

Sensitivity of the Procleix® Ultrio™ Assay in the Procleix and Fully Automated TIGRIS® Systems

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Abstract:

Aims: The Procleix Ultrio Assay is a Transcription-Mediated Amplification assay for the simultaneous detection of HIV-1, HCV and HBV in blood donations. The HIV-1, HCV and HBV Discriminatory Assays, containing specific probe reagents, are used to discriminate the three viruses in Ultrio reactive specimens. Here we present the analytical sensitivity of the four assays in the Procleix System and in the fully automated TIGRIS System. **Methods:** We tested serial dilution panels of the HIV-1, HCV and HBV WHO International Standards, as well as genetic variants, in the Ultrio and discriminatory assays on the Procleix and TIGRIS systems. **Results:** Probit analyses of the analytical sensitivity results indicate that the predicted 95% detection levels for HIV-1, HCV and HBV were approximately 19, 3 and 7 IU/mL, respectively, on both systems. In the Ultrio assay, 40 unique specimens infected with HCV genetic variants (types 1-6) were detected at 30 copies/mL in both systems. Forty-one unique HIV-1 specimens [groups M (A-G), N and O] and 55 unique HBV specimens (types A-G) were detected at 300 copies/mL in each system. Similar results were observed in the discriminatory assays for each system. **Conclusion:** These results indicate that the Ultrio and HIV-1, HCV and HBV Discriminatory Assays are very sensitive for the detection of prototype and subtype viral isolates. Assay performance was similar between the Procleix System and the fully automated TIGRIS System.

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