Test Definition: VZIKU

Zika Virus, PCR, Molecular Detection, Random, Urine

Overview

Useful For

Qualitative detection of Zika virus RNA in paired urine and serum from individuals meeting the Centers of Disease Control and Prevention Zika virus clinical or epidemiologic criteria

Testing Algorithm

Due to US Food and Drug Administration requirements, urine specimens must be tested in conjunction with a paired serum specimen. See Additional Testing Requirements

The following algorithms are available:
-Assessment for Zika Virus Infection
-Mosquito-borne Disease Laboratory Testing

Special Instructions

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

Highlights

Provides qualitative detection of Zika virus RNA from urine collected during the acute phase of infection.

Due to similar clinical presentations, testing for RNA or IgM-class antibodies to dengue and chikungunya viruses, concurrently with Zika virus testing, is strongly recommended.

For the most up to date Zika epidemiology and testing recommendations, visit www.cdc.gov/zika/.

Method Name

Real-Time Reverse Transcription Polymerase Chain Reaction (RT-PCR)/DNA Probe Hybridization

NY State Available

Yes

Specimen

Specimen Type

Urine

Ordering Guidance

Due to similar clinical presentations, testing for RNA or IgM-class antibodies to dengue and chikungunya viruses, concurrently with Zika virus testing, is strongly recommended.

Additional Testing Requirements

The US Food and Drug Administration requires that urine specimens be tested in conjunction with a paired serum specimen; order VZIKS / Zika Virus, PCR, Molecular Detection, Serum for the paired serum specimen.

Specimen Required

Container/Tube: Sterile container

Specimen Volume: 1 mL

Collection Instructions:

1. Collect random urine in a sterile container.
2. Label specimen as urine.

Forms

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

Specimen Minimum Volume

0.3 mL

Reject Due To

Other	Urine containing preservatives

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	7 days	
	Frozen	7 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 Southeast 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. Fever, headache, retro-orbital pain, conjunctivitis, maculopapular rash, myalgias and arthralgias are commonly reported among symptomatic patients. 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 form 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 (EUA) through the US Food and Drug Administration. 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 the Centers of Disease Control and Prevention testing guidelines visit www.cdc.gov/zika/.

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
Reference values apply to all ages.

Interpretation

A positive test result indicates the presence of Zika virus RNA in the specimen. The FDA requires that urine specimens be tested in conjunction with a paired serum specimen. However, a positive result in either specimen is consistent with recent infection.

A negative test result with a positive internal control indicates that Zika virus RNA is not detectable in the specimen.

A negative test result with a negative internal control is considered evidence of polymerase chain reaction inhibition or reagent failure. A new specimen should be collected for testing if clinically indicated.

Cautions

Assay is for in vitro diagnostic use under the Food and Drug Administration (FDA) Emergency Use Authorization (EUA) only.

Negative Zika virus reverse transcription polymerase chain reaction results do not preclude infection with Zika virus and should not be used as the sole basis for 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.

False-negative results may arise from degradation of Zika virus RNA during incorrect shipping or storage, and specimen collection after the period that Zika virus RNA is typically found in the patient (7 days-sera or 14 days-urine after onset of symptoms).

Supportive Data

The RealStar Zika virus RT-PCR Kit US by Altona Diagnostics received Emergency Use Authorization from the US Food and

Drug Administration (FDA) on May 13, 2016.

Details regarding the performance characteristics for the RealStar Zika virus RT-PCR kit, as established by the Altona Diagnostics, can be viewed at www.fda.gov/media/97712/download.

Clinical Reference

1. Oduyebo T, Igbinosa I, Petersen EE, et al: Update: Interim guidance for health care providers caring for women of reproductive age with possible Zika virus exposure-United States, July 2016. MMWR Morb Mortal Wkly Rep. 2016 Jul 25;65(29):739-744
2. US Food and Drug Administration. Emergency Use Authorizations (Medical Devices). Available at www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm
3. Waggoner JJ, Pinsky BA: Zika virus: Diagnostics for an emerging pandemic threat. J Clin Microbiol. 2016 Apr;54(4):860-867

Performance

Method Description

The RealStar Zika Virus RT-PCR Kit by Altona Diagnostics is a TaqMan assay employing a reverse transcriptase (RT) reaction to convert RNA to complementary DNA, followed by polymerase chain reaction (PCR) amplification of specific target sequences and detection by target specific probes. Probes specific for Zika RNA are labelled with the fluorophore FAM. The kit also contains an internal control labeled with the fluorophore JOE. The internal control is added to the nucleic acid extraction procedure and undergoes RT and amplification in parallel to Zika virus-specific RNA that may be present in patient specimens. The different dye-labeled probes allow detection of Zika virus and the internal control simultaneously in corresponding detector channels of the LC 480 instrument. The test can be completed within 120 minutes following RNA extraction and is completed in a closed system.(Package insert: RealStar Zika Virus RT-PCR Kit US. Altona Diagnostics; Version 1.1, 03/2017)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Report Available

Same day/1 to 5 days

Specimen Retention Time

7 days

Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

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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 received Emergency Use Authorization (EUA) 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

87662

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
VZIKU	Zika Virus PCR, Urine	85623-7

Result ID	Test Result Name	Result LOINC® Value
619458	Zika Urine PCR Result	85623-7
619459	Zika Urine PCR Interpretation	69048-7