Abstract 16-1111

Laboratory Evaluation of the GeneXpert HIV-1 Quant Viral Load Assay in Zimbabwe

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BACKGROUND

- In most resource-limited countries with a high HIV burden, current HIV viral load (VL) quantification technologies are restricted to centralized laboratories.
- This poses logistical challenges with sample transport and results delivery.
- New, simplified VL measurement technologies such as GeneXpert HIV-1 Quant (Xpert) have a potential to decentralize VL testing, and to simplify antiretroviral treatment (ART) monitoring.
- Cepheid GeneXpert is a polyvalent platform suitable for use near point-of-care.
- The diagnostic accuracy Xpert HIV-1 Quant assay for VL quantification, was evaluated in the National Microbiology Reference Laboratory (NMRL) in Harare, Zimbabwe, using bioMérieux NucliSENS EasyMag/EasyQ v2.0 (NucliSENS) as the reference standard.



Figure 1: Cepheid GeneXpert system

METHODS

- The study was conducted from June to September 2015.
- Paired EDTA anticoagulated venous whole blood samples were collected from 375 patients aged ≥18years, and on ART for ≥3months.
- Samples were sent to (NMRL) Harare, Zimbabwe for testing.
- Paired plasma samples were tested for HIV-1 VL on NucliSENS and Xpert following the manufacturers' instructions and laboratory SOPs.
- The technicians who performed the Xpert VL test were blinded to the result of the reference test.



Figure 2: NucliSENS easyMAG system

RESULTS

- 375 patients participated in the study, of whom 221 (58.9%) were female. Their median age was 40 years, and median time on ART was 4 years and 4 months.
- The mean bias between the two methods was -0.22 $\log_{10}$ copies/ml (95% confidence interval [CI]: -0.29 to -1.52), with limits of agreement (LOA) of -1.11 to 0.66 $\log_{10}$ copies/ml (p = 0.125) (Figure 3).
- At a threshold of 1,000 copies/ml, Xpert had a sensitivity of 98.2% (95% CI: 93.8 to 99.8%), and specificity of 97.7% (95% CI: 95.1 to 99.2%) (Table).

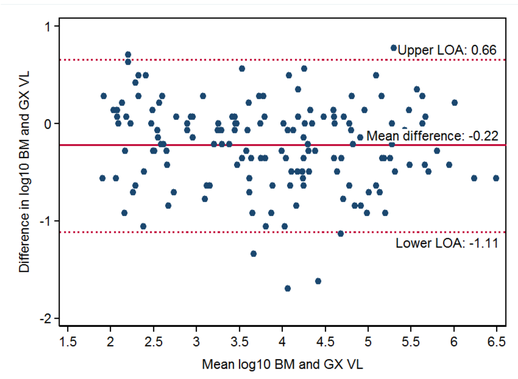


Figure 3: Bland-Altman plot comparing VL results measured on Xpert and NucliSENS

Table: Comparison of Xpert and NucliSENS VL results at a threshold of 1,000 copies/ml

bioMérieux NucliSENS v2.0	Xpert HIV-1 Quant ≥1,000 copies/ml	Xpert HIV-1 Quant <1,000 copies/ml	Total
≥1,000 copies/ml	110	2	112
<1,000 copies/ml	6	257	263
Total	116	259	375

CONCLUSIONS

- Xpert HIV-1 Quant is a promising test for decentralized VL testing in resource-limited settings.
- Further studies are needed to assess the feasibility and utility of using Xpert HIV-1 Quant for decentralized VL testing under conditions of intended use.
- Such studies should also assess the feasibility of using GeneXpert as a polyvalent platform for Xpert HIV-Quant, combined with other tests such as Xpert MTB/RIF and Xpert HIV-1 Qual.

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