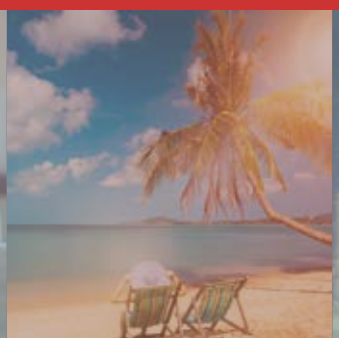
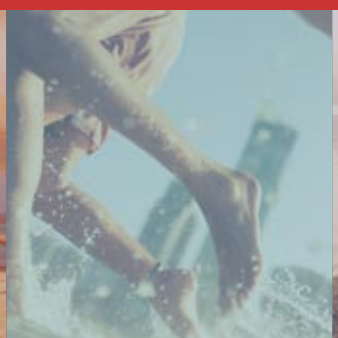
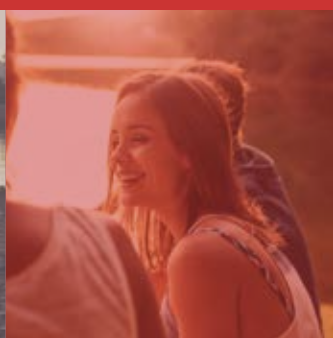
BioReference
LABORATORIES
an OPKO Health Company

Aptima® Zika Virus Assay

PROVIDING GREATER CERTAINTY IN TEST RESULTS AND HELPING TO REDUCE SUBSEQUENT SPREAD OF ZIKA INFECTION



WHAT IS **ZIKA VIRUS?**

Zika virus is a mosquito-borne virus transmitted by Aedes mosquitoes across tropical and subtropical regions. Outbreaks of Zika virus disease have recently been identified in Central America, South America, the Caribbean, the U.S. territories of Puerto Rico and the Virgin Islands, and the continental United States.

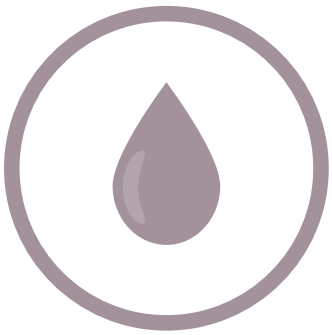
These recent outbreaks are a matter of international concern. The virus has a connection to severe congenital health consequences, especially in babies born to infected women. Zika is linked to and has lead to an increase of cases of microcephaly, a rare neurological condition, as well as other birth defects in babies born to infected mothers. The World Health Organization (WHO) has also determined a link between Zika and Guillain-Barré syndrome, a rare and life threatening condition in adults.

TRANSMISSION

The bite of an infected mosquito

A mother to her fetus

Unprotected sexual contact



Blood transfusion

SYMPTOMS

The symptoms tied to Zika virus are mild and many patients experience no symptoms at all, so early, accurate diagnosis is imperative. Common symptoms include:

- Fever
- Rash
- Joint Pain
- Conjunctivitis (red eyes)
- Muscle pain
- Headache

Patients who live in or have recently traveled to an area with Zika virus may have been infected with other mosquito-borne viral infections such as dengue or chikungunya, which often circulate in the same geographic regions and present similar clinical symptoms.

DIAGNOSING **ZIKA VIRUS**

The U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for several diagnostic tools for Zika virus, including the Aptima® Zika Virus assay*, a fast and highly sensitive test to identify Zika virus, now available at BioReference.

ACCURATE

The Zika Virus assay will help to ensure a more accurate diagnosis, offering moms-to-be, women who plan to become pregnant and healthcare providers greater certainty in their test results and helping to reduce subsequent spread of the infection.

SENSITIVE

The Zika Virus assay uses transcription mediated amplification to detect Zika virus in serum and urine. It can detect viral RNA in single-digit copies per mL, so you can feel confident in the results.

FAST

Zika Virus results will typically be available in 2 days (unless IgM testing is reflexed), giving physicians and patients peace of mind to proceed with family planning without the need to wait on government issued results from public health laboratories.

INCLUSIVE

The Zika Virus assay is inclusive of 76 tested strains, including 16 strains from Brazil, 2 strains from Puerto Rico, 3 strains from Mexico, and 4 strains from Panama.

