The newly developed NeuMoDx HIV-1 Quant Assay compared to the established Alinity m HIV-1 Assay for routine viral load measurement

P0035

Robert Ehret, E. Ahmed, S. Breuer, Martin Obermeier
Medical Center for Infectious Diseases (MIB), Berlin
Contact: ehret@mvz-mib.de

AIM

HIV-1 viral load measurement is an integral part of HIV-1 clinical management. We compared the clinical and analytical performance of the newly launched NeuMoDx HIV-1 Quant Assay (QIAGEN) with the Alinity m HIV-1 assay (Abbott) with special focus on the use of fresh clinical samples, diversity of subtypes and sensitivity of the assay. Because HIV integrase is a target of increasing importance in the treatment of infection and also one target of quantification lays within the integrase, samples that deviate in integrase from the consensus B wild type are also of particular interest.

METHODS

Fresh daily clinical routine samples (n=500) were tested first with the test of record (TOR Alinity m HIV-1) and immediately retested without any freeze-thaw cycles within 24h on the NeuMoDx system. HIV-1 subtypes were documented where available. A dilution series of the 4th WHO HIV-1 standard (replicates of 10 per level) was generated to confirm the 95% probit hit-rate based limit of detection. In addition, 25 frozen archived samples with a particularly large number of mutations in the integrase region (9 to 31 amino acid changes, both resistance-relevant and not relevant) were tested in order to document a possible bias due to non-matching primers/probes in the integrase gene (both assays target this gene). Discordant testing was performed with the Hologic Aptima assay.

RESULTS

Of 293 fresh samples below the quantification limit of 1.5 log IU/mL with the TOR, 9 samples showed a quantifiable result between 38 and 330 IU/mL (29-248 cop/mL) with NeuMoDx, with the remaining 284 samples confirmed with NeuMoDx. One of the nine samples had a “detected” result in the TOR, in two of five others retested samples with enough residual volumes the Aptima results showed also a “detected” and three samples were resulting in “not detected”. 200 RNA positive samples (126 samples with known subtype, 49 with a non-B subtype, viral load range from 1.8 to 7.2 log IU/mL) tested with both systems demonstrated in a linear regression model a slope of 0.86, intercept of 0.34 and a coefficient of determination (R^2) of 0.92. The Bland-Altman Plot resulted in a mean bias of 0.14 log IU/mL. Both analyses show a trend to a minor higher quantification of the NeuMoDx in the lower range around 2 log IU/mL and a minor lower quantification of the NeuMoDx above 4 log IU/mL. All tested subtypes showed good performance and no bias was detected in samples with high rates of integrase mutations. The 95% hit-rate of the NeuMoDx was calculated to be 53 IU/mL or 40 cop./mL (NeuMoDx conversion factor 0.75 copies/IU).

