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PUBLICATION SUMMARY

CLINICAL PERFORMANCE OF ALINITY M HBV ASSAY (CE)

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MULTICENTER CLINICAL EVALUATION OF ALINITY M HBV ASSAY PERFORMANCE

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BACKGROUND Despite the availability of an effective vaccine and potent antiviral drugs, chronic HBV infection remains a significant public health concern with approximately 257 million people worldwide infected and 1.34 million deaths associated with infection in 2015. Chronic HBV infection is a major cause of liver disease including cirrhosis and decompensated liver failure, as well as hepatocellular carcinoma (HCC). Assays based on nucleic acid technology (NAT) are recommended by international clinical practice guidelines. This paper details the findings of a multicenter study comparing performance of the Alinity m HBV Assay to four commercially available HBV viral load assays.

METHODS Residual serum (n=120) and plasma (n=1422) specimens from patients with chronic HBV infection were analyzed at nine international laboratories from Europe, Africa and Australia. A combination of fresh, refrigerated and frozen specimens were used for the study. Fresh samples were split into two aliquots for same day testing on the respective platforms and frozen samples were processed with minimal freeze-thaw cycles. Comparator assays were RealTime HBV assay (Abbott), CAP/CTM HBV v2.0 test or cobas HBV on cobas 6800 (Roche), or Aptima HBV Quant assay (Hologic).

- International multicenter study with 9 study sites
- Rapid detection and quantitation of HBV guides patient management
- Linear quantitation, high precisions and reproducibility provides confidence in results
- High correlation and low bias when compared with 4 HBV assays demonstrates excellent analytical performance

RESULTS Performance of the Alinity m HBV Assay was comparable to that of several HBV assays widely used in clinical practice. High precision and reproducibility of Alinity m HBV was found across the study sites. An excellent correlation (correlation coefficients ≥0.947) was seen between the Alinity m HBV assay and the four comparator HBV assays. The Alinity m HBV Assay demonstrated linear quantification of HBV DNA in plasma with a correlation coefficient of r = 0.99. For genotypes A to E, it was found that there is a significant correlation between HBV DNA levels measured in the same plasma specimen on Alinity m HBV and RealTime HBV or CAP/CTM HBV v2.0.

CONCLUSIONS The Alinity m HBV Assay (CE) is sensitive, reproducible and accurately quantifies HBV DNA in serum and plasma samples. Quantification is linear across the full dynamic range of the assay and covers values observed in untreated and treated patients with chronic HBV infection. As Alinity m is a fully automated, continuous and random access molecular diagnostic analyzer, there is the potential to enable same day reporting of HBV test results and shorten the time between diagnosis and treatment, which may improve patient management.

Reference: Bonanzinga S, Onelia F, Jackson K, Glass A, Maree L, Krügel M, Pacenti M, Gunson R, Goldstein E, García LM, Galán J-Carlos, Vilas A, Ehret R, Knechten H, Naeth G, Braun P, Obermeier M, Marlowe N, Palm MJ, Pfeifer K, Joseph AM, Dhein J, Reinhardt B, Lucic D, Chevaliez S, Multicenter Clinical Evaluation of Alinity m HBV Assay Performance, Journal of Clinical Virology (2020), doi: https://doi.org/10.1016/j.jcv.2020.104514

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