Tribal Vector Borne Disease Meeting
Inter Tribal Council of Arizona, Inc.
Tribal Epidemiology Center
February 13-15, 2018
Chandler, AZ

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CDC's Zika Virus Response
Centers for Disease Control and Prevention

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

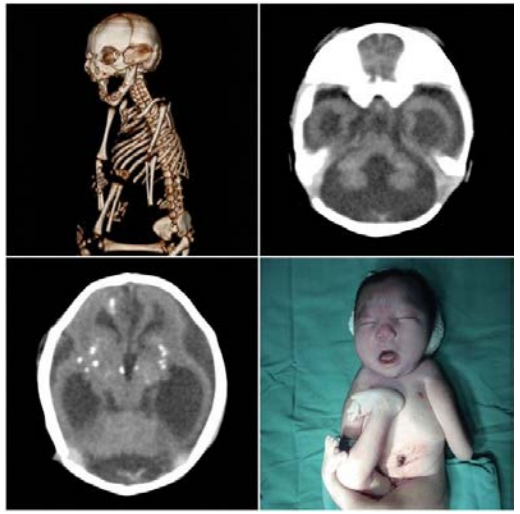
Topics to be covered

- Emerging data and Current state of epidemic
- Updated interim guidance for pregnant women
    - Emerging data and current state of epidemic
    - Updated recommendations for testing and interpretation of results
- Updated interim guidance for infants
- Pregnancy outcomes after maternal Zika virus exposure
    - Zika Pregnancy and Infant Registries
    - Findings from the Zika Pregnancy and Infant Registries and implications
- Summary and Post-response

Emerging Data and Current State of Epidemic

What Have We Learned About Zika Virus Infection?

Zika virus can cause serious brain abnormalities, microcephaly, and potentially other birth defects



Pattern of birth defects associated with Zika virus infection called **congenital Zika syndrome**

Estimated risk of congenital Zika syndrome from congenital Zika virus infection **5-10%**[1,2]

References:

1. Honein MA, Dawson AL, Petersen EE et al. Birth Defects Among Fetuses and Infants of US Women With Evidence of Possible Zika Virus Infection During Pregnancy. *JAMA*. 2017;317(1):59-68. doi:10.1001/jama.2016.19006

2. Shapiro-Mendoza CK, Rice ME, Galang RR, et al. Pregnancy Outcomes After Maternal Zika Virus Infection During Pregnancy — U.S. Territories, January 1, 2016–April 25, 2017. MMWR Morb Mortal Wkly Rep 2017;66:615-621. DOI: http://dx.doi.org/10.15585/mmwr.mm6623e1

Photo sources:

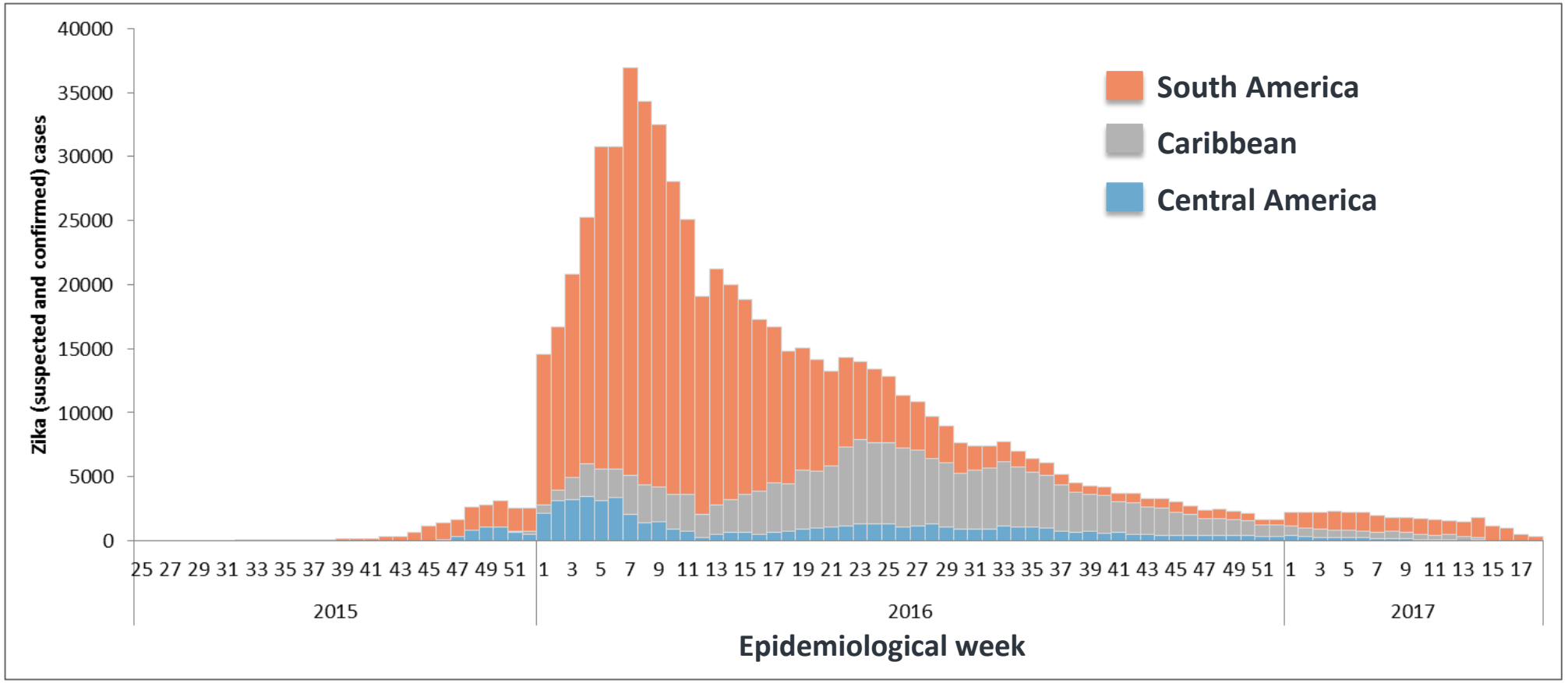
Moore CA, Staples JE, Dobyns WB, et al. Characterizing the Pattern of Anomalies in Congenital Zika Syndrome for Pediatric Clinicians. JAMA Pediatr. Soares de Oliveira-Szeinfeld P, Levine D, Suely de Oliveira Melo A, et al. Congenital brain abnormalities and zika virus: What the radiologist can expect to see prenatally and postnatally. Radiology 2016;281:203-218.

Big Picture: Emerging Data and Implications for Zika Testing

- Declining trend in reported cases of Zika infection leads to lower pretest probability and a higher proportion of positive test results being false
- Zika virus IgM antibodies can persist for months in some people, which could make it difficult for healthcare providers to use Zika IgM test results to determine whether an infection occurred during the current pregnancy versus prior to conception

Declining Trends in Reported Zika Cases in the Americas

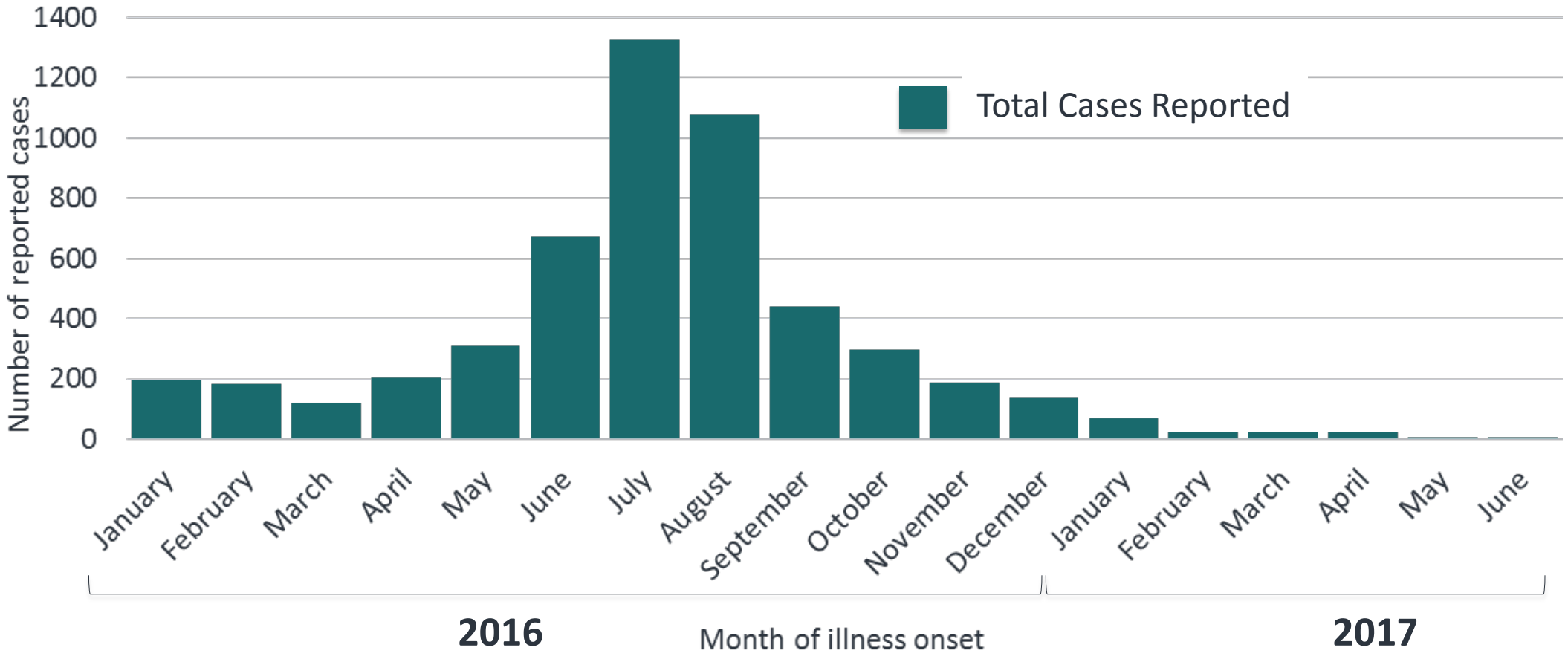
Confirmed and suspected Zika virus in the Americas, 2015–2017 (as of May 25, 2017)



PAHO Regional Zika Epidemiological Update (May 25, 2017):
http://www.paho.org/hq/index.php?option=com_content&view=article&id=11599&Itemid=41691&lang=en

Declining Trends in Reported Zika Virus Disease Cases in the US

Laboratory-confirmed Zika virus disease cases in US states and Washington, DC, 2016–2017 (as of July 5, 2017)



Prolonged Zika Virus IgM

- Zika virus IgM can persist beyond 12 weeks in a subset of infected people

- Unpublished preliminary data from Zika Virus Persistence (ZiPer) Study of persons with NAT-confirmed Zika virus disease
  - Zika virus IgM detected in 100% of participants at 8-15 days after symptom onset
  - Detectable IgM levels decreased over time, however some participants remained IgM positive for more than 7 months after symptom onset

CDC HAN-00402: https://emergency.cdc.gov/han/han00402.asp

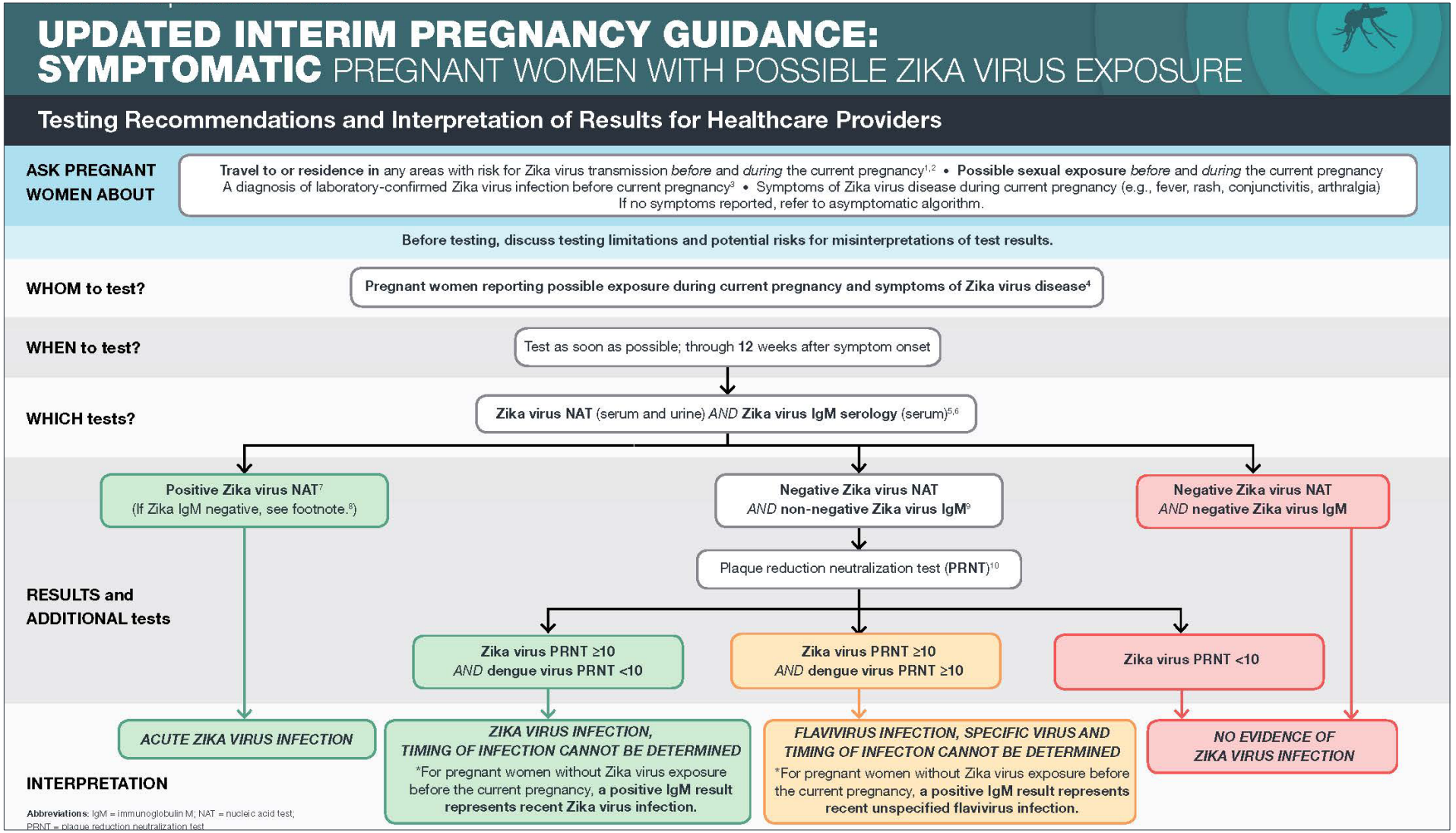
Updated Guidance – Pregnant women

Updated Guidance: Emphasis on Shared Decision-Making Model

- Updated guidance emphasizes a shared decision-making model for testing and screening pregnant women

