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## **AN EVALUATION OF WEST NILE VIRUS NAT ON US BLOOD DONORS**

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### **Background:**

Screening for West Nile Virus (WNV) by nucleic acid testing (NAT) may improve blood safety by decreasing the incidence of transfusion transmission. We attempted to determine how our donor population compared to the total US (incidence 0.014%, 6/03-12/03)

### **Methods:**

Beginning 7/1/03 plasma pools of 16 donations were tested by our NAT laboratory using a Transcription Mediated Amplification (TMA) assay. Reactive results were confirmed by testing an alternate sample by TMA, by testing using a validated alternate NAT methodology – polymerase chain reaction (PCR) and by a licensed serological method that detected IgM antibodies to WNV. TMA reactive donors were entered into a substudy and, after IRB approved informed consent was obtained, three Plasma Preparation Tubes were collected and tested for WNV by TMA, PCR and for anti-IgM production. Study participants were not compensated. All testing was performed under IND with strict adherence to the manufacturer's insert.

### **Results:**

As of 4/15/04, 438,020 specimens from 19 collection sites in the Eastern US were tested. At index donation, forty-three donors were WNV NAT reactive by TMA. 3/43 (6.98%) were reactive by TMA on the alternate sample, reactive by PCR and were classified as confirmed positive. 0/43 were IgM + at index donation. 40/438,020 (0.009%) initially reactive TMA results were not reproducible on alternate specimens or by PCR and were considered to be false positives. 25/43 (58.1%) returned for follow-up bleeds. 2/25 (8.0%) seroconverted (1 IgM and IgG +, 1 IgM +). 1/2 seroconverters (IgM +) remained viremic by TMA and PCR, but did not return for additional follow-up bleeds. 6/43 (14.0%) TMA reactive donors had a signal-to-cutoff ratio (S/CO) of >20, mean 25.6

(range 20.85-32.70) at index. 3/6 with a high S/CO were reactive by TMA (initial and alternate sample) and by PCR, these donors presented in September and October 2003. Specificity of pooled testing was 99.7% (23,784/23,855). Sample volume was adequate for testing; but, a shipment delay resulted in the three thawed specimens that were unsuitable for PCR testing.

### ***Conclusions:***

In the first 9 1/2 months of WNV NAT testing we report high specificity of pooled testing. Three confirmed cases of WNV viremia (TMA+ on initial and alternate specimen, PCR+) were detected in 1 per 146,007 donations, for an incidence 0.0007% which was well below that of the total US donor population. Our confirmed cases occurred in the fall months only. We saw a benefit in adding WNV NAT to the menu of blood testing since it successfully interdicted viremic blood donations from a volunteer blood donor population.1.MMWR 2004; 53:281-284.