Roche receives FDA Emergency Use Authorization for the cobas SARS-CoV-2 & Influenza A/B Test for use on the cobas 6800/8800 Systems

- **First commercial test for fully automated high throughput systems to detect and differentiate SARS-CoV-2, influenza A virus and/or influenza B virus with a single sample**
- **As COVID-19 and influenza infections can hardly be differentiated based on symptoms, healthcare professionals can confidently provide the right diagnosis and best course of treatment for patients**
- **Test for use on high throughput cobas 6800/8800 Systems will continue to support high volume testing**
- **This test is also available in markets accepting the CE mark**

Basel, 4 September 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the cobas® SARS-CoV-2 & Influenza A/B Test for use on the cobas® 6800/8800 Systems has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). This test is intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A and Influenza B in patients suspected by their healthcare provider of having a respiratory viral infection consistent with COVID-19. Additionally, it is available in markets accepting the CE mark.

“With the approaching flu season, this new test is particularly important as SARS-CoV-2 and influenza infections can hardly be differentiated by symptoms alone. Now, with a single test, healthcare professionals can confidently provide the right diagnosis and most effective treatment plan for their patients,” said Thomas Schinecker, CEO of Roche Diagnostics. “As a leader in diagnostics testing solutions, this launch demonstrates our ongoing commitment to stop the spread of serious infectious diseases by increasing access to accurate, reliable and efficient testing options.”

Roche’s widely-available, fully-automated cobas 6800/8800 Systems, which are used to perform the SARS-CoV-2 & Influenza A/B Test, 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. Roche is committed to delivering as many tests as possible within the limits of supply.

The test is another key addition to the comprehensive Roche diagnostic portfolio to help healthcare providers combat COVID-19 and make informed decisions for optimised patient care. Currently, this portfolio includes molecular, serology and digital solutions, which help during the initial stages of infection, during the recovery phase, as well as following the resolution of infection.

About cobas SARS-CoV-2 & Influenza A/B Test
The cobas SARS-CoV-2 & Influenza A/B Test is a multiplex reverse transcription polymerase chain reaction (RT-PCR) assay intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A virus, and Influenza B virus in nasal or nasopharyngeal swab samples collected from

individuals suspected of a respiratory infection, and is not intended for the detection of Influenza C virus. Under FDA EUA, the test can be taken by individuals suspected of a respiratory viral infection consistent with COVID-19 by their healthcare provider. The test runs on the cobas 6800/8800 Systems and has a full-process negative control, positive control and internal control. Multiplexing will increase lab efficiency and save resources in the labs.

Negative results do not preclude infection from SARS-CoV-2 or Influenza virus and should not be used as the sole basis of treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history and epidemiological information.

The cobas SARS-CoV-2 & Influenza A/B Test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. In the United States, the cobas SARS-CoV-2 & Influenza A/B Test for use on the cobas® 6800 and cobas® 8800 Systems is only for use under the FDA's Emergency Use Authorization.

About Emergency Use Authorization status

The cobas SARS-CoV-2 & Influenza A/B Test has not been FDA cleared or approved. It has been authorised by the FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform moderate and high complexity tests. The test has been authorised only for the detection of RNA from SARS-CoV-2 virus, Influenza A virus, and Influenza B virus and not any other viruses or pathogens. It is only authorised for the duration of the declaration that circumstances exist justifying the authorisation of the emergency use of in vitro diagnostics for detection and differentiation of SARS-CoV-2 virus, Influenza A, and Influenza B under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorisation is terminated or revoked sooner.

About SARS-CoV-2 (coronavirus)

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus (SARS-CoV-2) is a new strain which has not previously been identified in humans.[1]

Signs of infection include respiratory symptoms such as cough, shortness of breath, difficulty breathing, and fever. In more severe cases, pneumonia, severe acute respiratory syndrome, kidney failure and death can occur.

To control the spread of the infection, the World Health Organisation (WHO) recommends regular hand washing, covering mouth and nose when coughing and sneezing, and avoiding close contact with anyone showing symptoms of respiratory illness.

