CDC Zika IMS Sustaining the Zika Response in 2017
Blood Safety Task Force

March 30, 2017

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Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Disease

Overview

- Zika Virus Background
- Background on Blood, Organ, and Tissue Collection/Screening
- Blood Donor Screening
- Q&As
- Closing Remarks

Blood Safety Task Force

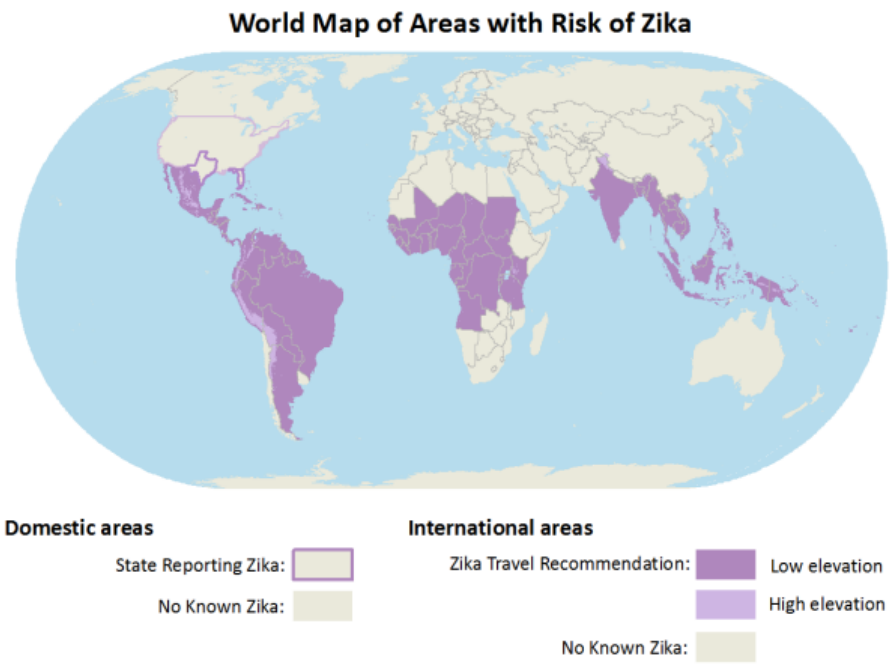
Zika Virus Background

Zika Virus

- Zika virus (ZIKV) is spread to people primarily through infected *Aedes* species mosquitoes (*Ae. aegypti* and *Ae. albopictus*)
- Many people infected with Zika won't have symptoms or will only have mild symptoms
- Zika infection during pregnancy can cause microcephaly and other severe brain defects

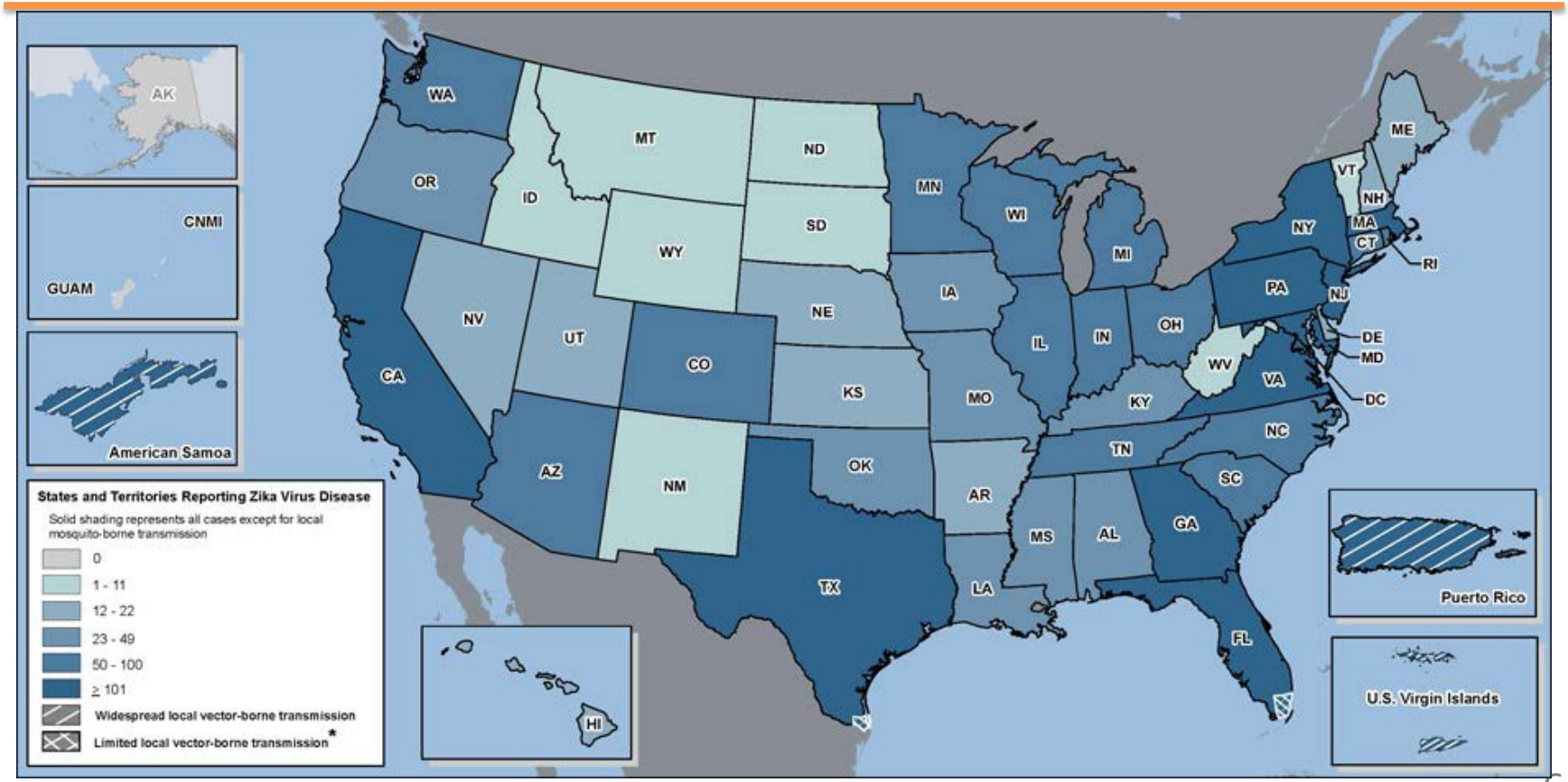
Where has Zika Been Found?

