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## **GEN-PROBE ALTERNATIVE WNV ASSAY: A TMA-BASED CONFIRMATORY ASSAY FOR WEST NILE VIRUS**

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### **Background:**

The Procleix® WNV Assay is an investigational amplified nucleic acid test (NAT) for screening blood donations for West Nile virus (WNV). For confirmation of initially reactive results obtained with the Procleix® WNV Assay, we developed the Gen-Probe Alternative (Alt) WNV Assay, an investigational assay that uses primers and probes that target a different region of the WNV genome than the Procleix® WNV Assay. Both WNV assays are based on Transcription-Mediated Amplification (TMA) and use the same semi-automated instrumentation and assay procedures as the FDA-licensed Procleix® HIV-1/HCV Assay.

### **Methods:**

To assess the analytical sensitivity of the Alt WNV Assay, we tested serial dilutions of WNV Lineage 1 and Lineage 2 virus from Boston Biomedica Inc. and an RNA transcript encoding a portion of the WNV genome. To assess specificity, we tested more than 1550 normal negative donors, problematic samples, and samples containing other blood borne viruses. We also determined the reproducibility of the Alt WNV Assay in panels tested by three operators, with three instrument sets, and with two kit lots. Lastly, a preliminary assessment of clinical sensitivity was conducted by testing clinical samples in the Alt WNV Assay.

### **Results:**

For determination of analytical sensitivity, we found that the Alt WNV Assay is capable of 100% detection of WNV RNA down to 30 copies/mL for both WNV Lineage 1 and 2 viruses; results were comparable to results obtained with the Procleix® WNV Assay. Analytical specificity in negative donors was 99.8%. The reproducibility study showed limited variability between operators, instruments, or kit lots. Of 208 donations that were confirmed WNV positive either by a kinetic PCR assay carried out at the Bayer

Reference Testing Lab (Berkeley, CA) or by IgM at Focus Labs (Cypress, CA), the Alt WNV Assay detected 200 (96%) of the samples.

***Conclusion:***

These results demonstrate the feasibility of using the Gen-Probe Alt WNV Assay to confirm results obtained with the Procleix® WNV Assay and other WNV NAT methods.