

Laboratory Update

Launch of Roche cobas® 6800 Quantitative BKV PCR Assay

Effective January 31, 2025, DMC University laboratories will offer a new assay for detection of BK virus (BKV) in plasma and urine specimens of transplant patients. The new assay replaces the current BKV PCR test.

The BKV test is an *in vitro* quantitative real time PCR assay performed on the Roche cobas® 6800 System. The test has been cleared by FDA and enables the detection and quantitation of BKV DNA in EDTA plasma and urine stabilized in cobas® PCR Media of infected patients.

For EDTA plasma samples, the assay has a reportable range of 21.5 IU/mL to 1.0E+08 IU/mL and 200 IU/mL to 1.0E+08 IU/mL for urine specimens. Please note that there is no conversion factor to convert results from current assay reported in copy/mL to IU/mL.

Higher BKV DNA levels are associated with increased risks for the development of Polyoma Virus Nephropathy and Hemorrhagic Cystitis in kidney transplant recipients and Hematopoietic stem cell transplants (HSCT).

The results from cobas® BKV are intended to for use as an aid in the management of BKV in transplant patients. Test result should be used in conjunction with clinical signs and symptoms and relevant laboratory findings. Test results must not be the sole basis for patient management decisions.

The test will be run Tuesday and Friday of each week.

Acceptable specimen: 5 ml of whole blood collected in BD Vacutainer® PPT™ Plasma Preparation Tubes or in sterile tubes with EDTA as the anticoagulant (lavender top tube). For urine collection, see the procedure using Cobas PCR Media below. Reliable results depend on proper sample collection, storage and handling procedures.

Thank you

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cobas[®] PCR Urine Sample Kit

For BKV PCR assay

Short guide¹ for urine sample collection

URINE SAMPLE

FOR THE PATIENT

1. COLLECT:

Prior to sampling, the patient should not have urinated for **at least one hour** and **female patient must not clean** the labial area.

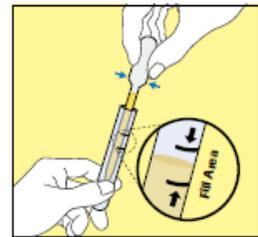
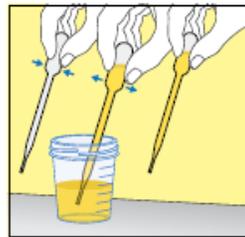
Ask the patient to provide the **first catch urine** (10-50mL) into a urine collection cup.



FOR HEALTHCARE PROFESSIONALS

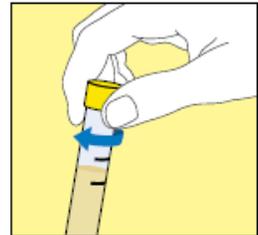
2. PIPET:

Use the provided disposable pipet to **transfer** (within 24 hours) the **urine** into the **cobas[®] PCR Media tube**. **The correct volume of urine has been added when the fluid level is between the two black lines on the tube label.**



3. CLOSE:

Tightly re-cap the tube.



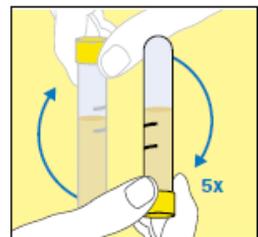
HANDLING PRECAUTIONS:

Use care to avoid splashing of contents.

4. MIX:

Invert the tube **5 times**.

The specimen is now ready for transport.



Transport: 2°C to 30°C • **Stability of sample:** 12 months