- Before 2015, Zika outbreaks occurred in Africa, Southeast Asia, and the Pacific Islands.
- Currently outbreaks are occurring in many countries and territories.



https://wwwnc.cdc.gov/travel/files/zika-areas-of-risk.pdf

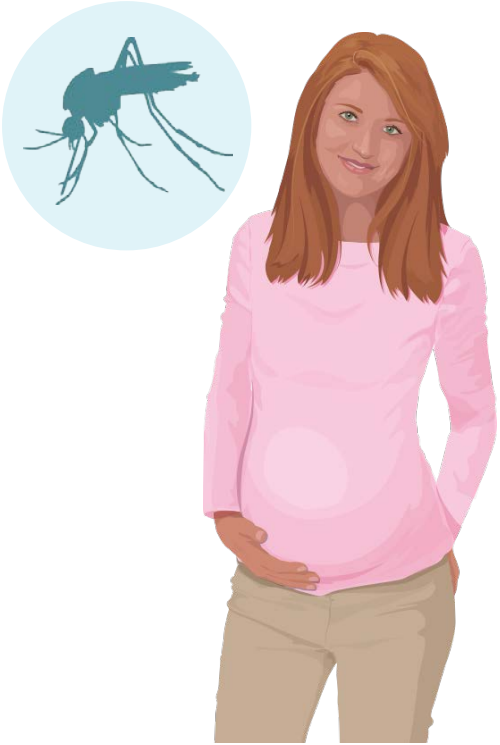
Zika Virus in the US, March 22, 2017



https://www.cdc.gov/zika/intheus/maps-zika-us.html#zika-cases-us

How is Zika Spread?

- Zika can be spread through
  - Mosquito bites
  - From a pregnant woman to her fetus
  - Sex with an infected person
  - Laboratory exposure
- Zika may be spread through blood transfusion.
- No reports of infants getting Zika through breastfeeding.



Zika Virus Vectors: *Aedes* Mosquitoes

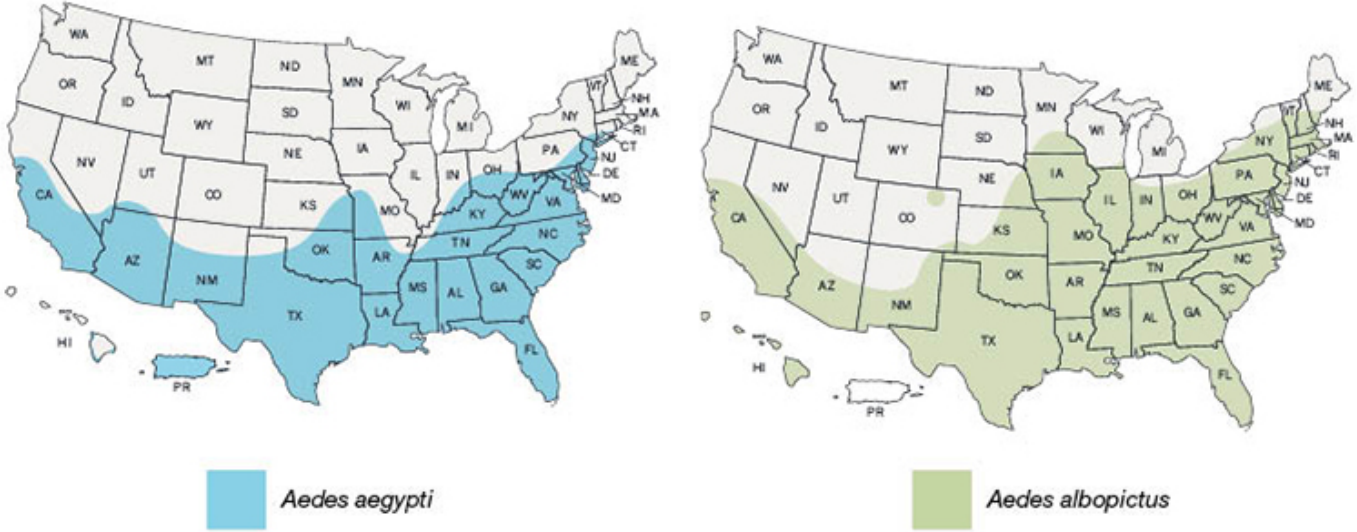
- *Aedes* species mosquitoes (*Aedes aegypti* and *Aedes albopictus*)
- Also transmit other viruses like dengue and chikungunya
- Lay eggs near water-holding containers
- Live in and around homes
- Bite during the day and at night

Aedes aegypti

Aedes albopictus

Ae. aegypti and *Ae. albopictus* Mosquitoes: Estimated Geographic Distribution in the United States

Estimated range of *Aedes albopictus* and *Aedes aegypti* in the United States, 2016*



*Maps have been updated from a variety of sources. These maps represent CDC's best estimate of the potential range of *Aedes aegypti* and *Aedes albopictus* in the United States. Maps are not meant to represent risk for spread of disease.

https://www.cdc.gov/zika/pdfs/zika-mosquito-maps.pdf

Clinical Presentation

- Clinical illness usually mild
- Most common symptoms
  - Fever (usually low-grade)
  - Rash (maculopapular; often pruritic)
  - Arthritis or arthralgia
  - Non-purulent conjunctivitis
  - Other symptoms include: muscle pain, headache
- Symptoms last several days to a week
- Severe disease uncommon
- Fatalities rare

Other Modes of Transmission

- Proven/Probable
  - Sexual contact
    - Male (symptomatic and asymptomatic) to female
    - Female (symptomatic) to male
    - Male (symptomatic) to male
  - Intrauterine
  - Perinatal from a viremic mother to newborn
  - Blood transfusions
- Possible
  - Breast milk
  - Organ and tissue transplantation

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Background on Blood, Organ, and Tissue Collection/Screening

Background

- **Blood**
  - Types of collection: whole blood and apheresis
  - Types of products: red blood cells, platelets, plasma
  - Screening: hepatitis B/C, HIV, human T-lymphotropic virus (HTLV), syphilis, West Nile virus, and Zika virus
- **Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)**
  - Types of products: corneas, bone, skin, heart valves, hematopoietic stem/progenitor cells (HPCs), reproductive tissues, etc.
  - Screening: hepatitis B/C, HIV, HTLV, syphilis, cytomegalovirus, chlamydia, gonorrhea
- **Solid Organs**
  - Types of products: kidney, heart, liver, etc.