- Clinical judgment is imperative
  - Decisions about testing should be informed by factors such as
    - Length of possible exposure
    - Type or location of travel
    - Intensity of Zika transmission
    - Presence of symptoms
    - Prevention measures
    - Preferences or concerns
    - Jurisdictional recommendations

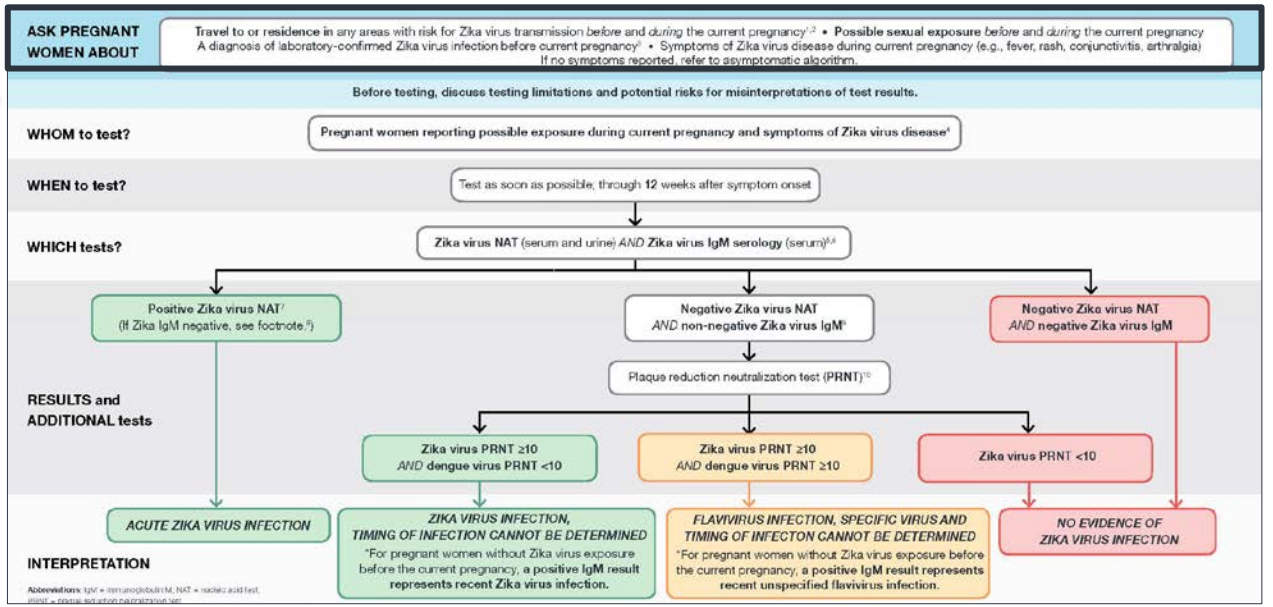
Symptomatic Pregnant Women with Possible Zika virus Exposure



Updated Guidance: Ask Pregnant Women

ASK PREGNANT WOMEN about

- Before and during current pregnancy:
  - Travel or residence in areas with risk for Zika virus transmission
  - Possible sexual exposure
- Diagnosis of laboratory-confirmed Zika virus infection before the current pregnancy
- Symptoms of Zika virus infection during the current pregnancy

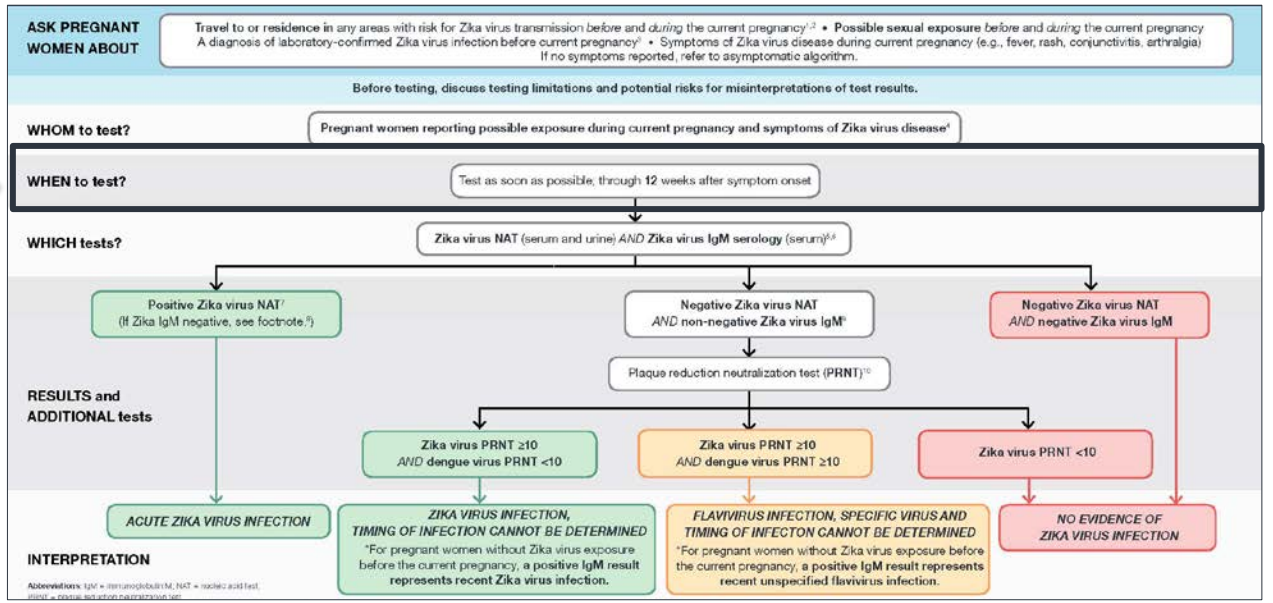


If no symptoms reported, refer to asymptomatic algorithm.

Updated Guidance: When to Test Symptomatic Pregnant Women

WHEN to test?

Test as soon as possible; through **12** weeks after symptom onset



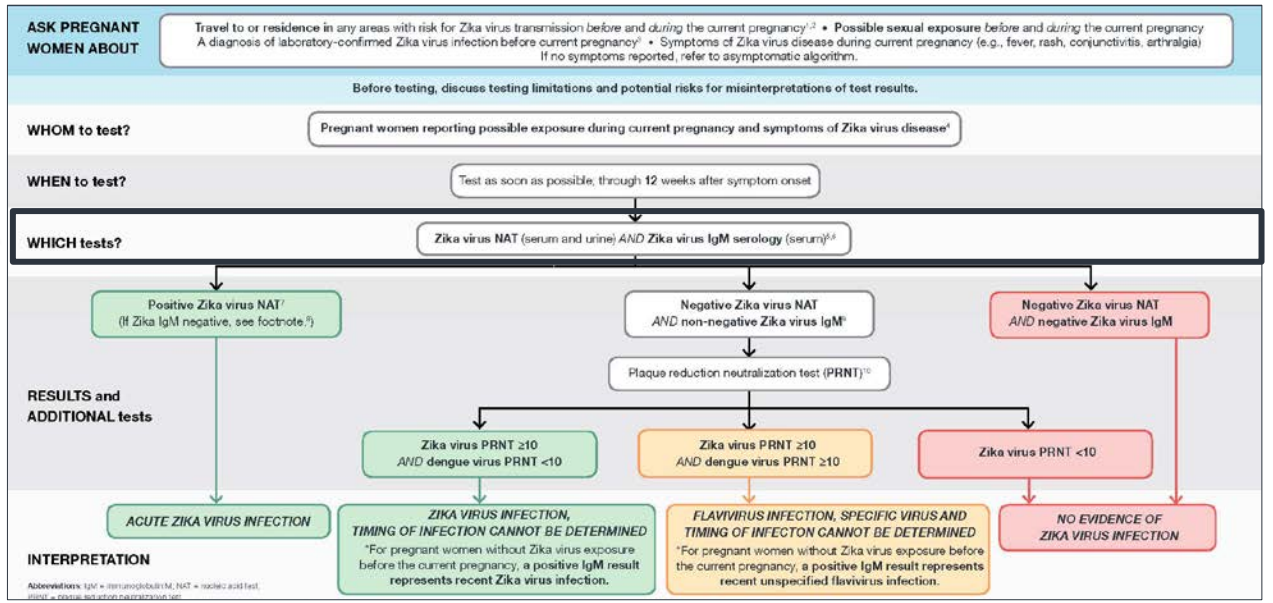
Updated Guidance: Which Tests for Symptomatic Pregnant Women

WHICH tests?

Zika virus NAT* (serum and urine)

AND

Zika virus IgM serology (serum)



NAT = nucleic acid testing

Updated Guidance: Test Results for Symptomatic Pregnant Women

RESULTS & INTERPRETATION

Positive Zika virus NAT on serum and urine specimens

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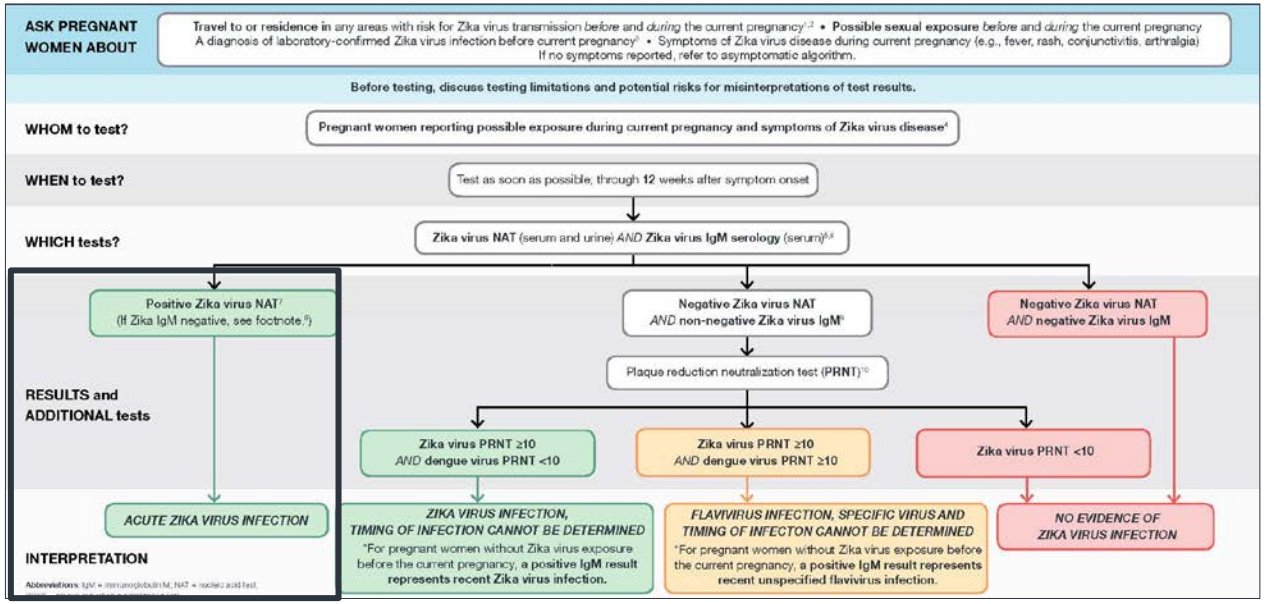
ACUTE ZIKA VIRUS INFECTION



Updated Guidance: Test Results for Symptomatic Pregnant Women

RESULTS & INTERPRETATION

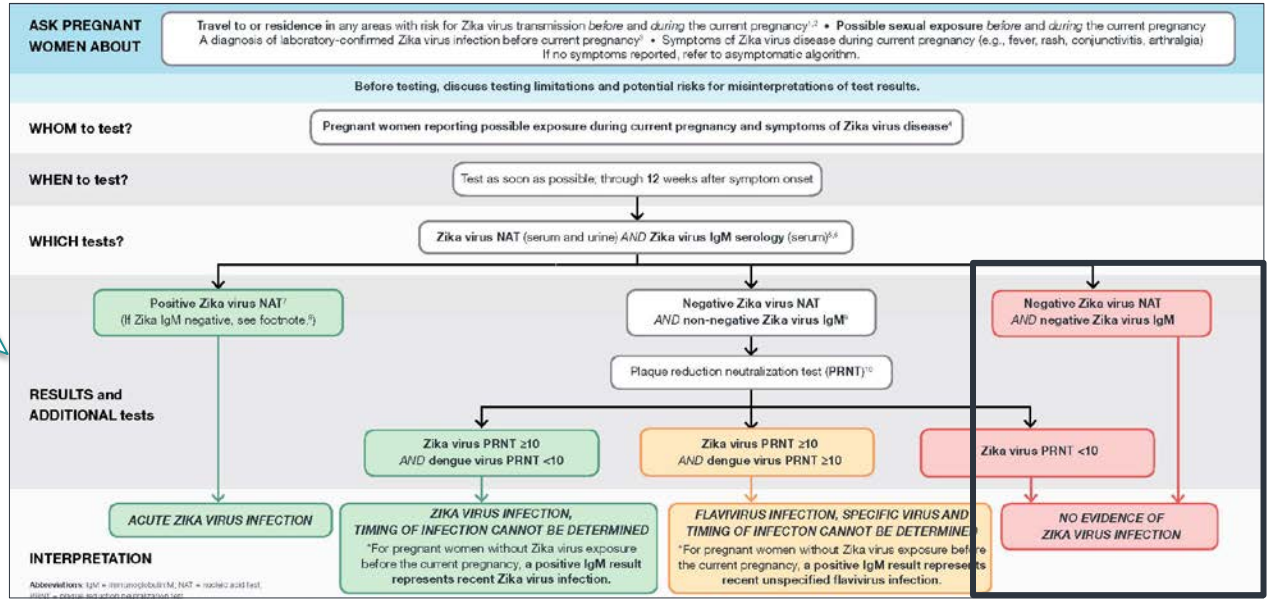
Negative Zika virus NAT

AND

Negative Zika virus IgM

↓

NO EVIDENCE OF ZIKA VIRUS INFECTION



Updated Guidance: Symptomatic Pregnant Women -- PRNT

RESULTS & ADDITIONAL TESTS

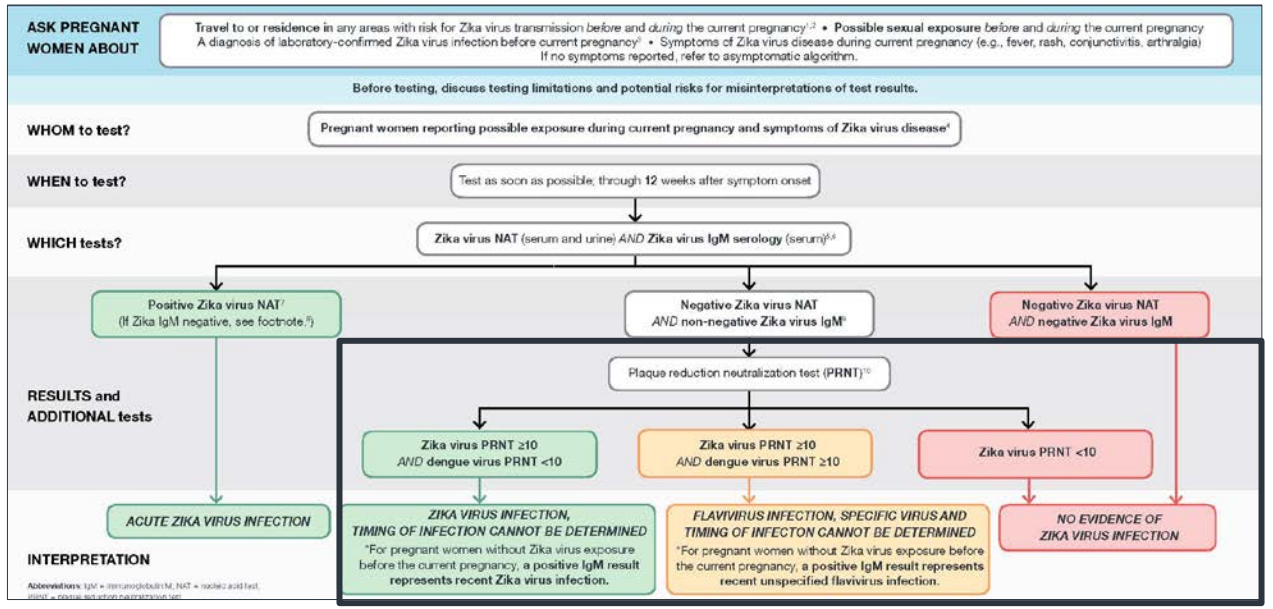
Negative Zika virus NAT

AND

Non-negative* Zika IgM

↓

Plaque reduction neutralization test (PRNT)



*Non-negative terms include positive, equivocal, presumptive positive, or possible. Terms listed here are only examples of assay interpretation terminology because nonnegative serology terminology varies by assay. For explanation of a specific interpretation, refer to the instructions for use for the specific assay performed. https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika

Updated Guidance: Symptomatic Pregnant Women

RESULTS & INTERPRETATION

Zika virus PRNT ≥10

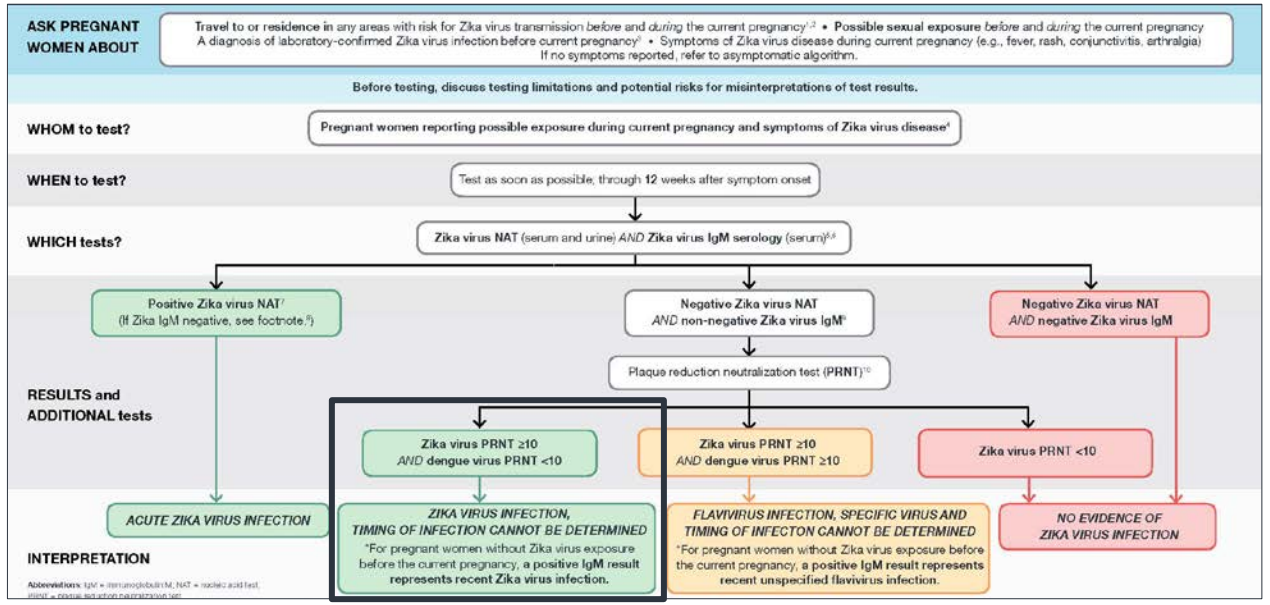
AND

dengue virus PRNT<10

↓

ZIKA VIRUS INFECTION, TIMING OF INFECTION CANNOT BE DETERMINED

For pregnant women without Zika virus exposure before the current pregnancy, ***a positive IgM result represents recent Zika virus infection.****



*For the purposes of this guidance, recent possible Zika virus exposure or Zika virus/flavivirus infection is defined as a possible exposure or infection during the current pregnancy or periconceptional period.

Updated Guidance: Symptomatic Pregnant Women

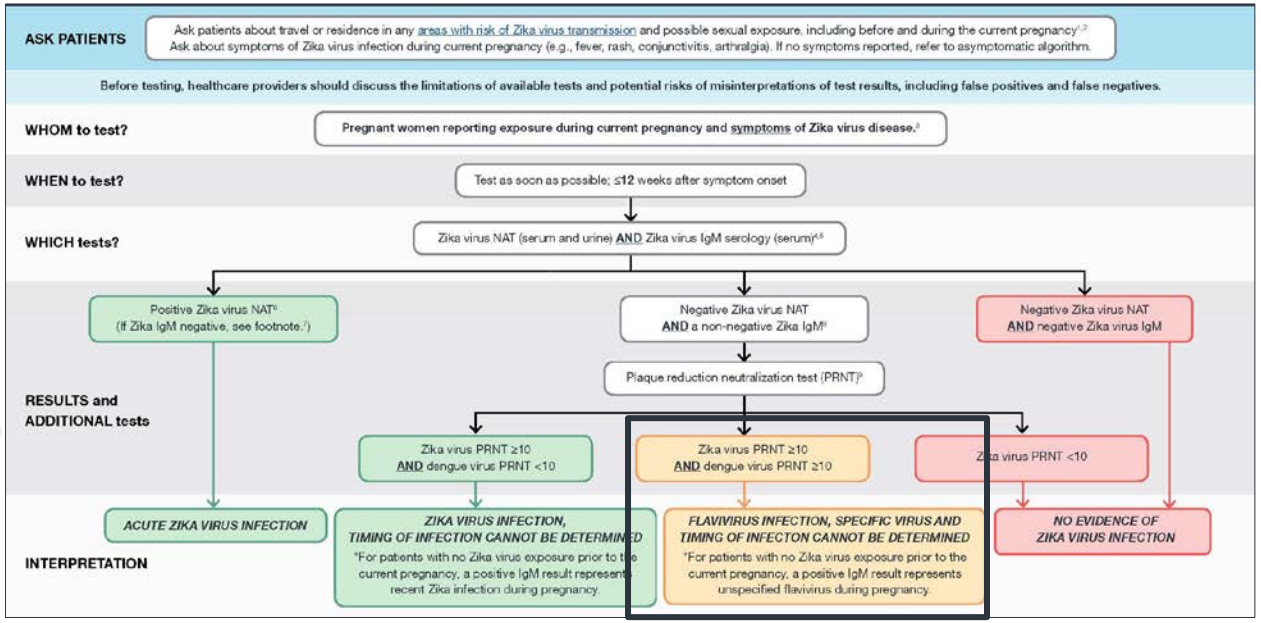
RESULTS & INTERPRETATION

Zika virus PRNT ≥10 **AND** dengue virus PRNT ≥10

↓

FLAVIVIRUS INFECTION, SPECIFIC VIRUS AND TIMING OF INFECTON CANNOT BE DETERMINED

For pregnant women without Zika virus exposure before the current pregnancy, ***a positive IgM result represents recent unspecified flavivirus infection.***



*For the purposes of this guidance, recent possible Zika virus exposure or Zika virus/flavivirus infection is defined as a possible exposure or infection during the current pregnancy or periconceptional period.

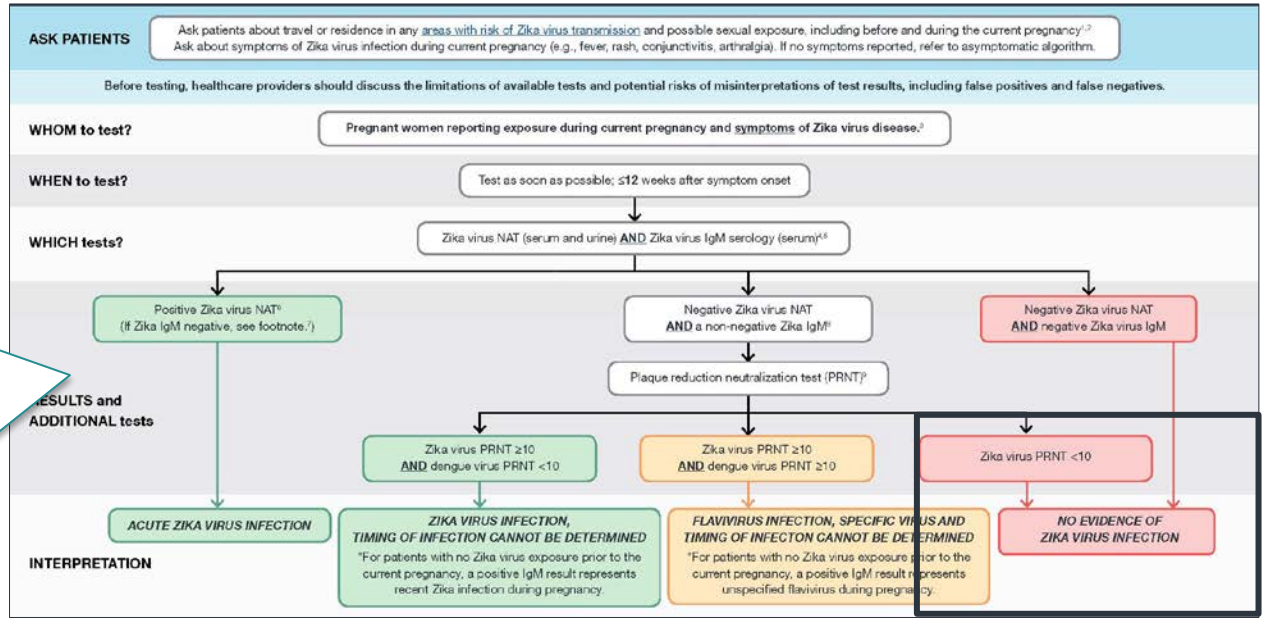
Updated Guidance: Symptomatic Pregnant Women

RESULTS & INTERPRETATION

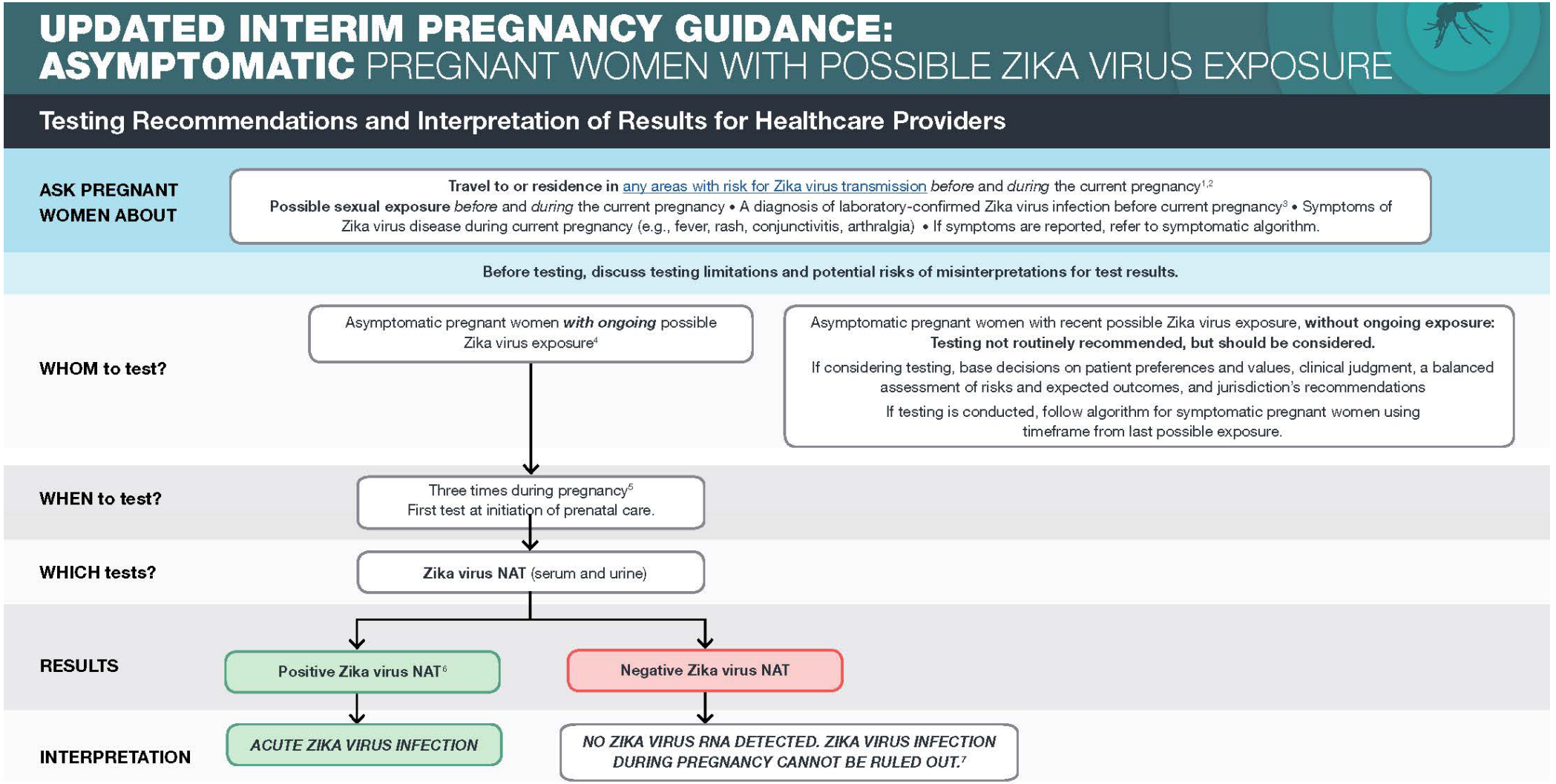
Zika virus PRNT <10

↓

NO EVIDENCE OF ZIKA VIRUS INFECTION



Asymptomatic Pregnant Women with Possible Zika Virus Exposure

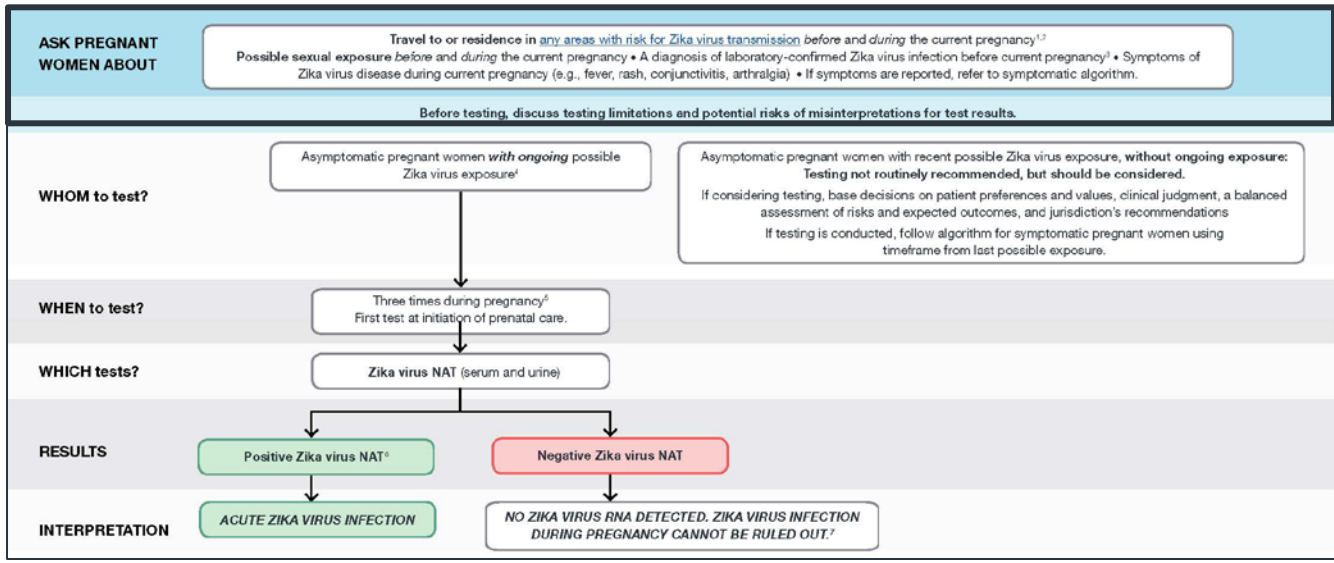


Updated Guidance: Asymptomatic Pregnant Women with Ongoing Possible Exposure

ASK PREGNANT WOMEN about

- Possible Zika exposure before and during current pregnancy
- Diagnosis of laboratory-confirmed Zika virus infection before pregnancy
- Presence of symptoms during current pregnancy

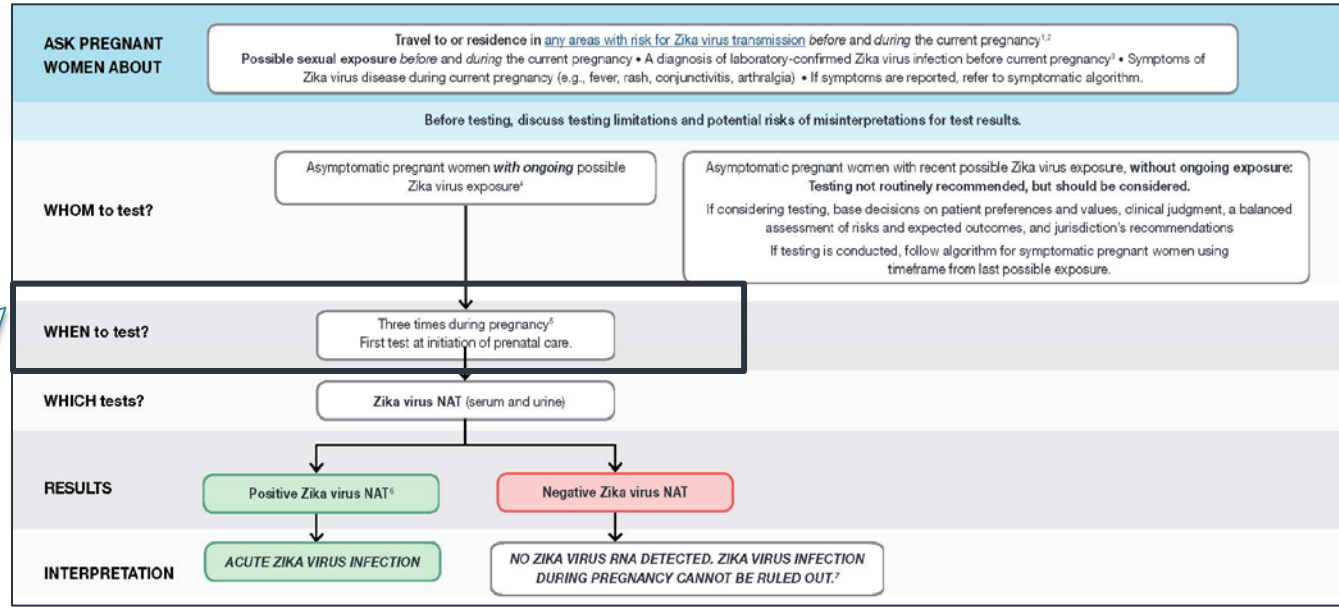
COUNSEL PATIENTS on Zika testing



If symptoms are reported, refer to symptomatic algorithm.

Updated Guidance: Asymptomatic Pregnant Women with Ongoing Possible Exposure

WHEN to test? WHICH tests?
Test with Zika virus NAT on serum and urine three times during pregnancy

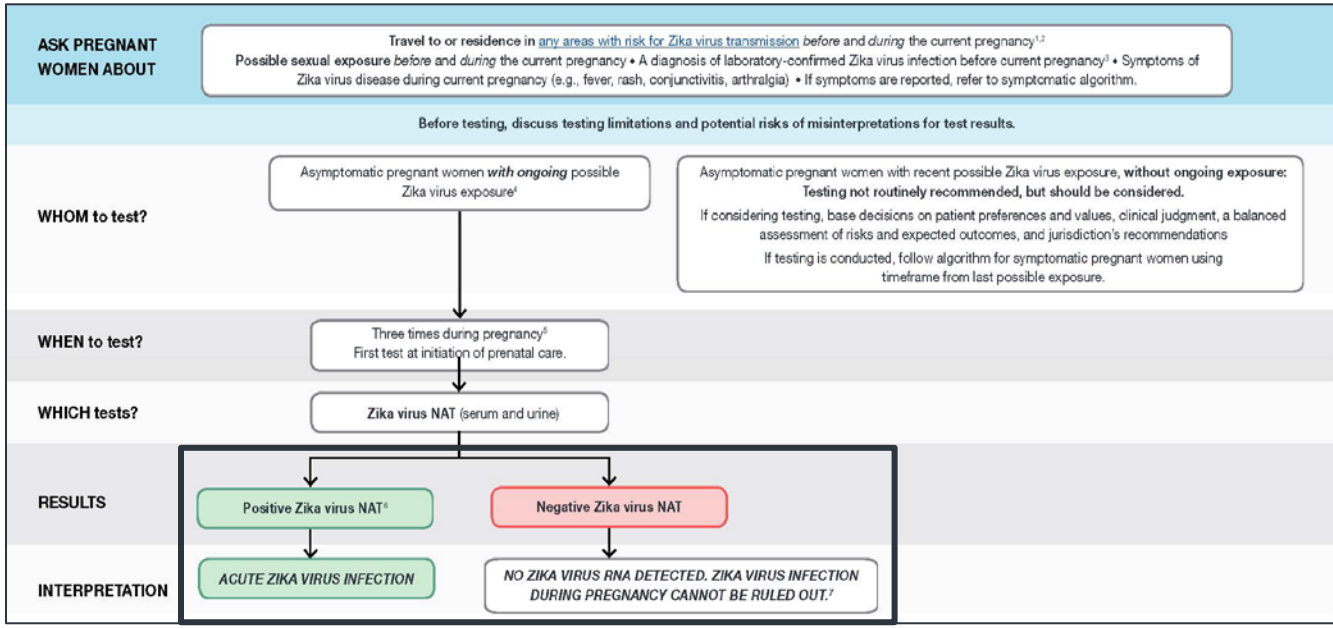


Updated Guidance: Asymptomatic Pregnant Women with Ongoing Possible Exposure

REFER TO TABLE 1 FOR INTERPRETATION

TABLE 1. Interpretation of results of nucleic acid and antibody testing for suspected Zika virus infection^, †, §, ¶, **, ††, §§ — United States, 2017

Zika NAT (serum)	Zika NAT (urine)	Zika virus and dengue virus IgM	Zika virus PRNT	Dengue virus PRNT	Interpretation and recommendations
Positive	Positive	Any result (either assay)	Not indicated	Not indicated	Acute Zika virus infection
Negative	Positive	Positive (either assay)	Not indicated	Not indicated	Acute Zika virus infection
Negative	Positive	Negative on both assays	Not indicated	Not indicated	Suggests acute Zika virus infection Repeat testing on original urine specimen. • If repeat NAT result is positive, interpret as evidence of acute Zika virus infection. • If repeat NAT result is negative, repeat Zika virus IgM antibody testing on a serum specimen collected ≥2 weeks after onset or possible exposure or specimen collection date. • If repeat IgM antibody result is positive, interpret as evidence of acute Zika virus infection. • If repeat IgM antibody result is not positive, interpret as no evidence of Zika virus infection.
Positive	Negative or not performed	Positive (either assay)	Not indicated	Not indicated	Acute Zika virus infection
Positive	Negative or not performed	Negative on both assays	Not indicated	Not indicated	Suggests acute Zika virus infection Repeat testing on original urine specimen. • If repeat NAT result is positive, interpret as evidence of acute Zika virus infection. • If repeat NAT result is negative, repeat Zika virus IgM antibody testing on a serum specimen collected ≥2 weeks after onset or possible exposure or specimen collection date. • If repeat IgM antibody result is positive, interpret as evidence of acute Zika virus infection. • If repeat IgM antibody result is not positive, interpret as no evidence of Zika virus infection.
Negative	Negative or not performed	Any non-negative result (either assay)	≥10	<10	Zika virus infection; timing of infection cannot be determined. • For patients with no Zika virus exposure prior to the current pregnancy, a positive IgM result represents Zika virus infection during pregnancy.
Negative	Negative or not performed	Any non-negative result (either assay)	<10	Any result	No evidence of Zika virus infection
Negative	Negative or not performed	Any non-negative result (either assay)	≥10	≥10	Flavivirus infection; specific virus cannot be identified; timing of infection cannot be determined • For patients with no Zika virus exposure prior to the current pregnancy, a positive IgM result represents unspecified flavivirus infection during pregnancy.
Negative	Negative or not performed	Positive for Zika virus AND negative for dengue virus	Not performed because PRNT is not recommended in certain area of residence (i.e. Puerto Rico)		Presumptive Zika virus infection; timing of infection cannot be determined.
Negative	Negative or not performed	Positive for Zika virus AND positive for dengue virus	Not performed because PRNT is not recommended in certain area of residence (i.e. Puerto Rico)		Presumptive flavivirus infection; timing of infection cannot be determined.
Negative	Negative or not performed	Equivocal (either or both assays)	Not performed because PRNT is not recommended in certain area of residence (i.e. Puerto Rico)		Insufficient information for interpretation. Consider repeat testing.
Negative	Negative or not performed	Negative on both assays	Not performed because PRNT is not recommended in certain area of residence (i.e. Puerto Rico)		No laboratory evidence of Zika virus infection



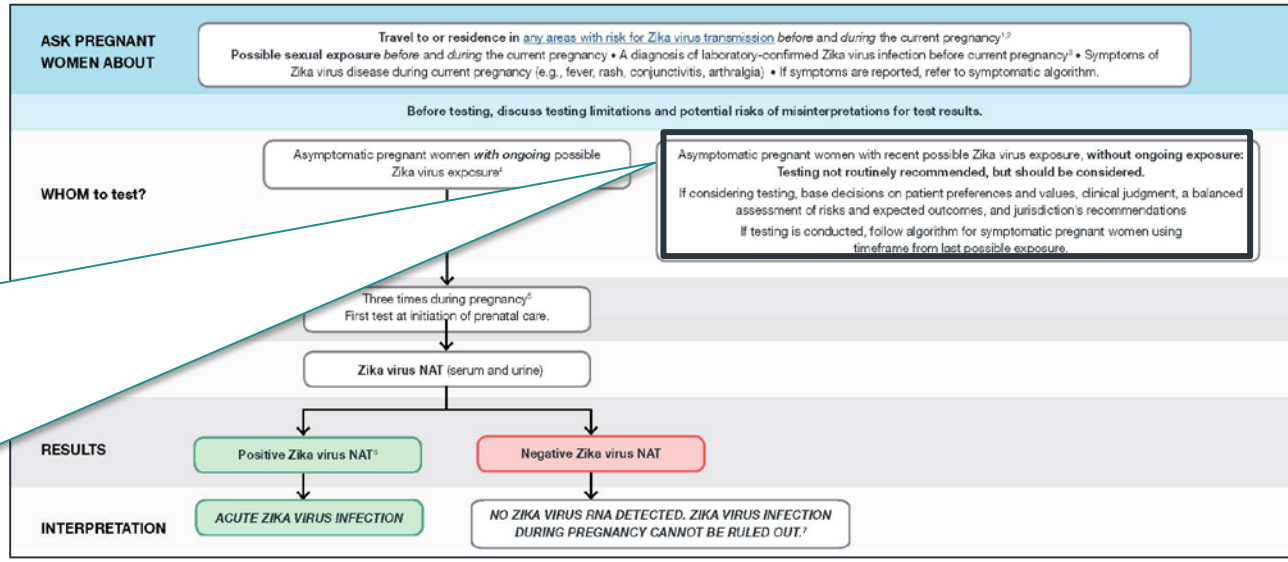
Updated Guidance: Asymptomatic Pregnant Women with Recent Possible Exposure, but without Ongoing Possible Exposure

WHOM to test

Testing is no longer routinely recommended.

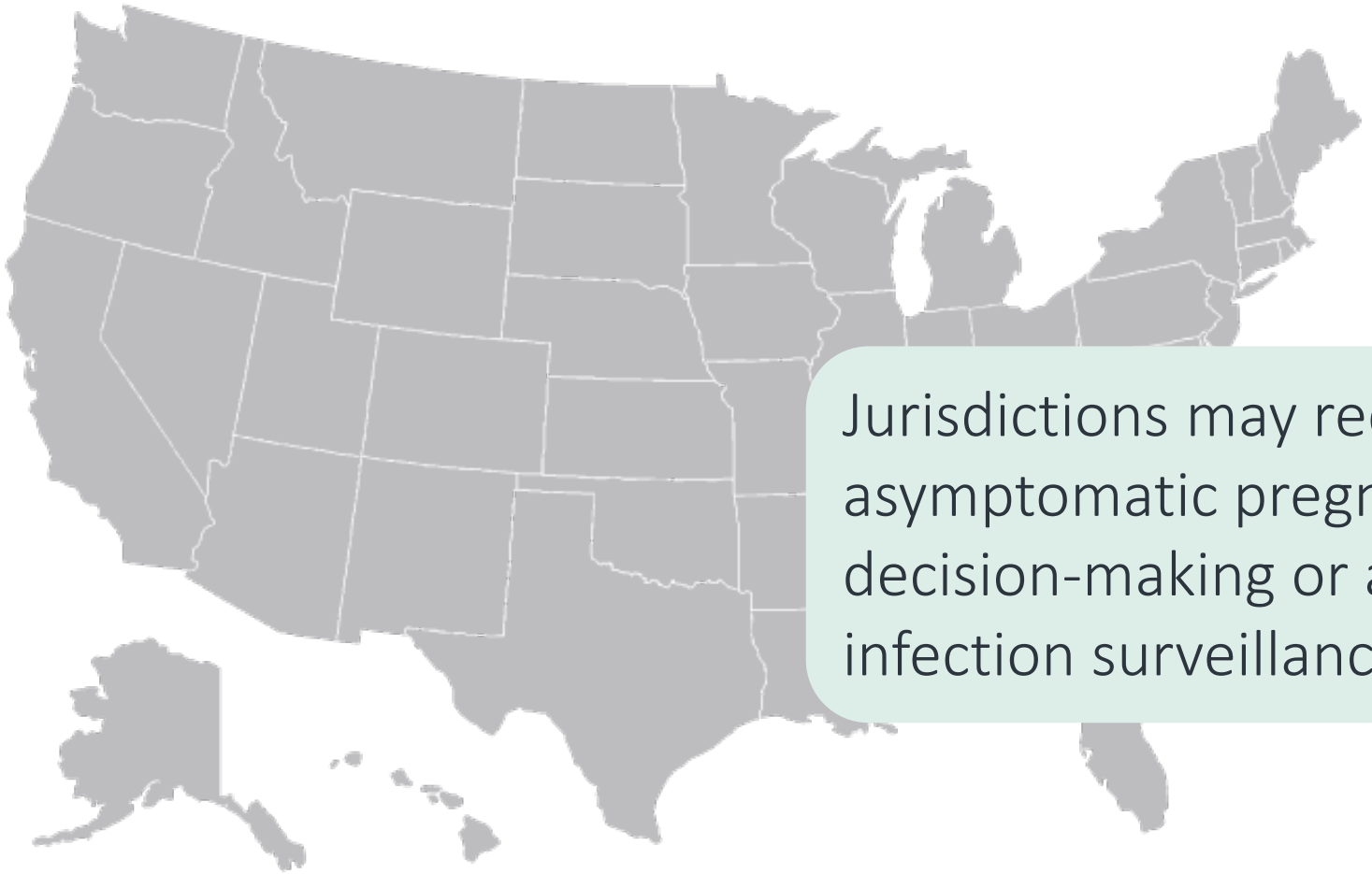
Testing should be considered using:

- A shared decision-making model based on patient preferences and values
  - Clinical judgment
  - A balanced assessment of risks and expected outcomes
  - Jurisdiction's recommendations



If testing is conducted, follow algorithm for symptomatic pregnant women using timeframe from last possible exposure.

Updated Guidance: Asymptomatic Pregnant Women with Possible Zika Virus Exposure



Jurisdictions may recommend testing of asymptomatic pregnant women for clinical decision-making or as part of Zika virus infection surveillance.

Updated Guidance: Testing of Placental and Fetal Tissues

Morbidity and Mortality Weekly Report

Evaluation of Placental and Fetal Tissue Specimens for Zika Virus Infection — 50 States and District of Columbia, January–December, 2016

Sarah Reagan-Steiner, MD[1]; Regina Simeone, MPH[2]; Elizabeth Simon, MPH[2]; Julu Bhatnagar, PhD[1]; Titilope Oduyebo, MD[3]; Rebecca Free, MD[4]; Amy M. Denison, PhD[1]; Demi B. Rabeneck, MS[1]; Sascha Ellington, MSPH[2]; Emily Petersen, MD[2]; Joy Gary, DVM[1]; Gillian Hale, MD[1]; M. Kelly Keating, DVM[1]; Roosecelis B. Martines, MD[1]; Atis Muehlenbachs, MD[1]; Jana Ritter, DVM[1]; Ellen Lee, MD[5]; Alexander Davidson, MPH[5]; Erin Conners, PhD[5]; Sarah Scotland, MPH[6]; Kayleigh Sandhu, MPH[6]; Andrea Bingham, PhD[7]; Elizabeth Kassens[7]; Lou Smith, MD[8]; Kirsten St. George, MD[8]; Nina Ahmad, MD[8]; Mary Tanner, MD[9,10]; Suzanne Beavers, MD[11]; Brooke Miers, MS[1,12]; Kelley VanMaldeghem, MPH[2]; Sumaiya Khan, MPH[2]; Ingrid Rabe, MBChB[13]; Carolyn Gould, MD[13]; Dana Meaney-Delman, MD[14]; Margaret A. Honein, PhD[2]; Wun-Ju Shieh, MD[1]; Denise J. Jamieson, MD[3]; Marc Fischer, MD[13]; Sherif R. Zaki, MD[1]; U.S. Zika Pregnancy Registry Collaboration; Zika Virus Response Epidemiology and Surveillance Task Force Pathology Team

Updated Guidance

Testing of placental tissues not routinely recommended for asymptomatic women without ongoing possible exposure when infant or fetus does not have Zika-associated birth defects

