Roche announces FDA authorisation for the first Epstein-Barr virus quantitative test on the cobas 6800/8800 Systems to improve care for transplant patients

- **FDA granted de novo class II for cobas EBV test following the agency's Breakthrough Device designation**
- **Accurate monitoring of Epstein-Barr virus DNA levels is critical, as they are associated with a range of life threatening-diseases including cancer in transplant patients**
- **Test meets World Health Organization standards for consistent result reporting among laboratories across the U.S., allowing for results to be easily comparable across hospitals and labs**

Basel, 5 August 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has authorised the cobas® EBV test. This is the first quantitative in vitro diagnostic test for Epstein-Barr virus (EBV) DNA in the United States. This authorisation gives healthcare professionals a key tool in monitoring transplant patients at risk for complications from infections or reactivations of EBV, by providing the ability to run a large number of patient tests for this virus in a short period of time.

"Monitoring of Epstein-Barr virus DNA can help prevent progression of life-threatening diseases, such as cancer in transplant patients," said Thomas Schinecker, CEO Roche Diagnostics. "The EBV test helps set a new standard of care for patients, as healthcare professionals now can act early in the management of this virus with best-in-class monitoring tools and can make more informed decisions when treating patients."

The cobas EBV test is a polymerase chain reaction (PCR) viral load test that runs on the fully automated and widely available cobas® 6800 and cobas® 8800 Systems. The test has been calibrated to the World Health Organization (WHO) International Standard. This means that test results are reported in international measures, making it possible for laboratories anywhere in the U.S. to obtain comparable results when measuring levels of EBV DNA.

The test was previously granted FDA Breakthrough Device designation, which enables an expedited review process for medical devices that provide improved treatment or diagnosis of life-threatening diseases or conditions.

About the cobas EBV test

The cobas EBV test is a real-time PCR (polymerase chain reaction) viral load test with dual target technology, which provides quantitative accuracy and guards against the risk of sequence variations that may be present in the Epstein-Barr virus. The cobas EBV test has robust coverage with a limit of detection of 18.8 IU/mL and an expanded linear range from 35 IU/mL to 1E+08 IU/mL in EDTA plasma.

The test offers an alternative to lab-developed tests (LDTs) or Assay Specific Reagents (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 EBV test can be run on the cobas 6800/8800 Systems providing absolute automation with proven performance and flexibility. Simultaneous testing with CMV or other virology tests leads to time savings and increased efficiency.

About Epstein-Barr virus (EBV)
Epstein-Barr virus is a member of the herpes virus family and has been associated with a range of cancers in transplant patients, such as post-transplant lymphoproliferative disorder (PTLD). Once infection with EBV occurs, the virus establishes as a latent form and can remain in the body. Most people harbor EBV with no long-term clinical ramifications.

EBV spreads most commonly through bodily fluids, primarily saliva. This does not always cause symptoms, but people with weakened immune systems, including transplant patients, are more likely to develop symptoms if EBV reactivates.[1]

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. The systems provide up to 96 results in about 3 hours and 384 results for the cobas 6800 System and 1,056 results for the cobas 8800 System in an 8-hour shift.*

Both systems make it possible for labs to perform up to three tests in the same run with no pre-sorting required. The systems also enable up to eight hours (cobas 6800 System) and four hours (cobas 8800 System) of walk-away time with minimal user interaction.*

These real-time PCR systems serve the areas of infectious disease, donor screening, sexual health, transplant, respiratory and antimicrobial stewardship.

Through an ever-increasing worldwide install base of cobas 6800/8800 Systems, labs are quickly and easily processing millions of tests per month to meet the changing demands of their communities, their customers and the patients relying on the results of each assay. Globally, labs know and trust that a Roche assay guarantees high precision, accuracy and traceability to World Health Organization standards.

Today, rapid advancements in healthcare technology, a shortage of skilled workers, industry-wide consolidation, and the proven need to be ready for the next outbreak have health systems looking to lay a reliable foundation for the future. 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 or http://diagnostics.roche.com.

*May vary based on workflow demands

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 eleventh 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 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 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.

References
[1] Kanakry JA, et al. The clinical significance of EBV DNA in the plasma and peripheral blood mononuclear cells of patients with or without EBV diseases. Blood. 2016; Apr 21;127(16):2007-17

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