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Increased frequency of viral loads above 100,000 HIV-1 RNA copies/ml measured by Roche Cobas TaqMan assay in comparison with Cobas Amplicor assay

The International AIDS Society-USA Antiretroviral Guidelines Panel raised concerns over results of several evaluation studies that consistently reported increased frequency of detectable plasma viremia by fully automated TaqMan HIV-1 RNA quantification assay version 1 (TaqMan v1, Roche Molecular Systems, Inc,Branchburg, NJ USA) in a substational proportion of treated patients who were previously considered complete virological responders based on undetectable plasma viremia measured by the standard Roche Amplicor assay (detection range for TaqMan v1 between 40-10 000 000 copies/ml, and for the Amplicor assay between 50-100 000 copies/ml for the ultrasensitive method and between 400-1 000 000 for standard method)([1]). In addition to being a surrogate marker for response to antiretroviral therapy (ART), viral load may be taken into consideration when deciding on possible treatment initiation in patients with > 350 CD4+ T-cells ([2,3]). The current International AIDS Society-USA and European AIDS Society (EACS) antiretroviral guidelines state that a viral load greater than 5.0 log10 HIV-1 RNA copies/ml should serve as an indicator that favors early treatment initiation, for patients with <350 CD4+ T-cells ([4,5]). A second version of the TaqMan assay (COBAS AmpliPrep/COBAS TaqMan HIV-1 Test v2.0) became commercially available in 2009. The aim of this study was to compare HIV-1 viral loads obtained by TaqMan assay v2.0 (quantification over the range of 20-10 000 000 copies/ml) and

standard Amplicor assay in 44 newly-diagnosed HIV-1 infected persons (39 patients:genotype B, 3 patients:genotype A, 2 patients:genotype C), with detectable viral load (>50 copies/ml of plasma) that entered clinical care at the national Reference center for HIV/AIDS in the period 2006-2008. SAS version 9.1 software was used for statistical analysis, and the degree of agreement between two techniques was represented by Bland and Altman curves. A range of agreement was defined as mean bias ±2 SD. Median values (range) were 4.68 (3.27-5.91) and 4.91 (3.67-6.90) $\log_{10}$ HIV-1 RNA copies/ml for the Amplicor and TaqMan assays, respectively. The plot of identity of Taqman v2.0 and Amplicor assays viral load measurements indicated that Taqman v2.0 assay measurements are generally higher than Amplicor assay measurements. The Bland-Altman plot indicated that the 95% limits of agreement between the two methods were asymmetrical and ranged from -1.39 to 0.69. The two methods do not consistently provide similar measures because there is a level of disagreement that includes discrepancies that can be clinically relevant of up to 1.72 log copies of HIV RNA per milliliter. The highest discordance in the two methods was obtained for genotype C samples (1.18 and 1.72 $\log_{10}$ copies of HIV-1 RNA higher values obtained by TaqMan v2.0 assay compared with Amplicor). The number of patients with a viral load >5 log10 HIV-1 RNA copies/ml was higher when using the TaqMan v2.0 assay (45%, 20 of 44 patients) compared with Amplicor assay (30%, 13 of 44 patients). In conclusion, TaqMan assay v2.0 provides consistently higher values of plasma viremia in newly-diagnosed patients (majority with genotype B) at entrance to care compared with standard Amplicor assay. Clinical implications and long-term prognostic significance of higher plasma viremia (particularly above

5.0 log10 HIV-1 RNA copies/ml) reported by TaqMan assay v2.0 in patients entering care should be carefully evaluated in the future.

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Figure 1. Bland-Altman plot for agreement between Cobas TaqMan and Cobas Amplicor assays for HIV-1 RNA quantification