Test Definition: CHIKS

Chikungunya Virus, PCR, Serum

Overview

Useful For

Qualitative detection of chikungunya virus in serum after early symptom onset (ideally <7 days)

This test is **not recommended** for screening healthy patients.

Highlights

Provides qualitative detection of chikungunya virus RNA from serum collected during the acute phase of infection.

This test is intended for evaluation of patients with a clinical history and symptoms consistent with chikungunya virus infection.

Testing Algorithm

See Mosquito-borne Disease Laboratory Testing in Special Instructions.

Special Instructions

- 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

Serum

Additional Testing Requirements

Due to the short period in which chikungunya RNA may be detected in serum, testing serum for IgM- and IgG-class antibodies to chikungunya virus is also recommended. See CHIKV / Chikungunya IgM and IgG, Antibody, Serum.

Testing for RNA or IgM-class antibodies to dengue and Zika viruses, concurrently with chikungunya virus testing should also be considered, given the overlapping clinical syndromes seen with these viruses.

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

0.3 mL

Reject Due To

Gross hemolysis	Reject
Samples that have been heat inactivated	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Frozen	7 days	

Clinical and Interpretive

Clinical Information

Chikungunya virus (CHIK) is an RNA virus of the genus *Alphavirus*, family *Togaviridae,* and is transmitted mainly through the bite of infected mosquitoes in the genus *Aedes* (*A aegypti* and *A albopictus*). This is the same mosquito that transmits dengue, yellow fever, and Zika viruses. Most people infected with chikungunya virus will develop some symptoms, most commonly fever and joint pain. There is no specific antiviral treatment for chikungunya virus infection.

Most cases of disease have occurred in Africa, Asia, Europe, and the Indian and Pacific Oceans, but transmission of CHIK has been identified in Caribbean countries and South American regions, as well as foci in the southern United States. Infection with chikungunya virus may be suspected based on symptoms (fever, joint pain, and headache) and recent history of travel. A diagnosis of CHIK infection can be confirmed through laboratory tests on serum or cerebrospinal fluid.

This assay is designed to detect only species of clinical significance and is to be used for patients with a clinical history and symptoms consistent with chikungunya infection.

Reference Values

Negative

Interpretation

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

A negative test result with a positive internal control indicates that chikungunya 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 designed to be used for patients with a clinical history and symptoms consistent with chikungunya infection.

Negative chikungunya virus real-time (RT)-PCR results do not preclude infection with chikungunya 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 chikungunya virus RNA during incorrect shipping or storage, and specimen collection after the period that chikungunya virus RNA is typically found in the patient (7 days after onset of symptoms).

Supportive Data

The following validation data supports the use of this assay for clinical testing.

Accuracy/Diagnostic Sensitivity and Specificity:

Clinical specimens, commercial samples, and a blinded panel of positive and negative samples provided by the CDC were used for the accuracy experiments. Testing was completed per the manufacturer's instructions, using the easy Mag (bioMerieux) for RNA extraction.

-Ninety five clinical serum specimens received from the Mayo Infectious Disease Serology Laboratory (IDS) were tested using the Altona RealStar (ARS) Chikungunya (CHIK) RT-PCR Kit 2.0 assay. These specimens had been submitted through Mayo Clinical Laboratories and sent to an external laboratory for serology (IgM IFA) and RT-PCR testing in 2014.

-Sixteen vials of human plasma from donor units collected in Puerto Rico extracted using the QIAGEN QIAamp Viral RNA Mini Kit.

-Spiking studies: To supplement the results, negative cerebrospinal fluid (CSF) specimens were spiked with viral RNA of CHIK and tested in a blinded fashion. The spiking material was heat inactivated (HI) CHIK culture fluid (CF).

The ARS CHIK results were compared to the consensus results of the ARS CHIK, a published assay by Lanciotti(1) and a commercial assay, the Bio-Rad ZDC Multiplex RT-PCR Assay (ZDC). The gold standard was considered the consensus between 2 of the 3 PCR assays.

