MAYO CLINIC LABORATORIES

# Test Definition: VZIKS

Zika Virus, PCR, Molecular Detection, Serum

## Overview

### Useful For

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

### Testing Algorithm

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 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/

### Method Name

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

### NY State Available

Yes

## Specimen

### Specimen Type

Serum

### Additional Testing Requirements

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. See the following:

CHIKV / Chikungunya IgM and IgG Antibody, Serum

CHIKS / Chikungunya Virus, PCR, Molecular Detection, Serum

DENGM / Dengue Virus Antibody, IgG and IgM, Serum

DENVP / Dengue Virus Antibody/Antigen Panel, Serum

DENGS / Dengue Virus, Molecular Detection, PCR, Serum

## Specimen Required

**Collection Container/Tube:**
**Preferred:** Serum gel
**Acceptable:** Red top
**Submission Container:** Sterile container
**Specimen Volume:** 0.5 mL Serum
**Collection Instructions:** Within 2 hours of collection, centrifuge and aliquot the serum into a sterile container.
**Additional Information:** Serum specimens not aliquoted from the serum gel collection tube into a sterile container **will be rejected**.

## Forms

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

## Specimen Minimum Volume

Serum: 0.3 mL

## Reject Due To

| | |
|---|---|
| Gross hemolysis | Reject |
| Heat-inactivated specimen | Reject |

## 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 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 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.

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

A negative test result with a negative internal control result is considered evidence of polymerase chain reaction 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 US Food and Drug Administration emergency use authorization 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 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 on May 13, 2016.

Details regarding the performance characteristics for the RealStar Zika virus RT-PCR kit, as established by 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;65(29):739-744
2. United States Food and Drug Administration. Emergency Use Authorizations (Medical Devices). Updated September 25, 2025. Accessed January 26, 2026. 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, followed by polymerase chain reaction (PCR) amplification of specific target sequences and detection by target specific probes. Probes specific for Zika RNA are labeled 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

1 to 5 days

### Specimen Retention Time

7 days

### Performing Laboratory Location

Mayo Clinic Laboratories - Rochester Main Campus

## 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 |
|---|---|---|
| VZIKS | Zika Virus PCR, Serum | 85622-9 |

| Result ID | Test Result Name | Result LOINC® Value |
|---|---|---|
| 619456 | Zika Serum PCR Result | 85622-9 |
| 619457 | Zika Serum PCR Interpretation | 69048-7 |