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

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>NA</td>
</tr>
<tr>
<td>Lipemia</td>
<td>NA</td>
</tr>
<tr>
<td>Icterus</td>
<td>NA</td>
</tr>
<tr>
<td>Other</td>
<td>Urine containing preservatives</td>
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Specimen Stability Information

<table>
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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
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<tbody>
<tr>
<td>Urine</td>
<td>Refrigerated (preferred)</td>
<td>7 days</td>
</tr>
<tr>
<td></td>
<td>Frozen</td>
<td>7 days</td>
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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 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

Details regarding the performance characteristics for the RealStar Zika virus RT-PCR kit, as established by the
Altona Diagnostics, can be viewed at

Clinical Reference
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

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
Test Definition: RZIKU
Zika Virus, PCR, Urine

- 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 or approved 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

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<th>Order LOINC Value</th>
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<tr>
<td>RZIKU</td>
<td>Zika Virus, PCR, Urine</td>
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<td>47916</td>
<td>Zika Urine PCR Result</td>
<td>85623-7</td>
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<tr>
<td>PREG1</td>
<td>Is patient pregnant?</td>
<td>11449-6</td>
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<tr>
<td>EXPO1</td>
<td>Has patient had Zika exposure?</td>
<td>88636-6</td>
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<tr>
<td>SYMP1</td>
<td>Has patient been symptomatic?</td>
<td>75325-1</td>
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<td>48058</td>
<td>Zika Urine Interpretation</td>
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