Blood Safety

- **No reported ZIKV transfusion-transmitted cases in the United States**
- **Probable ZIKV transfusion-transmitted cases in Brazil**
- **US Food and Drug Administration (FDA) issued industry guidance in Feb. 2016[1] and revised guidance in Aug. 2016[2]**
  - Blood collection centers in all states and US territories should perform ZIKV screening on all donations using a screening test authorized for use under an FDA investigational new drug (IND) application, or with a licensed test when available; or use an FDA-approved pathogen-reduction device for plasma and certain platelet products

[1] https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM486360.pdf
[2] https://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM518213.pdf

Blood Safety

Centers for Disease Control and Prevention
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SEARCH

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CDC > >Zika Virus Home > >Transmission

Zika and Blood Transfusion

Language: English

BLOOD AND TISSUE COLLECTION CENTERS

AREAS AT RISK

What we know

- On August 26, 2016, FDA issued revised guidance, recommending that blood centers in all states and U.S. territories screen individual units of donated whole blood and blood components with a blood screening test authorized for use by FDA under an investigational new drug (IND) application, or with a licensed test when available. Alternatively, and FDA-approved pathogen-reduction device may be used for plasma and certain platelet products.
- Most people infected with the Zika virus don't show any symptoms, blood donors may not know they have been infected.
- To date, there have been no confirmed transfusion-transmission cases of Zika virus in the United States. However, cases of Zika virus transmission through platelet transfusions have been documented in Brazil.

Zika Virus Blood Screening

- Blood donor screening on the basis of a questionnaire, without a laboratory test, is insufficient for identifying Zika-infected donors in areas with active mosquito-borne transmission of Zika virus due to the high rate of asymptomatic infection.
- Although there is no FDA-licensed test for Zika virus, testing for Zika became available through two separate Investigational New Drug (IND)

https://www.cdc.gov/zika/transmission/blood-transfusion.html

Blood and Tissue Safety

The areas listed under "Areas of Active Transmission in the US" can differ from those issued for travel guidance's because of additional concerns about potential risk for blood and tissue safety.

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Areas At Risk For Locally Acquired Vector-borne Zika Cases

Language: English

Zika virus information for the blood and tissue collection community

CDC is working with state health departments and blood and tissue collection organizations to help ensure the safety of our blood and tissue supply and reduce the risk of Zika virus transmission through blood transfusions and tissue transplants. Zika virus disease is a nationally notifiable condition. Cases are reported to CDC by state and local health departments using standard case definitions.

Special Notice – March 13, 2017

Potential Increased Risk to Blood and Tissue Safety

CDC has identified the potential for increased risk to blood and tissue safety in Miami-Dade County starting on June 15, 2016. The potential risk in Miami-Dade County did not meet the threshold for designation as an area of active transmission until July 29, 2016. CDC has also identified that since June 15, 2016, there has been a potential increased risk to blood and tissue safety in Broward and Palm Beach counties because of local travel of residents of these counties to areas of active transmission in Florida. The complete list of current and past areas of active transmission is provided below.

Guidance for Healthcare Providers Caring for Pregnant Women

FDA: 2017 Safety and Availability Communications

Areas of Active Transmission in the United States

To protect the US blood and tissue supply, CDC in collaboration with the US Food and Drug Administration (FDA) defines areas of active Zika virus transmission as having two or more locally acquired cases of Zika virus infection within 45 days. **These defined areas of risk can be different from areas for which CDC has issued travel guidance because of concerns about potential risk for blood and tissue safety.**

The following are areas of active transmission of Zika virus in the continental United States for the purpose of blood and tissue safety intervention:

- Miami-Dade County, Florida - As of July 29, 2016
  Florida Department of Health Confirms Local Transmission – click to view announcement
- Cameron County, Texas – As of December 9, 2016
  Texas Announces Additional Local Zika Cases in Cameron County

The following are *previously* listed areas of active transmission of Zika virus in the continental United States for the purpose of blood and tissue safety intervention:

- Palm Beach County, Florida – From August 24, 2016 – November 2, 2016*
  Florida Department of Health Zika Update - click to view announcement

*No new cases of local Zika virus transmission have been identified for a period of 45-days.

ZIKA & PREGNANCY

Travel notice posting dates for countries and territories with reported local mosquito transmission

https://www.cdc.gov/zika/areasatrisk.html

Zika Virus in the US, March 22, 2017

Laboratory-confirmed symptomatic Zika virus disease cases and presumptive viremic blood donors reported to ArboNET by states and territories — United States, 2015–2017 (as of March 22, 2017)

States	Symptomatic disease cases** (N=5,158) No. (%)	Presumptive viremic blood donors† (N=43) No. (%)
Alabama	40 (1)	0 (0)
Arizona	54 (1)	1 (2)
Arkansas	15 (<1)	0 (0)
California	434 (9)	5 (12)
Colorado	57 (1)	0 (0)
Connecticut	58 (1)	0 (0)
Delaware	17 (<1)	0 (0)
District of Columbia	34 (1)	0 (0)
Florida‡	1,109 (22)	26 (60)
Georgia	110 (2)	0 (0)
Hawaii	16 (<1)	0 (0)

https://www.cdc.gov/zika/intheus/maps-zika-us.html#zika-cases-us

Tissue Safety

- **Tissue screening is currently not available outside of research settings**
- **Tissue donors are screened for risk factors for Zika virus using questions that include residence in and travel history to area(s) of active transmission**
- **FDA's March 2016 guidance[1] includes ZIKV-related**
  - Recommendations for living donors
  - Recommendations for non-heart-beating (cadaveric) donors

