## Abstract:

Accurate and sensitive quantification of human immunodeficiency virus type 1 (HIV-1) RNA has been invaluable as a marker for disease prognosis and for clinical monitoring of HIV-1 disease. The first generation of commercially available HIV-1 RNA tests were optimized to detect the predominant HIV-1 subtype found in North America and Europe, subtype B. However, these tests are frequently suboptimal in detecting HIV-1 genetic forms or subtypes found in other parts of the world. The goal of the present study was to evaluate the performance of a new viral load assay with non-subtype B viruses. A transcription-mediated amplification method for detection and quantitation of diverse HIV-1 subtypes, called the Gen-Probe HIV-1 viral load assay, is under development. In this study we examined the performance of the Gen-Probe HIV-1 viral load assay relative to that of the commonly used commercial HIV-1 RNA assays using a panel of primary isolates from Kenya. For comparison, we included several subtype B cloned viruses, and we quantified each virus using an in-house quantitative-competitive reverse transcriptase PCR (QC-RT-PCR) method and gag(p24) antigen capture. The Gen-Probe HIV-1 viral load assay and a version of the Roche AMPLICOR HIV-1 MONITOR test (version 1.5) that was designed to detect a broader range of subtypes were both sensitive for the quantification of Kenyan primary isolates, which represented subtype A, C, and D viruses. The Gen-Probe HIV-1 viral load assay was more sensitive for the majority of viruses than the Roche AMPLICOR HIV-1 MONITOR test version 1.0, the Bayer Quantiplex HIV RNA 3.0 assay, or a QC-RT-PCR method in use in our laboratory, suggesting that it provides a useful method for quantifying HIV-1 RNAs from diverse parts of the world, including Africa.