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# MULTI-SITE STUDY OF THE PROCLEIX® WNV ASSAY USING THE ENHANCED SEMI-AUTOMATED SYSTEM COMPARED WITH THE TIGRIS® AUTOMATED SYSTEM (SP420)

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## Background:

The investigational PROCLEIX® West Nile Virus (WNV) assay uses Transcription Mediated Amplification (TMA) to detect WNV RNA in donated blood. A multi-site study was performed to compare performance of WNV TMA using the enhanced semi-automated PROCLEIX® System (eSAS) and the automated PROCLEIX® TIGRIS® System (TIGRIS).

## Methods:

TIGRIS testing was performed at 3 blood centers; eSAS testing was performed at Gen-Probe. Variability between systems was evaluated using a 510-member panel (410 negative samples including interfering substances and 100 positive samples including IgM+, IgM-; copy levels £ or >300 copies/mL); each panel member was tested in triplicate. Data were analyzed by comparing the percent correct detection of positive and negative replicates and 95% confidence intervals (CI); non-overlapping 95% CIs were considered significantly different. In addition, signal to cutoff (S/CO) ratios were compared for all groups of samples.

## Results:

1,524 eSAS and 4,554 TIGRIS valid test results were obtained. False-positive results occurred in replicate tests of 4 samples on eSAS and 3 on TIGRIS. False-negative results occurred on eSAS for one sample having <100 copies/mL (2 of 3 replicates). For positives, eSAS identified 92.6 to 100% (depending on copies/mL and IgM result) of samples tested, for a detection rate of 99.3 % (CI: 97.6, 99.9). Using TIGRIS, detection of positives was 100% (CI: 99.6, 100). For negative samples, eSAS nonreactive rate was 99.7% (CI: 99.2, 99.9) and TIGRIS was 99.9% (CI: 99.8,100). The overall accuracy for eSAS was 99.6 % (CI: 99.1, 99.9) and TIGRIS was 99.9% (CI: 99.8, 100). The percent detection was better with TIGRIS for positive samples by 0.7% (CI: -1.8, 0.5) and for negative samples by 0.2% (CI: -0.6, 0.1); both CIs included 0 and therefore, are not statistically different. The mean S/CO ± SD values for positive samples for eSAS were 29.32 ± 4.26 and for TIGRIS 30.35 ± 3.60. For negative samples, eSAS values were 0.12 ± 0.12 and TIGRIS values were 0.07 ± 0.09.

## Conclusions:

Within the scope of the study, equivalence was demonstrated between the two test platforms; however, there was a slightly higher agreement for both known positive and negative samples when using TIGRIS.