

# Comparison of the new Cepheid HIV VL XC Assay with the established Abbott Alinity m in HIV-1 viral load measurement

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## Background

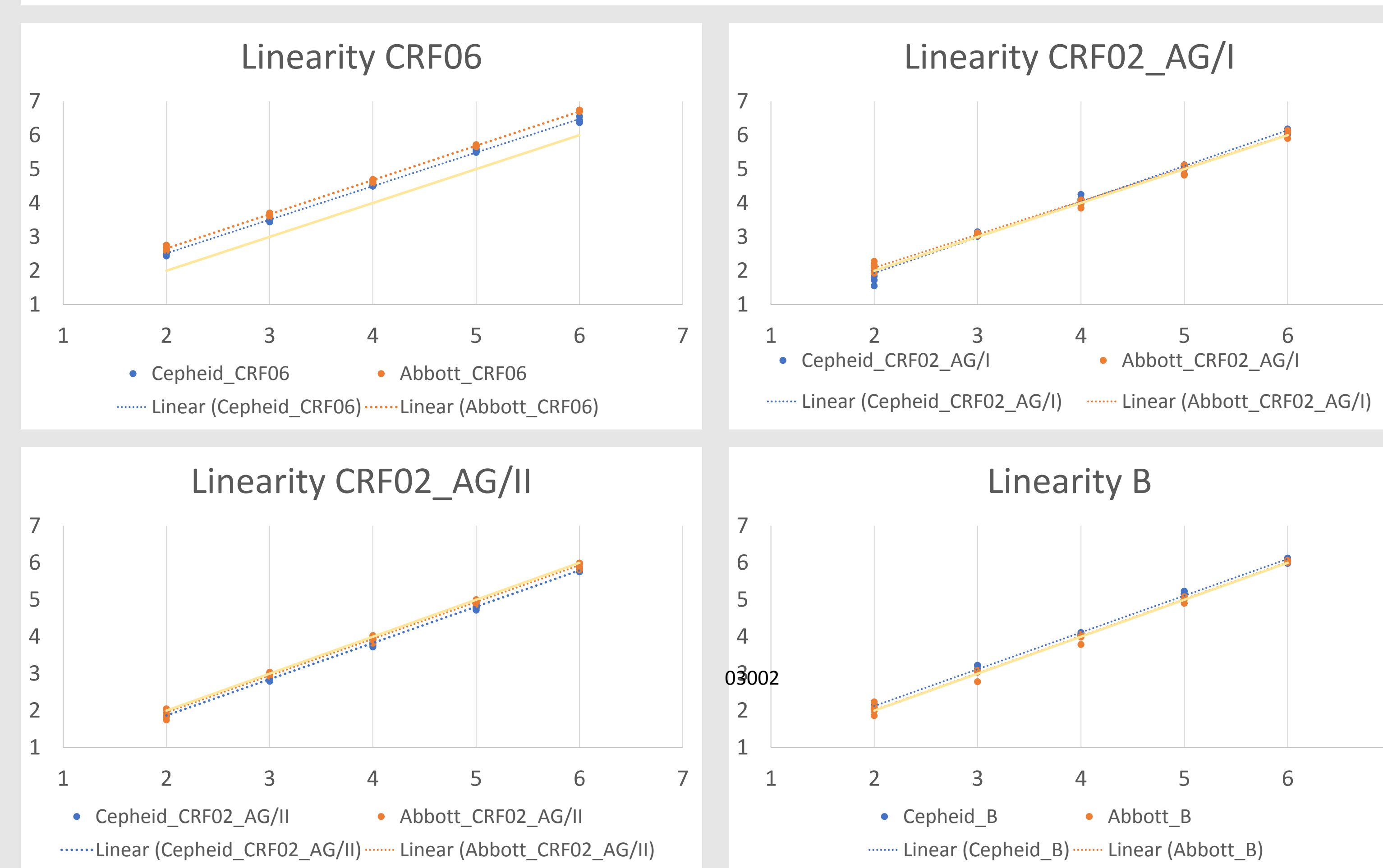
Xpert® HIV-1 Viral Load XC (HIV VL XC) test is a next generation assay to the current Xpert® HIV-1 Viral Load assay that uses a dual target approach to minimize the risk of under-quantification from rare mutations in primer probe binding regions. It is the same cartridge format on the GeneXpert® system. The manufacturer claims a lower limit of quantification (LLOQ) of 40 cps/mL and a lower limit of detection (LLOD) of 20 cps/mL.

A comparison with the Abbott Alinity m HIV-1 assay was performed, focusing on linearity, variation at the low-end, non-B subtypes, and integrase-inhibitor resistant samples.

## Methods

Fresh (n=164), frozen (mixed subtypes, n=99; with integrase resistance associated mutations (INI RAMS, n=20) and diluted (n=250) patient samples over the clinically relevant range of viral loads were tested. For linearity comparison we optimized two linear models minimizing the residual sum of squares (RSS) for each set of log-scaled viral loads. Three samples with known under-quantification in the Xpert® HIV-1 Viral Load test were retested with the new HIV VL XC cartridges.

