

PROCLEIX WNV Assay – Intended use

The PROCLEIX® WNV Assay is a qualitative in vitro nucleic acid assay system for the detection of West Nile Virus (WNV) RNA in plasma specimens from individual human donors, including volunteer donors of whole blood and blood components, and other living donors. It is also intended for use in testing plasma specimens to screen organ donors when specimens are obtained while the donor's heart is still beating, and in testing blood specimens to screen cadaveric (non-heart-beating) donors.

The assay is intended for use in testing individual donor samples. It also is intended for use in testing pools of human plasma comprised of equal aliquots of not more than 16 individual donations from volunteer donors of whole blood and blood components. This assay is not intended for use as an aid in the diagnosis of West Nile Virus infection.

Summary and Explanation of the Test

Screening of whole blood donations with NAT has been in place in the United States since early 1999 and licenses were granted for HIV-1 and HCV screening in 2002. The PROCLEIX WNV Assay uses the same technology to detect WNV RNA as the PROCLEIX® HIV-1/HCV Assay.

The PROCLEIX WNV Assay involves three main steps, which take place in a single tube:

- Target capture
- Amplification
- Detection

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