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ANALYTICAL SENSITIVITY AND SUBTYPE DETECTION OF THE PROCLEIX® ULTRIO™ ASSAY IN THE PROCLEIX® SYSTEM AND THE PROCLEIX® TIGRIS® SYSTEM

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Background:

The Procleix® Ultrio™ Assay (Ultrio) is a blood-screening assay based on Transcription-Mediated Amplification that simultaneously detects HIV-1, HCV and HBV. The HIV-1, HCV and HBV Discriminatory Assays contain specific probe reagents and are designed to discriminate the three viruses in Ultrio reactive specimens. In this study, the analytical and subtype sensitivities of the four assays were determined in the Procleix® System (Procleix) and in the fully-automated Procleix® TIGRIS® System (TIGRIS).

Methods:

Serial dilution panels of an HIV-1 virus stock as well as the HIV-1, HCV and HBV WHO International Standards were prepared and tested in the Ultrio and appropriate discriminatory assays using both the Procleix and TIGRIS Systems. Dilutions of HIV-1, HCV and HBV genetic variants of known concentrations were prepared and tested in the four assays on each system using three reagent lots.

Results:

Probit analyses of the analytical sensitivity results indicate that the predicted 95% detection level for the HIV-1 virus stock was approximately 38 copies/mL and for the HIV-1, HCV and HBV WHO International Standards were approximately 18, 4 and 8 IU/mL, respectively, in the Procleix System. In the TIGRIS System, the predicted 95% detection level for the HIV-1 virus stock was 29 copies/mL and for the HIV-1, HCV and HBV WHO standards approximately 20, 3, and 10 IU/mL for each respective virus. In the Ultrio assay, 60 unique specimens infected with HCV genetic variants (types 1-6) were detected at 300 copies/mL in both systems. Forty-eight unique HIV-1 specimens [groups M (A-G), N and O] and 57 unique HBV specimens (types A-G) were detected at £300 copies/mL in each system. Comparable performance was observed in the discriminatory assays with similar results obtained across reagent lots.

Conclusions:

These results indicate that the Ultrio and HIV-1, HCV and HBV Discriminatory Assays are very sensitive for the detection of HIV-1, HCV and HBV genetic variants in the Procleix System and in the TIGRIS System.