

## **Confirmation of Infection Among Donors Identified by Minipool and Individual Donation Nucleic Acid Testing (NAT) for West Nile Virus (WNV) in the United States From 2003-2005 (P5-030A)**

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**Background:** WNV NAT screening began in 2003. During 2003- 2005 all US programs performed WNV NAT in either minipools (MP), or in epidemic periods/locations, as individual donations (ID). With the licensure of test systems, confirmatory strategies are required.

**Methods:** Three blood systems contributed data (representing >80% of blood collected in the US). Donations were tested by either the Gen-Probe/Chiron WNV Assay (TMA) in pools of 16 or in pools of 6 by the Roche TaqScreen Assay (PCR). Confirmation of WNV infection in donors of index and follow up samples were performed by repeating the same NAT method, an alternate NAT method (in house or reference lab) and by antibody testing (Ab: IgM/IgG; reference lab).

**Results:** 1329 of 13.07 million donations confirmed NAT positive during the three WNV seasons (overall 1:10,000 frequency; range: 0.6 in 2004 to 1.6 in 2003) with the first confirmed positive donation of any season detected on May 3 and the last on Dec 1. ID NAT was required to detect 291 of 1329 (22%); 67 (5.3%) of the 291 were Ab negative and likely infectious. At index, 344 of 1329 (26%) were Ab+ (10 QNS for Ab; 216 with repeatable NAT+). Another 209 (16%) were Ab negative but repeat NAT+ (same or alternate NAT method); 19 of the 209 donors never seroconverted and 190 did not participate in follow up. Lastly, 766 (58%) donors were Ab negative at index and followed to seroconversion, of which 756 had index repeatable NAT positivity (of the 1181 total with repeat NAT+). Ten donors were both Ab negative and repeat NAT negative at index. Thus, confirmation at index by repeat NAT and/or Ab resolved 1309 of 1319 donors (algorithm sensitivity =99.24%). Sensitivity is 98.6% (756/766), if confined to only those donors who were followed to seroconversion. Of the 1329, 765 of 1013 tested (75%) had viral loads of >100 copies/mL of which 705 (92%) were Ab negative; these donors seroconverted at a median of 14 (IgM) to 17 (IgG) days; NAT positivity persisted in 42% for a median of 14 and maximum of 98 days. Rates of false positivity decreased from 1 to 0.21:10,000 donations screened over the 3 years; ID NAT accounted for a total of 65% of all false positives.

**Conclusions:** WNV screening using MP/ID NAT from 2003-2005 prevented the release of >2000 blood components of which 74% were Ab negative. The 5.3% of donors who were Ab negative at index and required ID NAT for detection (MP NAT-) likely would have transmitted infection to a recipient. Sensitivity of index NAT confirmatory algorithm (repeat NAT and/or Ab) was 99.24%; the 0.76% of donors not confirmed at index likely represents early infection detectable only sporadically by NAT.