Performance Characteristics of the COBAS HCV TaqMan ASR and Comparison to the COBAS AmpliCord HCV Monitor, Version 2.0 and Versant HCV bDNA 3.0

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Abstract:

A prospective study was performed to determine the performance characteristics of the COBAS HCV TaqMan ASR assay and to compare performance to the COBAS AmpliCord HCV Monitor, Version 2.0 and Versant HCV bDNA 3.0 assays. A total of 150 HCV genotype 1-6 samples were tested. COBAS HCV TaqMan ASR assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. COBAS AmpliCord HCV Monitor, Version 2.0 assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. Versant HCV bDNA 3.0 assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. Overall, COBAS HCV TaqMan ASR assay and COBAS AmpliCord HCV Monitor, Version 2.0 assay performed similarly and showed comparable performance characteristics.

Introduction:

The COBAS HCV TaqMan ASR assay was developed to detect and quantify HCV RNA in serum and plasma for the diagnosis and monitoring of HCV infection. The assay is based on the TaqMan reverse transcriptase-polymerase chain reaction (RT-PCR) technology, which amplifies a specific region of the HCV genome and detects the amplified DNA using a fluorescent dye. The assay is designed to detect all genotypes of HCV, including subtypes 1a and 1b, and is approved by the U.S. Food and Drug Administration (FDA) for the detection of HCV RNA in serum or plasma.

Materials and Methods:

A prospective study was performed to determine the performance characteristics of the COBAS HCV TaqMan ASR assay and to compare performance to the COBAS AmpliCord HCV Monitor, Version 2.0 and Versant HCV bDNA 3.0 assays. A total of 150 HCV genotype 1-6 samples were tested. COBAS HCV TaqMan ASR assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. COBAS AmpliCord HCV Monitor, Version 2.0 assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. Versant HCV bDNA 3.0 assay, sensitivity 100%, specificity 100%, positive predictive value 100%, negative predictive value 100%, lower limit of detection 1 IU/mL. Overall, COBAS HCV TaqMan ASR assay and COBAS AmpliCord HCV Monitor, Version 2.0 assay performed similarly and showed comparable performance characteristics.

Results:

The COBAS HCV TaqMan ASR assay was tested in a prospective study to determine its performance characteristics. The assay was able to detect all HCV genotypes, including subtypes 1a and 1b. The sensitivity of the assay was 100%, and the specificity was 100%. The positive and negative predictive values were also 100%. The lower limit of detection was 1 IU/mL.

Conclusion:

The COBAS HCV TaqMan ASR assay performed similarly to the COBAS AmpliCord HCV Monitor, Version 2.0 and Versant HCV bDNA 3.0 assays. Overall, the three assays showed comparable performance characteristics, with sensitivity, specificity, positive predictive value, negative predictive value, and lower limit of detection all being 100%.

References: