

Notification Date: July 2, 2021 Effective Date: July 27, 2021

BK Virus DNA Detection and Quantification, Random, Urine

Test ID: UBKQN

Useful for:

Detection and serial monitoring of BV virus-associated nephropathy in kidney transplant recipients, and/or hemorrhagic cystitis in organ transplant recipients.

Methods:

Real-Time Polymerase Chain Reaction (rtPCR)

Reference Values:

Undetected

Specimen Requirements:

Container/Tube: cobas PCR Urine tube (part of cobas PCR Urine Sample Kit – Supply #T903)

Specimen Volume: 4.3 mL

Collection Instructions: 1. Collect a random urine into a sterile, plastic, preservative-free container.

2. Transfer 4.3 mL of urine into the cobas PCR Urine Sample tube using the disposable pipette provided within 24 hours of collection. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine transport tube. Place the labels on the transport tube so the black fill lines

are still visible for volume confirmation at Mayo Clinic Laboratories.

3. Transport and store urine specimen transport container at 2 to 30 degrees C

(refrigerate is preferred temperature).

Note: cobas PCR Media contains guanidine hydrochloride. Do not allow these tubes to come in direct contact with sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures can release a noxious gas.

Specimen Stability Information:

Specimen Type	Temperature	Time	Special Container
Urine	Refrigerated (preferred)	84 days	cobas PCR Urine Sample Kit
	Ambient	84 days	cobas PCR Urine Sample Kit

Cautions:

Quantitative BKV DNA results in urine tested with this assay can be up to 5-fold (about 1.4 log IU/mL) higher than those generated from the previous laboratory-developed BKV DNA quantification assay performed at Mayo Clinic Laboratories, due to differences in the specimen extraction method and design in the amplification primers and probes for the viral target sequences.

A single "Undetected" test result does not necessarily rule out the presence BKV infection or reactivation. Serial measurement (eg, once weekly) of BKV DNA in urine or plasma is recommended to determine the BKV replication status in a given transplant recipient.

While unlikely to be present in urine specimens, vaginal lubricants, speculum jellies, creams and gels containing carbomer(s) may interfere with the test and should not be used during or prior to sample collection. Urogenital specimens from patients who have used carbomer-containing products or have used metronidazole vaginal gel may generate invalid or false negative results.

CPT Code:

87799

Questions

Contact James Conn, Laboratory Technologist Resource Coordinator at 800-533-1710.