Materials and Methods:

Replicates of diluted clinical samples. We have also assessed the concordance of the TaqMan and Versant assays in HBeAg interchangeably. The introduction of the World Health Organization (WHO) international standard for HBV DNA (97/746) (8) sample were processed.

2.40% at 5.62 and 4.16 log HBV DNA copies/mL, respectively. Between-run percent CV ranged from 0.35% to 1.46%

Clinical Correlation:

The relationship of the Versant assay to expected concentration of serially diluted high-titer samples was: log

Accuracy

Correlation Studies

Precision

Conclusions:

The Versant and TaqMan assays perform linearly with respect to the WHO international standard for HBV DNA (97/746) and are highly correlated between methods.

The Versant assay is linear from 2,000 to 100,000,000 HBV DNA copies/mL. The TaqMan assay appears to be more sensitive than the Versant assay and has a greater AMR.

The Versant assay displays excellent within and between run precision.

Correlation studies demonstrated significant non-agreement between the MDNA and TaqMan assays.

Variation between samples tested in TaqMan and Versant indicate that the same assay should be used to monitor patients being considered for or undergoing therapy for HBV infection.