[1] https://www.fda.gov/downloads/biologicsbloodvaccines/guidancecomplianceregulatoryinformation/guidances/tissue/ucm488582.pdf

Organ Safety

- **No ZIKV guidance has been issued by Health Resources and Services Administration (HRSA), but the Organ Procurement and Transplantation Network (OPTN) issued a statement on ZIKV in July 2016**
  - https://optn.transplant.hrsa.gov/news/guidance-on-zika-virus/

- **For questions related to ZIKV organ safety, contact the Blood Safety Task Force at eocevent281@cdc.gov**

Blood Safety Task Force

Blood Donor Screening

Zika Virus Investigational New Drug (IND) Applications

- **FDA authorized two IND applications for screening donated blood**
  - Roche Molecular Systems, Inc. – cobas® Zika Test
    - Authorized for use on March 30, 2016
    - Began with screening donations in Puerto Rico, now includes continental United States
    - Individual donation testing only
  - Grifols Diagnostic Solutions, Inc. – Procleix® Zika Virus Assay
    - Authorized for use on June 20, 2016
    - Focused on southern US, now includes all donations from continental US
    - Combination of pools (16-donations) and individual donation testing
      - Pool testing was discontinued after December 11, 2016

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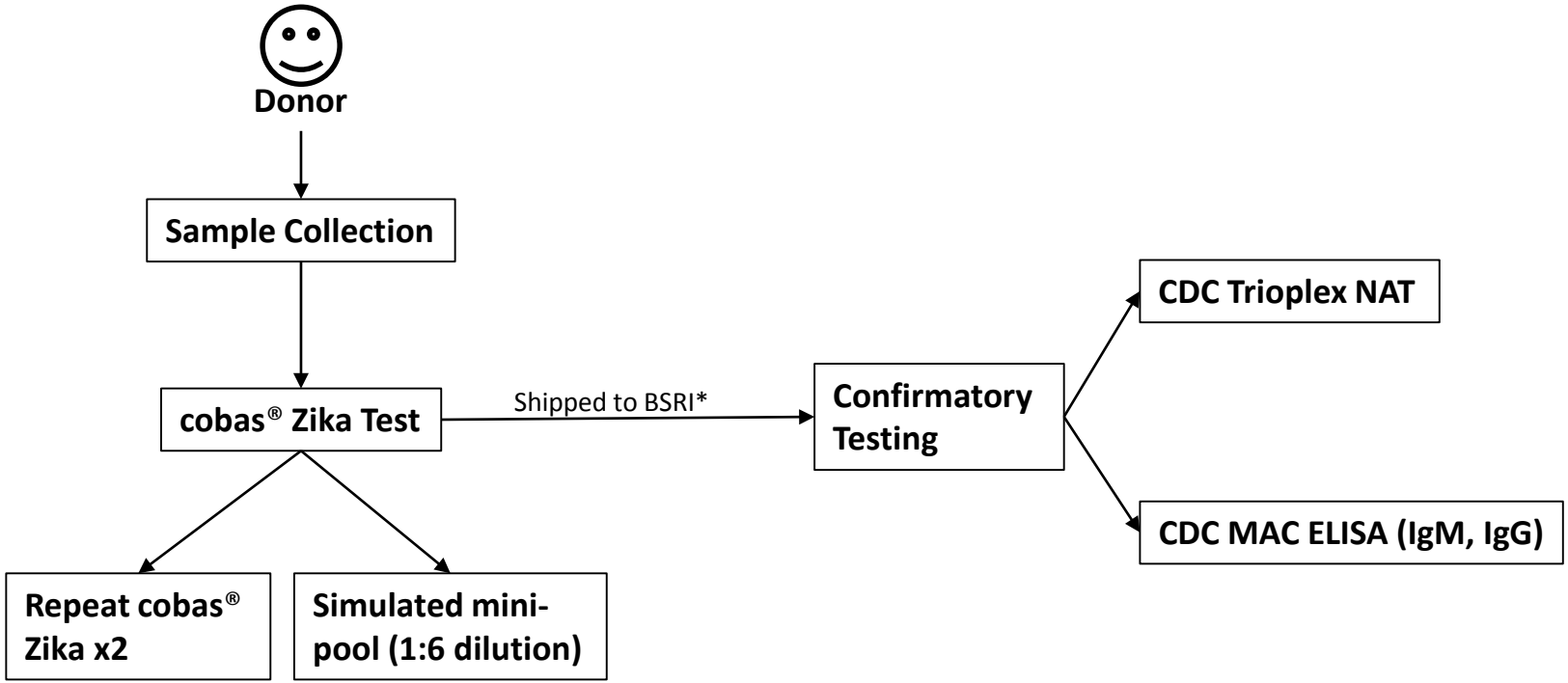
Blood Donor Screening – Roche Molecular Systems, Inc.

