World Academy of Science, Engineering and Technology
International Journal of Medical and Health Sciences
Vol:17, No:07, 2023

Multicenter Evaluation of the ACCESS HBsAg and ACCESS HBsAg Confirmatory Assays on the DxI 9000 ACCESS Immunoassay Analyzer, for the Detection of Hepatitis B Surface Antigen

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Abstract : Background: Beckman Coulter, Inc. has recently developed fully automated assays for the detection of HBsAg on a new immunoassay platform. The objective of this European multicenter study was to evaluate the performance of the ACCESS HBsAg and ACCESS HBsAg Confirmatory assays† on the recently CE-marked DxI 9000 ACCESS Immunoassay Analyzer. Methods: The clinical specificity of the ACCESS HBsAg and HBsAg Confirmatory assays was determined using HBsAg-negative samples from blood donors and hospitalized patients. The clinical sensitivity was determined using presumed HBsAg-positive samples. Sample HBsAg status was determined using a CE-marked HBsAg assay (Abbott ARCHITECT HBsAg Qualitative II, Roche Elecsys HBsAg II, or Abbott PRISM HBsAg assay) and a CE-marked HBsAg confirmatory assay (Abbott ARCHITECT HBsAg Qualitative II Confirmatory or Abbott PRISM HBsAg Confirmatory assay) according to manufacturer package inserts and pre-determined testing algorithms. False initial reactive rate was determined on fresh hospitalized patient samples. The sensitivity for the early detection of HBV infection was assessed internally on thirty (30) seroconversion panels. Results: Clinical specificity was 99.95% (95% CI, 99.86 – 99.99%) on 6047 blood donors and 99.71% (95%CI, 99.15 – 99.94%) on 1023 hospitalized patient samples. A total of six (6) samples were found false positive with the ACCESS HBsAg assay. None were confirmed for the presence of HBsAg with the ACCESS HBsAg Confirmatory assay. Clinical sensitivity on 455 HBsAg-positive samples was 100.00% (95% CI, 99.19 – 100.00%) for the ACCESS HBsAg assay alone and for the ACCESS HBsAg Confirmatory assay. The false initial reactive rate on 821 fresh hospitalized patient samples was 0.24% (95% CI, 0.03 – 0.87%). Results obtained on 30 seroconversion panels demonstrated that the ACCESS HBsAg assay had equivalent sensitivity performances compared to the Abbott ARCHITECT HBsAg Qualitative II assay with an average bleed difference since first reactive bleed of 0.13. All bleeds found reactive in ACCESS HBsAg assay were confirmed in ACCESS HBsAg Confirmatory assay. Conclusion: The newly developed ACCESS HBsAg and ACCESS HBsAg Confirmatory assays from Beckman Coulter have demonstrated high clinical sensitivity and specificity, equivalent to currently marketed HBsAg assays, as well as a low false initial reactive rate. †Pending achievement of CE compliance; not yet available for in vitro diagnostic use. 2023-11317 Beckman Coulter and the Beckman Coulter product and service marks mentioned herein are trademarks or registered trademarks of Beckman Coulter, Inc. in the United States and other countries. All other trademarks are the property of their respective owners.

Keywords : dxi 9000 access immunoassay analyzer, hbsag, hbv, hepatitis b surface antigen, hepatitis b virus, immunoassay
Conference Title : ICVID 2023 : International Conference on Virology and Infectious Diseases
Conference Location : Berlin, Germany
Conference Dates : July 17-18, 2023