FDA clears Cobas BKV test for urine samples

Feb. 12, 2021–Roche announced FDA 510(k) clearance of stabilized urine samples to be used with the Cobas BKV test on the Cobas 6800/8800 systems.

The Cobas BKV test is a real-time polymerase chain reaction test with dual-target technology that provides quantitative accuracy and guards against the risk of sequence variations that may be present in the BK virus. Urine stabilized in Cobas PCR media has a limit of detection of 12.2 IU/mL and a linear range from 200 IU/mL to 1E+08 IU/mL.

“Transplant patients face a number of significant challenges, including complications that can arise from viruses like BKV,” Ann Costello, head of Roche Diagnostic Solutions, said in a press statement. “With the FDA clearance of this noninvasive and easily collectable sample type, we now offer choices for clinicians using a standardized, automated solution to routinely monitor and manage infection risks.”

The test is also approved for use in CE markets with EDTA plasma and urine stabilized in Cobas PCR media as sample types.