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SPECIFICITY ANALYSIS OF THE PROCLEIX® HIV-1/HCV (MULTIPLEX AND DISCRIMINATORY) ASSAY WITH SOURCE PLASMA DONOR SAMPLES

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Background:

The objective of this study was to generate specificity data to support expanding the intended use claim of the Procleix® HIV-1/HCV Multiplex (Mx), Discriminatory HIV-1 (dHIV-1), and HCV (dHCV) assays to include screening of source plasma from paid donors. Procleix Assay high sensitivity with plasma samples has already been demonstrated.

Methods:

A linked study was performed on seronegative source plasma samples from paid donors. Specificity of the Procleix® Assays was determined against anti-HCV, anti-HIV, and HIV p24 antigen results. Discordants were tested with an alternative NAT. Source plasma samples represented industry standard of frozen storage time up to 181+ days and sample shipment (dry ice versus gel packs). Samples were sent to two sites for Mx, dHIV-1 and dHCV assay testing across three conformance reagent lots. Procleix assay testing was performed on 16-pooled (minipool) and single samples. Procleix® dHIV-1 and dHCV specificity was determined using a subset of 1,012 in each assay that were Mx nonreactive (NR).

Results:

A total of 19,200 seronegative paid plasma donor samples from 4,916 unique donors were evaluated for specificity across 20 Procleix Mx assay runs. In addition, 1,012 donor samples were tested by dHIV-1 and dHCV. Specificity for dry ice and gel pack samples was 100% for Mx and dHIV-1 assays. The dHCV Assay showed 100% and 99.7% (95% CI: 98.8 – 100.0) specificity for dry ice and gel pack samples, respectively. Of the total 19,046 unique donor samples tested in minipools, 14,130 (74%) were repeat donations. All donor samples tested in minipools were NR for the Procleix Mx assay. The 1,007 valid dHIV-1 results were all NR. Of the 1,006 valid dHCV results, 1,004 were NR and 2 were reactive with low signal to cut-off values: 2.48 and 1.70. However, these 2 samples were NR for Procleix Mx assay and Alt NAT HCV, therefore indicating initial false positive dHCV results. Overall Specificity (includes conformance lots, sites) was 100% (95% CI: 99.7-100) for Mx and dHIV-1 (95% CI: 99.6-100) and 99.8% (95% CI: 99.3-100) for dHCV.

Conclusions:

The high specificity (100% to 99.8%) of the Procleix Mx, dHIV-1 and dHCV assays compared to serology across multiple operators, test sites, shipping conditions and conformance lots confirms together with the high sensitivity shown previously, that the FDA-approved Procleix HIV-1/HCV Assay can be used effectively for source plasma donors as well as volunteer blood donors.