Media & Investor Release

Roche receives FDA clearance for COVID-19 PCR test for use on cobas 6800/8800 Systems

- **The cobas SARS-CoV-2 Qualitative test is one of the first COVID-19 PCR tests performed on an automated, high throughput platform to receive FDA 510(k) clearance.**
- **This FDA clearance will ensure that the healthcare community has access to timely, reliable and accurate COVID-19 PCR testing beyond the EUA period.**
- **Based on continuous analysis performed since the onset of the pandemic, all Roche molecular tests, including the cobas SARS-CoV-2 Qualitative test, detect all SARS-CoV-2 variants.**

Basel, 24 October 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance for the cobas® SARS-CoV-2 Qualitative PCR test for use on the fully automated cobas® 6800 and cobas® 8800 Systems. This standalone test is intended for the qualitative detection of SARS-CoV-2, the virus that causes COVID-19 disease, in nasal and nasopharyngeal samples from symptomatic patients who are suspected of having COVID-19 as determined by their healthcare provider.

The cobas SARS-CoV-2 Qualitative test has been available in the U.S. under Emergency Use Authorization (EUA) since March 2020 and was the first commercial molecular test to receive this status. The FDA clearance is based on a comprehensive package submitted to the agency, including analytical and clinical studies.

“We are pleased that we have achieved this regulatory milestone. Roche is fully committed to continuing our support and innovation for COVID-19 diagnostics to address evolving health care needs and to help keep communities safe,” said Thomas Schinecker, CEO of Roche Diagnostics. “We are actively working with health authorities to pursue FDA-cleared status for the tests in our COVID-19 portfolio. This will ensure clinicians and patients have continued access to accurate, reliable and efficient testing options.”

With the continued evolution of coronavirus variants and frequent surges happening around the world, Roche will continue to add diagnostic solutions to the global portfolio to help in the fight against COVID-19. For more information on how Roche is responding to the global COVID-19 public health crisis, please visit our COVID-19 response page.

About the cobas SARS-CoV-2 Qualitative assay

The cobas SARS-CoV-2 Qualitative assay is a single-well dual target assay, which includes both specific detection of SARS-CoV-2 and pan-sarbecovirus detection for the sarbecovirus subgenus that includes SARS-CoV-2. The test is a real-time RT-PCR test intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasal and nasopharyngeal swab specimens collected from symptomatic individuals suspected of COVID-19 by their

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healthcare provider. The test runs on the cobas 6800/8800 Systems and has a full-process negative control, positive control and internal control.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results are meant to be used in conjunction with clinical observations, patient history, recent exposures and epidemiological information, and laboratory data, in accordance with the guidelines provided by the relevant public health authorities.

The cobas® SARS-CoV-2 Qualitative assay is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and on the use of the cobas® 6800/8800 Systems.

About the cobas 6800/8800 Systems

The Roche cobas 6800/8800 Systems, which are used to perform the cobas SARS-CoV-2 test, provide results in three and half hours and offer improved operating efficiency, flexibility, and fastest time-to-results with the highest throughput providing up to 96 results in about three hours and a total of 1,440 results for the cobas 6800 System and 4,128 results for the cobas 8800 System in 24 hours. The test can be run simultaneously with other assays provided by Roche for use on the cobas 6800/8800 Systems.

For more information about the tests and system, please visit www.diagnostics.roche.com.

About Roche

Founded in 1896 in Basel, Switzerland, as one of the first industrial manufacturers of branded medicines, Roche has grown into the world's largest biotechnology company and the global leader in in-vitro diagnostics. The company pursues scientific excellence to discover and develop medicines and diagnostics for improving and saving the lives of people around the world. We are a pioneer in personalised healthcare and want to further transform how healthcare is delivered to have an even greater impact. To provide the best care for each person we partner with many stakeholders and combine our strengths in Diagnostics and Pharma with data insights from the clinical practice.

In recognizing our endeavor to pursue a long-term perspective in all we do, Roche has been named one of the most sustainable companies in the pharmaceuticals industry by the Dow Jones Sustainability Indices for the thirteenth consecutive year. This distinction also reflects our efforts to improve access to healthcare together with local partners in every country we work.

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.

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References

[1] World Health Organization [Internet; cited 2020 Jan]. Available from https://www.who.int/health-topics/coronavirus.

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