cobas® Zika Test Algorithm

Index Donation

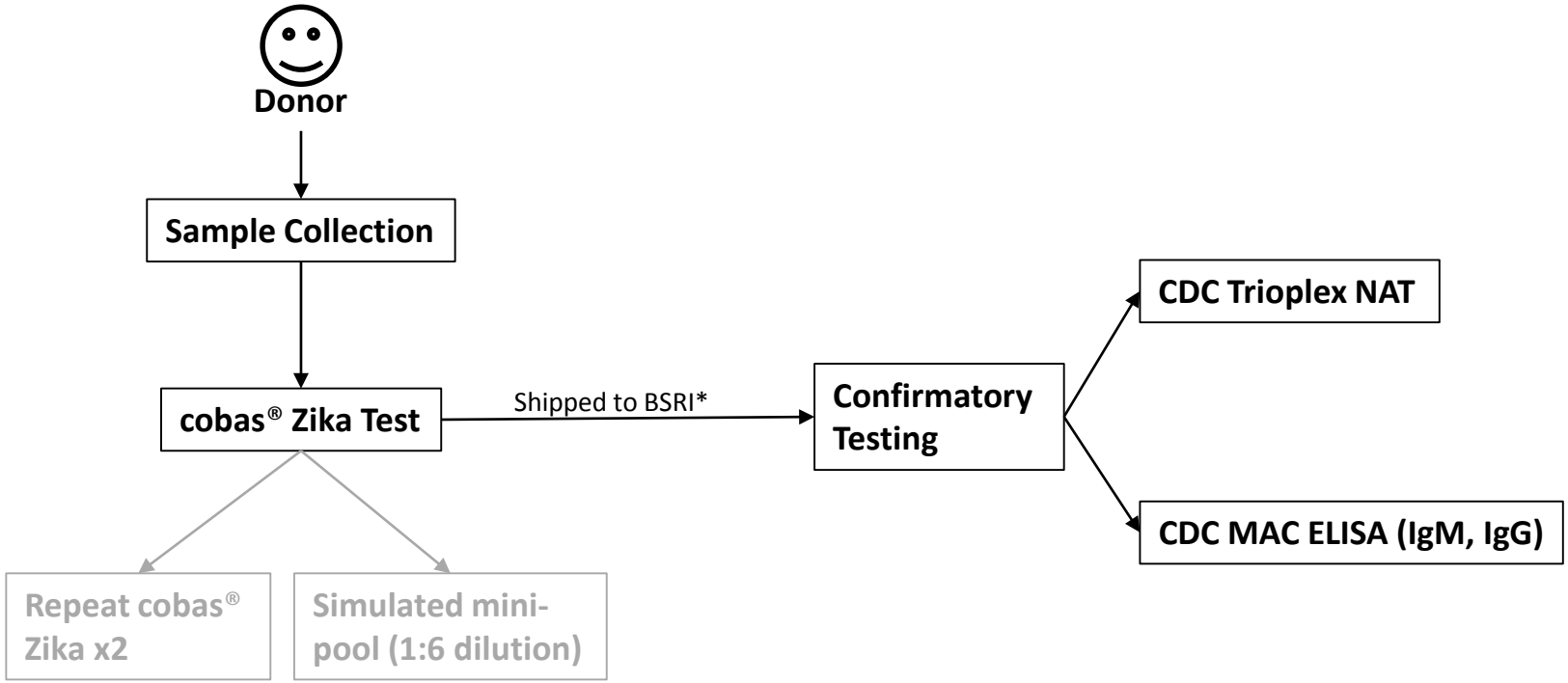


*BSRI – Blood Systems Research Institute, San Francisco, CA

cobas® Zika Test Algorithm

First Follow Up

Sample collected with 2-weeks of index donation

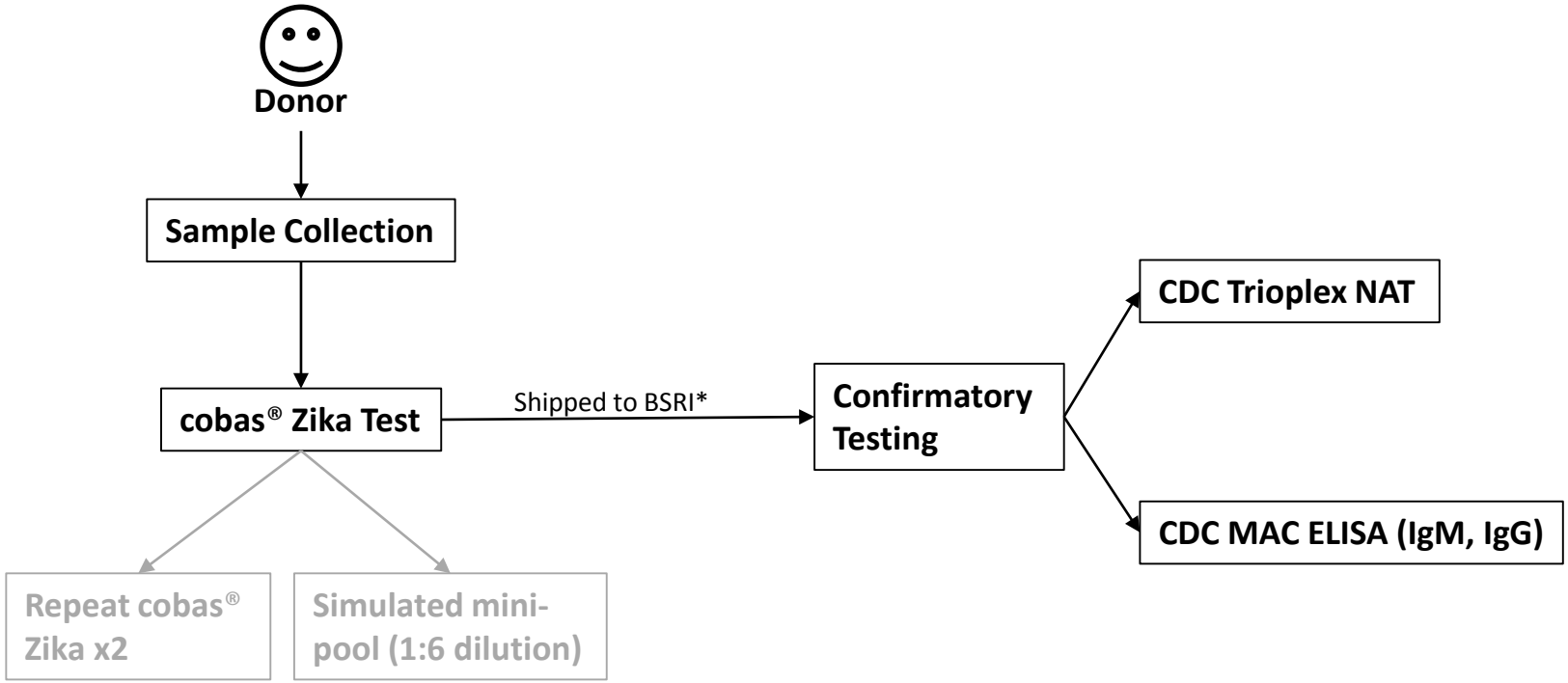


*BSRI – Blood Systems Research Institute, San Francisco, CA

cobas® Zika Test Algorithm

Second Follow Up

Sample collected 2-8 weeks after index donation



*BSRI – Blood Systems Research Institute, San Francisco, CA

cobas® Zika Test

Examples

