


MEMORANDUM

To: Users of Circular of Information
From: Margaret Hannan 
Director, Quality Systems Management
Date: July 18, 2018
Subject: Circular of Information Updates

Below are updates to the October 2017 FDA-approved AABB Circular of Information (COI).
The most recent change appears first.

Babesia Testing – Effective July 18, 2018

Blood Bank of Delmarva is currently participating in the Roche Molecular Systems, Inc. Clinical Study Protocol “A Prospective Study to Evaluate the Specificity of the **cobas**® Babesia test for use on the **cobas**® 6800/8800 Systems for Screening of Blood Donations for the Presence of Babesia Parasite DNA and RNA.” Based on information provided by Roche Molecular Systems, Inc. the following changes have been made to the COI:

COI CHANGES. Section: General Information for Whole Blood and All Blood Components, Testing of Donor Blood.

Units labeled as negative for Babesia were tested using an investigational nucleic acid test (NAT) and found to be negative.

BLOOD UNIT LABELING CHANGES.

Neg for Babesia by investigational NAT.

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ZIKV Testing - Effective November 14, 2017

Based on the 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 the Guidance for Industry: An Acceptable Circular of Information for the Use of Human Blood and Blood Components, December 2017, the following changes have been made to the COI:

COI CHANGES. Section: General Information for Whole Blood and All Blood Components, Testing of Donor Blood.

A licensed nucleic acid test (NAT) for Zika virus RNA has been performed and found to be nonreactive.

BLOOD UNIT LABELING CHANGES.

A licensed nucleic acid test (NAT) for Zika virus RNA has been performed and found to be nonreactive.