CDC GUIDANCE FOR TESTING

The Centers for Disease Control and Prevention (CDC) has released interim clinical guidance for the diagnosis and testing of Zika virus. Testing of specimens within the United States to determine possible Zika virus infection should be limited to specimens collected from patients meeting CDC's clinical and epidemiological criteria for testing. As Zika continues to be an area of evolving care and practice, you can check periodically for revisions and updates through the CDC's Zika website: **https://www.cdc.gov/zika/**

CLINICAL INDICATIONS

Current indications and guidelines as of July 26, 2016 are summarized below. Serology may consist of Zika IgM alone or in combination with Dengue IgM, and possibly Chikungunya IgM, depending on the clinical situation. Both Zika and Dengue are flaviviruses and may show serologic cross-reactivity. Please refer to CDC guidelines for further information on which serologic tests are appropriate, based on exposure history and the presence or absence of symptoms.

- **Exposed symptomatic individuals <14 days of symptom onset:** Recommend paired serum and urine molecular testing. If negative, suggest reflex to serology testing; follow up as per current CDC Guidance.
- **Exposed symptomatic individuals >14 days of symptom onset or exposed asymptomatic pregnant women 2-12 weeks after exposure:** Recommend serology testing. If positive, suggest paired serum and urine molecular testing; follow up as per current CDC Guidance.
- **Exposed asymptomatic pregnant women <14 days from exposure:** Recommend paired serum and urine molecular testing. If negative suggest serology testing; follow up as per current CDC Guidance.

TEST HIGHLIGHTS AND INFORMATION

TEST CODE	TEST NAME	METHODOLOGY	TAT	VOLUME	COLLECTION INSTRUCTIONS
J405-2	Zika RNA PCR w/ reflex to Zika IgM when negative	PCR & ELISA	5 Days	2.5 mL Blood Serum	Fill the Serum Separator (SST) tube completely, invert gently 2-3 times, let stand for 20 minutes, spin for 10-15 minutes. Transfer serum into the red plastic aliquot tube. Follow specimen labeling instructions provided. Note: Red transfer tube preferred, but not required. SST is acceptable.
J406-0	Zika RNA PCR Only	PCR	2 Days	1.5 mL Blood Serum	Fill the Serum Separator (SST) tube completely, invert gently 2-3 times, let stand for 20 minutes, spin for 10-15 minutes. Transfer serum into the red plastic aliquot tube. Follow specimen labeling instructions provided. Note: Red transfer tube preferred, but not required. SST is acceptable.
J407-8	Zika RNA PCR Only	PCR	2 Days	1.5 mL Urine	Collect urine in the sterile green container. Follow specimen labeling instructions provided. Note: When collecting urine, a patient-matched serum specimen is required for serological follow-up testing of negative PCR results, per the CDC testing algorithm.
J497-9	Anti-Zika Virus IgM Only	ELISA	5 Days	1.0 mL Blood Serum	Fill the Serum Separator (SST) tube completely, invert gently 2-3 times, let stand for 20 minutes, spin for 10-15 minutes. Transfer serum into the red plastic aliquot tube. Follow specimen labeling instructions provided. Note: Red transfer tube preferred, but not required. SST is acceptable.

Note: Acceptable matrices are only serum and urine. Plasma, semen, CSF, amniotic fluid are not acceptable.

IMPORTANT TEST NOTES

- **An Advanced Beneficiary Notice (ABN)** is required for all patients being tested for Zika virus, and can be obtained through your Account Executive, Customer Service, or on CareEvolve.
- **Serum samples** must be sent at ambient temperature or refrigerated, and must be received at the lab within 72 hours of collection. Specimen cannot be received frozen, or test will not be performed.
- **All Zika virus specimen** must be received in its own tube, and cannot be shared with other testing. Other testing will not be performed.
- **Samples should be labeled** with the specialized yellow specimen stickers, which can be obtained through Customer Service or the supply order form.
- **Please be sure** to answer the order entry (AOEs) questions on the requisition or thrrough CareEvolve or your EMR, as these answers are submitted to the state Department of Health.

ADDITIONAL RESOURCES

Centers for Disease Control and Prevention ▪ http://www.cdc.gov/zika/

World Health Organization ▪ http://www.who.int/topics/zika/en/

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*This test has not been FDA cleared or approved
*This test has been authorized by FDA under an EUA for use by clinical laboratories, including BioReference
*This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens
*This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection undersection 564(b)(1) of the Act, 21 U.S.C.§ 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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