Results:

-The ARS CHIK RT-PCR Kit detected 9 more chikungunya virus-positive specimens from the patient samples received from IDS than the Lanciotti and ZDC RT-PCR assays.

-Eight of the nine ARS CHIK+/Lanciotti-/ZDC- results were positive by chikungunya IgM EIA and/or chikungunya RT-PCR at another commercial reference lab, and therefore considered likely true positives. Final consensus sensitivity and specificity were 100% and 98% respectively

-There was 100% agreement with among the ARS CHIK, Lanciotti, and CDC Trioplex RT-PCR assays using a CDC validation panel.

-The CSF specimens spiked with HI chikungunya virus CF at low concentrations gave expected results in 44/44 specimens.

Analytical Specificity:

No cross-reactivity was observed with the ARS CHIK RT-PCR kit when tested against a comprehensive specificity panel which included 32 bacterial, fungal, and viral organisms from culture collections along with well characterized laboratory strains causing similar disease states, closely related organisms, or from organisms commonly found in the specimens tested.This included West Nile virus (lineage 1 and 2), dengue virus (types 1, 2, 3, and 4), tick-borne encephalitis virus, yellow fever virus, Japanese encephalitis virus, Zika virus, and poliovirus. The manufacturer had tested additional organisms as listed in the package insert.

Clinical Reference

1. Lanciotti RS, Kosoy OL, Laven JJ, et.al: Chikungunya virus in US travelers returning from India, 2006. Emerg Infect Dis 2007 May;13(5):764-767. Available at www.cdc.gov/eid

2. Johnson BW, Russell BJ, Goodman CH: Laboratory Diagnosis of Chikungunya Virus Infections and Commercial Sources for Diagnostic Assays. J Infect Dis 2016 Dec 15;214(suppl 5):S471-S474. Available at https://doi.org/10.1093/infdis/jiw274

3. Morrison TE: Reemergence of chikungunya virus. J Virol 2014 Oct;88(20):11644-11647

Performance

Method Description

The RealStar Chikungunya Virus RT-PCR Kit was developed by Altona Diagnostics to assist in the diagnosis of chikungunya (CHIK) infection by testing serum for CHIK RNA. The Altona RealStar Chikungunya (ARS CHIK) RT-PCR Kit 2.0 is a qualitative reverse transcription-PCR (RT-PCR) assay targeting the nonstructural protein (NS) 1 gene. The assay includes a heterologous amplification system (internal control: IC) to identify possible RT-PCR inhibition and to confirm the integrity of the reagents of the kit. Testing will be performed per the manufacturerâ€™s instructions using the LightCycler 480 following extraction with the NucliSENS easyMag (bioMerieux).

Real-time RT-PCR technology utilizes reverse-transcriptase (RT) reaction to convert RNA into complementary DNA (cDNA), PCR for the amplification of specific target sequences and target specific probes for the detection of the amplified DNA. The probes are labelled with fluorescent reporter and quencher dyes. Probes specific for CHIK RNA are labelled with the fluorophore FAM. The probe specific for theÂ IC is labeled with the fluorophore JOE. Using probes linked to distinguishable dyes enables the parallel detection of CHIK specific RNA and the IC in corresponding detector channels of the real-time PCR instrument.(Package insert: RealStar Chikungunya RT-PCR Kit 2.0. pp 1-17,1/2017)

PDF Report

No

Day(s) and Time(s) Test Performed

Tuesday, Thursday; 2 p.m.

Analytic Time

5 days

Maximum Laboratory Time

8 days

Specimen Retention Time

7 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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

CPT Code Information

87798

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
CHIKS	Chikungunya Virus, PCR, Serum	81152-1

Result ID	Test Result Name	Result LOINC Value
603833	Chikungunya Virus, PCR, Serum	81152-1