Fig. 3: Linearity with different subtypes



## Results

Xpert® HIV Viral Load XC assay showed excellent performance in routine use even in samples with low viremia and integrase region mutations. The Cepheid assay reached a comparable specificity and sensitivity as the Abbott assay in 80 preselected (Alinity) fresh samples that were undetectable or below 50 cps/mL (Tab.1). Correlation and Bland Altman plot (Fig.1+2) showed high concordance for fresh and archived samples including 86/99 non-B subtypes. The mean difference was below 0.1 log cps/mL (95% confidence interval = +/- 0.45 log cps/mL). Good linearity was shown by serial dilution (subtype B, CRF06\_cpx and two CRF02\_AG) from 6 log cps/mL to 2 log cps/mL (Fig.3). Mutations associated with resistance in the integrase were not found to impact results (Fig.4). The samples with known under-quantification in the Xpert® HIV-1 Viral Load assay now showed only a small difference to the Alinity m assay of +/-0.15 log cps/mL with the new HIV Viral Load XC assay (Tab.2).

Tab. 1: Preselected at low end of quantification

Cepheid HIV VL XC Assay	Abbott Alinity m HIV-1 Assay	
	not detected	20-50 cps/mL
not detected	27	2
<40 cps/mL	12	29
quantificated	1*	9**
sum	40	40

\*82 cps/mL \*\* 42-84 cps/mL

## Conclusions

The HIV-1 Viral Load XC test showed excellent correlation with Alinity m with high sensitivity, linearity and accuracy in the therapeutic relevant range for all tested HIV-1 subtypes. With a time to result of only 90 minutes this test is a safe, reliable and fast option for viral load monitoring and diagnosis of HIV-1 infection.

Tab. 2: Samples with known underquantification [cps/mL]

Sample-ID	Xpert® HIV-1 Viral Load	Alinity m	Xpert® HIV-1 Viral Load XC
19440134702	not detected	140.000	105.000
19450606902	not detected	121.000	168.000
19451321902	not detected	n.d.	228.000

