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## Overview

### Useful For

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

### 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](#)

### Highlights

Provides qualitative detection of Zika virus RNA from serum 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.

For the most up-to-date Zika epidemiology and testing recommendations, visit [www.cdc.gov/zika/](http://www.cdc.gov/zika/)

### Method Name

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

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### 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.

### Necessary Information

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

### Specimen Required

**Collection Container/Tube:**

**Preferred:** Serum gel

**Acceptable:** Red top

**Submission Container:** Sterile container

**Specimen Volume:** 0.5 mL

**Collection Instructions:**

1. Collect whole blood in a serum gel tube.
2. Centrifuge and aliquot the serum into a sterile container within 6 hours of collection.
3. Label specimen as serum.

**Forms**

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

**Specimen Minimum Volume**

0.25 mL

**Reject Due To**

All specimens will be evaluated at Mayo Clinic Laboratories for test suitability.

**Specimen Stability Information**

Specimen Type	Temperature	Time	Special Container
Serum	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 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/](http://www.cdc.gov/zika/).

These guidelines are reflected in [Assessment for Zika Virus Infection](#) in 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

A positive test result indicates the presence of Zika virus RNA in the specimen.

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 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](http://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](http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM501027.pdf)

### Clinical Reference

1. Oduyebo T, Igbinosa I, Petersen EE, et al: US Update: Interim Guidance for Health Care Providers Caring for Women of Reproductive Age with Possible Zika Virus Exposure-United States. Morb Mortal Wkly Rep MMWR 2016 Jul

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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](http://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](http://www.fda.gov/downloads/MedicalDevices/Safety/EmergencySituations/UCM501027.pdf))

### PDF Report

No

### Day(s) Performed

Tuesday, Thursday

### Report Available

5 to 8 days

### Specimen Retention Time

7 days

### Performing Laboratory Location

Rochester

## 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 Regional Manager. 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**

87662

**LOINC® Information**

Test ID	Test Order Name	Order LOINC® Value
RZIKS	Zika Virus, PCR, Serum	85622-9

Result ID	Test Result Name	Result LOINC® Value
47956	Zika Serum PCR Result	85622-9
48059	Zika Serum PCR Interpretation	69048-7
PREGY	Is patient pregnant?	11449-6
EXPOS	Has patient had Zika exposure?	88636-6
SYMP	Has patient been symptomatic?	75325-1