Abstract:

The diagnostic performance characteristics of the Versant HBV DNA 3.0 Assay (TaqMan) were compared to the COBAS TaqMan Analyte Specific Reagent (ASR) and COBAS HBV TaqMan ASR (TaqMan) assays. We have evaluated the linearity and precision of the Versant assay using WHO reference material. The relationship of the Versant assay to expected concentration of serially diluted high-titer samples was: log \( y = 0.836, \) \( \text{SEE} = 0.644 \). Slope of linear regression from data of 141 samples was close to 1.0. Between-run percent CV ranged from 0.35% at 7.96 log HBV DNA copies/mL to 1.46% at 4.20 log HBV DNA copies/mL. Between sample standard deviation was 0.068 (15.7% CV), between-run standard deviation was 0.064 logs (14.9% CV). Versant and TaqMan showed statistically significant non-linearity with \( R^2 = 0.924, n = 141, \text{SEE} = 0.485. \) A slope that was significantly different from 1.0 indicated non-linearity between assays. Versant and TaqMan showed excellent linearity between the range of 2,000 to 100,000,000 HBV DNA copies/mL. WHO International standard dilutions indicated that both assays agree with the international standard. All clinical samples diagnosed in both assays have been used to determine the analytical measurement range (AMR) of the assay, respectively. Error bars represent one standard deviation from the mean. The calibration coefficients are considered valid for a single lot of reagents only.

Materials and Methods:

We have evaluated the linearity and precision of the Versant assay using WHO reference material. The relationship of the Versant assay to expected concentration of serially diluted high-titer samples was: log \( y = 0.836, \) \( \text{SEE} = 0.644 \). Slope of linear regression from data of 141 samples was close to 1.0. Between-run percent CV ranged from 0.35% at 7.96 log HBV DNA copies/mL to 1.46% at 4.20 log HBV DNA copies/mL. Between sample standard deviation was 0.068 (15.7% CV), between-run standard deviation was 0.064 logs (14.9% CV). Versant and TaqMan showed statistically significant non-linearity with \( R^2 = 0.924, n = 141, \text{SEE} = 0.485. \) A slope that was significantly different from 1.0 indicated non-linearity between assays. Versant and TaqMan showed excellent linearity between the range of 2,000 to 100,000,000 HBV DNA copies/mL. WHO International standard dilutions indicated that both assays agree with the international standard. All clinical samples diagnosed in both assays have been used to determine the analytical measurement range (AMR) of the assay, respectively. Error bars represent one standard deviation from the mean. The calibration coefficients are considered valid for a single lot of reagents only.

Results:

Accuracy:

The relationship of the Versant assay to expected concentration of serially diluted high-titer samples was: log \( y = 0.836, \) \( \text{SEE} = 0.644 \). Slope of linear regression from data of 141 samples was close to 1.0. Between-run percent CV ranged from 0.35% at 7.96 log HBV DNA copies/mL to 1.46% at 4.20 log HBV DNA copies/mL. Between sample standard deviation was 0.068 (15.7% CV), between-run standard deviation was 0.064 logs (14.9% CV). Versant and TaqMan showed statistically significant non-linearity with \( R^2 = 0.924, n = 141, \text{SEE} = 0.485. \) A slope that was significantly different from 1.0 indicated non-linearity between assays. Versant and TaqMan showed excellent linearity between the range of 2,000 to 100,000,000 HBV DNA copies/mL. WHO International standard dilutions indicated that both assays agree with the international standard. All clinical samples diagnosed in both assays have been used to determine the analytical measurement range (AMR) of the assay, respectively. Error bars represent one standard deviation from the mean. The calibration coefficients are considered valid for a single lot of reagents only.

Correlation Studies:

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.