November 2, 2016

Dear Colleagues,

We would like to provide you with information on Zika testing for blood components.

Situation:

- In accordance with FDA's August 26, 2016 guidance, Bloodworks will implement investigational Zika virus testing of all blood donations collected beginning November 9, 2016.

Background:

Information abstracted from the AABB Association Bulletin #16-07:

- Zika infection: Zika, a flavivirus, is transmitted by Aedes mosquitoes, most commonly by A. aegypti
  - In about 80 percent of individuals, infection with Zika virus is asymptomatic; in the remaining 20 percent, a mild febrile illness consisting of rash, joint pain, muscle pain, conjunctivitis, and headache are most commonly described.
  - However, in adults, severe complications including Guillain-Barré and other neurological syndromes have been reported.
  - Zika virus can be transmitted from an infected mother to her fetus during pregnancy and is responsible for fetal loss, microcephaly, and other congenital neurological syndromes.
- Mode of transmission:
  - Mosquitoes bites by Aedes mosquitoes, most commonly by A. aegypti.
  - Intrauterine, perinatal
  - Sexual routes
  - Laboratory and healthcare setting exposure
  - Blood transfusion
- Transfusion Transmitted Zika:
  - Transfusion transmission has been documented. To date, there are four probable cases of transfusion transmission from three Zika-infected donors in Brazil. None of the four recipients who acquired transfusion-transmitted Zika developed symptoms attributable to the infection; however, the consequences of a transfusion-transmitted infection to a female during pregnancy remain unknown.
  - It is believed that Zika virus RNA can be detected in plasma for 1-2 weeks.
  - During the French Polynesian outbreak when it was found that 2.8 percent of asymptomatic blood donors tested positive for Zika viral RNA.
  - As of November 1, 2016, a few states in the US have reported confirmed-positive Zika virus infection in blood donors.
- FDA guidance on Zika testing for blood products
  - To ensure blood safety, FDA has recommended testing for Zika virus using ID-NAT (individual donation nucleic acid test) under an approved IND (investigational new drug) application until a licensed test is available, as one option to mitigate transfusion transmitted risk from transfusion.
  - FDA will require all blood products testing negative for Zika virus under IND to be labelled with an additional statement on the blood product bag as follows: "Neg for Zika Virus by investigational NAT"
  - Bloodworks will continue to apply travel deferrals until Zika testing begins.

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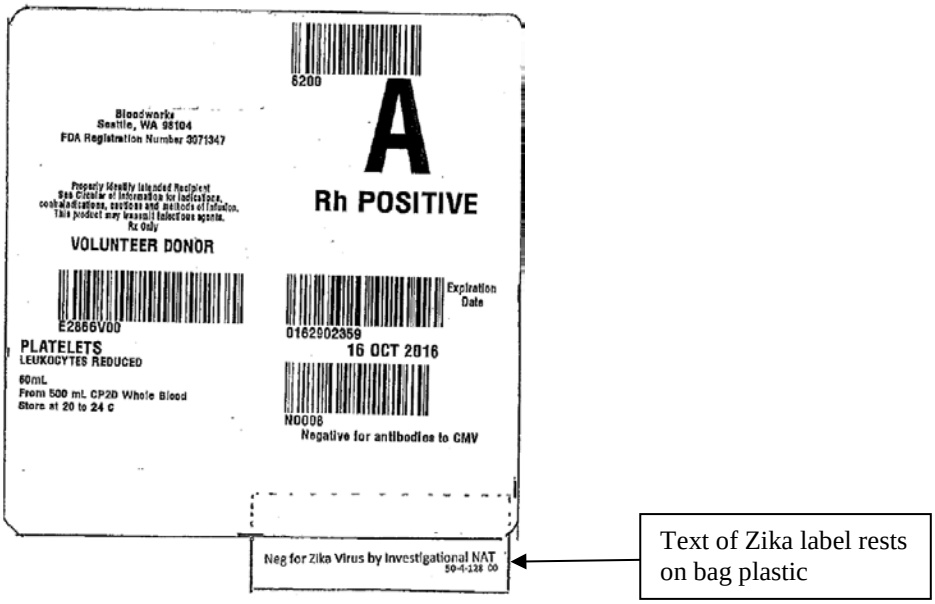
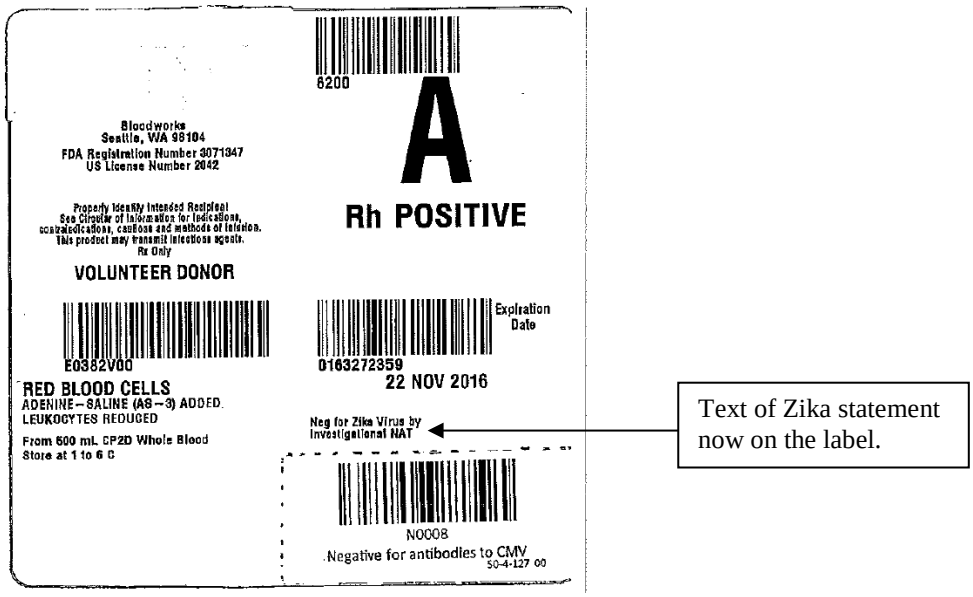
Assessment:

- Until the current inventory is fully replaced by Zika- tested products, there will be a dual inventory of Zika-tested and Zika-untested products.
- Products collected on or after November 9, 2016 will have a label that includes a Zika testing statement as shown below:



Or



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Recommendation:

- Please be aware of the Zika testing for blood components and related label changes
- Please be prepared to address any questions or concerns that your patients may have regarding this
- Please be aware that Zika virus disease is a nationally notifiable condition. Healthcare providers should report suspected Zika virus disease cases to their state, local, or territorial health department to facilitate diagnosis and mitigate risk of local transmission
- For additional information:
    - a. AABB Association Bulletin #16-07A (https://www.aabb.org/programs/publications/bulletins/Documents/ab16-07.pdf);
    - b. CDC (http://www.cdc.gov/zika/transmission/index.html)

Thank you for choosing us as your trusted health care partner in providing blood for your patients.

Sincerely yours,

Yanyun Wu, MD, Ph.D.
Chief Medical Officer
Bloodworks

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