

11/10/2022

Dear Colleagues:

I am writing to inform you that the **AABB Zika Virus (ZIKV) Biovigilance Network** platform will cease operations on **November 15, 2022**. AABB would like to thank all the participating blood collection establishments for contributing valuable data to this platform during the past few years.

The AABB ZIKV Biovigilance Network platform was established in 2016 as a collaboration between AABB & U.S. blood collection establishments in response to the Food and Drug Administration (FDA)'s February 2016 Guidance classifying ZIKV as a relevant transfusion-transmitted infection (RTTI) and requiring donor screening and testing. The platform collected and reported data for donations with reactive ZIKV Nucleic Acid Test (NAT) results and mapped these data to U.S. geographical locations. AABB deployed an enhanced ZIKV reporting platform in December 2018 to support blood safety and compliance with FDA's July 2018 ZIKV guidance.

The system collected 889 total reports of reactive cases, with 46 cases confirmed-positive for ZIKV, from AABB member blood collection facilities since the platform initiation in 2016. Throughout the past 6 years, the knowledge and strategies to address the risks for transfusion-transmitted ZIKV have matured. In March 2021, the FDA formally withdrew its July 2018 ZIKV guidance, stating that ZIKV is no longer classified as an RTTI under FDA's regulations because "the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential donor population." We are pleased that data from AABB's ZIKV Biovigilance Network presented during the March 2019 Blood Products Advisory Committee Meeting, at the invitation of the FDA, became part of the record considered by FDA when updating its recommendations.

In the absence of risk for transfusion-transmission, ZIKV testing requirements, and any application to improve blood safety, AABB will sunset the ZIKV Biovigilance Network platform. AABB appreciates your participation in the platform and your contributions to its success. Participating facilities can request a copy of the data they submitted to the platform by emailing hemovigilance@aabb.org.

AABB will continue to support the West Nile Virus (WNV) platform as part of AABB's mission to improve blood safety, because WNV testing is still required to mitigate risk for transfusion-transmission.

AABB hopes that this notification allows sufficient time for your blood center to update standard operating procedure if you have not already. Please

contact hemovigilance@aabb.org if you have questions or would like to request a revised timeline.

Best regards,

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