

**PREVENTION OF WEST NILE VIRUS TRANSMISSION BY BLOOD TRANSFUSION: A COMPARAISON OF NAT SCREENING ASSAYS (SP417)**

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**Background:**

Transfusion-transmitted WNV infections were first reported in 2002, which led to development of both nucleic acid amplification tests (NAT) and viral load (VL) assays. During the westward spread of WNV across the United States, NAT-reactive cases were identified by blood bank WNV NAT screening. An understanding of the dynamics of WNV RNA has important implications for donor screening. Therefore, during the 2003 and 2004 epidemics, viral loads of NAT-reactive cases were determined using diverse VL assays. We conducted a study to evaluate the comparative performance of these diverse VL assays.

**Methods:**

As WNV NAT-reactive donation were identified by Blood Systems Laboratories (BSL), plasma units were recalled, subaliquoted and stored at -80°C until needed. Additionally, NAT-reactive donors were offered enrollment into a follow-up study. Identical aliquots from 48 confirmed NAT-reactive blood donors were sent to Chiron Corporation, Canadian Blood Services (CBS), National Genetics Institute (NGI) and CDC for viral load testing.

**Results:**

The results from this study are presented in the table. A total of 18% (Chiron), 17% (NGI), 26% (CDC) and 21% (CBS) of the 48 study specimens are in the 0.0-0.9 and 1.0-1.9 Copies (log<sub>10</sub>) categories. This is attributable to the viral dynamics of WNV and the corresponding variance in low viral load reporting styles. On the other hand a total of 15% (Chiron), 21% (NGI), 4% (CDC) and 21% (CBS) of the 48 study specimens had viral loads within the 5.0-5.9 and 6.0-6.9 Copies (log<sub>10</sub>) categories.

Friedman's nonparametric analysis of variance (ANOVA) of the data was statistically significant (p-value = 0.0005). F-tests indicate that the significance is attributable to differences between the PCR test types (p-value < 0.0001) rather than differences between panel members (p-value = 1.000).

**Conclusion:**

In general, a high correlation and good agreement was observed between three of the four VL assays (i.e. Chiron, Canadian Blood Services, and NGI). Nevertheless, the CDC results are significantly lower than the other three assays.

STUDY RESULTS		Chiron	NGI	CDC	CBS
Copies (log <sub>10</sub> )	Copies/mL	Assay* (#/%)	Assay** (#/%)	Assay*** (#/%)	Assay (#/%)
<b>0.0 - 0.9</b>	0 - 9.9	5(10%)	8(17%)	6(12.5%)	8(17%)
<b>1.0 - 1.9</b>	10 - 99.9	4(8%)	0(0%)	6(12.5%)	2(4%)
<b>2.0 - 2.9</b>	100 - 999.9	7(15%)	6(12%)	11(23%)	0(0%)
<b>3.0 - 3.9</b>	1000 - 9999.9	11(23%)	10(21%)	10(21%)	16(33%)
<b>4.0 - 4.9</b>	10,000 - 99,999.9	14(29%)	14(29%)	13(27%)	12(25%)
<b>5.0 - 5.9</b>	100,000 - 999,999.9	7(15%)	9(19%)	2(4%)	10(21%)
<b>6.0 - 6.9</b>	1,000,000 - 10,000,000	0(0%)	1(2%)	0(0%)	0(0%)
<b>Total</b>		48	48	48	48

\* Values outside the range of the assay calibrators were obtained by extrapolation; \*\*Values reported as "<100 copies/mL" were assigned a copy/mL value of "90 copies/mL"; \*\*\* Values reported as "50% positive in replicated testing" were assigned a copy/mL value of "0".