Overview

Useful For

Screening for the presence of IgM-class antibodies to Zika virus in symptomatic pregnant women with either travel to a Zika virus endemic region or who have had sexual exposure to an individual with Zika virus

Highlights

This assay is a screening test for IgM-class antibodies to Zika virus. A presumptive positive result by this assay is not diagnostic for Zika virus infection andÂ confirmatory testing may be required as determined by your local health department. Confirmatory testing by a molecular assay for detection of Zika virus RNA may also be considered.

This assay should be used in patients presenting at least 2 weeks postsymptom onset or last possible exposure to Zika virus. Reverse transcription-polymerase chain reaction (RT-PCR) for Zika virus RNA detection should be ordered in patients with less than 2 weeks of symptoms or postexposure.

A single negative result by the Zika IgM enzyme-linked immunosorbent assay (ELISA) should not be used to rule-out infection as the specimen may have been collected prior to the development of detectable antibodies.

Asymptomatic pregnant women with ongoing exposure to Zika virus (eg, residence in Zika virus endemic region) should not be tested for IgM antibodies to Zika virus, but rather by molecular assays for Zika virus at least 3 times during pregnancy. Due to seropersistence of IgM-class antibodies to Zika virus for months after infection, they cannot be used to reliably distinguish recent from past infection.

Testing of asymptomatic pregnant women without ongoing exposure to Zika virus is no longer routinely recommended. Testing consideration should be made using a shared patient-provider decision-making model, one in which patients and providers work together to make decisions about testing and care plans.

Testing Algorithm

The following algorithms are available in Special Instructions:

-Assessment for Zika Virus Infection

-Mosquito-borne Disease Laboratory Testing

Special Instructions

- Assessment for Zika Virus Infection
- Mosquito-borne Disease Laboratory Testing

Method Name

IgM Antibody Capture Enzyme-Linked Immunosorbent Assay (MAC-ELISA)

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This test is not intended for medical-legal use.

The Centers for Disease Control and Prevention recommend real-time reverse transcription polymerase chain reaction (RT-PCR) for Zika virus (ZIKV) on serum and urine to diagnose Zika virus infection. These are available as RZIKU / Zika Virus, PCR, Molecular Detection, Random, Urine and RZIKS / Zika Virus, PCR, Molecular Detection, Serum.

Additional Testing Requirements

Confirmatory testing of positive Zika virus IgM results may be required as determined by your local health department.

Due to similar clinical presentation and cross reactivity, testing for IgM-class antibodies to dengue virus, concurrently with Zika virus IgM testing, is recommended, order DENVP / Dengue Virus Antibody/Antigen Panel, Serum.

Necessary Information

Three answers are required for order entry questions. The only acceptable answers are **Yes** or **No**.

If ordering electronically, record at order entry.

If not ordering electronically, provide the answers to the following questions with the specimen:

1. Is the patient pregnant?

2. Has the patient traveled to or is a resident of a Zika endemic region?

3. Does the patient currently have or recently had Zika symptoms?

Specimen Required

Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Specimen Volume: 2.5 mL

Forms

If not ordering electronically, complete, print, and send a Microbiology Test Request (T244) with the specimen.

Specimen Minimum Volume

2 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen	30 days	

Clinical and Interpretive

Clinical Information

Zika virus is an RNA virus in the genus Flavivirus and is primarily transmitted through the bite of an infected *Aedes* species mosquito. Other means of transmission include through transfusion of blood and blood products, sexually through genital secretions, perinatally, vertically from mother to fetus, and potentially through contact with other body secretions such as tears and sweat.

Historically, most cases of Zika virus infection have occurred in parts of Africa and South-East Asia. However, Zika virus emerged in South America in early 2015 and is now endemic in over 50 countries in South, Central, and North America, including in several US territories and focal regions of the southern United States.

The majority (approximately 80%) of individuals infected with Zika virus are asymptomatic. Among symptomatic patients, fever, headache, retro-orbital pain, conjunctivitis, maculopapular rash, myalgias, and arthralgias are commonly reported. Notably, these symptoms are not distinct and can be seen with other emerging arboviruses, including dengue and chikungunya. Therefore, diagnostic testing for each of these viruses is recommended in patients returning for areas where these viruses cocirculate. Intrauterine or prenatal infection with Zika virus has been causally linked to development of microcephaly, with the greatest risk for fetal abnormality occurring if the infection is acquired during the first trimester. Finally, Zika virus has also been associated with development of Guillain-Barre syndrome.

A number of Zika virus serologic and nucleic acid amplification tests (NAAT) have received emergency use authorization (EUA) through the Food and Drug Administration (FDA). The recommended tests vary by the patient's symptoms, course of illness, and whether or not the patient is pregnant.

For the most up-to-date information regarding Centers for Disease Control and Prevention (CDC) testing guidelines visit www.cdc.gov/zika/.

These guidelines are reflected in Assessment for Zika Virus Infection Special Instructions:

Zika virus testing is not recommended for asymptomatic couples attempting conception, given the potential for false-positive and false-negative results. Additionally, it is well established the Zika virus may remain in reproductive fluids, despite negative serologic and molecular test results in blood and urine.

Reference Values

Negative

Interpretation

See Assessment for Zika Virus Infection in Special Instructions for a review of the recommended testing and interpretation of results. For the most recent Centers for Disease Control and Prevention (CDC) guidelines for Zika virus testing visit www.cdc.gov/zika/.

