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MAYO CLINIC LABORATORIES

Test Definition: VZIKM

Zika Virus, IgM Antibody Capture ELISA, Serum

Overview

Useful For

Screening for the presence of IgM-class antibodies to Zika virus

This test is **not intended for** medical-legal use.

This test is **not recommended for** asymptomatic couples attempting conception.

Testing Algorithm

For more information see:
-Assessment for Zika Virus Infection
-Mosquito-borne Disease Laboratory Testing

Special Instructions

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

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. 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 post-symptom onset or last possible exposure to Zika virus. Reverse transcription-polymerase chain reaction 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 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, this test 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.

Method Name

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

NY State Available

Yes

Specimen

Specimen Type
Serum

Ordering Guidance
For specimens collected less than 14 days post-symptom onset or possible Zika virus exposure, reverse transcription polymerase chain reaction testing for Zika virus using serum and urine is recommended to exclude a false-negative Zika virus IgM result. For more information see VZIKU / Zika Virus, PCR, Urine and VZIKS / Zika Virus, PCR, Serum.

Additional Testing Requirements
This is a screening test for Zika virus. As required by your local health department, confirmatory testing of a presumptive positive result may be necessary.

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

Specimen Required
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL
Collection Instructions:
1. Allow blood to clot at ambient temperature (20-25 degrees C) for 30 to 60 minutes, then centrifuge and aliquot serum into plastic vial.
2. Send serum specimen frozen.

Forms
If not ordering electronically, complete, print, and send an Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume
0.8 mL

Reject Due To

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

Cord blood	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen	30 days	

Clinical & 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 have received emergency use authorization through the US Food and Drug Administration. The recommended tests vary by the patient's symptoms, course of illness, and whether the patient is pregnant.

The most up-to-date information regarding Centers for Disease Control and Prevention testing guidelines is available at www.cdc.gov/zika/index.html.

These guidelines are reflected in Assessment for Zika Virus Infection.

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 for a review of the recommended testing and interpretation of results. For the most recent Centers for Disease Control and Prevention guidelines for Zika virus testing visit www.cdc.gov/zika/index.html

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. 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, 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 and/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 post symptom 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 reverse transcription polymerase chain reaction for Zika virus may also be warranted.

False-negative results can arise from specimen collection prior to development of an IgM antibody response (less than 4 days post-symptom 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.

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

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(29):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):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, and a normal cell antigen 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 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 ZIKV Detect 2.0 IgM Capture ELISA. InBios International, Inc; 09/23/2021)

PDF Report

No

Day(s) Performed

Bimonthly on the first and third Wednesday; fifth Wednesday when applicable

Report Available

Same day/1 to 14 days

Specimen Retention Time

90 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Superior Drive

Fees & 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 account representative. For assistance, contact Customer Service.

Test Classification

This test has been cleared, approved, or is exempt by the US 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
VZIKM	Zika Virus MAC-ELISA, IgM, S	80824-6

Result ID	Test Result Name	Result LOINC® Value
VZIKM	Zika Virus MAC-ELISA, IgM, S	80824-6