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SPECIFICITY ANALYSIS OF THE PROCLEIX® ULTRIO™ ASSAYS WITH VOLUNTEER BLOOD DONOR SPECIMENS

Sally Caglioti, Joan D McAuley, Robert C Williams, Gene Robertson, Jennifer Jones, Pam Ostboe, Larry Morgan

Background:

The Procleix® Ultrio™ Assay simultaneously detects HIV-1, HCV RNA and HBV DNA in plasma. The study objective was to generate specificity data as part of a clinical study to evaluate the Procleix Ultrio Assay (ULT) and the associated Ultrio Discriminatory Assays (dHIV-1, dHCV, dHBV). Data from these assays were compared to licensed screening assays: Procleix® HIV-1/HCV (Mx) and Discriminatory HIV-1, HCV as well as serologic tests for HBsAg and anti-HBc.

Methods:

Specificity was evaluated using 52,016 donor specimens in paired master pool tubes (MPTs) of 16 specimens and 6,012 ULT individual donor specimens (IDS). MPTs and IDS were tested across 3 conformance reagent lots. Reactive (Rx) Procleix ULT or Mx IDS were tested with the respective Discriminatory Assay(s). Discordant specimens were further tested with an alternate NAT PCR. IDS were tested for the ULT discriminatory specificity analysis.

Results:

Within 3,251 MPTs, the nonreactive (NR) ULT mean S/CO was 0.08 ± 0.06 and 15.3 SD to the cutoff. Specificity for MPT ULT was 99.38%. ULT specificity for IDS was 99.67%, dHIV-1 99.7%, dHCV 99.1% and dHBV 99.8%. NAT PCR HIV-1 and HCV tests for false positive (FP) resolution were NR. There were 608 IDS tested for Procleix ULT and Mx. The agreement between Procleix screening assays was: 473/473 NR (100%), 119/135 Rx (88%); discordant specimens included dHBV and FPs. For Procleix Discriminatory Assays: dHCV 4/4 NR (100%), 72/72 Rx (100%); dHIV-1 51/51 NR (100%), 3/3 Rx (100%). There were 4,134 IDS tested for ULT and serology (HBsAg, HBc) of which 63 specimens had ULT confirmatory and serology. The agreement between Procleix ULT and HBsAg assays was: 4,071/4,073 NR (99.9%), 8/61 Rx (13%); the 53 discordant specimens included: ULT dHIV-1 Rx, dHCV Rx or FPs. For ULT

dHBV and HBsAg tests: 54/54 NR (100%), 8/9 Rx (89%). The agreement between Procleix ULT and HbC tests showed 4,054/4,073 NR (99.5%), with 19 HbC Rx/ULT NR; 17/61 Rx (28%); 44 discordant specimens included: ULT dHIV-1 Rx, dHCV Rx or FPs. For ULT dHBV and HbC tests: 47/54 NR (87%), 8/9 Rx (89%). The 1 NR HBsAg/HbC ULT dHBV Rx did not confirm on PCR HBV. Within the discordant ULT NR/HbV serology Rx group, 44/44 (100%) specimens were HBV PCR NR. Further investigation of discordant tests is in progress.

Conclusions:

The evaluation shows high specificities for Procleix Ultrio MPT at 99.38% and IDS at 99.67% and dHIV-1 at 99.7%, dHCV at 99.1% and dHBV 99.8%. The Procleix Ultrio Assay shows comparable specificity to the FDA-approved Procleix Mx and HBV serology tests. This preliminary data suggests that the Procleix Ultrio and its associated Discriminatory Assays are efficacious for blood donor screening.