

Guidance for Reporting and Follow-up of Zika Virus Infected Blood Donors and Local Transmission of Zika Virus in California

August 2016

Executive Summary:

Zika virus is a blood-borne virus transmitted primarily through the bite of a mosquito. There is a potential for Zika virus to be transmitted via blood transfusion¹ and theoretically through organ transplantation.² Communication between blood banks, local health departments (LHD), and the California Department of Public Health (CDPH) regarding potential Zika transfusion-related cases follows typical transfusion/transplantation communication and includes:

- If a Zika-positive person who donated blood in the 120 days prior to illness is identified by the LHD, the LHD should notify CDPH (contact information below) who will notify CDPH Laboratory Field Services (LFS) to follow up with blood banks.
- If a transfusion or transplant recipient tests positive for Zika virus and in completing the Zika Virus Infection case report form, the LHD determines that a possible source of infection was via receipt of blood transfusion or organ transplantation, the LHD should immediately notify CDPH who will notify CDPH LFS to follow up with blood banks and transplantation facilities.
- Any infected donors identified through laboratory screening for Zika virus of donated blood should be reported by the blood bank to the LHD in which the donor resides or to CDPH if testing is performed by an out-of-state testing facility or if the county of residence is not obvious.
- The CDPH Laboratory Field Services program should notify licensed blood banks in California when local transmission of Zika virus (as defined below) has been identified in California.

Background:

Zika virus is transmitted primarily through the bite of a mosquito. There is also the potential for Zika virus to be transmitted via blood transfusion¹ and theoretically through organ transplantation.² The purpose of this document is to recommend communication pathways between blood banks, local health departments (LHDs), and the California Department of Public Health (CDPH) on reporting and follow-up of Zika infections detected in blood donors, those who recently donated blood, or individuals who received potentially infected blood donations or organ transplants. This document also offers guidance on communications with blood banks following the detection of local transmission of Zika virus and builds on the proposal from the Council of State and Territorial Epidemiologists (CSTE) on blood bank notification of Zika virus transmission areas in the contiguous United States.³ Follow-up and reporting of Zika virus infections in blood donors is essential to prevent further infection via blood transfusion and to assess risk of local transmission. Awareness of where Zika virus may be transmitted locally will help blood banks assess prior probability of Zika-infection in a donor, useful for test interpretation of positive test results.

Zika virus disease was made nationally reportable in 2016.⁴ It is reportable in California by physicians to LHDs who in turn report to CDPH. In addition, asymptomatic Zika virus infections, such as those identified in pregnant women or blood donors are also reportable to LHDs and CDPH.

The United States Food and Drug Administration (FDA) has announced the availability of an investigational test to screen blood donations for Zika virus.^{5, 6} FDA currently recommends that blood banks in California test all donations using an investigational individual donor nucleic acid test (ID-NAT) for ZIKV under an investigational new drug (IND) application or when available, a licensed test, or have all donations pathogen-reduced using an FDA-approved pathogen reduction device. The FDA also recommends that blood banks discontinue providing donors with ZIKV educational materials and stop screening donors for ZIKV risk factors, such as travel history, and deferring them as previously recommended in the February 2016 FDA guidance. As per current FDA guidance, if a donor volunteers a recent history of ZIKV infection, blood banks must not collect blood or blood components from that individual. FDA recommends that such a

donor be deferred for 120 days after a positive viral test or the resolution of symptoms, whichever timeframe is longer.⁶

In California, the *Aedes* mosquito species that are known to transmit Zika virus are found in limited areas in 12 counties (as of August 2016).⁷ To date, no local mosquito-borne transmission of Zika virus has been documented, and the overall risk of local mosquito-borne transmission is low. Zika cases reported in California are posted online.⁸ A document, [Guidance for Surveillance of and Response to Invasive *Aedes* Mosquitoes and Dengue, Chikungunya, and Zika in California](#), outlines responsibilities and response guidance for LHDs and vector control agencies in the various phases of either invasive *Aedes* mosquito detection or arbovirus transmission detection.⁹

