

# FIELD EVALUATION OF POINT OF CARE CEPHEID GENEXPERT HIV QUAL FOR EARLY INFANT DIAGNOSIS

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# Gaps in Current Early Infant Diagnosis Cascade

- Poor access to and delays in EID testing
  - 2014: 51% of 1.2 million HIV-exposed children in SSA had access to EID testing: limited testing capacity
  - First test at age 6 months or later (WHO recommends first test at 6 weeks)
- Delays or no return of test results
  - Median time of 21 days from sample collection to delivery of results
  - Only 50% of children who are tested receive their test results
- Poor initiation of HIV-positive infants on treatment
  - Kenya study: 44% of HIV- positive infants never reached ART clinic

# Study objective

- Evaluate performance of Cepheid Xpert HIV-1 Qual in Ndhiwa sub-County compared to standard of care platform - Roche Cobas® AmpliPrep/Cobas® TaqMan® HIV-1 Test (CAP/CTM) qualitative PCR
  - using dried blood spots.
  - Measure sensitivity, specificity, PPV and NPV

# Results

- 3814 mother/baby pairs were included in the study.
  - 968 babies HIV exposed
- 34 (3.5%) were concordantly HIV positive using both platforms
- 9 discordant results (0.9%) found and resolved after repeat run
  - Sample integrity
  - mislabeling and sample mix-up
- Overall machine error rate of 0.9%
  - power supply issue
  - Signal loss
  - Insufficient sample
- Overall sensitivity of 97.1% and a specificity of 100%
- Positive Predictive Value and Negative Predictive Value of 100% and 99.9% respectively
- SPC fail errors; 36

# Correspondence between Cepheid and Roche CAP/CTM qualitative PCR

	Reference assay (CAP/CTM)		
Xpert POC			
Positive	34	0	34
Negative	1	933	934
Sum (n=)	35	933	968
	Point estimate	Lower CI	Upper CI
Sensitivity	97.1%	85.1%	99.9%
Specificity	100.0%	99.6%	100.0%
Device errors	Total #	Rate	
	9	0.9%	

# Conclusion and recommendations

- The high specificity of Cepheid Genexpert is an important attribute for POC assays as it provides confidence for improving access, diagnosis and linkage to care of HIV-positive infants.
- Both platforms hold a place in the current EID set up and POC does not eliminate the need for the bigger platform
- Need to address ways of managing discordant results between POC and SOC platforms.
- Need for additional QA: Post scale-up EQA
- M and E plan that allows for linking data with the national EID network
  - security, ownership, storage and access

# Acknowledgement

- MSF Epicenter
- UNITAID – co-funding the study
- Ndhiwa community, study participants and research staff
- Ministry of Health – Ndhiwa sub-county and Homabay County
- KEMRI Kisumu HIV research staff