Poster No. 165

Performance evaluation of the novel AltoStar® HIV RT-PCR Kit 1.5 on the fully automated AltoStar® Automation System AM 16 platform

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Background

Low HIV-1 viral loads represent clinically relevant values for virologic monitoring of HIV-infected patients receiving ART, because they may dictate a need for antiretroviral regimen changes due to an early appreciation of therapy failure. It is accepted that an increase of HIV-1 RNA viral load from a suppressed condition may predict virologic failure, with a gradation of rebound risk that directly correlates with the degree of viremia.
Therefore, monitoring is recommended by current guidelines to determine the efficacy of treatment. The goal of therapy is to reach a sustained virologic response, which is defined as “undetectable” HIV RNA plasma concentration using a sensitive HIV RNA quantitation assay with a lower limit of quantification of ≤ 50 copies/ml.
The AltoStar® HIV RT-PCR Kit 1.5 is a novel assay, which recently received CE-IVD mark and fulfills this requirement.

Objectives

AltoStar® HIV RT-PCR Kit 1.5 performance evaluation on the AltoStar® Automation System AM16.

Materials and methods

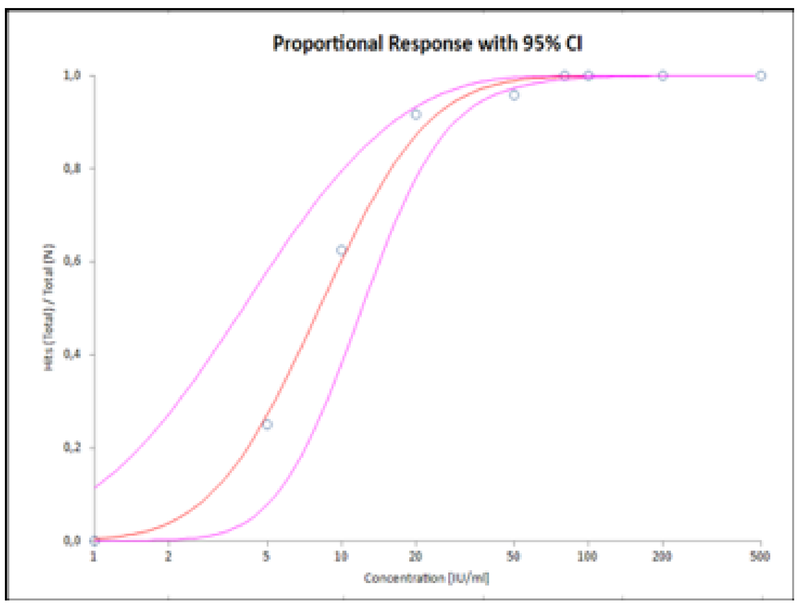
We used the 4th International Standard for HIV-1 RNA (16/164) provided by the National Institute for Biological Standards and Controls (NIBSC) to determine the limit of detection (LoD). For testing relevant HIV-1 subtypes and their respective LoDs the 2nd WHO International Reference Panel Preparation for HIV-1 Subtypes for NAT (Main, NIBSC) and the HIV-1 Subtypes panel provided by the University of Erlangen were used.

The diagnostic performance of the AltoStar® Automation System was compared to the cobas® HIV-1 assay on the cobas® 6800 system (both Roche). In total, 238 samples from HIV-1 infected patients were analyzed. We assessed diagnostic sensitivity and specificity and compared quantitative results by linear regression analysis and Bland-Altman Plot.

Results

The LoD of the AltoStar® Workflow for the detection of HIV-1 in EDTA plasma was 30 IU/ml compared to 13 copies/ml [≙ 21.7 IU/ml*] claimed by Roche.
The analytical specificity was 100% as assessed on 100 HIV-1 RNA negative samples.
The diagnostic sensitivity and specificity of the AltoStar® assay was 96% and 99%, respectively.
There was very good correlation between quantitative results obtained with the AltoStar® Workflow and the cobas® 6800 system (correlation coefficient R = 0.97 (R^2 = 0.95).

* The conversion factor of the cobas® HIV-1 is 0.6 copies / 1 IU (International Unit).



Limit of Detection: The LoD was determined by testing serial dilutions of WHO International Standard for HIV (NIBSC) prepared in HIV negative human EDTA plasma. Probit analysis of the data was used to determine the concentration detected with 95% probability. The limit of detection is 30.0 IU/ml (95% confidence interval 21.3 to 54.3 IU/ml).

The LoD for all other genotypes was verified by testing at least 20 replicates of the LoD value following CLSI Guideline EP-17A “Protocols for the Determination of Limits of Detection and Limits of Quantitation”.

4×4 Table: Comparison of qualitative results for all valid samples included in the analysis.

