPTN 035
 - Abbott LCX was being pulled from the market
 - Amplicor/Cobas was not FDA approved for female urine GC testing
 - ProbeTec had as good or better sensitivity compared to other NAAT on the market at that time
 - Becton Dickinson could provide service for instrument in Africa and India

New generation of NAAT in 2008

- Gen-Probe Aptima
- Abbott M2000
- ProbeTec Viper
- All three extract and purify the DNA
 - Less indeterminate results
 - Higher sensitivity
- All three are moderately complex to use
- None are FDA approved for rectal testing

Cepheid GeneXpert

- Instrument extracts, purifies, and amplifies the DNA from sample in a closed system.
- Designed for testing in remote locations if needed and to be easy to use and repair
- RT-PCR targets chromosomal DNA
 - 2 target for GC and 1 of CT
- Sample adequacy control
- GC/CT testing FDA approved 2012

Instrument range in size from 1 to 16 sample modules



Processing specimens

- Swab or urine in transport tube
 - Stable at 4°C for 60 days
- Add 300 µL of sample to cartridge
- Insert into instrument
- Results in 90 minutes

Comparison of GeneXpert to ProbeTec Viper & Gen-Probe

- Gados, 2012
 - 1722 female, vaginal and urine specimens
 - CT: 98.7% sensitivity, 99.4% specificity
 - GC: 100% sensitivity, 99.9% specificity

Comparison of GeneXpert and M2000 to Roche Amplicor

- Dize & Gaydos, 2013
- 300 eye swabs of children in Tanzania
- Tested for CT only
- Used Gen-Probe Aptima for confirmation
- M2000: 100% sensitivity, 98% specificity
- GeneXpert: 100% sensitivity, 100% specificity

Justification for using GeneXpert

- Comparable sensitivity and specificity to other NAAT
- Less chance for cross-contamination with closed system
- Very easy to use
- Takes up less space than other NAAT instruments
- Widely used in Africa for TB testing

Validation of the GeneXpert by MTN

- November 2013 MTN NL testing duplicate swabs from 500 men and women
 - Vaginal
 - Rectal
 - Pharyngeal
 - Urine
- Test with Gen-Probe and GeneXpert for GC/CT

Questions

- Do you have GeneXpert in your lab?
- What is it used to test and how often is it used?
- How many samples do you test for GC/CT with ProbeTec per week or month?
- Is there another instrument you would consider instead of GeneXpert ?