INTERPRETATION INFORMATION SHEET

ZIKV (ZIKA Virus) Assay

Creative Testing Solutions screens blood donations for ZIKA Virus (ZIKV). This testing uses Transcription Mediated Amplification (TMA) nucleic acid amplification testing (NAT).

NAT is routinely performed by first pooling samples from multiple donors as prescribed by the manufacturer's instructions for use, then testing the pool for the presence of viral nucleic acid. ZIKV-NAT testing was initially implemented at CTS using individual donor testing but CTS will begin implementation of pooled ZIKA testing in the near future. If the pool tests reactive, the individual donation samples in the pool are individually tested (IDS) to identify the reactive donation. An alternate sample from each individual Zika reactive donation will be retested to verify consistent reactivity. This retest is performed to help with determination of donor status as described in the table below.

All Zika reactive donations, regardless of the repeat NAT result, are reflexed for IgM antibody testing using a qualitative immunochromatographic assay to provide a more complete picture of the meaning of the initial NAT-reactive test result. Zika IgM detection is considered presumptive but not definitive for Zika infection as false positive results are possible in individuals with a history of infection with other flaviviruses. Additional testing is recommended for Zika IgM reactive donations prior to diagnosis and/or clinical management decisions.

PRNT (plaque reduction neutralization testing) is performed if the qualitative IgM is presumptive positive to help determine that the IgM reactivity is most likely due to exposure to Zika virus. The assay is performed by mixing serial dilutions of serum with constant concentrations of virus, in equal volumes. The mixture is then added to cell culture monolayers to assess antibody presence. Inhibited virus growth in the cell culture monolayers is indicative of the presence of neutralizing antibody in serum. The Zika PRNT detects the presence of neutralizing antibody directed against the Zika virus but there is still a potential that cross-reactivity with other flaviviruses such as Dengue may occur.

These tests work together and must be used in combination with clinical observations and exposure history to indicate the status of the donor. The most likely scenarios are described in the table below:

ZIKA NAT (TMA)	Retest ZIKA NAT (TMA)	Anti-ZIKA IgM (EIA)	ZIKA PRNT	Most likely interpretation
Reactive	Reactive	Negative	Not indicated	▪ Recent infection where not enough time has elapsed for IgM to develop
		Presumptive Positive	Positive/ Negative	▪ ZIKA infection at time of donation
Reactive	Negative	Negative	Not indicated	▪ False positive result due to TMA assay non-specificity
		Presumptive Positive	Positive	▪ ZIKA infection at time of donation (potential low level viremia)

References:
Chembio Diagnostic Systems, Inc., Chembio DPP Zika IgM Assay Instructions for Use, September 22, 2017. 17-4041-0 Rev 1
https://www.health.ny.gov/diseases/zika_virus/providers.htm; Content source: New York State Department of Health; Zika Virus Information for Health Care Professionals; Revised March 2018
https://www.cdc.gov/zika/transmission/blood-transfusion.html; Content source: Centers for Disease Control and Prevention; page last reviewed August 9, 2018; page last updated August 9, 2018

Revision History

Revision	Implemented	Reason
Initial Release	12/03/18	Implementation of licensed ZIKA NAT donor screening