Performance of an Ultra-sensitive HBsAg Assay

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Background: Detection of Hepatitis B surface antigen (HBsAg) is important as HBsAg loss in chronic hepatitis B (CHB) indicates functional cure. Current HBsAg assays have a limit of detection (LOD) around 0.05 IU/mL. The purpose of this study is to evaluate clinical performance of the ultrasensitive (US) ABBOTT ARCHITECT HBsAg Next qualitative assay with a reported LOD of 0.005 IU/mL.

Methods: The LOD was confirmed by testing dilutions of two WHO International standards in duplicate over five days. Simple precision testing was completed by testing 20 replicates of five controls and patient specimens. 145 low positive or negative samples, from 101 patients, were also tested. These included samples from patients with: past CHB and “functional cure”; occult hepatitis B infection (OBI); loss of HBsAg after treatment cessation; low positive HBsAg levels; and negative samples.

Results: The US Next assay detected 20 replicates of WHO standards at 0.005 IU/mL. Five controls tested 20 times yielded concordant results. 21 low-positive samples with HBsAg levels 0.1-10 IU/mL were also detected. One sample from 3 OBI patients was reactive, as well as 4 of 38 samples from patients with past exposure. 2 of 15 negative samples from a treatment cessation trial were reactive, but subsequent samples were non-reactive. 15 of 34 samples from patients with past CHB were reactive; 5 were confirmed by neutralization and 3 were not. 1 sample from 24 patients with no history of CHB, was reactive but not confirmed. Finally, of 9 patient samples from HIV-HBV coinfection who demonstrated HBsAg loss, 1 was reactive and confirmed positive.

Conclusion: The US Next assay was simple, highly sensitive and reproducible. Overall 9 HBsAg-negative samples with routine assays were reactive and confirmed positive. While this endorses the sensitivity of the assay, further research is warranted to explore the potential to enhance clinical relevance.

Disclosure of Interest Statement: The US HBsAg Next assay reagents and ARCHITECT i1000 were provided by Abbott Australasia for this evaluation.