Presumptive Zika Positive:

IgM-class antibodies to Zika virus (ZIKV) detected. This is a preliminary result and does not confirm evidence of ZIKV infection. Confirmatory testing may be required as determined by your local health department.Â False-positive results may occur in patients with other current or prior flavivirus infections (eg, dengue virus). For patients with less than 7 days of symptoms or last possible exposure to ZIKV, real-time reverse transcription polymerase chain reaction (RT-PCR) for ZIKV on serum and urine is recommended. A positive ZIKV RT-PCR result on either specimen is confirmatory for ZIKV infection.

Other Flavivirus Positive:

Antibodies to a flavivirus, not ZIKV, were detected. Consider targeted testing for IgM-class antibodies to dengue or West Nile viruses as appropriate, taking into consideration patient exposure and presentation.

Negative:

No evidence of IgM-class antibodies to ZIKV. For specimens collected less than 7 days postsymptom onset or possible ZIKV exposure, RT-PCR for ZIKV on serum and urine to exclude a false-negative ZIKV IgM result is recommended. For symptomatic patients with travel to dengue endemic areas, testing for IgM antibodies to dengue virus is also recommended.

Cautions

A presumptive positive result by this test only suggests infection with Zika virus. This result should not be considered as diagnostic for Zika virus infection. False-positive results may occur in patients infected with other, closely related flaviviruses, including dengue virus, or in patients who have been vaccinated against yellow fever virus. Only limited evaluation of cross-reactivity with flaviviruses or arboviruses has been conducted. Therefore, confirmatory testing of presumptive or possible positive samples may be required and should be performed as determined by the local health department. Evaluation of sample by real-time polymerase chain reaction (PCR) for Zika virus may also be warranted.

Testing of asymptomatic pregnant women with possible exposure, but without ongoing exposure to Zika virus, is not routinely recommended.

False-negative results can arise from specimen collection prior to development of an IgM antibody response (<4 days postsymptom onset) or after IgM levels have decreased below detectable levels.

Negative results from at-risk individuals who are immunosuppressed should be interpreted with caution.

Negative results do not preclude infection with Zika virus and should not be used as the sole basis of patient treatment or management decisions. All results should be interpreted by a trained professional in conjunction with review of the patient's exposure history and clinical signs and symptoms.

Zika and dengue virus infections presents with symptoms similar to other arboviruses that cocirculate in areas where Zika virus is currently endemic. Diagnostic testing to rule out these infections (eg, chikungunya) and other similar presenting infection should be considered.

Clinical Reference

1. Oduyebo T, Polen KD, Walke HT, et al: Update: Interim guidance for health care providers caring for pregnant women with possible Zika virus exposure - United States (Including U.S. Territories), July 2017. MMWR Morb Mortal Wkly Rep. 2017;66:781-793

2. Waggoner JJ, Pinsky BA: Zika virus: Diagnostics for an emerging pandemic threat. J Clin Microbiol. 2016;54(4):860-867

3. Theel ES, Hata DJ: Diagnostic testing for Zika virus: A post outbreak update. J Clin Microbiol. 2018;56(4) pii: e01972-17. doi: 10.1128/JCM.01972-17

Performance

Method Description

The ZIKV Detect *2*.0 IgM Capture enzyme-linked immunosorbent assay (ELISA) is for the detection of human IgM antibodies targeting the Zika virus (ZIKV) envelope glycoproteins. Polystyrene microtiter wells are precoated with polyclonal capture antibodies against human IgM. Positive control, negative control, and patient serum samples are diluted into a sample dilution buffer and then added to the ELISA plate in appropriate locations. After incubation and washing, a subsequent ready-to-use (RTU) ZIKV antigen (Zika Ag), a cross-reactive control antigen (CCA) and a normal cell antigen (NCA) are added separately to each corresponding well. After incubation and washing, a RTU secondary antibody solution is added to each well. After a subsequent incubation and wash steps, an enzyme conjugate solution comprising horseradish peroxidase-labeled antimouse antibody is added to each well. After washing, wells are incubated with a tetramethylbenzidine (TMB) substrate. An acidic stop solution is then added, and the degree of enzymatic turnover is determined by the absorbance (optical density) measurement at 450 nanometers. If human IgM antibodies targeting the ZIKV envelope glycoproteins are present, a complex is formed consisting of the IgM, antigen, secondary antibody, and conjugate. If IgM antibodies targeting the ZIKV envelope glycoproteins are not present, then the antigen, antibody, and conjugate are washed away.(Package insert: InBios Zika Detect 2.0 IgM Capture ELISA. InBios International, Inc; 05/23/2019)

PDF Report

No

Day(s) Performed

Tuesday

Report Available

Same day/1 to 7 days

Specimen Retention Time

90 days

Performing Laboratory Location

Rochester

Fees and Codes

Fees

- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved or is exempt by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information

86794

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
PNZIK	Prenatal Zika Virus MAC-ELISA,IgM,S	80824-6

Result ID	Test Result Name	Result LOINC Value
PZIKV	Prenatal Zika Virus MAC-ELISA IgM,S	80824-6
PREGO	Pregnant?	11449-6
TRVL	Travel to/Resident of Zika Region?	8691-8
SYMPS	Current or prior Zika symptoms?	75325-1