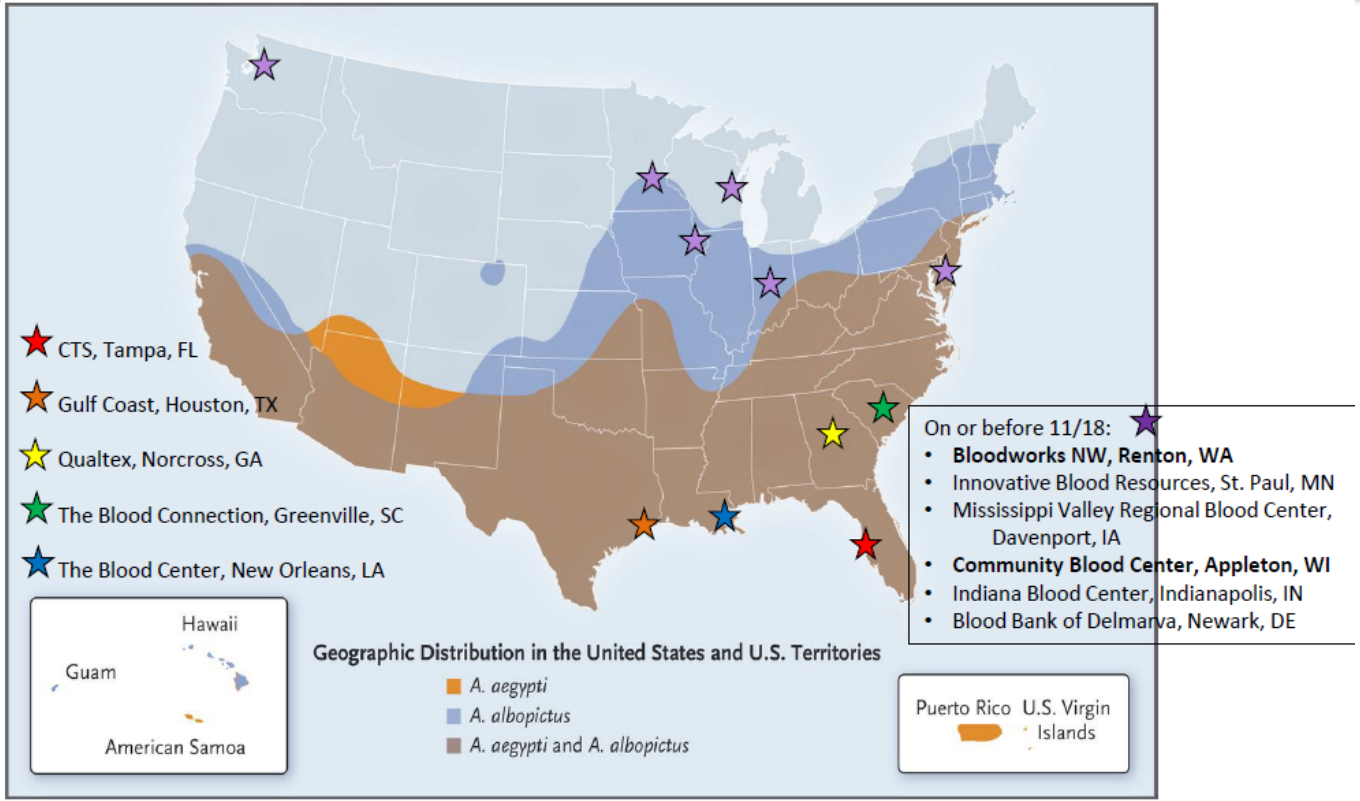
Donor #	Testing Lab	cobas® Zika Repeat tests	Simulated Pool (1:6 dilution)	Alternative NAT	IgM	IgG
1	Lab A	NR/NR	NR	NR	Negative	Negative
2	Lab B	NR/NR	NR	NR	Negative	Negative
3	**Lab C**	**R/R**	**R**	**R**	**Equivocal**	**Positive**
4	**Lab C**	**R/NR**	**NR**	**NR**	**Positive**	**Equivocal**
5	**Lab B**	**R/NR**	**R**	**R**	**Positive**	**Positive**
6	Lab B	NR/NR	NR	NR	Negative	Negative
7	**Lab A**	**R**	**R**	**R**	**Negative**	**Negative**

NR – Non-Reactive; R - Reactive

Provided by Roche Molecular Systems, Inc.

