World Academy of Science, Engineering and Technology
International Journal of Medical and Health Sciences
Vol:17, No:01, 2023

Multicenter Evaluation of the ACCESS Anti-HCV Assay on the DxI 9000 ACCESS Immunoassay Analyzer, for the Detection of Hepatitis C Virus Antibody

Authors : Dan W. Rhodes, Juliane Hey, Magali Karagueuzian, Florianne Martinez, Yael Sandowski, Vanessa Roulet, Mahmoud Badawi, Mohammed-Amine Chakir, Valérie Simon, Jérémie Gautier, Françoise Le Boulaire, Catherine Coignard, Claire Vincent, Sandrine Greaume, Isabelle Voisin

Abstract : Background: Beckman Coulter, Inc. (BEC) has recently developed a fully automated second-generation anti-HCV test on a new immunoassay platform. The objective of this multicenter study conducted in Europe was to evaluate the performance of the ACCESS anti-HCV assay on the recently CE-marked DxI 9000 ACCESS Immunoassay Analyzer as an aid in the diagnosis of HCV (Hepatitis C Virus) infection and as a screening test for blood and plasma donors. Methods: The clinical specificity of the ACCESS anti-HCV assay was determined using HCV antibody-negative samples from blood donors and hospitalized patients. Sample antibody status was determined by a CE-marked anti-HCV assay (Abbott ARCHITECTTM anti-HCV assay or Abbott PRISM HCV assay) with an additional confirmation method (Immunoblot testing with INNO-LIATM HCV Score - Fujirebio), if necessary, according to pre-determined testing algorithms. The clinical sensitivity was determined using known HCV antibody-positive samples, identified positive by Immunoblot testing with INNO-LIATM HCV Score - Fujirebio. HCV RNA PCR or genotyping was available on all Immunoblot positive samples for further characterization. The false initial reactive rate was determined on fresh samples from blood donors and hospitalized patients. Thirty (30) commercially available seroconversion panels were tested to assess the sensitivity for early detection of HCV infection. The study was conducted from November 2019 to March 2022. Three (3) external sites and one (1) internal site participated. Results: Clinical specificity (95% CI) was 99.7% (99.6 – 99.8%) on 5852 blood donors and 99.0% (98.4 – 99.4%) on 1527 hospitalized patient samples. There were 15 discrepant samples (positive on ACCESS anti-HCV assay and negative on both ARCHITECT and Immunoblot) observed with hospitalized patient samples, and of note, additional HCV RNA PCR results showed five (5) samples had positive HCV RNA PCR results despite the absence of HCV antibody detection by ARCHITECT and Immunoblot, suggesting a better sensitivity of the ACCESS anti-HCV assay with these five samples compared to the ARCHITECT and Immunoblot anti-HCV assays. Clinical sensitivity (95% CI) on 510 well-characterized, known HCV antibody-positive samples was 100.0% (99.3 – 100.0%), including 353 samples with known HCV genotypes (1 to 6). The overall false initial reactive rate (95% CI) on 6630 patient samples was 0.02% (0.00 – 0.09%). Results obtained on 30 seroconversion panels demonstrated that the ACCESS anti-HCV assay had equivalent sensitivity performances, with an average bleed difference since the first reactive bleed below one (1), compared to the ARCHITECTTM anti-HCV assay. Conclusion: The newly developed ACCESS anti-HCV assay from BEC for use on the DxI 9000 ACCESS Immunoassay Analyzer demonstrated high clinical sensitivity and specificity, equivalent to currently marketed anti-HCV assays, as well as a low false initial reactive rate.

Keywords : DxI 9000 ACCESS Immunoassay Analyzer, HCV, HCV antibody, Hepatitis C virus, immunoassay
Conference Title : ICVID 2023 : International Conference on Virology and Infectious Diseases
Conference Location : London, United Kingdom
Conference Dates : January 23-24, 2023