

Memo

To: User of Circular of Information

From: Christine Driscoll, Director, Regulatory Affairs and Donna Strauss,
Executive Director, Core Operations

Date: December 21, 2017

Re: Circular of Information Update

In accordance with Food and Drug Administration (FDA) Guidance for Industry: Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components, August 2016, and Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components, December 2017, New York Blood Center is providing an update to the ZIKV language.

The following information is to be considered a part of the Circular of Information as it applies to the *General Information for Whole Blood and All Blood Components, Testing of Donor Blood* section.

Units labeled as negative for Zika virus RNA were tested with an Investigational nucleic acid test (NAT) and found to be nonreactive.

BLOOD UNIT LABELING: Blood units tested with Procleix Zika Virus Assay and found negative will be labeled: "Neg for Zika by Investigational NAT".

Units labeled as negative for Zika virus using an FDA licensed test.

BLOOD UNIT LABELING: A licensed nucleic acid test (NAT) for Zika Virus RNA has been performed and found to be nonreactive.