

CLIENT NOTICE

Blood Services Update ● Zika Testing

Notification Date: 21 JUL 2021 Effective Date: 11 AUG 2021

Discontinuation of Zika Testing

As of May 12, 2021, the Food and Drug Administration (FDA) has withdrawn its July 2018 Zika virus (ZIKV) testing guidance, stating that "testing for ZIKV, or pathogen reduction as an alternative to testing for ZIKV, is not necessary to comply with the requirements of 21 CFR 610.40(a)(3)." The agency determined that ZIKV is no longer a relevant transfusion-transmitted infection (RTTI) under FDA's regulations because the virus no longer has sufficient incidence and/or prevalence to affect the potential donor population.

Detailed information on the basis of this decision can be found here: https://www.fda.gov/media/148549/download.

For blood collected on or after August 11, 2021, South Bend Medical Foundation will no longer perform testing for Zika Virus. An updated Circular of Information can be found on August 12, 2021 in the Client Resources section of our website: https://www.sbmf.org/client-resources

If you have further questions, please reach out to your Account Executive; Laura Balciunas, 574-309-2591 or Meghan Berkheiser, 574-286-0287.

SBMF online Test Directory

Questions: Please contact CLIENT SUPPORT at 574-236-7263

Client Notices are distributed electronically.

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