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SENSITIVITY AND SPECIFICITY OF THE PROCLEIX® WNV ASSAY ON THE AUTOMATED PROCLEIX® TIGRIS® SYSTEM, AND COMPATIBILITY WITH THE PROCLEIX® ULTRIO™ ASSAY

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Background:

The risk of West Nile virus (WNV) transfusion transmission has been reduced by nucleic acid testing (NAT) of donated blood. Individual donor testing (IDT) could improve NAT efficacy and safety compared to testing minipools but implementation of IDT using the current semi-automated system challenges the capacity of most testing facilities. The Procleix® TIGRIS® System, under clinical validation at Gen-Probe, is ideal for IDT because it fully automates NAT. A WNV TIGRIS Assay Definition Module (ADM) has been developed and we present here the sensitivity and specificity of the WNV Assay on TIGRIS and compatibility of the Procleix® WNV and Ultrio™ Assays when tested on a single TIGRIS instrument.

Methods:

Sensitivity was determined using a WNV Lineage 1 viral standard prepared by Health Canada, and a clinical sensitivity panel from Blood Systems Research Institute. Specificity was tested using fresh plasma samples from normal blood donors. Inter-assay compatibility was validated by sequentially testing the Procleix Ultrio Assay with negative and positive HIV-1, HCV, and HBV samples, followed by testing of the Procleix WNV Assay with negative and positive WNV samples.

Results:

Probit analysis of the results with a viral panel at 100, 30, 10, 3, 1, and 0 c/mL determined that the 95% detection level was 8.88 c/mL (95% confidence interval 6.78-13.62 c/mL) for the WNV Assay on TIGRIS. Testing of clinical sensitivity panels yielded results comparable to those obtained using the semi-automated system. The WNV Assay on TIGRIS was used to test 6,407 negative normal donor samples in which 3 false positive results were observed for a specificity rate of 99.95%. When WNV and

Ultrio Assays were tested in consecutive runs, each met specifications for sensitivity and specificity. The system correctly verified reagents, expiration dates, inventory consumption, and processed the results of each assay independently.

Conclusions:

The WNV Assay on the TIGRIS System is sensitive and highly specific. There are no practically significant differences in analytical performance of the assay on TIGRIS when compared to the semi-automated system. The WNV Assay was shown to be compatible with the Ultrio Assay on TIGRIS. These characteristics suggest that the WNV Assay on TIGRIS will be an effective and flexible solution for fully automated NAT.