

Paediatric HIV Point of Care Testing: Field Evaluation of the Performance of Cepheid and Alere Qualitative HIV Assays in a Soweto Academic Hospital

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Method

- Study was conducted over ±6months at a tertiary hospital in Soweto, SA
- Inclusion criteria
 - 1) HIV-exposed neonates at high risk of HIV transmission
 - 2) Treatment-naïve (excluding prophylaxis) children ≤18 months old, where an HIV PCR test is indicated.
- Additional whole blood sampled – routine HIV PCR test
- Each specimen tested on 3 instruments and only the Roche result returned
 - 1) Standard of care NHLS HIV PCR qualitative assay – Roche CAP/CTM v2 (laboratory assay)
 - 2) Alere Q HIV-1/2 Detect POC technology (point of care assay)
 - 3) Cepheid GeneXpert HIV-1 Qual POC technology (point of care assay)

Results and Discussion

- From 01 December 2015 to 10 June 2016, 173 patients were enrolled
 - 127 neonates ≤ 7 days old
 - 46 children > 7 days and ≤ 18 months old

	NHLS	Alere POC	Cepheid POC
Positive	51	51	51
Negative	119	122	122
Indeterminate	2	0	0
Invalid result	1	0	0
Total	173	173	173

Results and Discussion

- Sensitivity = 0.9808 (95% CI: 0.8988 to 0.9966)
- Specificity = 0.9917 (95% CI: 0.9543 to 0.9985)
- Acceptable error rates have been observed for both POC technologies
 - Alere error rate = 5.46%
 - Cepheid error rate = 1.70%
- VL measured around the time of POC testing
 - ranged from 368 to $>1 \times 10^7$ copies/ml
 - Suggests adequate POC limits of detection

Conclusion

- EID POC testing performed well when operated by nurses outside of the laboratory environment.
- EID POC is an accurate alternative for HIV PCR testing in the field.
- The manner in which EID POC may be integrated into a busy hospital setting is yet to be determined.