

Recommended guidance for reporting West Nile viremic blood donors to state and/or local public health departments and reporting donors who subsequently develop West Nile virus illness to blood collection facilities (Drafted: June 16, 2003)

Introduction:

In 2002, investigations of transfusion-associated West Nile viral illnesses revealed that West Nile viremia was present in as many as 1 in 1,000 donors in areas reporting high numbers of West Nile meningoencephalitis cases and that the blood components from such donors were infectious.

In 2003, to reduce transmission through blood components, blood collection facilities will:

- Screen blood donations for West Nile virus RNA using investigational, nucleic acid amplification tests (NAT)
- Add screening questions to identify and exclude persons who exhibit fever and headache in the week prior to donation
- Immediately remove and quarantine all blood components associated with a NAT-reactive donation (these will either be destroyed or used for research purposes).

Based on the nearly 3,000 cases of West Nile meningoencephalitis that occurred in 2002, there may have been tens to hundreds of asymptomatic, viremic blood donors last year. If a similarly-sized epidemic occurs in 2003, notifying state health officials of these viremic donors may enhance states' West Nile virus surveillance efforts.

In addition, in 2003, during case investigations, state and local health departments may identify persons with West Nile viral illness who donated blood in the two weeks prior to illness onset. Because these persons may have been viremic at the time of donation, it is important for health departments to notify the appropriate blood bank that one of their donors subsequently developed a suspected West Nile viral illness. This will result in the immediate removal of any non-transfused blood components derived from the potentially infectious donation.

The following is intended to serve as a suggested guidance document for blood collection agencies to report West Nile viremic donors to state health departments and for state and local health departments to report recent blood donors who subsequently developed West Nile viral illness to appropriate blood collection facilities.

Overview:

Approximately 30 US testing laboratories will perform West Nile virus (WNV) NAT using kits produced by Roche and GenProbe / Chiron. Each day, testing labs will receive plasma samples contained in pilot tubes from donations submitted by numerous blood collection agencies; these plasma samples will be pooled and tested for WNV RNA in addition to testing for HIV and HCV RNA. Pools of six to 16 donations will be made for testing depending on the kit manufacturer. When a reactive pool is identified, each component sample will be tested individually to identify a potentially infectious donation. Test results will be reported to the original blood collection agency where the derived blood components will be immediately removed, if indicated.

In addition, further testing will be done to determine whether the initial NAT result was a true- or false-positive. This confirmatory testing will include one or more of the three following methods:

- Retesting the same plasma aliquot with an alternative NAT (either a different manufacturer or the same manufacturer but using a different set of primers)
- Testing the retrieved index frozen plasma unit using the same NAT manufacturer that was initially used for screening
- Serologic testing of a follow-up donor sample to determine if seroconversion to WNV occurred.

It is expected that repeat NAT of the same plasma aliquot or sample from the retrieved index plasma unit may take up to one to two weeks for completion and that donor follow-up serology testing may take longer than several weeks to complete.

Blood collection facility notification to state health departments:

Each licensed blood collection agency that receives results from their testing lab will be responsible for reporting viremic donors to the appropriate state health department in a timely fashion. The individual testing labs will not be responsible for informing state health departments of reactive tests.

A viremic donor should be reported to the state health department after confirmatory testing has been completed or within two weeks of the donation, whichever comes first. Each licensed blood collection agency will call or e-mail the following information to the state health department of the donor's resident state as determined by the donor's ZIP code given at the time of donation:

- Case identification number assigned by the blood center (this tracking code should be different from the index blood unit identification number or other operational identification numbers. It is intended to be used to track the case investigation)
- Donor's date of birth
- Donor's gender
- Donor's date of donation
- Donor's ZIP code

In some settings, states may also request additional donor information; this should be individually negotiated between a given state and a given blood collection facility.

State/local health department notification to blood collection facilities:

Rapid identification of persons with suspected West Nile encephalitis would allow blood collection facilities to remove potentially infectious blood components that may not have been originally identified by NAT screening. To do this, blood collection facilities must be immediately notified about persons with illnesses suspected to be due to WNV.

State or local health departments should inquire of all persons in whom WNV infection is being considered whether they have donated blood in the two weeks prior to illness onset. If such a donation is identified, it is incumbent for the investigator to determine the blood collection facility where the donation was given and to immediately notify this blood collection facility with the following information:

- Donor's name and date of birth (this is the minimum information required to allow blood collection facilities to track the donation)
- Social security number (if available)
- Date of donation (or approximate date if exact date unknown)
- Donor's gender
- Illness onset date
- Donor's ZIP code
- Donor's resident state

With this information, it is expected that the blood collection facility will be able to retrieve all in-date blood components and hold them until the WNV infection status has been determined. In the event that the WNV infection is confirmed, the retrieved components will be destroyed or used for research purposes regardless of any subsequent amplification testing and its result.