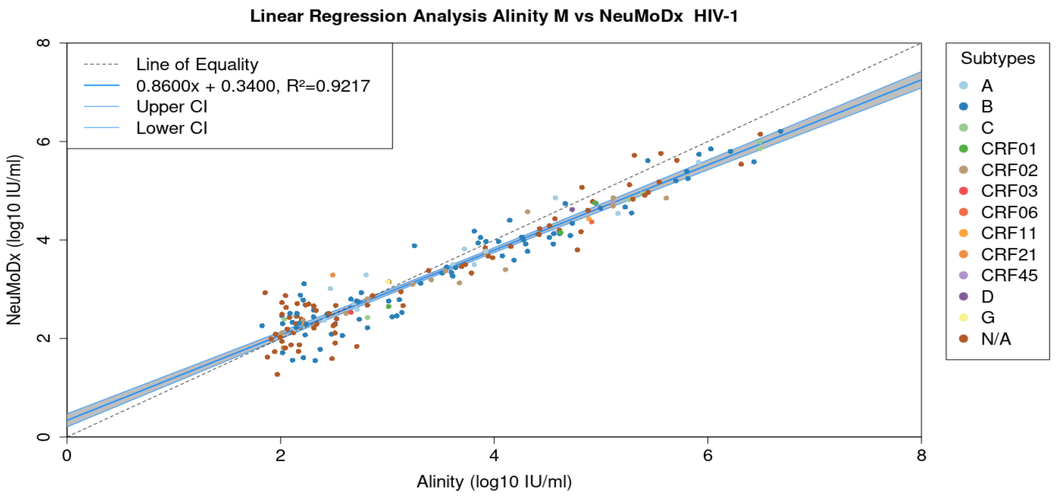

Fig. 1: Deming regression of HIV log IU/mL Alinity M vs. NeuMoDx

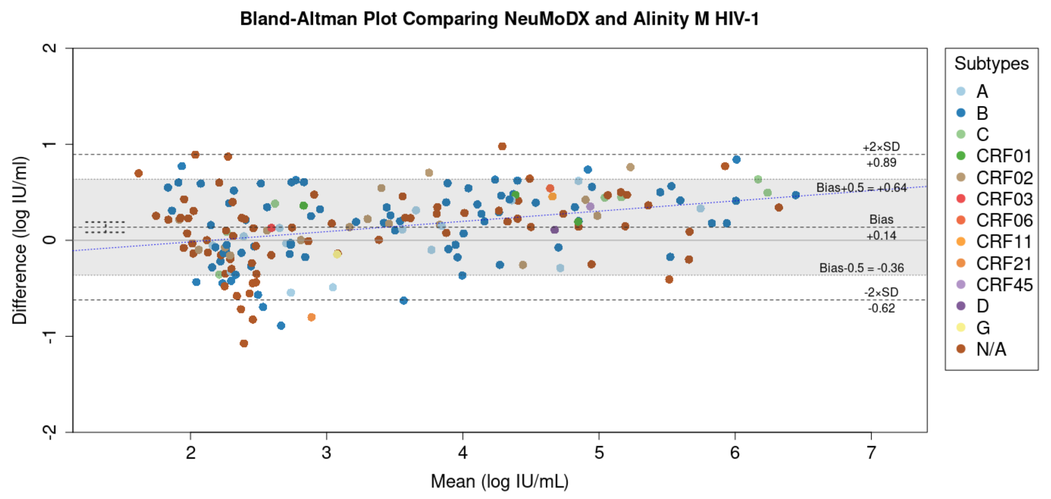

Fig. 2: Bland-Altman Plot of HIV log IU/mL Alinity M vs. NeuMoDx

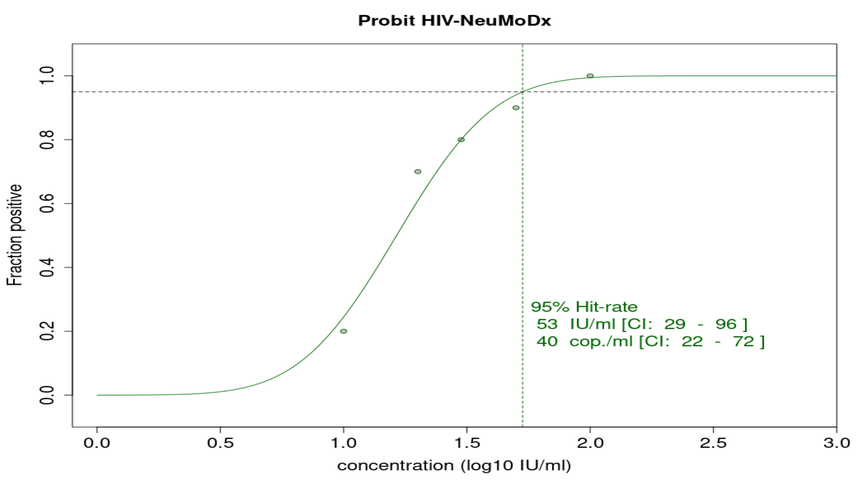

Fig. 3: 95% hitrate in Probit analysis for the NeuMoDx HIV Quant Assay

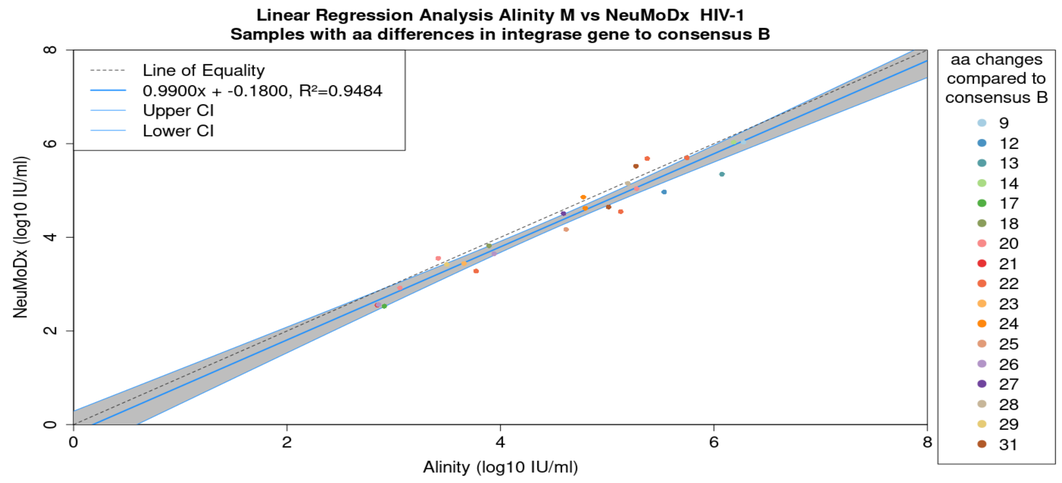

Fig. 4: Deming regression of samples with known aa differences to consensus B in the Integrase gene, log IU/mL Alinity M vs. NeuMoDx

CONCLUSIONS

A high correlation between the NeuMoDx HIV-1 Quant Assay and the Alinity m HIV-1 assay was demonstrated. A minor higher quantification of the NeuMoDx assay in the low range was observed, which should not impact patient management. Variation in this low range is always higher than in the upper range. The performance showed no irregularities in any tested subtype and no weaknesses in samples with highly mutated integrases. The true random access capability of the NeuMoDx platform is valuable tool in clinical routine.

Acknowledgements
The study was funded by QIAGEN.

Medical Center for Infectious Diseases,

34th ECCMID
Barcelona, Spain
27 – 30 April 2024
The congress of ESCMID