Fig. 1: Correlation fresh samples

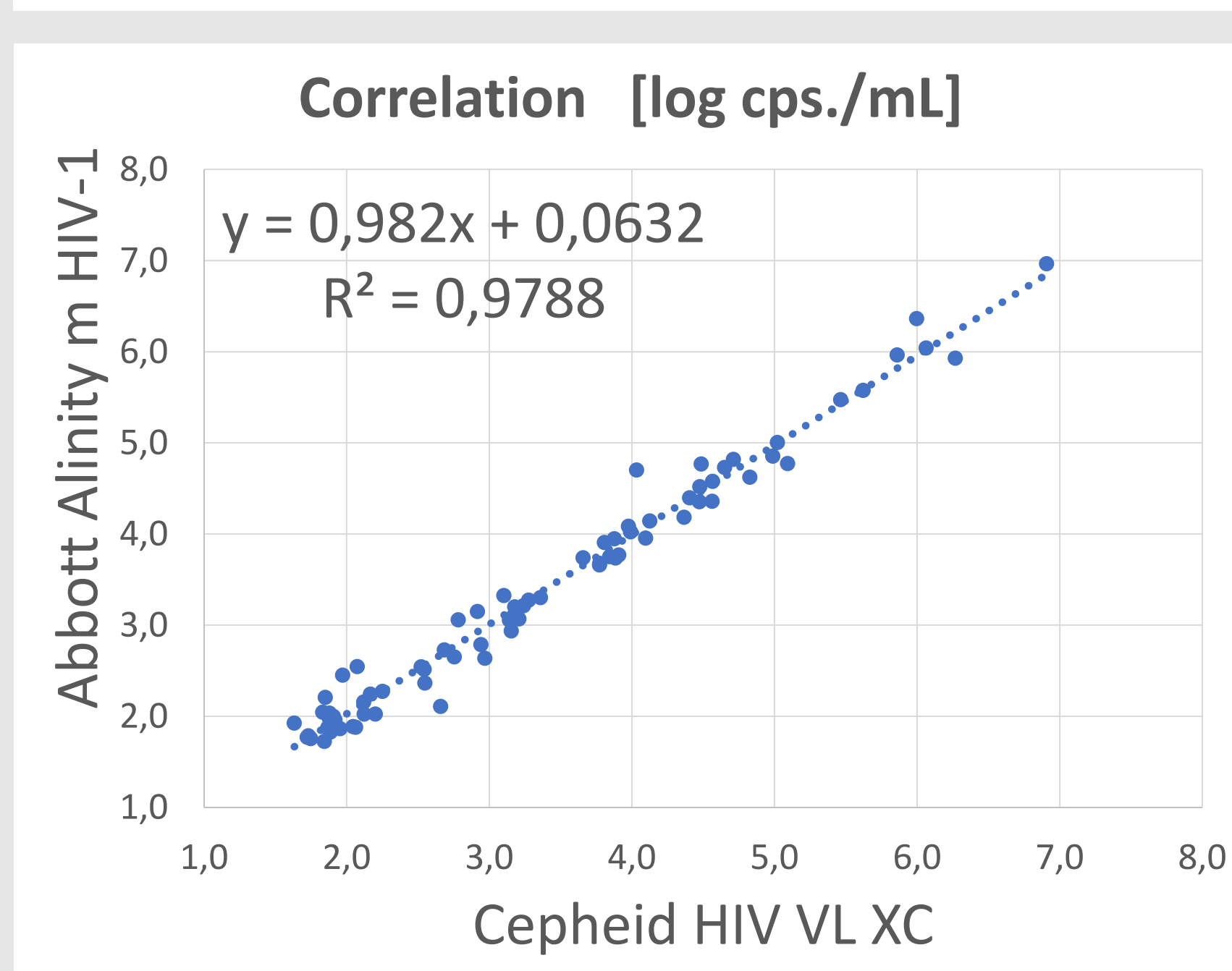


Fig. 2: Bland-Altman plot

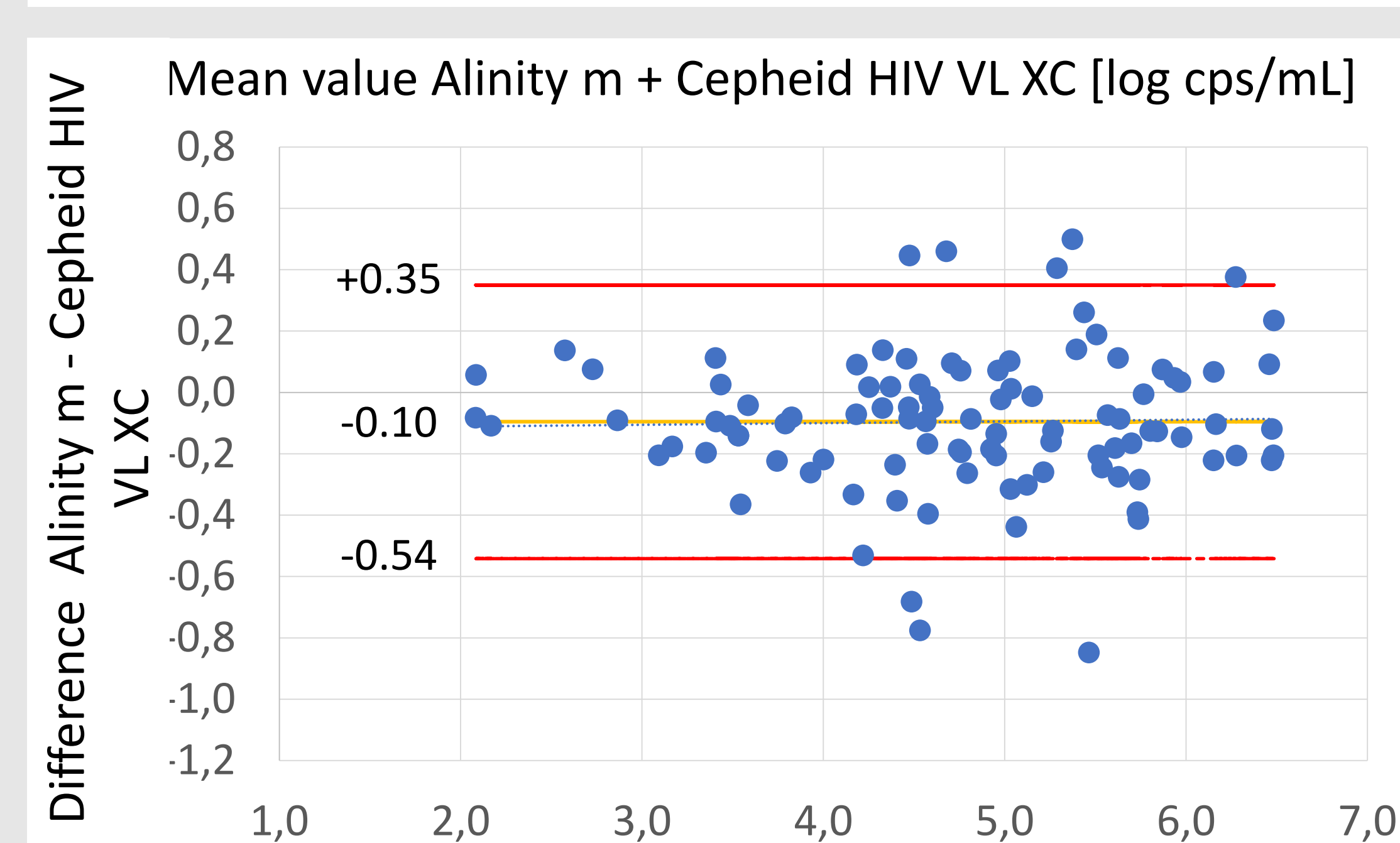


Fig. 4: Viral load in samples with INI RAMS

