Overview

Useful For
Aids in diagnosing progressive multifocal leukoencephalopathy due to JC virus (JCV)

This test is not to be used as a diagnostic tool for Creutzfeldt-Jakob disease (CJD).

Testing Algorithm
See Meningitis/Encephalitis Panel Algorithm in Special Instructions.

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

Supplies: Aliquot Tube, 5 mL (T465)

Preferred: 12 x 75-mm screw cap vial (T465)

Acceptable: Sterile screw cap vial

Container/Tube: Sterile 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


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<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
<th>Special Container</th>
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<tbody>
<tr>
<td>CSF</td>
<td>Refrigerated (preferred)</td>
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</tr>
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**Clinical and 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 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 range 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/mL). The 26 spiked specimens were run in a blinded manner with 14 negative (nonspike) specimens. 100% of the spiked specimens were positive and 100% of the nonspike specimens were negative.

**Analytical Sensitivity/Limit of Detection (LoD):**

The lower limit of detection (LoD) of this assay is 10 DNA target copies per mL in CSF.

**Analytical Specificity:**
No PCR signal was obtained from the extracts of 15 viral isolates that may cause similar symptoms or be found in the CSF, including herpes simples virus (HSV) types 1 and 2, Epstein-Barr virus (EBV), cytomegalovirus (CMV), 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

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 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)
Test Definition: LCJC
JC Virus PCR, CSF

Day(s) and Time(s) Test Performed
Monday through Friday

Analytic Time
Monday through Thursday: 2 days; Friday, Saturday: 3 days

Maximum Laboratory Time
5 days

Specimen Retention Time
1 week

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

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<td>JC Virus PCR, CSF</td>
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