



## NEWS RELEASE

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### **FDA Revises Zika Testing Requirements for Blood and Components**

*Final guidance recommendations include testing all blood donations collected in the United States and its territories for Zika.*

**WASHINGTON (September 1, 2016)** — The U.S. Food and Drug Administration (FDA) issued a final guidance on August 26 regarding testing for Zika virus in blood and blood components to reduce the risk of transmission by transfusion. America's Blood Centers recognizes and shares the FDA's commitment to safety.

The guidance requires implementation of Zika virus testing for all blood donations within the next 4 to 12 weeks or sooner based on whether local mosquito-borne transmission exists or travel-related Zika infections.

"America's Blood Centers and its member blood centers are committed to the safest possible blood supply and will work with the test manufacturers to comply with the FDA Guidance," said America's Blood Centers' Chief Medical Officer Louis Katz, MD. "We do not believe the guidance should impact supply unless requirements to get specific consent from donors for testing with the investigational assays lead to refusals from many donors."

Blood donation testing remains ongoing for all blood donors in Florida, which is currently the only place where (limited) local transmission has been observed. Additionally, member blood centers of America's Blood Centers in the state of Texas have implemented Zika virus blood donation testing in high risk areas and testing will continue to expand throughout the Gulf Coast region in accordance with the FDA guidance. Selective testing to qualify otherwise deferred donors is ongoing at other member blood centers.

"Both testing labs and the test vendors are working feverishly to allow testing to start on time in the areas subject to the 12 week timeline," said Dr. Katz. "My conversations with the vendors suggest that if all goes smoothly, that goal is feasible. Accordingly, whether things go smoothly involves an incredibly complex set of processes. The amount of work to do this in short timeframes is titanic."

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**About America's Blood Centers**

Founded in 1962, [America's Blood Centers](#) is North America's largest network of community-based, independent blood programs. Recognized by the U.S. Congress for its critical work in patient care and disaster preparedness and response, the federation operates more than 600 blood donor centers providing half of the U.S., and a quarter of the Canadian blood supply.

These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America. America's Blood Centers' U.S. members are licensed and regulated by the U.S. Food and Drug Administration. Canadian members are regulated by Health Canada.