Roche BKV test FDA cleared on Cobas 6800/8800 systems

Sept. 9, 2020—Roche received FDA 510(k) clearance for the Cobas BKV test on the Cobas 6800 and 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. The test has robust coverage with a limit of detection of 21.5 IU/mL and an expanded linear range from 21.5 IU/mL to 1E+08 IU/mL in EDTA plasma.

“This FDA clearance allows Roche to offer health care professionals a transplant testing portfolio that includes cytomegalovirus, Epstein-Barr virus, and BK virus so they can simultaneously monitor and improve care for transplant patients who are at risk for these common infections or viral reactivations, which can cause further illness or death,” Thomas Schinecker, CEO Roche Diagnostics, said in a press release.

The BKV test offers an alternative to lab-developed tests or analyte-specific reagent combinations, potentially minimizing variability and complexity in testing, reducing workload, and alleviating risk for laboratories.