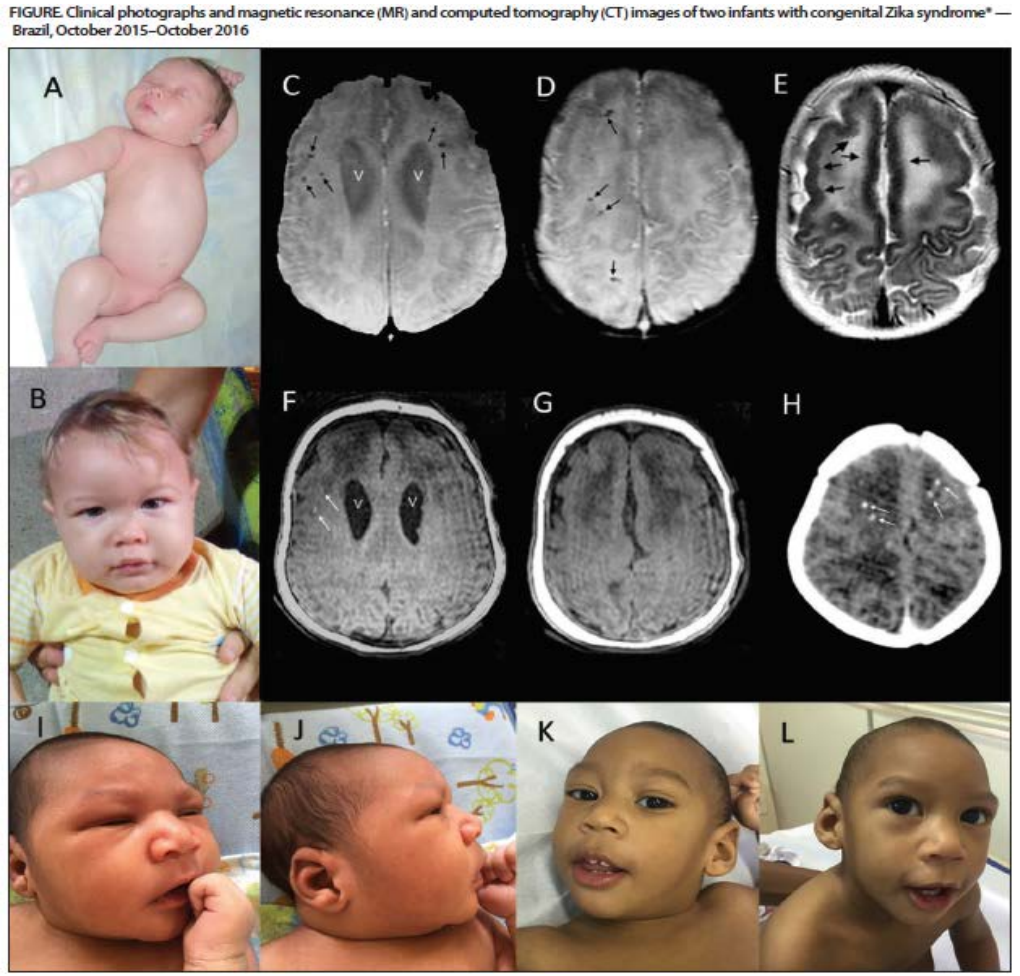
Recommendations to Prevent Zika Virus Infection Have not Changed

Do Not Travel	• Pregnant women should **not** travel to areas with risk for Zika virus transmission
Prevent Mosquito Bites	• If a pregnant woman lives in or travels to an area with risk for Zika virus transmission, she should take steps to prevent mosquito bites
Prevent Sexual Transmission	• Take steps to prevent sexual transmission of Zika from a partner who lives in or traveled to an area with risk for Zika virus transmission

Updated Guidance – Infants

Emerging Data on Congenital Zika Virus Infection

- Eye problems in infants without microcephaly or other brain anomalies
- Postnatal-onset microcephaly in infants
- Postnatal-onset hydrocephalus
- Abnormalities on sleep electroencephalogram (EEG) without recognized seizures
- Diaphragmatic paralysis



Postnatal-onset microcephaly

Van Der Linden et al., MMWR Morb Mortal Wkly Rep 2016;65(47):1343-1348.

Updated Interim Guidance for Infants with Possible Congenital Zika Virus Infection

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 66 / No. 41
October 20, 2017

Update: Interim Guidance for the Diagnosis, Evaluation, and Management of Infants with Possible Congenital Zika Virus Infection — United States, October 2017

Tolulope Adebanjo, MD[1,2]; Shana Godfred-Cato, DO[3]; Laura Viens, MD[4]; Marc Fischer, MD[5]; J. Erin Staples, MD, PhD[5]; Wendi Kuhnert-Tallman, PhD[6]; Henry Walke, MD[7]; Titilope Oduyebo, MD[8]; Kara Polen, MPH[9]; Georgina Peacock, MD[10]; Dana Meaney-Delman, MD[6]; Margaret A. Honein, PhD[9]; Sonja A. Rasmussen, MD[11]; Cynthia A. Moore, MD, PhD[9]; Contributors

Forum on the Diagnosis, Evaluation, and Management of Zika Virus Infection among Infants

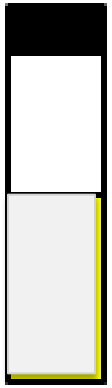
Updated interim guidance based on:

- Current, limited data about the clinical aspects of Zika virus infection
- Individual expert opinions collected during the Forum
- Knowledge about other congenital infections

Diagnosis of Congenital Zika Virus Infection

Serum
Zika virus NAT
Zika virus IgM

Urine
Zika virus NAT
Zika virus IgM



CSF (if obtained for other purposes)
Zika virus NAT
Zika virus IgM

Perform as early as possible, preferably within the first few days after birth

Testing specimens within the first few weeks to months after birth might still be useful

Standard Evaluation for Infants with Possible Congenital Zika Virus Exposure

- Comprehensive physical examination (includes growth parameters)
- Age-appropriate vision screening and developmental monitoring and screening using validated tools
- Standard newborn hearing screen at birth, preferably using auditory brainstem response (ABR) methodology

Updated Interim Guidance

For infants born to women with possible Zika virus exposure during pregnancy

Infants **with** clinical findings consistent with congenital Zika syndrome

Infants with Clinical Findings Consistent with Congenital Zika Syndrome: Initial Evaluation

- Standard evaluation
- Zika virus NAT and IgM testing
- Testing for Zika virus NAT and IgM on CSF should be considered
- Head ultrasound by 1 month of age
- Comprehensive ophthalmologic exam by 1 month of age
- Automated ABR [If newborn hearing screen passed using otoacoustic emissions [OAE] methodology]
- Evaluate for other causes of congenital anomalies

- Refer to developmental specialist and early intervention services
- Family support services

Consider additional consultations with

- Infectious disease specialist
- Clinical geneticist
- Neurologist
- Other clinical specialists based on clinical findings of infant

Consider fewer consultations for the evaluation of severely affected infants who are receiving palliative care

Infants with Clinical Findings Consistent with Congenital Zika Syndrome: Follow-up Care

- Standard evaluation with routine preventive care and immunizations at every well-child visit
- Follow-up visits with ophthalmology should occur based on ophthalmology recommendations
- Continue subspecialty care

Updated Interim Guidance

For infants born to women with possible Zika virus exposure during pregnancy

Infants **with** clinical findings consistent with congenital Zika syndrome

Infants **without** clinical findings consistent with congenital Zika syndrome born to mothers **with** laboratory evidence of possible Zika virus infection during pregnancy

Infants without Clinical Findings Consistent with Congenital Zika Syndrome Born to Mothers with Laboratory Evidence of Possible Zika Virus Infection during Pregnancy: Initial Evaluation

- Standard evaluation
- Zika virus NAT and IgM testing
- Head ultrasound by 1 month of age
- Comprehensive ophthalmologic exam by 1 month of age
- Automated ABR (If newborn hearing screen passed using OAE methodology)

Infants without Clinical Findings Consistent with Congenital Zika Syndrome Born to Mothers with Laboratory Evidence of Possible Zika Virus Infection during Pregnancy: Follow-up Care

- Standard evaluation with routine preventive care and immunizations at every well-child visit
- Follow-up visits with ophthalmology should occur based on ophthalmology recommendations
- If findings consistent with congenital Zika syndrome are identified, further evaluation should follow recommendations for **infants with clinical findings consistent with congenital Zika syndrome**

Infants without Clinical Findings Consistent with Congenital Zika Syndrome Born to Mothers with Laboratory Evidence of Possible Zika Virus Infection during Pregnancy: Follow-up Care

- Standard evaluation with routine preventive care and immunizations at every well-child visit
- Follow-up visits with ophthalmology should occur based on ophthalmology recommendations
- If findings consistent with congenital Zika syndrome are identified, further evaluation should follow recommendations for **infants with clinical findings consistent with congenital Zika syndrome**

Laboratory evidence of possible congenital Zika infection

- Follow recommendations for infants with clinical findings even in the absence of clinically apparent abnormalities

Infants without Clinical Findings Consistent with Congenital Zika Syndrome Born to Mothers with Laboratory Evidence of Possible Zika Virus Infection during Pregnancy: Follow-up Care

- Standard evaluation with routine preventive care and immunizations at every well-child visit
- Follow-up visits with ophthalmology should occur based on ophthalmology recommendations
- If findings consistent with congenital Zika syndrome are identified, further evaluation should follow recommendations for **infants with clinical findings consistent with congenital Zika syndrome**

No laboratory evidence of possible congenital Zika infection

- Congenital Zika virus infection is unlikely
- Infant should continue to receive routine care, and healthcare providers should remain alert for any new findings of congenital Zika virus infection

Updated Interim Guidance

For infants born to women with possible Zika virus exposure during pregnancy

Infants **with** clinical findings consistent with congenital Zika syndrome

Infants **without** clinical findings consistent with congenital Zika syndrome born to mothers **with** laboratory evidence of possible Zika virus infection during pregnancy

Infants **without** clinical findings consistent with congenital Zika syndrome born to mothers **without** laboratory evidence of Zika virus infection during pregnancy

Infants without Clinical Findings Consistent with Congenital Zika Syndrome Born to Mothers without Laboratory Evidence of Zika Virus Infection during Pregnancy

- Laboratory testing and clinical evaluation beyond a standard evaluation **are not routinely recommended.**
- If findings suggestive of congenital Zika syndrome are identified at any time, refer to appropriate specialists and evaluate for congenital Zika virus infection

Key Changes from the Previous Guidance

- Initial evaluation can occur before or after hospital discharge

- **Infants with laboratory evidence of congenital Zika virus infection**
  - » Repeat ABR is no longer recommended at age 4-6 months if the newborn hearing screen was passed using ABR methodology or if automated ABR at 1 month is passed

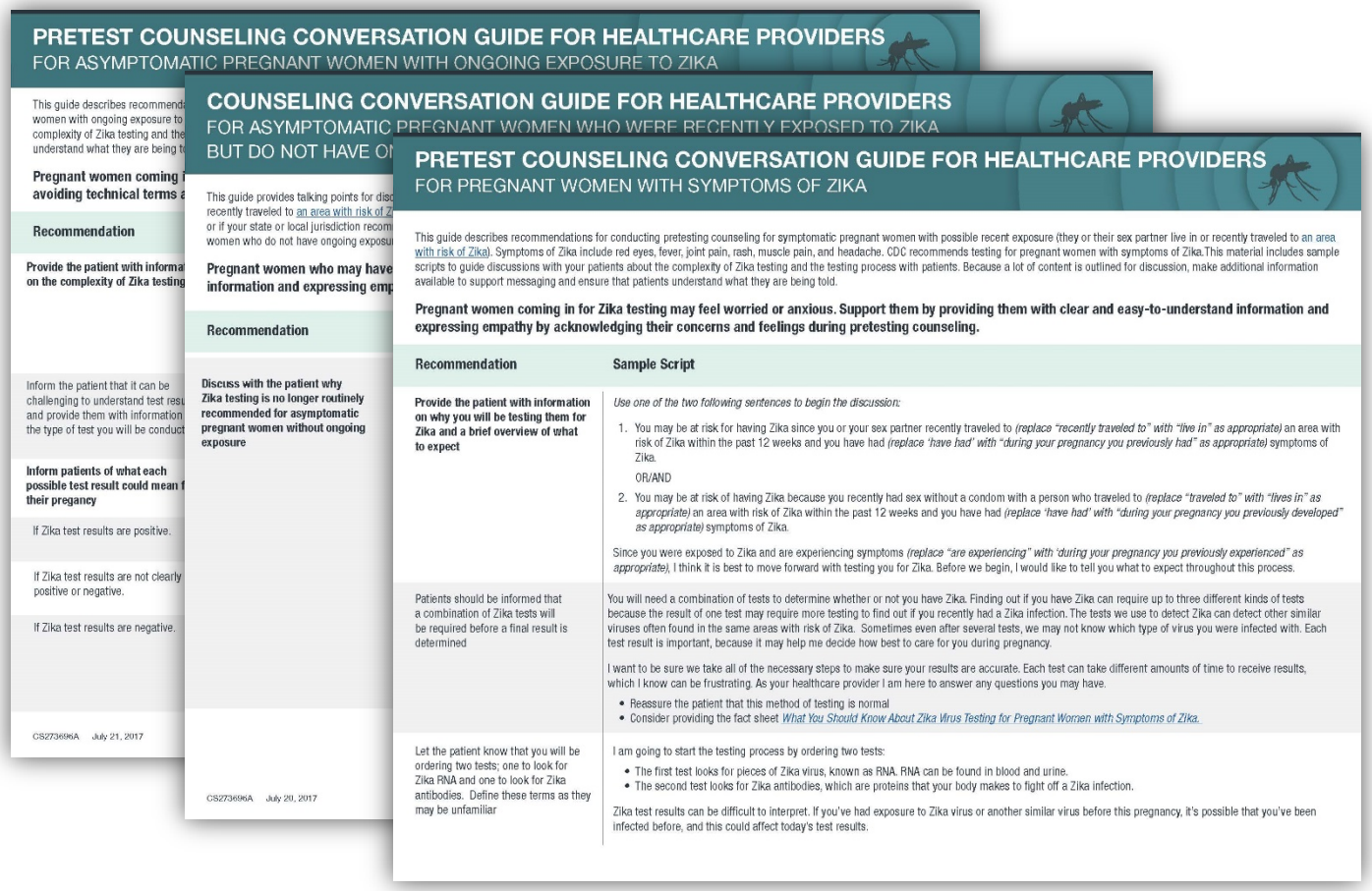
- **Infants with clinical findings consistent with congenital Zika syndrome**
  - » Maintain vigilance for emerging findings associated with congenital Zika virus infection
  - » Transfer to a hospital with subspecialty care is not necessary unless there is an urgent clinical need
  - » No set recommendation to perform thyroid screening

Key Changes from the Previous Guidance – cont.

