Test Definition: LCBKP

BK Virus DNA by PCR, P

Overview

Useful For

Rapid detection of BK virus DNA

Method Name

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

NY State Available

Yes

Specimen

Specimen Type

Plasma EDTA

Specimen Required

Collection Container/Tube: Lavender top (EDTA)

Submission Container/Tube: Screw-capped, sterile container

Specimen Volume: 1 mL

Collection Instructions: Spin down and separate plasma within 24 hours of collection.

Forms

If not ordering electronically, complete, print, and send 1 of the following forms with the specimen:

-Renal Diagnostics Test Request (T830)

-Microbiology Test Request (T244)

Specimen Minimum Volume

0.5 mL

Reject Due To

Gross hemolysis	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	Refrigerated (preferred)	14 days	
	Frozen	14 days	

Clinical and Interpretive

Clinical Information

Polyomaviruses are small (45 nm, approximately 5,000 base pairs), DNA-containing viruses and include 3 closely related viruses of clinical significance, Simian virus 40 (SV-40), JC virus (JCV), and BK virus (BKV). SV-40 naturally infects rhesus monkeys but can infect humans, while BKV and JCV cause productive infection only in humans.(1,2) Acquisition of BKV begins in infancy. Serological evidence of infection by BKV is present in 37% of individuals by 5 years of age and over 80% of adolescents.

BKV is an important cause of interstitial nephritis and associated nephropathy (BKVAN) in recipients of kidney transplants. Up to 5% of renal allograft recipients can be affected, and among those patients the average time from transplant to diagnosis is about 40 weeks (range 6-150).(3) PCR analysis of BKV DNA in the plasma is the most widely used blood test for the laboratory diagnosis of BKV-associated nephropathy. Importantly, the presence of BKV DNA in blood reflects the dynamics of the disease: the conversion of plasma from negative to positive for BKV DNA after transplantation, the presence of DNA in plasma in conjunction with the persistence of nephropathy, and its disappearance from plasma after the reduction of immunosuppressive therapy.(4-8) Viral loads of aboveÂ 10,000 copies/mL in plasma may indicate a risk for BKVAN (see QBK / BK Virus, Molecular Detection, Quantitative, PCR, Plasma).

Reference Values

Negative

Interpretation

Results of plasma tests are reported in terms of the presence or absence of BK virus (BKV).

Detection of BKV DNA in clinical specimens may support the clinical diagnosis of renal or urologic disease due to BKV. Correlation of qualitative results with clinical presentation and BK viral load in urine and/or plasma is recommended.

Cautions

A negative result does not rule out the possibility of BK virus (BKV) infection.

This assay is for use in patients with appropriate risk factors for BKV-associated disease and is not indicated for screening of asymptomatic patients.

Supportive Data

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

Accuracy/Diagnostic Sensitivity and Specificity:

Results from this real-time PCR assay on the LightCycler (LC PCR) were compared to a previous PCR assay (directed to VP2 region of the polyoma virus based on a published method) on 112 plasma specimens and 108 urine specimens. Using the previous method as the gold standard, the diagnostic sensitivity and specificity is 94% and 90% for plasma and 100% and 100% for urine, respectively. The discrepant samples had low viral DNA copy numbers (<5,000 copies/mL) and may not have been reproducible.

Supplemental Data (Spiking Studies):

To supplement the above data, 30 negative plasma and urine specimens were spiked with BK virus (BKV)-positive

control plasmid near the limit of detection (LoD). The 30-spiked specimens were run in a blinded manner along with 57 plasma and 58 urine negative (nonspiked) specimens. 100% of the spiked specimens were positive and 100% of the nonspiked specimens were negative.

Analytical Sensitivity/LoD:

The LoD of this assay is 244 DNA target copies per mL in urine and plasma.

Analytical Specificity:

No PCR signal was obtained from the extracts of a variety of human viruses that can be found in urine or plasma, including cytomegalovirus, Epstein-Barr virus, human herpesvirus-6, enterovirus, adenovirus, and mumps virus.

Precision:

Inter-assay precision was 100% and intra-assay precision was 100%.

Reference Range:

The reference range of BKV in plasma is negative.

In renal transplant patients, plasma viral load copies of >10,000 copies/mL may indicate increased risk of BKV disease. Therefore, a quantitative test may be appropriate in this population (see QBK / BK Virus, Molecular Detection, Quantitative, PCR, Plasma).

Reportable Range:

This is a qualitative assay and the results are reported as negative or positive for targeted BKV.

Clinical Reference

1. Kazory A, Ducloux D: Renal transplantation and polyomavirus infection: recent clinical facts and controversies. Transplant Infect Dis 2003;5(2):65

2. Vilchez RA, Arrington AS, Butel JS: Polyomaviruses in kidney transplant recipients. Am J Transplant 2002;2(5):481

3. Hirsch HH: Polyomavirus BK nephropathy: a (re-)emerging complication in renal transplantation. Am J Transplant 2002;2(1):25-30

4. Randhawa PS, Demetris AJ: Nephropathy due to polyomavirus type BK. N Engl J Med 2000;342:1361-1363

5. Volker NT, Klimkait IF, Binet P, et al: Testing for polyomavirus type BK DNA in plasma to identify renal-allograft recipients with viral nephropathy. N Engl J Med 2000;342:1309-1315

6. Hariharan S: BK virus nephritis after renal transplantation. Kidney Int 2006;69:655-662

7. Blanckaert K, De Vriese AS: Current recommendations for diagnosis and management of polyoma BK virus nephropathy in renal transplant recipients. Nephrol Dial Transplant 2006;21(12):3364-3367

8. Viscount HB, Eid AJ, Espy MJ, et al: Polyomavirus polymerase chain reaction as a surrogate marker of polyomavirus-associated nephropathy. Transplantation 2007;84(3):340-345

Performance

Method Description

Viral nucleic acid is extracted by the MagNA Pure automated instrument (Roche Applied Science) from the specimen. Primers are directed to the large T antigen gene, which is a conserved sequence specific for BK virus. This assay does not detect JC virus or SV-40 (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)

PDF Report

No

Day(s) and Time(s) Test Performed

Monday, Wednesday, Friday; 6 a.m.

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

Test Definition: LCBKP

BK Virus DNA by PCR, P

Test ID	Test Order Name	Order LOINC Value
LCBKP	BK Virus DNA by PCR, P	32362-6

Result ID	Test Result Name	Result LOINC Value
56084	BK Virus PCR, P	32362-6