Performance evaluation of cobas® HIV-1 for high throughput HIV viral load testing

Abstract

Objective: High viral load testing is recommended for all patients on antiretroviral treatment. As viral load monitoring continues to become widespread, highly sensitive and specific HIV viral load tests that support high throughput testing are needed to evaluate the performance characteristics of the new assays. We aimed to bring high throughput viral load monitoring with a lower sample volume and excellent precision.

Methods: The performance of the cobas® HIV-1 test was evaluated for limit of detection (LOD), precision, accuracy, sensitivity, specificity, comparability with the COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 assay, and potential interfering substances, and primary tube equivalency.

Results: The LOD of the assay was demonstrated at 20 copies/mL. A linearity panel with concentrations spanning the linear range of both assays and comprising a mix of subtypes (Figure 2). A coefficient of variation of approximately 50% to 1.00E+07 copies/mL. The standard deviation of log_{10} titers was within 0.17 log_{10} titers of positive HIV-1 RNA, and positive results were obtained on all samples with HIV-1 RNA. Positive results were obtained on all samples with HIV-1 RNA. Mean log_{10} titers of positive HIV-1 RNA were all within ±0.17 log_{10} titers of the mean log_{10} titers of calibrator controls with the same amount of HIV-1 RNA but no known potential interferents.

Background

The World Health Organization recommends treatment and viral load monitoring for all patients with HIV.

Unstated has released new target for 2020, where 90% of people living with HIV are diagnosed, 90% of those diagnosed with HIV are on antiretroviral treatment, and 90% of those on treatment have suppressed viral loads.

Viral testing is a critical step in the diagnosis and management of HIV.

Conclusion: The cobas® HIV-1 assay is highly sensitive and specific for viral load monitoring. It is a critical step in the diagnosis and management of HIV.

Sensitivity

Repetitive collected plasma samples from 360 HIV-1 infected patients with detectable HIV-1 RNA on TaqMan® HIV-1 testing were tested using two cobas® HIV-1 tests. A valid quantitative result was obtained in 265 of the 360 samples, resulting in a sensitivity of 73.8%. An additional validation study was performed to assess sensitivity on clinical samples at an external site. Remains of HCV-positive samples from HIV-1 patients with detectable HIV-1 RNA were tested, and positive results were obtained on all samples, resulting in a sensitivity of 100% (22.0 IU/mL).

Specificity

Six hundred HIV-negative plasma samples from individual donors were also tested using two cobas® HIV-1 tests. All samples tested negative for HIV-1 RNA, resulting in a diagnostic specificity of 100%.

Precision analysis of cobas® HIV-1 was performed using 48 replicates per concentration level across three reagent lots. The standard deviation of log_{10} titers of positive HIV-1 RNA was all within ±0.17 log_{10} titers of the mean log_{10} titers of calibrator controls with the same amount of HIV-1 RNA but no known potential interferents.

Conclusions

The cobas® HIV-1 assay is highly sensitive and specific for viral load monitoring. It is a critical step in the diagnosis and management of HIV.

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