West Nile Virus NAT Policy

Purpose

This is the LifeServe policy for triggering and de-triggering WNV ID-NAT. This policy outlines the minimal triggering criteria for conversion from minipool NAT (MP-NAT) to individual donation NAT (ID-NAT), and reversion from ID-NAT to MP-NAT for allogeneic and autologous donations.

In accordance with the AABB Bulletin #08-03, a presumed viremic donation (PVD) is defined as an initially reactive donation that repeats as reactive on the original sample from the donation. Donations initially reactive using Roche cobas TaqScreen WNV Test, must be repeated to determine if they are PVDs. Back testing may be performed at the request of the Medical department.

An initially reactive sample that is not a PVD is not counted toward triggering, but should still be submitted for confirmatory testing. A confirmed positive donor is defined as having repeat NAT or IgM antibody reactivity on a second independent sample from the donation or from a follow up sample.

Trigger Areas Defined

Testing for a defined area will convert from MP-NAT to ID-NAT based on any one of the following indications of increased WNV activity in that area.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Defined Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>WNV PVD in a County in (or Adjacent to) LifeServe Territory.</td>
<td></td>
</tr>
<tr>
<td>When a WNV PVD occurs, the donor’s zip code defines the center of a circle with a radius of 25 miles. Donations from donors living within that circle will be tested with ID NAT (i.e. the area is triggered). This includes positive donors collected or reported by another blood center with a known zip code. If the zip code is not known, donations within a 45 mile radius from the center of the county will be tested ID-NAT.</td>
<td></td>
</tr>
</tbody>
</table>
New Activity Reported

For 3 or more new reports of epidemiologic activity in a county in (or adjacent to) LifeServe territory in the previous week, the center zipcode of that county will define the center of a circle with a 45 mile radius. Donations from donors living within that circle will be tested with ID NAT.

WNV activity that is more than 2 weeks old will be evaluated by the Medical Director on a case by case basis to determine if triggering is indicated.

**Trigger Activity**

When a defined geographic area has reached its trigger, conversion to ID-NAT will occur ideally within 48 hours of the most recent reactive donation responsible for the trigger being reached. If the conversion to ID-NAT cannot take place within this period, retrospective testing of retained samples will be considered from donations dating back to the collection date when the triggering criteria were met. ID-NAT will stay in force for a defined area for a minimum of 14 days if there is no new activity that would meet the above triggers. If, during the 14 days of ID-NAT testing, an additional PVD occurs, ID-NAT will remain in force for a minimum of 14 days. Assessments as to when to de-trigger will be made at 7-day intervals (e.g., 21 days, 28 days after triggering), corresponding with updates to public health surveillance sites, to determine when MP-NAT should be resumed.

**Data Reporting**

LifeServe will report data for initial reactive donations within 24 hours of verification of the test results to the American Association of Blood Banking (AABB). LifeServe will communicate WNV trigger information with regional and adjacent blood centers.