

## Multi-Site Clinical Evaluation of the Procleix<sup>®</sup> WNV Assay on the Semi-Automated System (SP395)

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**Background:** The Procleix WNV Assay is a qualitative in vitro nucleic acid amplification test (NAT) for detection of West Nile virus (WNV). This Transcription-Mediated Amplification (TMA) assay was initially used for blood screening in the US under an investigative protocol starting in June 2003 and was later licensed for use on the semi-automated instrument system (eSAS) in December 2005. We report the results from a multi-site clinical trial conducted to determine assay performance characteristics and support licensure on the eSAS platform.

**Methods:** Three clinical studies were conducted to support the Procleix WNV Assay intended use on the eSAS platform: 1) clinical specificity 2) clinical sensitivity in known positive samples and 3) reproducibility. Three reagent lots were used in each study. The clinical specificity study was conducted at the American Red Cross National Testing Lab Detroit (ARC), Blood Systems Laboratories Tempe (BSLT), Oklahoma Blood Institute (OBI), and Michigan Community Blood Center (MCBC). Specificity was determined by testing 16,885 16- sample pools and 43,508 individual donor samples (IDS) from whole blood donations. Reactive results were compared to results from a commercial IgM assay and/or from a validated Alternate NAT. In sensitivity studies, conducted at ARC and BSLT, 202 known-positive samples were tested neat and 203 were tested diluted 1:16. The reproducibility study, conducted at ARC, BSLT, and Florida Blood Services (FBS), assessed intra- and inter-run, inter-lot, and inter-site variability using a 10-member panel of negative samples and WNV positive samples (ranging from 50 to 10,000 copies/mL). Six operators tested panels on multiple days using 3 reagent kit lots.

**Results:** Pool specificity was 99.95% (95% confidence interval [CI]: 99.90-99.98%); IDS specificity was 99.89 (95% CI: 99.86 - 99.92). Clinical sensitivity in known positive samples was 100% (95% CI: 98.2- 100) and 91.6% (95% CI: 86.9- 95.0) in samples diluted 1:16. Results from the reproducibility study indicated that for positive samples, as measured by analyte S/CO values, intra-run variability was the largest source of variability, with a coefficient of variation (CV) of 11.8%, compared to interassay (7.4%), inter-site (3.9%), and inter-lot (2.1%). Similarly, for negative panel members, as measured by internal control S/CO values, intra-run variability was largest with a CV of 5.8%.

**Conclusions:** These clinical studies demonstrated high sensitivity, specificity, and reproducibility for the Procleix WNV Assay on the eSAS platform. The difference in clinical sensitivity between neat and 1:16 diluted samples underscores the need for IDS testing during peak epidemic periods.