Diagnostics Communications |

Media/roche.com statement in response to new Omicron variant of SARS-CoV-2 (B.1.1.529)

Viruses mutate over time, and SARS-CoV-2 is no exception. Mutations in viruses occur naturally, and the more they circulate, the more likely they are to mutate. Accurate detection and differentiation of SARS-CoV-2 mutations can help assess the spread of circulating variants and monitor their potential impact on therapeutics, vaccines and public health interventions.

Roche has analysed the publicly available sequences of the SARS-CoV-2 Omicron variant SARS-CoV-2 (B.1.1.529). We compared them to the design of all tests employed to detect an acute or past SARS-CoV-2 infection to understand any implication of these mutations. We continue to assess the situation.

Based on these first investigations the following assays are not impacted:

PCR tests	- cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems - cobas® SARS-CoV-2 & Influenza A/B Tests for use on the cobas® 6800/8800 Systems - cobas® SARS-CoV-2 for use on the cobas® Liat® System - cobas® SARS-CoV-2 & Influenza A/B Tests for use on the cobas® Liat® System - cobas® SARS-CoV-2 Variant Set 1 Test for use on the cobas® 6800/8800 Systems (research-use-only) - GenMark ePlex® Respiratory Pathogen Panel 2 (RP2 Panel) - TIB MOLBIOL LightMix® Modular SARS-CoV-2 for use on Lightcycler and cobas z480 analyzer (CE-IVD and research-use-only)
Antibody tests	- Elecsys® Anti-SARS-CoV-2 Antibody Test
Antigen tests	- Elecsys® SARS-CoV-2 Antigen Test - SARS-CoV-2 Rapid Antigen Tests (SD Biosensor Inc.)

We have also begun initial investigations into our other SARS-CoV-2 tests. While we do not anticipate that any tests/assays will be affected, we will complete our investigation before confirming.

Researchers continuously monitor for new variants and their prevalence. Understanding these is an important part of analysing any changes to the virus' characteristics and if these changes could cause the virus to act differently in ways that are significant to public health. If ignored or left unchecked, these variants can spread rapidly and become serious health risks. It is why we at Roche, and researchers across the globe, are keenly focused on studying these variants to quickly learn more, and understand if we need to adapt interventions such as therapeutics and vaccines, to control and prevent the spread of the virus.

Our highly committed colleagues and partners have conducted these evaluations at an unprecedented speed and we

are confident that we will be able to provide equally quick reassurance on the impact of potential future variants on our tests.

"Viruses naturally evolve over time. While most mutations do not have a clinical impact, some variants need to be tracked carefully as they seem to spread more easily and quickly," said Thomas Schinecker, CEO Roche Diagnostics. "Continued surveillance is essential for public health. Our Diagnostics solutions provide laboratories a fast and efficient way to investigate these variants found in infected individuals and the potential impact on existing therapies, vaccines and tests."

About Roche's response to the COVID-19 pandemic

As a leading healthcare company, we are doing all we can to support countries in their fight against COVID-19 and minimising its impact. We have developed a growing number of diagnostic solutions that help to detect and diagnose the infection, as well as providing digital support to healthcare systems. We also continue to identify, develop, and support therapies which can play a role in treating the disease.

The impact of COVID-19 goes beyond those who contract it. That is why we are working with healthcare providers, laboratories, authorities, and organisations to help make sure patients continue to receive the tests, treatment and care they need during these challenging times. Building on a longstanding tradition of partnerships, we are working together with governments and others to make healthcare stronger and more sustainable in the future.

Reliable, high-quality testing is essential to help healthcare systems overcome this pandemic and Roche has so far launched 21 diagnostics solutions to help minimise the impact of COVID-19. As soon as the novel SARS-CoV-2 virus was sequenced in early 2020, we got to work. On 13 March 2020 we became the first company to receive U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for a high-volume molecular test to detect the virus. Since then, we have continued to add a range of diagnostics solutions to our global portfolio to help in the fight against COVID-19. In addition to the gold standard PCR test, we have developed antigen tests to help diagnose the virus in settings where there is limited molecular laboratory infrastructure, rapid antigen tests where the virus can be detected on the spot, tests that can test for both flu and COVID-19 at the same time, both high throughput and at the point of care, and tests that can detect virus antibodies that can help monitor the spread of the virus and can also support in vaccine development. In March 2021 the SARS-CoV-2 variant test was launched, designed to detect key spike mutations.

Aside from these tests we have also looked at how we can support care for patients who have COVID-19, receiving an U.S. 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, a digital algorithm that could help simplify the screening, diagnosis, and monitoring of respiratory-compromised patients with COVID-19. Roche is working closely with

governments and health authorities around the world, and has significantly increased production to support availability of tests globally.

Roche is also actively involved in understanding the potential of the existing pharmaceuticals portfolio and is researching options for the future. In 2020, Roche entered into a number of new partnerships, including with Regeneron and Gilead to develop, manufacture and distribute molecules that can potentially both treat and prevent COVID-19.

Roche entered a partnership with Regeneron to jointly develop Ronapreve™ (casirivimab and imdevimab, known as REGEN-COV™ in the United States [US]). The antibody combination has been approved for use in the European Union and Japan, and conditionally in the United Kingdom and Australia, and is authorised for emergency or temporary pandemic use in additional territories such as the U.S. and Canada. In addition, the World Health Organization recommended the use of Ronapreve for the treatment of patients with COVID-19.

In addition, we have explored the potential of our existing medicine Actemra/RoActemra in three global phase III clinical trials investigating its safety and efficacy in COVID-19 associated pneumonia (COVACTA, EMPACTA and REMDACTA). In June 2021, Actemra/RoActemra received an EUA from the U.S. FDA for the intravenous treatment of COVID-19 in hospitalised adults and paediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation. In addition, the World Health Organization recommended the use of Actemra/RoActemra for the treatment of certain patients with COVID-19.

For more information on how Roche is responding to the global COVID-19 pandemic, please visit our COVID-19 response page.

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