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PROCLEIX® WNV ASSAY SPECIFICITY AND REPRODUCIBILITY ANALYSIS AT A BLOOD SCREENING LABORATORY (SP421)

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Background:

The PROCLEIX® West Nile Virus (WNV) Assay is an investigational nucleic acid test (NAT) for the detection of WNV RNA in blood donations. A multi-site pivotal study was conducted to determine assay performance. The specificity and reproducibility of the PROCLEIX WNV Assay at one blood center is reported here.

Methods:

Linked blood donations were tested in the PROCLEIX WNV Assay as part of 16-sample pools or as individual donor samples (IDS) using 3 lots. Reactive samples were tested in an IgM assay and in WNV alternate NAT and the donor was sent for follow-up. Follow-up included IDS testing in the PROCLEIX WNV Assay, IgM assay, and alternate NAT. Results were used to determine specificity and corresponding 95% confidence intervals (CI). Samples were also tested in an IgG assay at index and follow-up; results were used for information only. Replicates of a 10-member WNV panel including varying target copy levels were tested with 3 lots to determine assay reproducibility. Reproducibility was determined by calculating percent agreement with expected outcome and the coefficient of variation (CV) of signal among lots, operators, and inter and intra assay runs.

Results:

There were 10,506 samples from 16-sample pools and 20,425 IDS with valid and complete test results. The overall specificity was 99.94% (CI: 99.88%-99.98%) in 16-sample pools. Across lots, specificity in pooled samples ranged from 99.84% to 99.98%. The specificity was 99.89% (CI: 99.83%-99.93%) in IDS. Across lots, specificity in IDS ranged from 99.74% to 99.95%. Of 46 samples with false positive results, all were IgM and IgG seronegative and alternate NAT non-reactive with the exception of 1 sample with IgG seropositive results from a fifth follow-up donation. There were 715 valid test results included in the reproducibility analysis. Percent agreements with expected outcome were 100% for all panel members across operators and overall. Little difference was found in signal values among operators, lots, or runs or within runs.

Conclusions:

This single site report showed similar specificity of the PROCLEIX WNV Assay in pooled samples and IDS. The reproducibility of the assay was robust; there was little variation among operators, lots and runs and within runs.