

Evaluation of Analytical Sensitivity of Chiron Target Capture HBV DNA Assay for HBV Detection, and Comparison with NGI SuperQuant™ HBV DNA Assay (SP184)

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Background: The Chiron Target Capture (CTC) HBV DNA Assay involves using oligonucleotide-coated magnetic particles for targetspecific capture of HBV DNA followed by real time PCR amplification using primers developed at Chiron (a division of Novartis, Emeryville, CA). The analytical sensitivity of CTC HBV DNA Assay was analyzed by testing HBV Acrometrix standard and HBV WHO standard dilution panels. The WHO standard panel was also tested by the NGI SuperQuant™ HBV DNA Assay (SuperQuant™). The quantitative results and the analytical sensitivity from these tests were compared.

Method: The Acrometrix and WHO HBV standards were serially diluted in HIV-1, HCV, and HBV NAT negative and EIA negative CPD plasma (Chiron) and delipidized/defibrinated sera (Acrometrix) and analyzed by Chiron Target Capture HBV DNA Assay. The probit analysis was performed for the test results to estimate the 50% and 95% detection levels with 95% fiducial limits. Similar dilutions of the WHO HBV standard were evaluated by SuperQuant™, but a limited number of results are presently available. The CTC HBV DNA Assay was performed at Novartis Vaccines & Diagnostics (Emeryville, CA) under GLP conditions. The SuperQuant™ HBV DNA Assay was performed at the National Genetics Institute (Los Angeles, CA).

Results: The 95% and 50% detection levels (with 95% fiducial limits) are calculated to be 2.2 IU/mL (1.5-5.5 IU/mL) and 0.8 IU/mL (0.6-1.2 IU/mL), respectively, for the WHO standard and 10.2 geq/mL (7.0-42.4 geq/mL) and 4.3 geq/mL (2.7-5.9 geq/mL), respectively, for the Acrometrix standard. Based on the limited experimental data available, the 95% detection level of the SuperQuant™ assay was ~ 20 IU/mL, which is consistent with the previously published lower limit of detection of 100 copies/mL.

Conclusion: Based on this limited dataset, the Chiron Target Capture HBV DNA Assay achieved lower LOD and exhibited more accurate analytic sensitivity results than the SuperQuant™ assay.