

## Roche receives first FDA clearance for urine sample type for BK virus quantitative test to aid in the improvement of care for transplant patients

- **Detection of BK virus in urine may be indicative of early infection in immunocompromised transplant patients**
- **Early detection is critical as complications due to infection after transplantation are one of the main causes of post-operative morbidity and mortality<sup>1</sup>**
- **Healthcare professionals and their patients now have a choice between stabilised urine and plasma samples to better manage transplant infections caused by BK virus**

Pleasanton, 11 February 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced the U.S. Food and Drug Administration (FDA) 510K clearance of stabilised urine samples to be used with the **cobas®** BKV Test on the **cobas®** 6800/8800 Systems. This test, previously designated as a Breakthrough Device by the FDA and cleared for use with ethylenediaminetetraacetic acid (EDTA) plasma samples to aid in the management of BK virus (BKV) in transplant patients, now also delivers enhanced diagnosis of disease via non-invasive, easily collected, prepared and stored urine samples.

BKV can cause severe complications in immunocompromised transplant patients. Higher BKV DNA levels can often be present in urine prior to plasma, serving as an early predictor of an impending infection. A urine sample stabilised in **cobas®** PCR Media allows the integrity of urine results to be maintained, making storage and transportation simpler without the need for sample refrigeration.

“Transplant patients face a number of significant challenges, including complications that can arise from viruses like BKV,” said Ann Costello, Head Roche Diagnostic Solutions. “With the FDA clearance of this non-invasive and easily collectable sample type, we now offer choices for clinicians using a standardised, automated solution to routinely monitor and manage infection risks. Together with our viral load tests for Cytomegalovirus and Epstein-Barr virus, we are committed to bringing better care to transplant patients.”

The cobas BKV Test runs on the widely available, high-throughput cobas 6800/8800 Systems. It is also approved for use in CE markets with EDTA plasma and urine stabilised in cobas PCR Media as sample types.

### About the cobas BKV Test

The cobas BKV Test is a real-time polymerase chain reaction (PCR) 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 cobas BKV 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. Urine stabilised 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.

The test offers an alternative to lab-developed tests (LDTs) or Analyte Specific Reagent (ASR) combinations, potentially minimising variability and complexity in testing, reducing workload and alleviating risk for laboratories. The test supports the goal of result standardisation across institutions by providing reproducible, high-quality results for clinical decision-making.

The fully automated cobas BKV, **cobas**® CMV and **cobas**® EBV Tests can run on the cobas 6800/8800 Systems simultaneously, providing absolute automation with proven performance and flexibility, leading to time savings and increased efficiency.

## About BK polyomavirus

BK polyomavirus (BKV) is a member of the polyomavirus family that can cause transplant-associated complications including nephropathy in kidney transplantation and hemorrhagic cystitis in hematopoietic stem cell transplantation. Infection can occur early in life, often with no symptoms. After primary infection, the virus can remain inactive throughout life, only to possibly reactivate in immunocompromised individuals, such as patients who receive solid-organ transplants. For kidney transplant patients, BKV infection is considered the most common viral complication, causing polyomavirus nephropathy (PVN) in up to 10 percent of kidney transplant recipients, and about 50 percent of PVN-affected patients will experience transplant graft failure.<sup>2</sup> BKV is also associated with hemorrhagic cystitis after allogeneic hematopoietic stem cell transplantation.<sup>3</sup>

## About the cobas 6800/8800 Systems

When every moment matters, the fully automated cobas 6800/8800 Systems offer the fastest time to results with the highest throughput and the longest walk-away time available among automated molecular platforms. With proven performance, absolute automation and unmatched flexibility delivering unparalleled throughput 24/7 — cobas 6800/8800 Systems are designed to ensure a lab's long-term sustainability and success ... now, more than ever. Learn more now: [www.cobas68008800.com](http://www.cobas68008800.com)

## About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit [www.roche.com](http://www.roche.com).

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## References

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- [3] Hirsch HH, Randhawa PS; AST Infectious Diseases Community of Practice. BK polyomavirus in solid organ transplantation-Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant.* 2019;33(9):e13528. doi:10.1111/ctr.13528

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