About Roche's response to the COVID-19 pandemic

The COVID-19 pandemic continues to evolve globally with varying developments from country to country and we are partnering with healthcare providers, laboratories, authorities and organisations to help make sure that patients receive the tests, treatment and care they need. This new test is an additional step in Roche's fight against the COVID-19 pandemic, which has already included:

- Launching COVID-19 diagnostic tests for active infection and the detection of antibodies in patients who have been exposed to the virus,
- Investigating treatments from our existing portfolio to better understand their potential to treat patients with COVID-19,
- Increasing manufacturing and supply chain capacity to meet product demand across our portfolio within the wider context of COVID-19 treatment, and
- Ensuring the supply of our existing medicines and diagnostics to patients around the world under exceptional conditions.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic. On 13 March we received FDA Emergency Use Authorisation for a high-volume molecular test to detect SARS-CoV-2, the virus that causes COVID-19, which is also available in countries accepting the CE Mark. On 3 May, Roche announced that its COVID-19 antibody test, aimed at detecting the presence of antibodies in the blood, also received FDA Emergency Use Authorisation and is available in markets accepting the CE mark. Also in June we received an FDA EUA for the Elecsys® IL-6 test to assist in identifying severe inflammatory response in patients with confirmed COVID-19, as well as launching Roche v-TAC, which could help simplify the screening, diagnosis and monitoring of patients with respiratory compromise in the current COVID-19 pandemic. In July, we added a Rapid Antibody Test, with SD Biosensor as distribution partner, to our portfolio, that allows the detection of antibodies against Covid-19 at the point of care. On 1 September we announced that we will launch a SARS-CoV-2 Rapid Antigen Test, in late September, for markets accepting the CE Mark. We also intend to file for Emergency Use Authorisation (EUA) to the U.S. Food and Drug Administration (FDA). The SARS-CoV-2 Rapid Antigen Test is for use in point of care settings for both symptomatic and asymptomatic people.
Roche is working closely with governments and health authorities around the world, and has significantly increased production to help ensure availability of tests globally.

We are actively involved in understanding the potential of our existing portfolio and are researching options for the future. Roche has an ongoing clinical trial program evaluating the role of Actemra©/RoActemra© (tocilizumab) in COVID-19 pneumonia. On 29 July we announced that the COVACTA trial did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality. The study was the first global, randomised, double-blind, placebo-controlled phase III trial investigating Actemra/RoActemra in this setting. Roche remains committed to continuing the Actemra/RoActemra clinical trial programme in COVID-19 to further explore Actemra/RoActemra in other treatment settings, including in combination with an antiviral. In addition to COVACTA, Roche has initiated several studies to further investigate Actemra/RoActemra as a potential treatment for patients with COVID-19 associated pneumonia, including two phase III clinical trials, REMDACTA and EMPACTA, as well as the phase II MARIPOSA trial. Roche has further initiated an internal early research programme focused on the development of medicines for COVID-19 and is engaged in multiple research collaborations. On 19 August, we announced a partnership with Regeneron to develop, manufacture and distribute REGN-COV2, Regeneron's investigational antiviral antibody combination, to people around the globe.

In these exceptional times, Roche stands together with governments, healthcare providers and all those working to overcome the pandemic.

About Influenza A and B (flu)
Influenza is an acute respiratory illness caused by infection with the influenza virus. Influenza viruses consist of three types: Influenza A, Influenza B, and Influenza C. In the U.S., Influenza A/H1N1, A/H3N2 and Influenza B are the predominant seasonal viruses. Influenza A and B viruses are among the leading causes of respiratory infections, estimated to affect 5-10% of adults and 20-30% of children every year worldwide. Influenza is primarily spread by breathing in infected droplets formed when a person with the flu sneezes, coughs, or talks. Symptoms include fever, cough, headache, fatigue, muscle pain, sore throat, and runny nose. Elderly people, young children and people with weakened immune systems or chronic medical conditions can be at high risk for serious disease. Each year, approximately 3 to 5 million people develop severe illness and 290,000 to 650,000 people die from the flu.[2]

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

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 Organisation 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.

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References

[1] https://www.who.int/health-topics/coronavirus. Accessed 23Jan2020.
[2] http://www.who.int/mediacentre/factsheets/fs211/en/. Accessed 7Jul2020.

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