Test Definition: RZIKU

Zika Virus, PCR, Urine

Overview

Useful For

Qualitative detection of Zika virus RNA in paired urine and serum from individuals meeting CDC Zika virus clinical or epidemiologic criteria

Highlights

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

This test is intended for the evaluation of pregnant women and symptomatic nonpregnant individuals with potential exposure to Zika virus.

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/

Testing Algorithm

The FDA requires that urine specimens be tested in conjunction with a paired serum specimen; order RZIKS / Zika Virus, PCR, Molecular Detection, Serum for the paired serum specimen.

The following algorithms are available in Special Instructions:

-Assessment for Zika Virus Infection in Nonpregnant Individuals

-Assessment for Zika Virus Infection in Pregnant Women

-Mosquito-borne Disease Laboratory Testing

Special Instructions

- Assessment for Zika Virus Infection in Pregnant Women
- Assessment for Zika Virus Infection in Nonpregnant Individuals
- Mosquito-borne Disease Laboratory Testing

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Urine

Advisory Information

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 FDA requires that urine specimens be tested in conjunction with a paired serum specimen; order RZIKS / Zika Virus, PCR, Molecular Detection, Serum for the paired serum specimen.

Necessary Information

Order questions and answers concerning pregnancy, exposure, and display of symptoms are required.

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.

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 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* speciesmosquito. 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 CDC testing guidelines visit www.cdc.gov/zika/.

These guidelines are reflected in the following MCL testing algorithms in Special Instructions:

-Assessment for Zika Virus Infection in Nonpregnant Individuals

-Assessment for Zika Virus Infection in Pregnant Women

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

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 PCR inhibition or reagent failure. A new specimen should be collected for testing if clinically indicated.

Cautions

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

Negative Zika virus RT-PCR 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 FDA on May 13, 2016. The letter can be accessed at www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM501023.pdf

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/downloads/MedicalDevices/Safety/EmergencySituations/UCM501027.pdf

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. MMWR Morb Mortal Wkly Rep 2016 Jul 25;65:739-744

2. United States 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;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 (cDNA), followed by 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 that is labeled with the fluorophore JOE. The internal control is added to the nucleic acid extraction procedure and undergoes reverse transcription and amplification in parallel to Zika virus specific RNA that may be present in patient specimens. The different dye labeled probes allows 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 available at www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM501027.pdf)

PDF Report

No

Day(s) and Time(s) Test Performed

Tuesday, Thursday; 7 a.m.

Analytic Time

5 days

Maximum Laboratory Time

8 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

87662

LOINC® Information

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

Result ID	Test Result Name	Result LOINC Value
47916	Zika Urine PCR Result	85623-7
PREG1	Is patient pregnant?	11449-6
EXPO1	Has patient had Zika exposure?	88636-6
SYMP1	Has patient been symptomatic?	75325-1
48058	Zika Urine Interpretation	69048-7