Local transmission of Zika virus may be detected by local or state health authorities or local vector control agencies may detect infected mosquitoes.³ Guidance for communication of such detections is provided in the response plan and includes joint communication among LHDs, CDPH, and vector control agencies to enhance mosquito and human surveillance as well as inform the public.⁹ Blood banks should be included in this joint communication. The CDPH Laboratory Field Services program should notify licensed blood banks in California when local transmission has been identified in California. The area of local transmission will be delineated based on the number of human cases, the geographic location of the cases, the distribution of *Aedes* mosquitoes in the region, and the detection of Zika virus in mosquitoes. Potential boundaries may include one or more adjacent zip codes, cities, or counties. LHDs, CDPH and local vector control agencies will collaborate to determine the area at risk for local transmission. The area of local transmission risk should be provided to blood banks by CDPH Laboratory Field Services.

Blood banks must report any infected donors to the local health department in which the donor resides or to CDPH if testing is performed by an out-of-state testing facility or if the county of residence is not obvious. Positive test results can be reported to CDPH by FAX at 916-552-9725 or by phone at 916-552-9730, or email to VBDS@cdph.ca.gov.

There are scenarios where, in the course of completing the Zika Virus Infection case report form, the LHD may identify a Zika-positive case-patient of concern to blood banks. For example, a Zika-positive person who donated blood in the 120 days prior to illness may be identified. In a second scenario, a transfusion or transplant recipient may test positive for Zika virus and in completing the Zika Virus Infection case report form, the LHD may determine that a possible source of infection was via receipt of blood transfusion or organ transplantation. The local health department should notify CDPH when such scenarios occur. CDPH Laboratory Field Services will work with the appropriate blood bank or organ donation facility to identify persons at risk for infection and track potentially infected blood products.

Questions about Zika reporting issues should be directed to the CDPH Vector-Borne Disease Section (VBDS@cdph.ca.gov, 916-552-9730).

Questions about communications with blood banks should be directed to CDPH Laboratory Field Services (LFScc@cdph.ca.gov, 510-620-3800 or 213-620-6160).

If the primary point of contact cannot be reached, or for after-hours reporting, the CDPH duty officer can be reached at 1-800-971-9631 or 916-328-3605.

Reference List

- ¹ U.S. Centers for Disease Control and Prevention. [Zika Virus Transmission](https://www.cdc.gov/zika/prevention/transmission-methods.html). Available from <https://www.cdc.gov/zika/prevention/transmission-methods.html>
- ² U.S. Food and Drug Administration. Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products Guidance for Industry. 2016
<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM488582.pdf>
- ³ Council of State and Territorial Epidemiologists. CSTE Proposal for Blood Bank Notification of Zika Virus Transmission Areas. Atlanta Georgia: Council of State and Territorial Epidemiologists; 2016 May 5. 1-2 p.
- ⁴ U.S. Centers for Disease Control and Prevention. [Zika Virus Disease and Zika Virus, Congenital Infection. 2016 Case Definition, Approved June 2016](https://ndc.services.cdc.gov/case-definitions/zika-virus-disease-and-zika-virus-infection-2016-06-01/). 2016 Available from <https://ndc.services.cdc.gov/case-definitions/zika-virus-disease-and-zika-virus-infection-2016-06-01/>
- ⁵ U.S. Food and Drug Administration. FDA allows use of investigational test to screen blood donations for Zika virus. 2016
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm493081.htm>
- ⁶ Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components. Guidance for Industry 2016 August.
<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf>
- ⁷ [Invasive Aedes in California](https://cdphdata.maps.arcgis.com/apps/webappviewer/index.html?id=57367199287a4d18a2cecf107854255b). 2016 Available from <https://cdphdata.maps.arcgis.com/apps/webappviewer/index.html?id=57367199287a4d18a2cecf107854255b>
- ⁸ California Department of Public Health. [CDPH Update on Number of Zika Cases in California](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TravelAssociatedCasesofZikaVirusinCA.pdf). Available from <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/TravelAssociatedCasesofZikaVirusinCA.pdf>
- ⁹ [Guidance for Surveillance of and Response to Invasive Aedes Mosquitoes and Dengue, Chikungunya, and Zika in California](https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/InvasiveAedesSurveillanceandResponseinCA.pdf). 2017 Available from <https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/InvasiveAedesSurveillanceandResponseinCA.pdf>