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Important Information for Blood Establishments Regarding Zika Virus Transmission Risk in the World

The Centers for Disease Control and Prevention (CDC) has changed information on its [Blood and Tissue Safety webpage](#) used to communicate epidemiological information about Zika virus (ZIKV) to the blood and tissue collection community. CDC had previously identified areas with active transmission risk in other countries by using travel notice start and end dates; however, identification of risk areas involving other countries and territories will now be provided using a [world map of areas with risk of Zika](#). Areas with active ZIKV transmission risk in the United States will continue to be defined at the county level within a state, including risk start and end dates, as listed on the CDC webpage for [Blood and Tissue Safety](#).

The CDC reports that, based on laboratory analyses and mathematical modeling, a conservative yet plausible estimate for introduction of ZIKV and substantive risk of exposure in North America, South America, Central America, and the Caribbean is January 1, 2014 (1,2,3). Furthermore, scientific evidence confirms ZIKV presence in some African and Asian countries for decades, in some cases dating back to the 1950's (4,5,6). Therefore, the possibility of mosquito-borne ZIKV transmission to travelers may have started before the travel notice dates originally posted on the [Blood and Tissue Safety webpage](#).

In February 2016, the FDA issued "Recommendations for Donor Screening, Deferral and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Guidance: Guidance for Industry," and recommended that blood should not be collected in areas with active transmission of ZIKV, or from travelers to such areas, until testing for ZIKV or pathogen reduction was implemented. In August 2016, the FDA issued "[Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components; Guidance for Industry](#)," recommending testing for ZIKV or use of a pathogen-reduction technology. This guidance recommended immediate testing in states and territories with one or more locally acquired cases of ZIKV. Nationwide testing was phased in rapidly over a 12-week period.

Considerations for Blood Establishments

FDA's current guidance contains recommendations regarding ZIKV and the blood supply. CDC has added new epidemiological information to its website regarding potential Zika risk related to travel outside the United States that has implications for blood establishments. As a precaution, blood establishments may wish to consider whether to take additional measures to address the possibility of risk of ZIKV from in-date blood components (e.g., frozen red blood cells) collected from travelers to countries identified by CDC at risk for Zika prior to the implementation of donor deferral or blood donor screening tests for ZIKV.

FDA is providing establishments with this notification of potential risk to blood safety out of an abundance of caution. At this time, the potential risk to in-date blood components (e.g., frozen red blood cells) is believed to be small enough that no formal regulatory action is required by the FDA.

Blood establishments may exercise discretion regarding product disposition should they become aware of donor travel to a country identified by CDC at risk for Zika prior to the implementation of donor deferral or blood donor screening tests for ZIKV. Regarding ZIKV untested blood components, blood establishments that are contacted by a donor who reported travel since January 1, 2014, to at risk countries may wish to consider whether to quarantine undistributed, in-date blood components from

the donor (i.e., frozen red blood cells) and whether to notify consignees to quarantine such blood components so that they will not be transfused.

References

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