

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**

Urine

Specimen Required

Container/Tube: Sterile urine container

Specimen Volume: 1 mL

Collection Instructions: Collect a random urine specimen.

Forms

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

[-Microbiology Test Request](#) (T244)

[-Renal Diagnostics Test Request](#) (T830)

Specimen Minimum Volume

0.5 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
Urine	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; 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 age 5 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) However, BKV DNA is typically detectable in urine prior to plasma and may serve as an indication of impending BKVAN. Viral loads of above 100,000 copies/mL in urine may also indicate a risk for BKVAN (see QBKU / BK Virus, Molecular Detection, Quantitative, PCR, Urine).

Reference Values

Negative

Interpretation

Results of urine 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 BK-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 specimens 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/Limit of Detection (LoD):

The lower LoD of this assay is 244 DNA target copies/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 intraassay precision was 100%.

Reference Range:

The reference range of BKV in urine is negative.

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 ID	Test Order Name	Order LOINC Value
LCBK	BK Virus PCR, U	33978-8

Result ID	Test Result Name	Result LOINC Value
88910	BK Virus PCR, U	33978-8