

## Evaluation of PROCLEIX<sup>®</sup> WNV Assay Performance with Cadaveric Samples on the Semi-Automated ESAS and Fully Automated TIGRIS<sup>®</sup> Systems (SP396)

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**Background:** The PROCLEIX WNV Assay is a qualitative in vitro nucleic acid amplification test (NAT) for the detection of West Nile virus (WNV). Initially used for blood screening in the United States (US) under an investigative protocol starting in May 2003, this Transcription-Mediated Amplification (TMA) assay, was licensed by the FDA for use on the semi-automated instrument system (eSAS) in December 2005. The fully automated TIGRIS System is currently used under an investigative protocol in the US. We report assay performance, reproducibility, and viral stability testing in cadaveric blood specimens on the eSAS and TIGRIS systems.

**Methods:** Cadaveric samples were evaluated with the PROCLEIX WNV Assay to determine sensitivity, specificity, reproducibility, limit of detection (LOD), and viral stability. Control serum or plasma samples from living donors were used for comparison in all assay performance studies. Sensitivity, specificity, and reproducibility studies were performed with 3 reagent lots on individual serum and plasma samples on both systems. Samples for sensitivity (n = 45, eSAS; n = 51, TIGRIS System) and reproducibility studies (20 donors, 6 replicates each) were spiked with WNV to 150 copies/mL. Negative specimens were used for specificity studies. The LOD was determined by testing 3-fold dilutions of WNV (100 to 3 copies/mL, 40 replicates each) in pooled samples from cadaveric serum, cadaveric plasma, control serum, and control plasma. For the stability studies, WNV positive samples were incubated at 25 C for one day and at 8 C for an additional 2 to 7 days. Cadaveric serum (32 donors, 6 replicates each) and cadaveric plasma samples (34 donors, 6 replicates each) were tested at a final WNV concentration of 150 copies/mL.

**Results:** Sensitivity and specificity were 100% for cadaveric and control samples on both systems. All WNV spiked samples in the reproducibility study were reactive, indicating high reproducibility of the assay. The 95% LOD was 15.0 copies/mL for cadaveric plasma samples and 18.5 copies/mL for control plasma samples. The 95% LOD was 32.8 copies/mL for cadaveric serum samples and 32.4 copies/mL for control serum samples. WNV was stable in cadaveric plasma and serum samples for 8 and 3 days, respectively.

**Conclusions:** Performance of the PROCLEIX WNV Assay with cadaveric samples on both eSAS and TIGRIS systems was found to be sensitive, specific, and reproducible. The LOD study showed no significant differences in sensitivity between cadaveric and living donor samples, but sensitivity was greater in plasma compared to serum. WNV was also more stable in cadaveric plasma samples than in cadaveric serum samples.