MAYO CLINIC LABORATORIES

Test Definition: CHIKC

Chikungunya Virus, PCR, Molecular Detection, Spinal Fluid

Overview

Useful For

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

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

Testing Algorithm

For more information see Mosquito-borne Disease Laboratory Testing

Special Instructions

- Mosquito-borne Disease Laboratory Testing

Highlights

This test provides qualitative detection of chikungunya virus RNA from cerebrospinal fluid 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.

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

CSF

Additional Testing Requirements

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

Specimen Required

Collection Container/Tube:

Preferred: Vial number 2

Acceptable: Any vial number

Submission Container/Tube: Sterile screw cap vial
Specimen Volume: 0.5 mL
Collection Instructions: Do not centrifuge or heat inactivate.

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

Heat-inactivated specimen	Reject

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information
Chikungunya virus (CHIK) is an RNA virus of the genus *Alphavirus*, family *Togaviridae* transmitted mainly through the bite of infected mosquitoes in the genus *Aedes* (*Aedes aegypti* and *Aedes 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
Reference values apply to all ages.

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 polymerase chain reaction 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 reverse transcription polymerase chain reaction 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 Centers for Disease Control and Prevention (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 Clinic Laboratories and sent to an external laboratory for serology (IgM IFA) and reverse transcription polymerase chain reaction (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 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;13(5):764-767
2. Johnson BW, Russell BJ, Goodman CH. Laboratory diagnosis of chikungunya virus infections and commercial sources for diagnostic assays. J Infect Dis. 2016;214(suppl 5):S471-S474. doi:10.1093/infdis/jiw274
3. Morrison TE. Reemergence of chikungunya virus. J Virol. 2014;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 cerebrospinal fluid 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 1 (*NS1*) 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 manufacturer's instructions using the LightCycler 480 following extraction with the NucliSENS easyMag (bioMerieux).

Real-time RT-PCR technology utilizes a reverse-transcriptase reaction to convert RNA into complementary DNA, 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 the 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. Altona Diagnostics; 01/2017)

PDF Report

No

Day(s) Performed

Monday, Wednesday, Friday

Test Definition: CHIKC

Chikungunya Virus, PCR, Molecular Detection, Spinal Fluid

Report Available
Same day/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 was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. It has not been cleared or approved by the US Food and Drug Administration.

CPT Code Information
87798

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
CHIKC	Chikungunya Virus, PCR, CSF	81153-9

Result ID	Test Result Name	Result LOINC® Value
603832	Chikungunya Virus, PCR, CSF	81153-9