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EARLIER DETECTION OF HUMAN IMMUNODEFICIENCY TYPE 1, HEPATITIS C AND HEPATITIS B VIRUSES USING THE PROCLEIX® ULTRIO™ ASSAY ON THE PROCLEIX® SYSTEM AND PROCLEIX® TIGRIS® SYSTEM COMPARED TO SEROLOGY

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Background

The Procleix® Ultrio™ (Ultrio) Assay and associated Procleix HIV-1, HCV, and HBV Discriminatory Assays (dHIV-1, dHCV, and dHBV) are investigational nucleic acid tests designed for the simultaneous detection of human immunodeficiency virus type 1 (HIV 1) RNA, hepatitis C virus (HCV) RNA, and hepatitis B virus (HBV) DNA in human plasma. The assays can be performed on the semi-automated Procleix System and on the fully automated Procleix TIGRIS® (TIGRIS) System.

Aims

The study objective was to assess the ability of the Ultrio Assay and associated discriminatory assays to reduce the detection windows for HIV-1, HCV, and HBV. Commercially available seroconversion panels were used for testing.

Methods

HIV-1 (n=13), HCV (n=12), and HBV (n=16) seroconversion panels were tested neat and diluted (1:8 and 1:16) in the Ultrio Assay. Panels were tested neat in the appropriate discriminatory assay. Times to detection of HIV-1, HCV, and HBV nucleic acids in seroconversion panels were compared to the vendor's historical data on time to detection of antibody and/or antigen using licensed or validated serologic tests. These reference tests were: (i) Abbott HIVAB HIV-1/HIV-2 (rDNA) EIA (Abbott Laboratories, Abbott Park, IL), (ii) Abbott HIVAG-1 Monoclonal (Abbott Laboratories, Abbott Park, IL) or Coulter HIV-1 p24 Ag Assay (Coulter Corporation, Miami, FL), (iii) Ortho HCV Version 3.0 ELISA Test System (Ortho-Clinical Diagnostics, Inc., Raritan, NJ), and (iv) Abbott PRISM HBsAg (Abbott Laboratories, Abbott Park, IL) or Ortho Antibody to HBsAg ELISA Test System 3 (Ortho-Clinical Diagnostics, Inc. Raritan, NJ). The median number of days to detection was calculated for each sample preparation in each assay, as appropriate.

Results

The Ultrio Assay and appropriate discriminatory assays were able to detect HIV-1, HCV, and HBV infection in neat samples, on both systems, earlier than the reference tests (a median of at least 14 days earlier than HIV-1 antibody, 7 days earlier than HIV-1 p24 antigen, 32 days earlier than HCV antibody, and 15 days earlier than HBV surface antigen serologic tests, respectively). The reductions of the detection windows for HIV-1 and HCV were similar in most neat and diluted panel members. For HBV in the Ultrio Assay, the dynamics of viral production during the acute infection phase resulted in a greater reduction of the detection window in neat panels than in diluted panels (a median of at least 17 days neat versus 11.5 days diluted 1:8 and 6 days diluted 1:16). The median numbers of days to HIV-1, HCV, and HBV detection by the Procleix Ultrio Assay was similar between the Procleix and TIGRIS systems.

Summary/Conclusions

The Procleix Ultrio Assay, using either the Procleix or TIGRIS systems, demonstrated excellent clinical sensitivity and utility since it significantly reduced the post-infection detection window for HIV-1, HCV, and HBV when compared to serologic tests.