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Independent Analytical Evaluation of the cobas® 5800 System for HIV-1 Quantitative and HIV-1/HIV-2 Qualitative Nucleic Acid Tests

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BACKGROUND

Roche Diagnostics recently announced that the COBAS® AmpliPrep/COBAS® TaqMan (CAP/CTM) system, widely used across low-and middle-income countries for HIV viral load (VL) and early infant diagnosis (EID) testing, will be phased out by early 2024 and will be replaced by the Roche cobas® 5800 System (c5800). The c5800 is a new low- to mid-throughput PCR based nucleic acid testing system which performs both HIV-1 Quantitative Nucleic Acid Testing for VL and HIV-1/HIV-2 Qualitative Testing for HIV EID. The combination of confirmatory HIV testing and differentiation of heterotypic (HIV-1/2) and homotypic (HIV-1 or HIV-2) infections into one single test will provide clinicians with critical diagnostic data for personalized management of patients with HIV. This is particularly important in West African countries where incidence of HIV-2 is high.

To confirm manufacturer's performance claims, an independent analytical evaluation of the c5800 System for HIV-1 VL using plasma and HIV-1/HIV-2 qualitative testing for EID using dried blood spots (DBS) was conducted.

METHODS

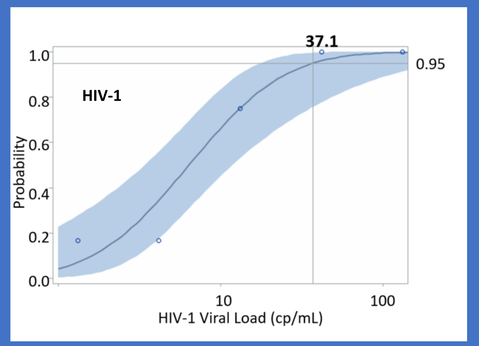
HIV-negative plasma or whole blood was spiked with either WHO 4th HIV-1 International Standard, 2nd HIV-2 International Standard, or cultured virus. Testing was performed using the HIV-1 Quantitative or HIV-1/HIV-2 Qualitative Nucleic Acid Test workflow. Analytical performances, including precision, linearity, subtype detection, and cross-contamination, were evaluated. For the qualitative assay, reproducibility, cross-contamination, and subtype coverage for HIV-1 A, B, C, D, CRF02-AG, and HIV-2 were determined. For both assays, the limit of detection (LOD) was calculated using PROBIT analysis, and error rates were assessed.

cobas® 5800 System

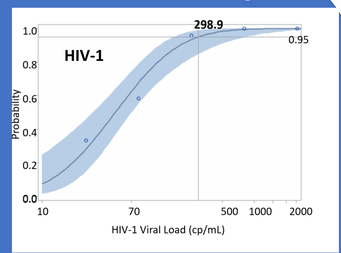
RESULTS

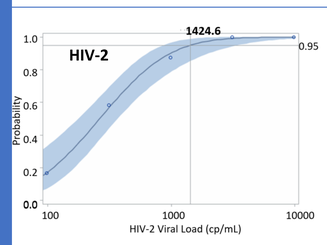
Limit of Detection

HIV-1 Quantitative Test for VL using Plasma*



Qualitative Test for using DBS*

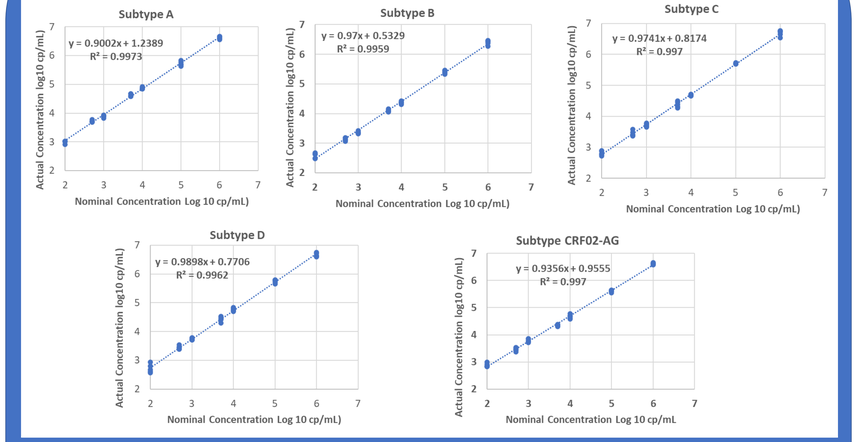




* Predicted Probabilities for Frequency with 95% Confidence Limits

The LOD for the HIV-1 Quantitative Test was 37.1 copies/mL, the LODs for HIV-1/HIV-2 Qualitative Test were 299 copies/mL and 1425 copies/mL for HIV-1 and HIV-2, respectively.

Linearity among five HIV-1 Subtypes



The correlation between the nominal and actual VL concentration of five subtypes was high with the R^2 correlation coefficients were all 0.996 or higher.

RESULTS (continued)

- **Reproducibility: 100% reproducibility was detected among HIV-1 plasma for VL and for HIV-1/HIV-2 DBS samples for EID over five days, by two separate testers using two different reagent lots.**
- **HIV Subtype Coverage: The five major HIV-1 subtypes evaluated were all detected.**
- **Cross-contamination: No cross-contamination was detected for either VL or EID workflows.**
- **Error Rate: 0% for HIV-1 Quantitative Test from 435 tests; 0.48% for the HIV-1/HIV-2 Qualitative Test from 415 tests.**

CONCLUSIONS

- **We report here the first independent evaluation for HIV-1 VL and HIV-1/HIV-2 EID testing workflows on the c5800 system.**
- **This evaluation verified the manufacturer's analytical performance claims for both assays.**
- **The c5800 combines the capacity to conduct HIV-1 VL and HIV infection with differentiation of HIV-1 and HIV-2, which will prove to be a useful tool in HIV diagnosis and treatment monitoring.**
- **Findings from this evaluation will be used to guide the implementation of the c5800 HIV VL and EID assay workflows in countries supported by the President's Emergency Plan for AIDS Relief (PEPFAR).**

ACKNOWLEDGMENTS

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