Total number of samples: 238		cobas® HIV-1 test	
		POSITIVE	NEGATIVE
AltoStar® HIV RT-PCR Kit 1.5	POSITIVE	140	1
	NEGATIVE	6	91

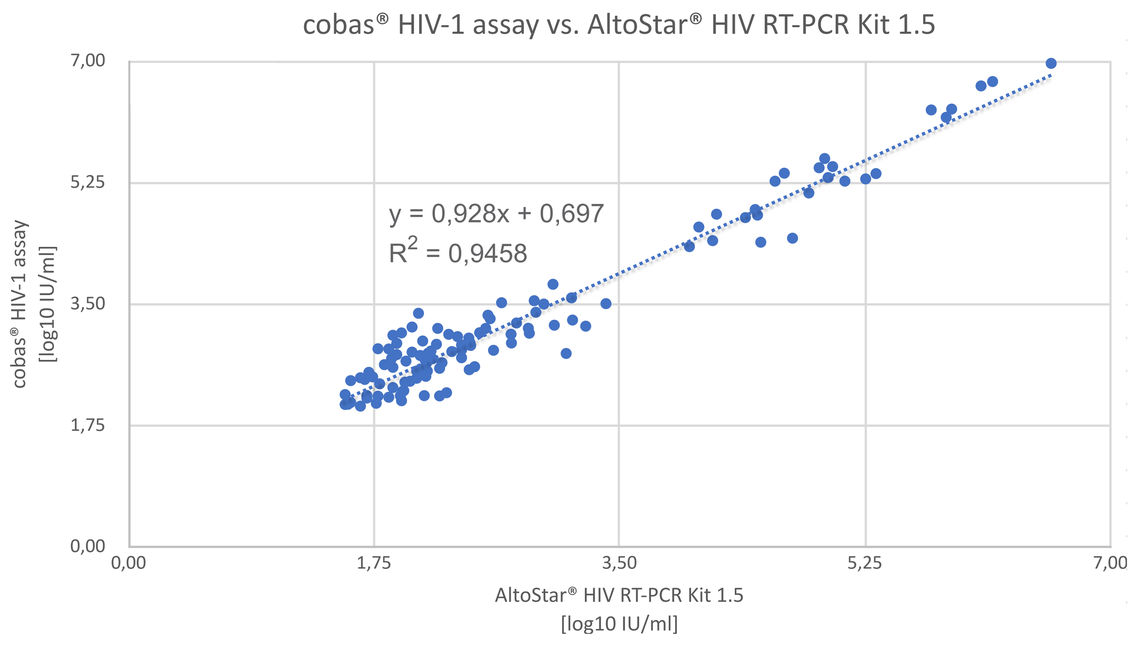


Figure 1: Linear regression of the quantitative results for HIV-1 obtained with cobas® HIV-1 test (reference) and the AltoStar® HIV RT-PCR Kit 1.5.

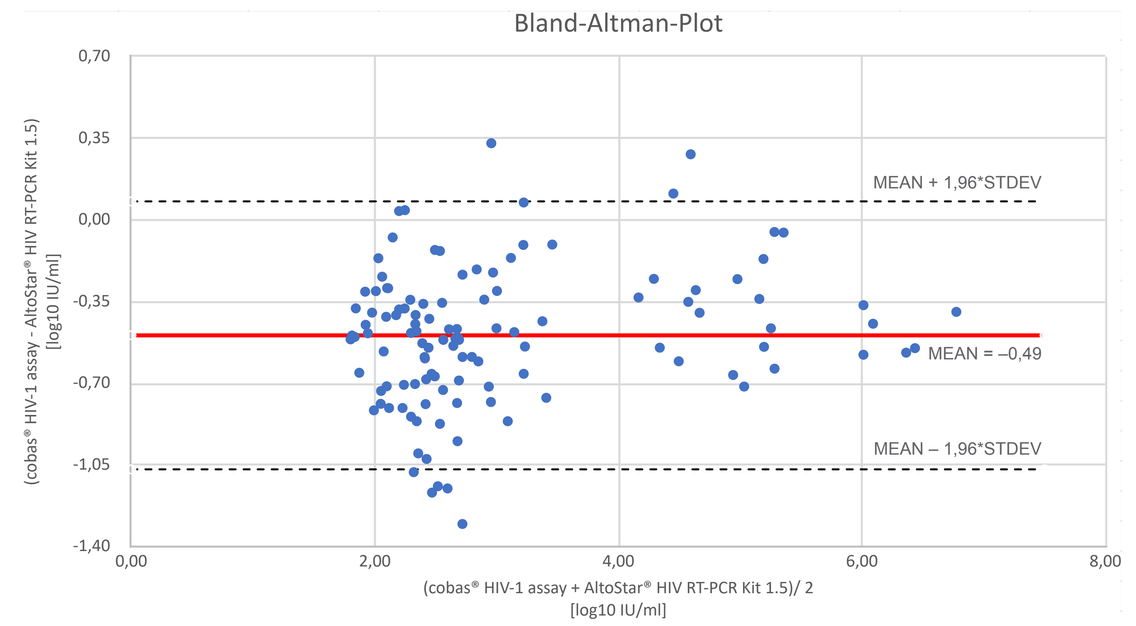


Figure 2: Bland-Altman Plot for comparison of mean differences of quantitative results generated with the cobas® HIV-1 test (reference) and the AltoStar® HIV RT-PCR Kit 1.5.

Conclusions

The AltoStar® HIV RT-PCR Kit 1.5 in combination with the AltoStar®Automation System AM16 demonstrated an analytical and diagnostic performance comparable to that of a currently market-leading HIV-1 assay. It may aid in clinical decision making of HIV-1 infected patients.

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[1] Amendola *et al.*; J Clin Microbiol. 2014 Jun; 52(6): 2019–2026.

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