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USING PROCLEIX® WEST NILE VIRUS NAT FOR TESTING 24,312 INDIVIDUAL DONOR SAMPLES: LESSONS LEARNED DURING 2003

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Background:

The FDA approved use of investigational nucleic acid amplification tests (NAT) for West Nile Virus (WNV) for blood donations in June 2003. We began using the Procleix® WNV Assay (Gen-Probe Incorporated) on individual donations on July 1, 2003, with IRB approval.

Methodology:

All donor samples were tested individually using the FDA approved algorithm. Samples testing repeat reactive were sent to three other laboratories for additional testing. Donors with repeat reactive results were contacted and, following informed consent, enrolled in further research studies. Verification of infection was determined by reactivity in an alternative NAT test (not the one used in our laboratory), followed by seroconversion to IgM in at least one of the samples drawn. Initially, all repeat reactive donors were interviewed on one or more occasions about symptoms.

Results:

Of 24,312 WNV tests performed between 07/01/2003 and 03/30/2004, there were 174 initially reactive samples (0.72%), 22 (12.6%) of which were repeat reactive (RR), for a RR rate of 0.09% (or approximately 1/1000 overall). However, only two RR samples (9% of RRs, 0.008% of all donations tested) were confirmed positive by an alternate NAT test and followup IgM seroconversion, for a confirmed positive rate of 1/12,500. (Three other RR samples were positive by alternative NAT testing, but the donors have not returned for followup.) The initial S/COs for the two documented positive samples were 32.93 and 35.3, respectively, with repeat S/CO of 32.36 and 35.21. (In contrast, the non-confirmed samples had an initial S/CO result ranging between 1.0-28.68 [mean of 4.6]). Excluding the two true positives, the range of S/CO in the second test run for the other 20 initially reactive samples was 0.01-6.23, with a mean of 1.99.

Discussion:

Performance characteristics of this assay showed a sensitivity of 100% and a specificity of 99.3%. However, while the negative predictive value was 100%, the positive predictive value was <1%. Changes in specimen preparation and technical experience affected the number of RR (but not confirmed) results from a high of 59 in July to 28 in August, then to 5 in September, 8 in October, 18 in November, 21 in December, 20 in January, 3 in February and 10 in March.

Conclusions:

IDT with Procleix WNV Assay yielded an unacceptably high level (99%) of false positive initial test results. Adjustment of the S/CO ratio to >10.5 would have eliminated 159 of 172 (92.5%) FPs in our samples. However, the 13 samples (7.5%) with S/COs as high as 28.68 (range 17.49 to 28.68) that did not repeat are of particular concern. No obvious reason for these results could be determined after close examination. Further optimization of this WNV NAT for use on individual donation samples would be welcome.