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Abstract (poster session)

The QIAGEN artus HIV-1 QS-RGQ viral load assay shows high concordance to the Abbott m2000rt HIV-1 viral load and the Roche CAP/CTM HIV-1 test v2.0 assay

M. Obermeier*, A. Moritz, U. Küsters, G. Wall, T. Berg (Berlin, Hilden, DE)

Objectives: Quantitative measurement of viral load is one of the major parameters for therapy monitoring in HIV infected patients. The newly available artus HIV-1 QS-RGQ viral load assay provides a complete workflow of sample preparation, PCR setup, amplification and detection as a CE-IVD compliant workflow, whilst remaining highly flexible. As all three platforms employ different target regions for the PCR amplification, with Abbott using Integrase, QIAGEN using LTR and Roche using LTR and gag regions, we analysed clinical routine samples with all three assays in parallel to test for concordance of results. As HIV-1 shows a high genetic diversity we also compared the viral load results from selected non-B-subtype samples between the Abbott and the QIAGEN assay. Material and methods: HIV-1 viral load was determined in 53 routine diagnostic samples using the artus HIV-1 QS-RGQ viral load assay, the Abbott m2000rt HIV-1 viral load assay and the Roche CAP/CTM HIV-1 test v 2.0 assay. All three assays were compared by linear regression analysis and Bland-Altman plotting. In addition to 19 non-B-subtype samples (5 subtype A, 3 C, 1 D, 1 F, 1 G, 1 CRF01_AE, 6 CRF02_AG, 1 CRF06_cpx) from clinical routine testing, 8 samples from the NIBSC panel were analysed with the QIAGEN and the Abbott assay. Results: Comparison of the QIAGEN assay against the Abbott assay showed a coefficient of determination (R^2) of 0.9 (QIAGEN vs. Roche also 0.9, Abbott vs. Roche also 0.9). Analysis of Bland-Altman plots showed a slight tendency for higher quantification of $0.2 \log_{10} \text{ c/ml}$ by the QIAGEN and the Roche assays compared to the Abbott assay, while no such difference could be seen between the QIAGEN and the Roche assays. The high coefficient of determination (R^2) of 0.9 between the QIAGEN assay and Abbott assay could also be confirmed for the non-B subtype samples. Conclusions: All three assays showed a high concordance of results, which could also be confirmed for non-B-subtype virus for the QIAGEN and the Abbott assay. Although different target regions are used for HIV-1 quantification, standardisation of the assays to the WHO standard material by the manufacturers allows for interchanging these assays in routine diagnostics. The QIAGEN and the Roche assay show a trend for higher quantification compared to the Abbott assay. As the average of the results are only slightly higher there is no risk for falsely classifying these differences as significantly relevant for the patients.