## ABSTRACT

**Background:** As a consequence of a high maternal HIV prevalence, approximately 270,000 HIV exposed infants are born per annum, requiring interventions to prevent mother to child transmission of HIV. However, among infants who do become infected with HIV, the exposure to maternal and infant prophylactic antiretroviral regimens may lead to indeterminate and false-negative HIV PCR results. To address these challenges, inclusion of numerous assays within the national early infant diagnosis (EID) algorithm may need to be considered.

**Objectives:** The objective was to evaluate the diagnostic performance of the Hologic Aptima HIV-1 Quant Dx assay (Hologic Gen-Probe, Inc., San Diego, CA), in detecting HIV infection in neonates, and the GeneXpert HIV-1 Qualitative Assay (Cepheid, Sunnyvale, CA, USA) as a consecutive test in infants with an HIV-detected screening test.

**Methods:** Specimens were collected from HIV-exposed neonates for whom birth testing was performed using ethylenediaminetetraacetic acid whole blood samples at four tertiary sites in Gauteng between June 2014 to January 2020. The performance of the Aptima, compared with the Cobas® AmpliPrep/Cobas® TaqMan HIV-1 Qualitative Test v2.0 (CAP/CTM), and the performance of the Xpert EID, compared with HIV status on CAP/CTM follow-up testing, were determined as proportions with 95% confidence intervals.

**Results:** The Aptima assay had a sensitivity of 93.75% (95% CI: 79.19%-99.23%), specificity of 99.4% (95% CI: 97.83%-99.93%), positive predictive value (PPV) of 93.75% (95% CI: 78.98%-98.36%), negative predictive value (NPV) of 99.4% (95% CI: 97.73%-99.84%), and overall accuracy of 98.9% (95% CI: 97.2%-99.7%).

As a consecutive assay, the Xpert EID yielded a sensitivity of 96.5% (95% CI: 92.1%-98.9%), specificity of 100% (95% CI: 54.1%-100%), PPV of 100% (95% CI: 100%), NPV of 54.5% (95% CI: 33.7%-74.1%), and overall accuracy of 96.7% (95% CI: 92.4%-98.9%%).

**Conclusion:** The Aptima assay and the Xpert EID demonstrated good EID diagnostic performance. The Aptima assay can be used as an alternate assay within South Africa's National Health Laboratory Service. The Xpert EID can be used as a consecutive test for patients with an HIV-detected screening test, and will reduce diagnostic uncertainty and time to final result.