BKV BK Virus DNA by PCR - Quantitative

GA Test Code	**3700**
Method	Quantitative Real-Time Polymerase Chain Reaction (qPCR)
Specimens	***Note: It is recommended that blood and urine be serially tested.*** **Whole Blood (ACD or EDTA)**: 5.0 (min 3.0) mL, ambient (4 days), refrigerated (7 days). **Urine**: 10.0 (min 5.0) mL, refrigerated (7 days). **Plasma (ACD, EDTA, or PPT)**: 3.0 (min 1.0) mL, separated/centrifuged within 6 hours, refrigerated or frozen *(do not freeze in PPT).* If storing longer than 24 hours, store frozen. **Serum**: 2.0 (min 1.0) mL, refrigerated (7 days) or frozen. **CSF**: 1.0 (min 0.2) mL, refrigerated (7 days) or frozen. **Bone Marrow**: 3.0 (min 2.0) mL, refrigerated (7 days).
Causes for Rejection	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; blood in heparin; plasma frozen in PPT.
Reference Range	Not Detected (< 500 copies/mL)
Quantitative Range	500 to 1.0 x 10^{10} BKV DNA copies/mL
Turnaround Time	Same or Next Day
CPT Code	87799

Description

This test was developed and its performance characteristics determined by Genetic Assays. It has not been cleared nor approved by the U.S. FDA. The FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes. It should not be regarded as investigational or for research. Genetic Assays is certified under CLIA as qualified to perform high-complexity testing. BK virus (BKV) DNA quantification is based upon the real-time PCR amplification and detection of BKV genomic DNA. A value of less than 500 BKV DNA copies/mL indicates that the patient's viral load is below the quantitative limit of this assay, and does not indicate that the patient is not infected with BKV.

Clinical Utility

Real-time PCR detection for BKV is a sensitive and specific method to diagnose viral nephropathy and primary infection associated with respiratory illness in children. The detection and monitoring of BKV, common in children undergoing stem cell transplantation (SCT) and renal transplant patients, allows the physician to appropriately treat the primary and reactivated infection.

Clinical studies support the parallel testing of urine and blood plasma by PCR to confirm the presence of BKV. Mild immune impairment can lead to increased virus replication and the presence of the virus in urine. Testing of urine and blood from immunosuppressed patients alerts the physician to asymptomatic reactivation of BKV. Blood and urine viral loads tend to decrease after treatment by antiviral therapies. The viral load of urine is typically 4-6 log orders higher than the viral load of blood. The viral load from urine may be detected earlier than the blood viral load and tends to take longer to decrease compared to the blood viral load. Thus, it is recommended that both blood and urine be serially tested.

Watzinger, et al. Real-Time Quantitative PCR Assays for Detection and Monitoring of Pathogenic Human Viruses in Immunosuppressed Pediatric Patients. *Journal of Clinical Microbiology* Nov. 2004; 42/11: 5189-5198.

Reploeg, et al. BK Virus: A Clinical Review. *Clinical Infectious Diseases* 2001; 33: 191-202.

Hirsch et al. Testing for polyomavirus type BK DNA in plasma to identify renal-allograft recipients with viral nephropathy. *N Engl J Med* 2000; 342:1309-15.