- **Infants without clinical findings born to mothers with laboratory evidence of possible Zika virus infection**
  - » Comprehensive eye examination by an ophthalmologist in all infants

- **Infants without clinical findings born to mothers without laboratory evidence of possible Zika virus infection**
  - » Testing and clinical evaluation for Zika virus infection beyond a standard evaluation and routine pediatric care are not routinely recommended

Clinical Tools for Implementing Guidance



PRETEST COUNSELING CONVERSATION GUIDE FOR HEALTHCARE PROVIDERS
FOR ASYMPTOMATIC PREGNANT WOMEN WITH ONGOING EXPOSURE TO ZIKA

This guide describes recommenda
women with ongoing exposure to
complexity of Zika testing and the
understand what they are being t

Pregnant women coming i
avoiding technical terms a

Recommendation

Provide the patient with informa
on the complexity of Zika testing

Inform the patient that it can be
challenging to understand test resu
and provide them with information
the type of test you will be conduct

Inform patients of what each
possible test result could mean f
their pregancy

If Zika test results are positive.

If Zika test results are not clearly
positive or negative.

If Zika test results are negative.

CS273696A July 21, 2017

COUNSELING CONVERSATION GUIDE FOR HEALTHCARE PROVIDERS
FOR ASYMPTOMATIC PREGNANT WOMEN WHO WERE RECENTLY EXPOSED TO ZIKA
BUT DO NOT HAVE O

This guide provides talking points for disc
recently traveled to an area with risk of Z
or if your state or local jurisdiction recom
women who do not have ongoing exposu

Pregnant women who may have
information and expressing emp

Recommendation

Discuss with the patient why
Zika testing is no longer routinely
recommended for asymptomatic
pregnant women without ongoing
exposure

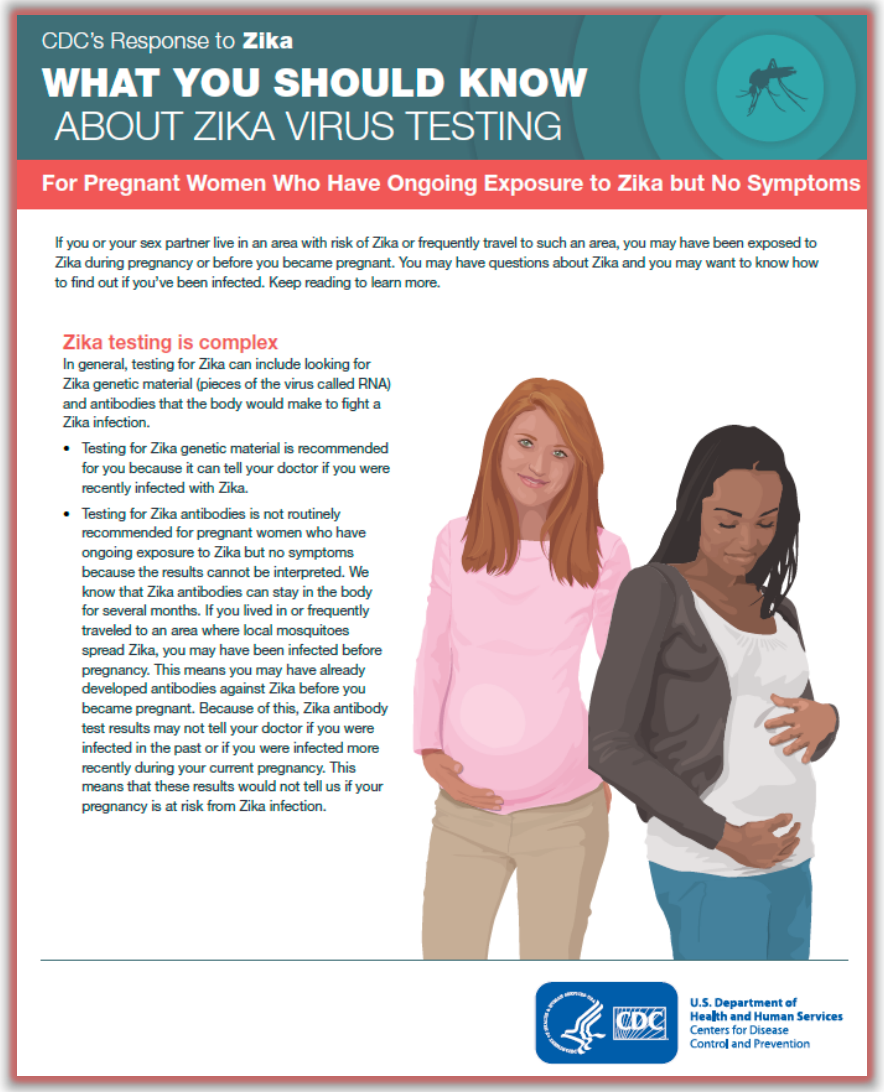
CS273696A July 20, 2017

PRETEST COUNSELING CONVERSATION GUIDE FOR HEALTHCARE PROVIDERS
FOR PREGNANT WOMEN WITH SYMPTOMS OF ZIKA

This guide describes recommendations for conducting pretesting counseling for symptomatic pregnant women with possible recent exposure (they or their sex partner live in or recently traveled to an area with risk of Zika). Symptoms of Zika include red eyes, fever, joint pain, rash, muscle pain, and headache. CDC recommends testing for pregnant women with symptoms of Zika.This material includes sample scripts to guide discussions with your patients about the complexity of Zika testing and the testing process with patients. Because a lot of content is outlined for discussion, make additional information available to support messaging and ensure that patients understand what they are being told.

Pregnant women coming in for Zika testing may feel worried or anxious. Support them by providing them with clear and easy-to-understand information and expressing empathy by acknowledging their concerns and feelings during pretesting counseling.

Recommendation	Sample Script
Provide the patient with information on why you will be testing them for Zika and a brief overview of what to expect	*Use one of the two following sentences to begin the discussion:* 1. You may be at risk for having Zika since you or your sex partner recently traveled to *(replace "recently traveled to" with "live in" as appropriate)* an area with risk of Zika within the past 12 weeks and you have had *(replace 'have had' with "during your pregnancy you previously had" as appropriate)* symptoms of Zika. OR/AND 2. You may be at risk of having Zika because you recently had sex without a condom with a person who traveled to *(replace "traveled to" with "lives in" as appropriate)* an area with risk of Zika within the past 12 weeks and you have had *(replace 'have had' with "during your pregnancy you previously developed" as appropriate)* symptoms of Zika. Since you were exposed to Zika and are experiencing symptoms *(replace "are experiencing" with "during your pregnancy you previously experienced" as appropriate)*, I think it is best to move forward with testing you for Zika. Before we begin, I would like to tell you what to expect throughout this process.
Patients should be informed that a combination of Zika tests will be required before a final result is determined	You will need a combination of tests to determine whether or not you have Zika. Finding out if you have Zika can require up to three different kinds of tests because the result of one test may require more testing to find out if you recently had a Zika infection. The tests we use to detect Zika can detect other similar viruses often found in the same areas with risk of Zika. Sometimes even after several tests, we may not know which type of virus you were infected with. Each test result is important, because it may help me decide how best to care for you during pregnancy. I want to be sure we take all of the necessary steps to make sure your results are accurate. Each test can take different amounts of time to receive results, which I know can be frustrating. As your healthcare provider I am here to answer any questions you may have. • Reassure the patient that this method of testing is normal • Consider providing the fact sheet *What You Should Know About Zika Virus Testing for Pregnant Women with Symptoms of Zika.*
Let the patient know that you will be ordering two tests; one to look for Zika RNA and one to look for Zika antibodies. Define these terms as they may be unfamiliar	I am going to start the testing process by ordering two tests: • The first test looks for pieces of Zika virus, known as RNA. RNA can be found in blood and urine. • The second test looks for Zika antibodies, which are proteins that your body makes to fight off a Zika infection. Zika test results can be difficult to interpret. If you've had exposure to Zika virus or another similar virus before this pregnancy, it's possible that you've been infected before, and this could affect today's test results.



CDC's Response to **Zika**

WHAT YOU SHOULD KNOW
ABOUT ZIKA VIRUS TESTING

For Pregnant Women Who Have Ongoing Exposure to Zika but No Symptoms

If you or your sex partner live in an area with risk of Zika or frequently travel to such an area, you may have been exposed to Zika during pregnancy or before you became pregnant. You may have questions about Zika and you may want to know how to find out if you've been infected. Keep reading to learn more.

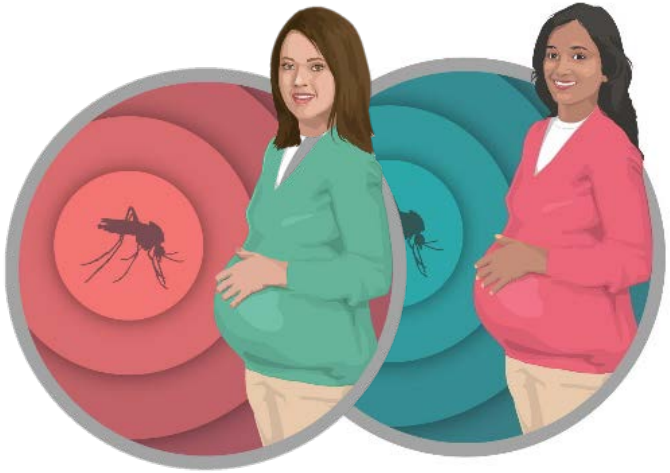
Zika testing is complex

In general, testing for Zika can include looking for Zika genetic material (pieces of the virus called RNA) and antibodies that the body would make to fight a Zika infection.

- Testing for Zika genetic material is recommended for you because it can tell your doctor if you were recently infected with Zika.
- Testing for Zika antibodies is not routinely recommended for pregnant women who have ongoing exposure to Zika but no symptoms because the results cannot be interpreted. We know that Zika antibodies can stay in the body for several months. If you lived in or frequently traveled to an area where local mosquitoes spread Zika, you may have been infected before pregnancy. This means you may have already developed antibodies against Zika before you became pregnant. Because of this, Zika antibody test results may not tell your doctor if you were infected in the past or if you were infected more recently during your current pregnancy. This means that these results would not tell us if your pregnancy is at risk from Zika infection.

Pregnancy Outcomes After Maternal Zika Virus Infection During Pregnancy — US Territories, January 1, 2016–April 25, 2017

US Zika Pregnancy Registry and Puerto Rico Zika Active Pregnancy Surveillance System



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Zika Pregnancy and Infant Registries: US Zika Pregnancy Registry and Zika Active Pregnancy Surveillance System (ZAPSS)

Purpose of registries

- To monitor pregnancy and infant outcomes in pregnancies with laboratory evidence of possible Zika virus infection
  - Estimate number of infants with birth defects
  - Provide data to inform phenotype of congenital Zika syndrome
  - Help ensure infants are linked to care

Zika Pregnancy and Infant Registries: Who is Included

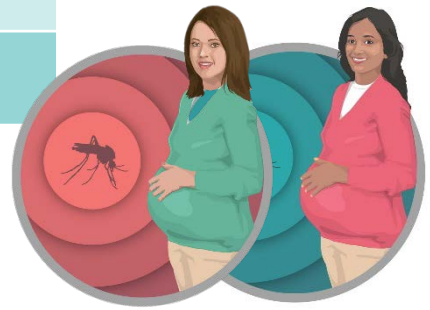
Pregnant women in the 50 US states and US territories.

Pregnant women with laboratory evidence of possible Zika virus infection (regardless of whether they have symptoms) and their exposed infants.

