Carter BloodCare

To: Carter BloodCare Customers
From: Hospital Relations Department
Date: September 24, 2018
Re: UPDATE – Zika virus testing

Background:
On July 5, 2018, FDA approved the Procleix Zika virus assay, manufactured by Grifols Diagnostics Solutions, Inc. The Procleix Zika virus assay is a qualitative nucleic acid test for the detection of Zika virus RNA in individual plasma specimens obtained from volunteer donors of whole blood and blood components for transfusion. The assay is intended for use by blood collection establishments to detect Zika virus in blood donations.

Additionally, on July 9, 2018, the FDA published revised recommendations for the testing of Zika virus. The guidance states that blood establishments must test all donations collected in the United States and its territories with a licensed nucleic acid test for ZIKV, using either ID NAT or minipool (MP) NAT. The guidance explains the basis for FDA's determination that universal MP NAT screening, with certain conditions identified to trigger ID NAT when local mosquito-borne ZIKV transmission is presumed in a collection area, provides an adequate and appropriate safeguard against the current and future risk of ZIKV transmission through blood transfusion.

Creative Testing Solutions (CTS) performs the infectious disease testing for Carter BloodCare. While the FDA approved the Procleix Zika assay on July 5, 2018, CTS was allowed to continue using the investigational Procleix Zika virus assay until existing inventory is depleted.

Impact to client:
Creative Testing Solutions anticipates the implementation of the FDA approved Procleix Zika virus assay using universal MP NAT screening by November 2018. The effective date will be shared as final determinations are made.

The statement *Neg for Zika by Investigational NAT* on products will be discontinued for any blood donations subsequent to implementation.

The Circular of Information will be modified to reflect the change in testing.

The effect of licensure on pricing is undetermined at this time.

Related links:
https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf

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