MAYO CLINIC LABORATORIES

Test Definition: JCPCR

JC Virus, Molecular Detection, PCR, Spinal Fluid

Overview

Useful For

Aiding in diagnosing progressive multifocal leukoencephalopathy due to JC virus

This test is **not to be used** as a diagnostic tool for Creutzfeldt-Jakob disease

This test is **not recommended for** screening asymptomatic patients

Testing Algorithm

For more information see Meningitis/Encephalitis Panel Algorithm.

Special Instructions

- Meningitis/Encephalitis Panel Algorithm

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

CSF

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.

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

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

Specimen Stability Information

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

Clinical & Interpretive

Clinical Information

JC virus (JCV), a member of the genus *Polyomavirus*, is a small nonenveloped DNA-containing virus. Primary infection occurs in early childhood, with a prevalence of greater than 80%.(1) The virus is latent but can reactivate in immunosuppressed patients, especially those with AIDS.

JCV is recognized as the etiologic agent of progressive multifocal leukoencephalopathy (PML), a fatal demyelinating disease of the central nervous system.(2,3) Histologic examination of brain biopsy tissue may reveal characteristic pathologic changes localized mainly in oligodendrocytes and astrocytes. Detection of JCV DNA by polymerase chain reaction (PCR) (target gene, large T antigen) in the cerebrospinal fluid specimens of patients with suspected PML infection has replaced the need for biopsy tissue for laboratory diagnosis.(4) Importantly, the PCR test is specific with no cross-reaction with BK virus, a closely related polyomavirus.

Reference Values

Negative

Interpretation

Detection of JC virus (JCV) DNA supports the clinical diagnosis of progressive multifocal leukoencephalopathy due to JCV.

Cautions

A negative result does not rule out the possibility of JC virus (JCV) infection.

The reference value in cerebrospinal fluid is "negative" for this assay, although JCV DNA may be detectable in the absence of clinical symptoms in certain patient populations.(5,6) However, this assay is only to be used for patients with appropriate neurological and neuroradiological features of progressive multifocal leukoencephalopathy and is not indicated for screening asymptomatic patients.

Supportive Data

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

Accuracy:
Twenty-six negative cerebrospinal fluid (CSF) specimens were spiked with JC virus (JCV)-positive control plasmid at the limit of detection (approximately 10 targets/mcL). The 26 spiked specimens were run in a blinded manner with 14 negative (non-spiked) specimens. One hundred percent of the spiked specimens were positive, and 100% of the non-spiked specimens were negative.

Analytical Sensitivity/Limit of Detection:
The lower limit of detection of this assay is 10 DNA target copies per mcL in CSF.

Analytical Specificity:
No polymerase chain reaction signal was obtained from the extracts of 15 viral isolates that may cause similar symptoms or be found in the CSF, including herpes simplex virus types 1 and 2, Epstein-Barr virus, cytomegalovirus, human herpesvirus (HHV)-6, HHV-7, HHV-8, enterovirus, mumps, adenovirus, BK virus, and Simian virus 40 (SV40).

Precision:
Interassay precision was 100% and intraassay precision was 100%.

Reference Range:
The reference range in CSF is "negative" for this assay.

Reportable Range:
This is a qualitative assay, and the results are reported as either negative or positive for targeted JCV DNA.

Clinical Reference

1. Safak M, Khalili K. An overview: human polyomavirus JC virus and its associated disorders. J Neurovirol. 2003;9 Suppl 1:3-9
2. Khalili K, White MK. Human demyelinating disease and the polyomavirus JCV. Mult Scler. 2006;12(2):133-142
3. Ahsan N, Shah KV. Polyomaviruses and human diseases. Adv Exp Med Biol. 2006;577:1-18
4. Romero JR, Kimberlin DW. Molecular diagnosis of viral infections of the central nervous system. Clin Lab Med. 2003;23(4):843-865
5. Chen Y, Bord E, Tompkins T, et al. Asymptomatic reactivation of JC virus in patients treated with natalizumab. N Engl J Med. 2009;361(11):1067-1074
6. Egli A, Infanti L, Dumoulin A, et al. Prevalence of polyomavirus BK and JC infection and replication in 400 healthy donors. J Infect Dis. 2009;199(6):837-846
7. Kartau M, Auvinen E, Verkkoniemi-Ahola A, et al. JC polyomavirus DNA detection in clinical practice. J Clin Virol. 2022;146:105051. doi:10.1016/j.jcv.2021.105051

Performance

Method Description

Viral nucleic acid is extracted from the specimen using the MagNA Pure automated instrument (Roche Applied Science). Primers are directed to the large T antigen gene, which is a conserved sequence specific for JC virus (JCV). This assay detects only JCV; it does not detect BK virus or Simian virus 40 (SV40) (other polyomaviruses). The LightCycler instrument (Roche Applied Science) amplifies and monitors the development of target nucleic acid sequences after the annealing step during polymerase chain reaction (PCR) cycling. This automated PCR system can rapidly detect amplicon development through stringent air-controlled temperature cycling in capillary cuvettes. The detection of amplified products is based on the fluorescence resonance energy transfer (FRET) principle. For FRET product detection, a hybridization probe with a donor fluorophore, fluorescein, on the 3'-end is excited by an external light source and emits light that is absorbed by a second hybridization probe with an acceptor fluorophore, LC-Red 640, at the 5'-end. The

acceptor fluorophore then emits a light of a different wavelength that can be measured with a signal that is proportional to the amount of specific PCR product.(Unpublished Mayo method)

PDF Report
No

Day(s) Performed
Monday through Sunday

Report Available
Same day/ 1 to 4 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
JCPCR	JC Virus, PCR, CSF	33295-7

Result ID	Test Result Name	Result LOINC® Value
618305	JC Virus, PCR, CSF	33295-7