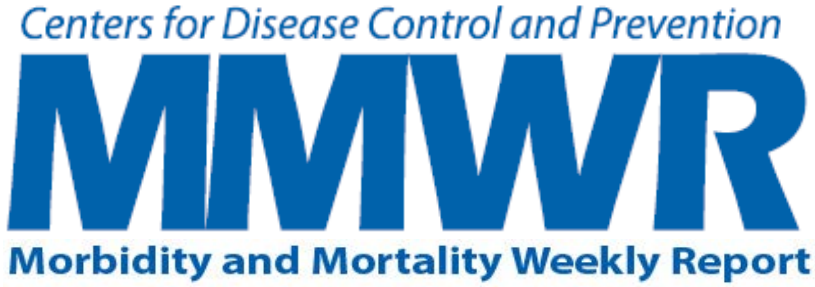
Infants with laboratory evidence of congenital Zika virus infection (regardless of whether they have symptoms) and their mothers.

Zika Pregnancy and Infant Registries: A Comparison

Registry Feature	US Zika Pregnancy Registry	Zika Active Pregnancy Surveillance System
Location	50 States and District of Columbia, US territories and Freely Associated States excluding Puerto Rico	Puerto Rico
Maternal Eligibility	Pregnant women with laboratory evidence of Zika	Pregnant women with laboratory evidence of Zika
Infant Follow-Up	Through 1st year of life	Through 3rd year of life



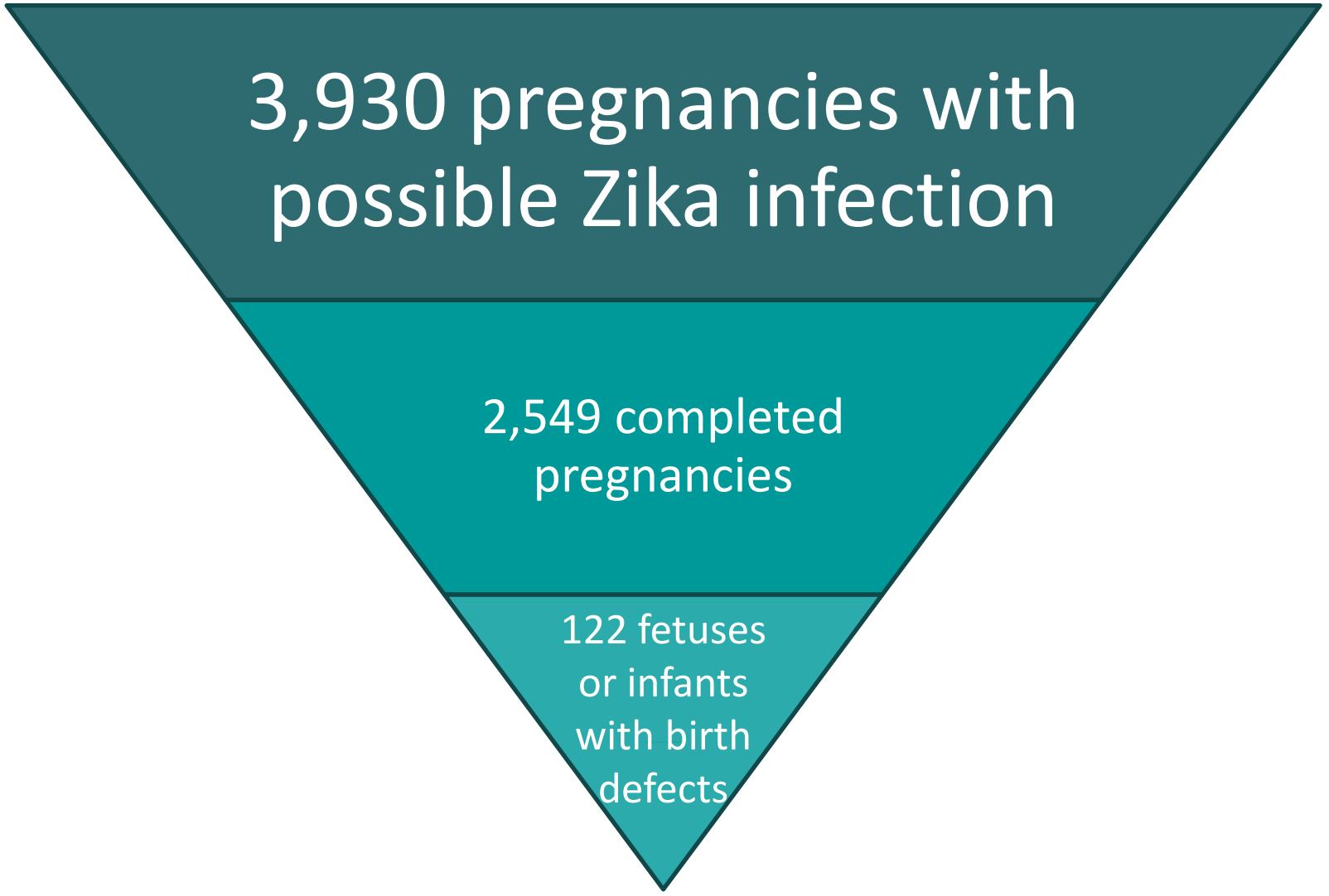
Pregnancy Outcomes Following Zika Virus Infection during Pregnancy in US Territories



- Provides data from women and infants living in American Samoa, the Commonwealth of Puerto Rico, the Federated States of Micronesia, the Republic of the Marshall Islands, and the US Virgin Islands

- Data reported to the US Zika Pregnancy Registry and the Puerto Rico Zika Active Pregnancy Surveillance System from January 1, 2016- April 25, 2017

Zika-Related Pregnancy Outcomes in US Territories



Results from Zika Pregnancy and Infant Registries

Findings	US States and DC USZPR[1] % (95% CI)	US Territories USZPR/ZAPPS[2] % (95% CI)
Symptomatic vs. Asymptomatic		
% Symptomatic with birth defects	8 (4-13)	5 (4-6)
% Asymptomatic with birth defects	12 (7-19)	7 (4-11)
Birth Defects by Trimester of Infection at DX		
First trimester	15 (8-26)	8 (5-12)
Second trimester	--	5 (4-7)
Third trimester	--	4 (3-6)

1. Reynolds MR, Jones AM, Petersen EE, et al. Vital Signs: Update on Zika Virus–Associated Birth Defects and Evaluation of All U.S. Infants with Congenital Zika Virus Exposure — U.S. Zika Pregnancy Registry, 2016. MMWR Morb Mortal Wkly Rep 2017;66:366-373. DOI: http://dx.doi.org/10.15585/mmwr.mm6613e1.
2. Shapiro-Mendoza CK, Rice ME, Galang RR, et al. Pregnancy Outcomes After Maternal Zika Virus Infection During Pregnancy — U.S. Territories, January 1, 2016–April 25, 2017. MMWR Morb Mortal Wkly Rep 2017;66:615-621. DOI: http://dx.doi.org/10.15585/mmwr.mm6623e1

Public Health Implications

- Highest proportion of Zika-associated birth defects among those with Zika virus infection during first and early second trimester of pregnancy
  - » More data are needed to explore whether women infected in the third trimester are at risk for:
    - having a baby with birth defects
    - other adverse pregnancy outcomes

- Identification and follow-up care of infants can facilitate timely and appropriate clinical intervention services and assessment of future needs

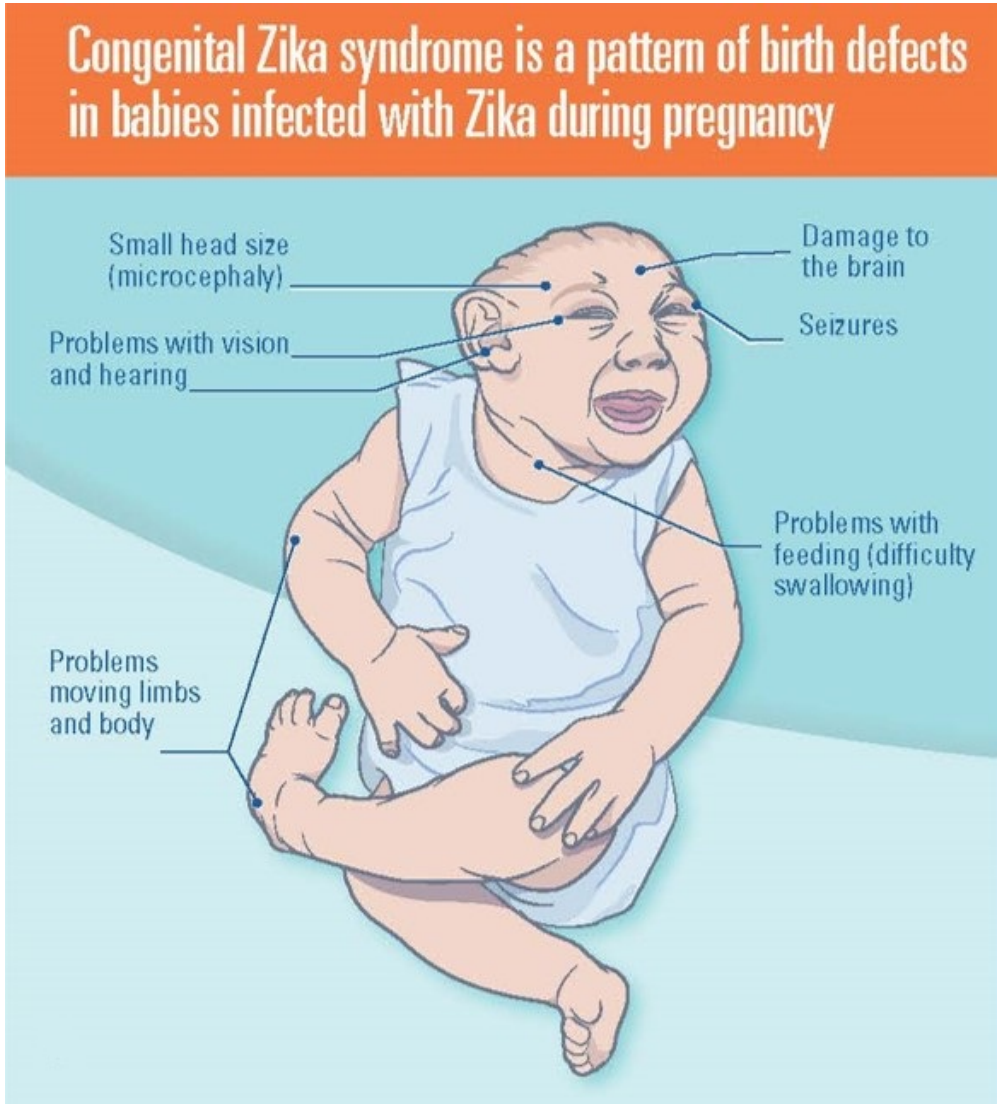
- Monitoring of affected pregnancies and continued follow-up care for infants is critical to elucidating the impact of congenital Zika virus infection

What You Can Do to Help

- Educate families on Zika virus prevention
- Ask about possible Zika virus exposure
- Provide all needed tests and follow-up care
- Support infants and families
- Report to the Zika virus pregnancy and infant registries

Summary

- Zika virus infection diagnosed during any trimester of pregnancy poses a risk to the fetus
- The absence or presence of symptoms in patients with confirmed Zika virus infection does not appear to affect the risk of birth defects
- Healthcare providers can educate patients, follow CDC recommendations for screening and testing, support infants and families, and report to the Zika pregnancy and infant registries



Summary and Key Messages

Summary

- Declining transmission and new data on Zika virus persistence increase complexity of testing
- Updated guidance places emphasis on shared decision-making based on patient preferences, clinical judgment, and in line with jurisdictional recommendations
- Zika virus infection poses a risk to all pregnancies, regardless of timing of possible exposure and symptoms
- Congenital Zika virus infection can lead to poor ophthalmologic outcomes in the presence and absence of other birth defects

Key Message Post “Deactivation of the response”

- Deactivation does not mean that the threat of Zika has lessened in importance or that people are no longer at risk of infection.
  - Zika is still a risk for pregnant women.
  - Protecting pregnant women, fetuses, and babies in the United States from Zika requires CDC to maintain constant vigilance on all fronts.
- CDC remains committed to protecting the health of Americans, and in particular pregnant women, fetuses, and infants most at risk of adverse health outcomes associated with Zika, and will continue working 24/7 to protect the nation from the threat of Zika.
- We know that babies will continue to be born with congenital Zika syndrome in 2018 and beyond, underscoring the need to stay committed to following these infants and ensuring care.
- The number of Zika cases in 2017 was lower than at this time during 2016, but Zika cases continue to be reported by many countries around the world.

Sharing Up-to-Date Information

- Providing updated clinical guidance
- Responding to your inquiries:
  - Email: ZikaMCH@cdc.gov
  - Zika Pregnancy Hotline: 770-488-7100
  - CDC-INFO: (800-232-4636)

http://www.cdc.gov/zika

Special thanks

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- Kate Grismala and Tori Reaves, USET
- Audience

Thank you!

More information on Zika: **www.cdc.gov/zika**

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

END