

## Comparison of Ultra Sensitive Amplicor HIV-1 Monitor Test, NucliSens HIV-1 QT and HIV-1 RNA bDNA Technologies for Quantitation of Plasma HIV-1 RNA in HIV-1 Infected Individuals

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| <i>Abstract Category:</i> | Laboratory-based Confirmatory Algorithms Using Supplemental Western Blot, Indirect Immunofluorescence, or Nucleic Acid Amplification Tests |
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### OBJECTIVE

Quantitation of viral load is an important part of prognosis and effective clinical management of HIV-1 infected individuals. Introduction of new antiretroviral drugs, improved treatment regimens and increase in access to diagnostic services has led to an increase in life span of HIV-1 infected individuals worldwide. Currently various methods are available for measurement of HIV-1 RNA levels with sensitivity limits ranging from 25 to 400 copies per ml and there are various ongoing studies that are evaluating the clinical significance of viral load levels in this range. In the current study, we compared 3 methods of HIV-1 RNA quantitation, Ultra sensitive Amplicor HIV-1 monitor Test (v1.5, Roche), NucliSens HIV-1 QT (bioMerieux) and Versant HIV-1 RNA bDNA assay (v3.0, Siemens) in parallel from plasma specimens of 72 HIV-1 infected individuals.

### METHODS

Whole blood EDTA specimens from 72 HIV-1 infected individuals were submitted to the Laboratory for Clinical and Biological Studies, University of Miami, FL for routine quantitation of plasma HIV-1 RNA. Quantitation of plasma HIV-1 RNA was performed in parallel using the three technologies according to protocols provided by the manufacturers. All the statistical evaluations were carried out using the SPSS software (v 14.0).

### RESULTS

Among 72 plasma specimens, HIV-1 RNA was detected in 40 each by Amplicor and bDNA (sensitivity, 56%) and 44 by NucliSens (sensitivity, 60%). As expected, HIV-1 RNA levels obtained from all the three methods had a highly significant positive correlation (Pearson Correlation,  $P < 0.001$ ). However, on comparing the technologies on one to one basis we observed that HIV-1 RNA levels obtained with Amplicor and bDNA had higher linear association ( $r = 0.995$ ) versus Amplicor and NucliSens ( $r = 0.967$ ) or NucliSens and bDNA ( $r = 0.975$ ). Comparison of mean HIV-1 RNA levels obtained using the three methods showed no significant difference (One way ANOVA,  $P = 0.488$ ).

### CONCLUSIONS

Viral load measurement at low copy numbers is subject to constraints imposed by the inherent variability of the assay technology. Our results show that three technologies produce concordant results in terms of sensitivity and Amplicor and bDNA show excellent agreement with each other in quantitation of HIV-1 RNA.