



TECHNICAL NOTICE

SOUTH BEND MEDICAL FOUNDATION

November 2009

BK Virus by Real-Time PCR

Effective Date: November 16, 2009

Performing Department: Molecular Pathology

Method: Genomic DNA is isolated from the patient sample and testing is performed using a real-time PCR method.

South Bend Medical Foundation (SBMF) offers a quantitative PCR-based test for the quantification of BK virus DNA. The assay is able to quantify BK virus DNA in the linear range of 300 to 1,000,000 copies/mL. A “not detected” result indicates either an absence of BK virus in the specimen or the presence of a viral load at a level that is below the assay detection limit. A result that indicates the presence of BK virus should be evaluated in conjunction with clinical presentation. Diagnosis of BK virus infection should not rely solely on the result of the PCR test.

A standardized international calibration is not currently available for BK virus PCR test. Caution should be taken when interpreting results obtained by different assay methodologies in different laboratories. A correlation study has been conducted comparing 20 blood and urine samples between the SBMF assay and the previous test that was offered through SBMF. The two methods compared relatively well with a mean difference of 0.8 Log.

This test was developed and its performance characteristics were determined by SBMF Laboratory. The U.S. Food and Drug Administration (FDA) has not approved or cleared this test. However, the FDA has determined that such clearance or approval is not necessary. This test is used for clinical purposes and should not be regarded as investigational or for research. The results are not intended to be used as the sole means for clinical diagnosis or patient management decisions. SBMF is authorized under Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing. This test is performed pursuant to an agreement with Roche Molecular Systems, Inc.

Use: Detect the presence of BK virus and, if present, quantify and result as “copies/mL” or “Log copies/mL”

Clinical Significance:

BK Virus (BKV) is a member of polyoma viruses, a DNA virus in the family *Polyomaviridae*, which also includes other closely related viruses, JC virus and simian virus 40. BKV is a common cause of asymptomatic infection in immunocompetent individuals. Seroconversion occurs in approximately 70% of the population between the ages of 5 and 8. Human symptomatic infections usually occur in immunocompromised patients. BKV causes cystitis (non-hemorrhagic and hemorrhagic) and ureteral stenosis in bone marrow and solid organ transplant recipients, and polyomavirus-associated nephropathy (PVAN) in renal transplant recipients. The prevalence of PVAN in transplant recipients varies from 1 to 10%, and the rates of allograft loss range from 10 to 80%.

Reference Range: • Not detected

Specimen Requirements and Collection:

Preferred Specimen: • Serum from gold top (SST) or red top (serum) tube (maintain as sterile) –or–
• Urine, random, in a sterile plastic container with tightly fitting lid

Alternate Specimen: • Plasma from lavender top (EDTA) or pale yellow top (ACD) tube (maintain as sterile)

Requested Volume: • 1.0 mL

Minimum Volume: • 0.5 mL

Stability: • 8 hours room temperature (20-30°C) • 3 days (72 hours) refrigerated (2-8°C) • 1 month frozen (-20°C)

Storage/Transport: • Refrigerated (3 days) or frozen

Testing Schedule: • Wednesday • If received by 8:00 am Wednesday, will be reported by the following Friday

Order: • BK Virus, Quantitative, by RT-PCR, Serum or Plasma Test #: 36156 CPT: • 87799

• BK Virus, Quantitative, by RT-PCR, Urine Test #: 36158 CPT: • 87799

Please direct comments or questions regarding this notice to C. Kurtis Kim, M.D., Deborah H. Sun, Ph.D., or Sally Cornwall. South Bend Medical Foundation, (574) 234-4176 or (800) 544-0925.

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530 N. Lafayette Boulevard • South Bend, IN 46601 • (574) 234-4176

Elkhart (574) 293-8441 • (800) 544-0925

Robert J. Tomec, M.D. • *Medical Director*