cobas® Zika Test

Testing Laboratories in the United States



Map from Peterson LR, NEJM, April 2016

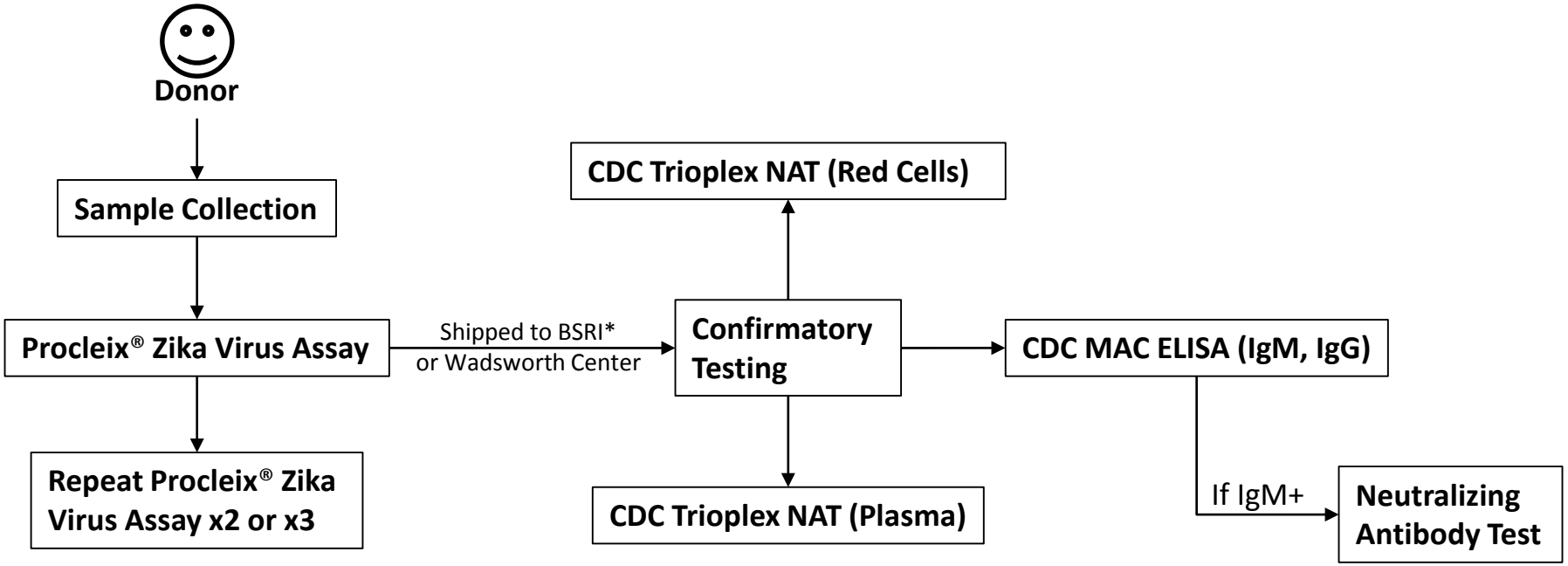
Modified Image from Roche Molecular Systems, Inc.

Blood Safety Task Force

Blood Donor Screening – Hologic, Inc. and Grifols, Inc.

