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PERFORMANCE ASSESSMENT OF THE PROCLEIX® WNV ASSAY

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Background:

The safety of routine blood screening improved in 1999 with the use of Procleix® Transcription Mediated Amplification (TMA) technology for HIV-1/HCV RNA. In July 2003, TMA was implemented to detect West Nile Virus (WNV) RNA in Master Pool Tubes (MPTs) of 16 and individual donor samples (IDS) from units intended for transfusion. The Procleix® WNV Assay uses the same semi-automated instrumentation and assay procedures as the Procleix® HIV-1/HCV Assay (Mx). Donor screening requires efficient and valid test results as delays can adversely affect the donor blood supply. Therefore, the Procleix WNV and HIV-1/HCV (Mx) Assay performances were evaluated and compared.

Methods:

The evaluation included 105,507 MPT analyte samples of which 53,464 were tested by Mx (51%) and 52,043 were tested by WNV (49.1%), from July 29, 2003 through March 31, 2004. Samples were tested across 2,059 assay runs: 1,075 (52%) for Mx and 984 (48%) for WNV. Assay performance criteria included: valid, invalid, suspect assay runs (control failures or exceeding the 10% rule) and MPT true positive (TP), false positive (FP), true negative (TN) and invalid results.

Results:

There were 94.4% (1,015/1,075) MX valid runs. Run failures (n=60) were due to: 1.0% (11/1075) invalid controls, 2.8% (30/1,075) operator errors and 1.8% (19/1,075) suspect runs. There were 95% (935/984) WNV valid runs. Run failures (n=49) were due to: 1.8% (18/984) invalid controls, 2.8% (26/984) operator errors and 0.6% (5/984) suspect runs. For the Mx MPT analyte results there were 1.9% (990/53,464) TP; 0.3% (171/53,464) FP; 97% (51,855/53,464) TN and 0.8% (448/53,464) internal control (IC) failures. For the WNV MPT analyte results there were 0.42% (220/52,043) TP; 0.19% (101/52,043) FP; 99.03% (51,537/52,043) TN and 0.36% (185/52,043) IC failures. The positive

predictive value and percent accuracy was 98.1% for Mx MPT and 99.58% for WNV MPT. For the overall Procleix® assay performance evaluation, there is a slight statistically significant difference in the Procleix® HIV-1/HCV (Mx) and WNV performance $p < 0.02$, with WNV having fewer preventable and suspect runs, but a higher number of invalid calibrators. Within the valid Procleix Assay runs, the analyte performance is highly significant with WNV having fewer FP, invalids and TN results, $p < 0.0001$.

Conclusions:

The data demonstrate that the Procleix® Assay System using semi-automated instrumentation can be used effectively to detect Mx and WNV RNA in a high volume laboratory. The Procleix® HIV-1/HCV (Mx) and WNV Assays have an overall low incidence of run failures, with 94.4 to 95% successful runs, respectively. The variation in the assay and analyte performance demonstrates that Procleix WNV Assay has a higher level of assay run and analyte result reliability compared to that of the Mx assay.