

Zika Testing Poses Challenges for Blood Centers

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Introduction

On August 26, the Food and Drug Administration (FDA) issued an [updated guidance](#) recommending that all U.S. blood centers begin testing donations for Zika virus (ZIKV) using an investigational test cleared by FDA. While the recommendation is nonbinding, all blood centers are expected to comply.

Blood donations in Puerto Rico and Florida, the only areas within the United States where local mosquito-borne ZIKV transmission has been confirmed, are already being tested. Testing is also being conducted on donations in high-risk areas of Texas.

The guidance is the latest in a series of steps to prevent the spread of ZIKV in the blood supply. In February, FDA released a set of [donor screening and deferral recommendations](#), which U.S. blood banks implemented. The agency also recommended suspending blood collections in areas where ZIKV was found to be spreading locally by mosquitoes until testing could be implemented.

Zika-related donor deferrals have exacerbated an already tight U.S. blood supply this summer. In July, the nation's blood bankers issued a [joint appeal for blood donors](#) to sustain inventories across the country. Blood centers also face the challenge of recovering the costs of ZIKV testing.

Figure 1. An American Red Cross Worker Testing Donated Blood



Source: U.S. Department of Defense, 2006.

Evolution of the Zika Threat

ZIKV is [transmitted](#) by infected mosquitoes or sexual contact, from mother to fetus, and through contaminated blood transfusion. [Prenatal ZIKV infection](#) can cause severe birth defects, including microcephaly.

ZIKV is thought to have [arrived in the Western Hemisphere](#) early in 2015. Until recently, most U.S. cases of ZIKV infection were among travelers returning from areas with [local transmission](#) of ZIKV (i.e., areas where [Aedes mosquitoes](#) are spreading the virus). Puerto Rico has experienced local transmission of ZIKV since November 2015 and has been [hard hit](#), with about [14,000 locally acquired infections](#) reported to date. [Two counties in Florida](#) have also had local transmission.

While CDC does not anticipate widespread local transmission of ZIKV on the U.S. mainland, it has not ruled out additional "hot spots" of local transmission emerging in the coming weeks.

For the purpose of blood safety, CDC and FDA define [areas of active transmission of ZIKV](#) as "having two or more locally acquired cases of Zika virus infection within 45 days." Active transmission can occur in areas with both [Aedes mosquitoes](#) and large numbers of [travel-associated ZIKV cases](#). Of potential concern are U.S. states in the South, and along the East and West Coasts.

Response of FDA and the Blood Banks

On February 16, 2016, FDA issued [donor education, screening, and deferral recommendations](#) for immediate implementation to reduce the risk of transmitting ZIKV through the blood supply.

FDA provided two sets of recommendations. It advised blood centers in [areas without active transmission](#), which at the time included the entire continental United States, to defer for four weeks potential donors who (1) reported traveling to an area with active ZIKV transmission (e.g., Puerto Rico, Mexico), (2) engaged in behaviors (including sexual contact) that may have exposed them to ZIKV, or (3) reported symptoms suggestive of ZIKV infection.

In [areas with active transmission](#), which at the time included only Puerto Rico, FDA was more prescriptive. It recommended suspending blood collections until a ZIKV test was available and, in the meantime, procuring blood products from areas without active transmission. As a result, blood collections in Puerto Rico were halted, and shipments of blood products were flown in from the U.S. mainland.

On March 30, FDA announced the availability of a [test for ZIKV in donated blood](#) under an Investigational New Drug (IND) application, the first of two such tests. Blood centers in Puerto Rico resumed collections and began sending

samples to a facility in Florida that had implemented the investigational ZIKV test. Blood centers in Florida [began testing](#) their donors in late July when the first local ZIKV cases were identified in Miami.

(The IND test used for donated blood is different from ZIKV tests used to diagnose illness in patients. Currently, there are no FDA-approved ZIKV diagnostic tests, but FDA has granted [emergency use authorizations \[EUAs\]](#) for several tests under development.)

The [updated guidance](#) recommends that the following states implement testing by September 23: Alabama, Arizona, California, Georgia, Hawaii, Louisiana, Mississippi, New Mexico, New York, South Carolina, and Texas. These states were chosen because of their proximity to areas with cases of local mosquito-borne ZIKV or because of other epidemiological factors, such as the number of travel-related cases. All other states and territories should implement testing by November 18.

Blood centers struggle to maintain adequate inventories during the summer when donors are on vacation and colleges are out of session. ZIKV donor deferral is just one of several factors that have made the summer of 2016 more challenging for blood centers than usual.

The guidance should help increase donations in the coming weeks because it allows blood centers that institute testing to [discontinue verbal donor screening and deferral](#) for ZIKV risk factors, such as travel history. FDA argues that screening donors in areas with local ZIKV transmission based on their medical history is of limited value given that about 80% of infected individuals show no symptoms.

While all blood centers intend to comply with the guidance, some question whether universal ZIKV testing goes beyond what is necessary to protect the blood supply. For state and local public health officials, testing of blood donors acts as a surveillance system for identifying ZIKV infection in otherwise healthy individuals.

Implementing ZIKV testing is a complex and costly process, though cost recovery is permitted under the IND protocol. In Florida, blood centers reportedly have been able to recover ZIKV testing costs from the hospitals they sell blood products to. Whether blood centers in other parts of the country will be able to recover their testing costs is unclear.