Procleix® Zika Virus Assay Algorithm

Index Donation

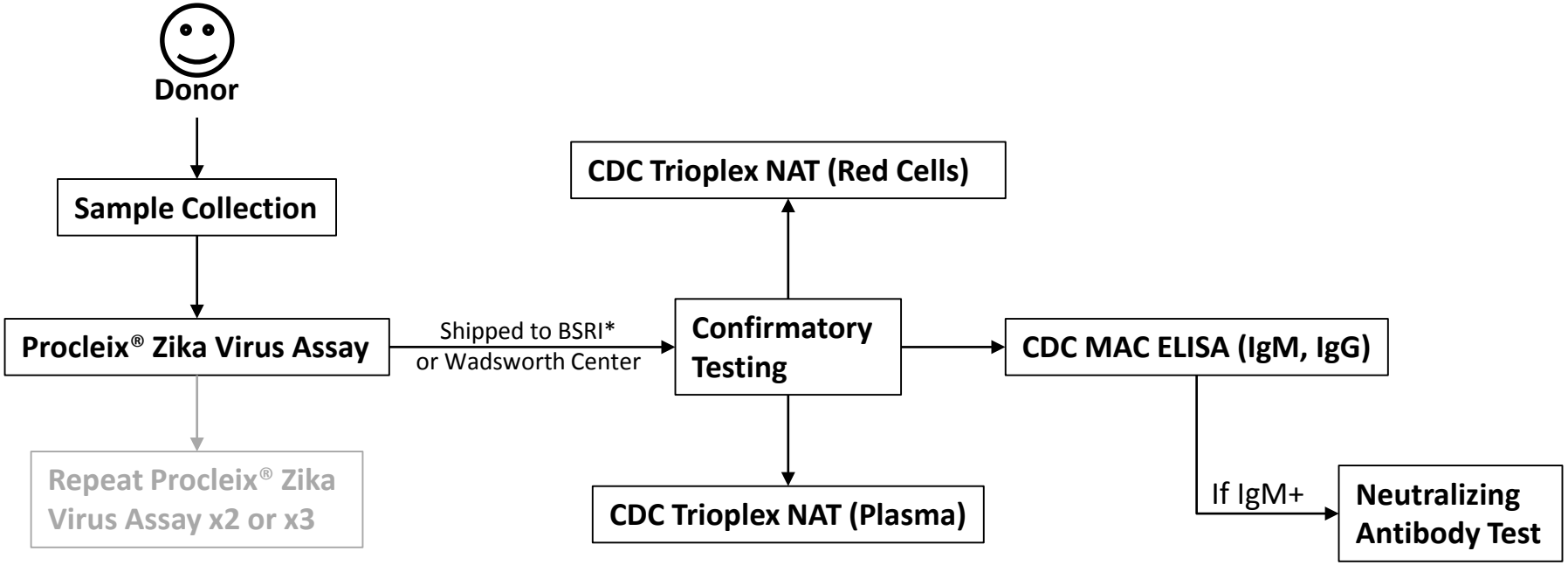


*BSRI – Blood Systems Research Institute, San Francisco, CA

Procleix® Zika Virus Assay Algorithm

First Follow Up

Approximately 7 days after index donation



*BSRI – Blood Systems Research Institute, San Francisco, CA

Procleix® Zika Virus Assay Algorithm

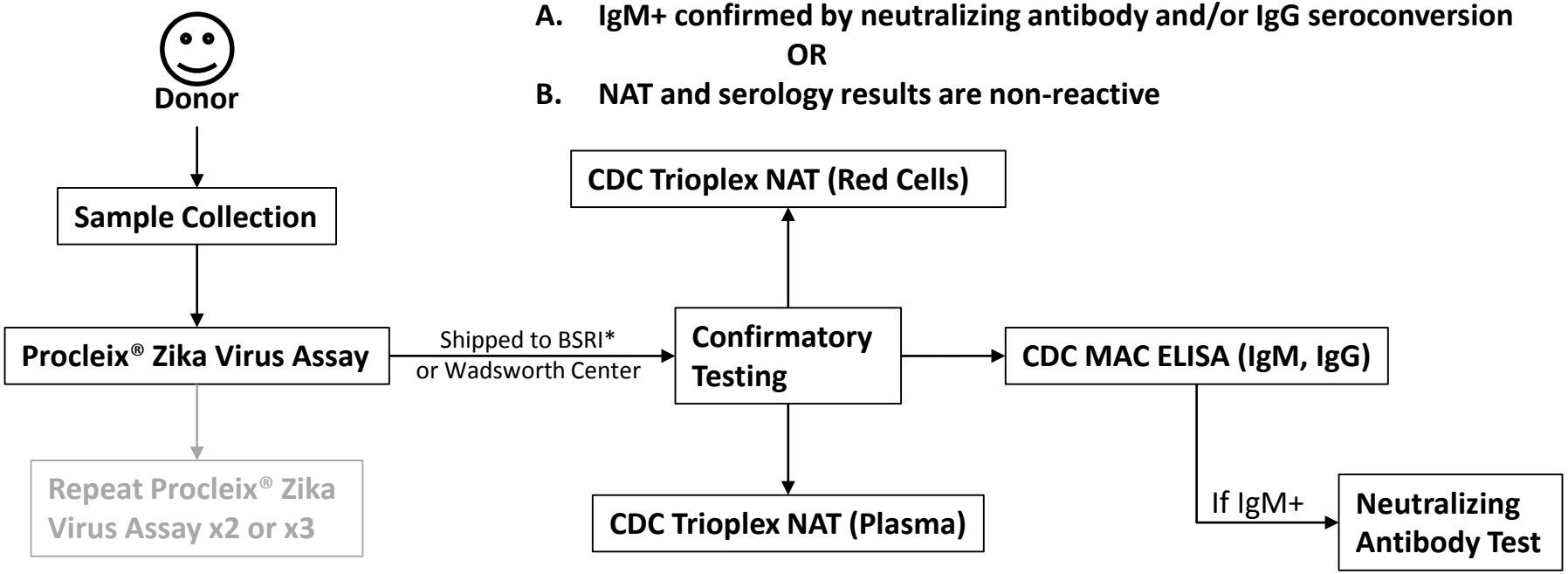
Additional Follow Ups

Approximately every week until donor is Procleix Zika Virus Assay non-reactive and

A. IgM+ confirmed by neutralizing antibody and/or IgG seroconversion

OR

B. NAT and serology results are non-reactive



*BSRI – Blood Systems Research Institute, San Francisco, CA

Procleix® Zika Virus Assay

Examples

Index Donation				Follow-up Sample
Donor #	Procleix Zika Virus Assay	Alternative NAT	Serology	Procleix Zika Virus Assay, Alternative NAT, and/or Serology
1	**Reactive**	**Reactive**	**Nonreactive**	**Nonreactive**
2	**Reactive**	**Nonreactive**	**Nonreactive**	**Reactive**
3	Reactive	Nonreactive	Nonreactive	Nonreactive
4	Reactive	Missing	Nonreactive	Nonreactive
5	Reactive	Nonreactive	Missing	Nonreactive
6	**Reactive**	**Nonreactive**	**Missing**	**Reactive**

Provided by Grifols Diagnostic Solutions, Inc.

Procleix® Zika Virus Assay

Testing Site

Testing Sites	Testing Start Date
American Red Cross (Charlotte, NC)	6/20/2016
American Red Cross (St. Louis, MO)	8/29/2016
American Red Cross (Portland, OR)	9/6/2016
Creative Testing Solutions (Phoenix, AZ)	7/18/2016
Creative Testing Solutions (Dallas, TX)	7/18/2016
Oklahoma Blood Institute (Oklahoma City, OK)	9/21/2016
MD Anderson (Houston, TX)	9/21/2016
Blood Assurance (TN)	9/25/2016
Inova Blood Services (VA)	9/28/2016
Rhode Island Blood Center (Providence, RI)	11/19/2016
Labs, Inc. (Centenial, CO)	11/16/2016
Interstate Blood (Memphis, MO)	12/12/2016

Provided by Grifols Diagnostic Solutions, Inc.

Key Messages

- **Blood donor screening is now occurring nationwide through two assays**
- **State health departments (SHDs) and blood banks should ensure procedures are in place for sharing information regarding positive blood donors**
  - Examples: FL DOH and OneBlood, TX DSHS and Gulf Coast Regional Blood Center
- **Blood donation screening may help public health identify new areas of transmission**
- **Presumptive viremic donors (PVDs) should be reported to ArboNET**
  - Updated ArboNET instructions for reporting blood donors was distributed by CSTE
- **Tissue donor screening is not currently included under INDs**
- **SHDs and tissue banks should strengthen communication regarding ZIKV and tissue donations**
- **Resources are available on the CDC Blood Safety Website**
  - Investigational toolkit: Transfusion-Transmitted Infections
  - https://www.cdc.gov/zika/transmsion/blood-transfusion.html

Questions

Closing Remarks

TELECONFERENCE OVERVIEW	DATE/TIME/LOCATION
Laboratory Task Force **Eddie Ades, Robert Lanciotti, Christy Ottendorfer**	Wed 3/15/2017 / 2pm–3pm EDT - Domestic Wed 3/15/2017 / 5 pm–6 pm EDT - Islands Bridge Line: 1(888)972-6716/ Passcode: 6721430
Joint Information Center/Communications **Cathy Young, John O'Connor**	Wed 3/22/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Epidemiology Task Force **Stacey Martin, Carolyn Gould**	Thurs 3/23/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Vector Issues Team **Janet McAllister, Audrey Lenhart**	Tues 3/28/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Policy and Partnerships **Sue Visser, Melody Stevens**	Wed 3/29/2017 / 1:30pm–2:30pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Pregnancy and Birth Defects Task Force (including surveillance) **Peggy Honein, Dana Meaney-Delman, Suzanne Gilboa**	Wed 3/29/2017 / 3pm–4pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Blood Safety Task Force **Sustainment Strategy Discussions** **Koo Chung, Matt Kuehnert**	Thurs 3/30/2017 / 2pm–3pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430
Medical Investigations Team **Sustainment Strategy Discussions** **Maleeka Glover**	Thurs 3/30/2017 / 3:30pm–4:30pm / Rm 5116 Bridge Line: 1(888)972-6716/ Passcode: 6721430

Thank You!

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.