# Roche has rapidly developed additional testing options to differentiate mutations in the Omicron SARS-CoV-2 variant

- **Roche subsidiary TIB Molbiol rapidly developed additional testing options to differentiate mutations in the Omicron SARS-CoV-2 variant, as they continue to offer new and accurate detection solutions**
- **Three new testing kits are among the first to specify the mutations of the recently discovered Omicron variant, and can help manage the evolving COVID-19 pandemic**
- **Use of these new tests assess the spread of circulating variants and can help monitor the potential impact of therapeutics, vaccines, and public health interventions**
- **Roche has analysed the publicly available sequences of the SARS-CoV-2 Omicron variant and concluded that all of our PCR tests correctly identify COVID including the new variant**

Basel, 3 December 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) and TIB Molbiol, a newly acquired subsidiary within the Roche Diagnostics division, have added three additional Research Use Only (RUO) test kits for the detection of mutations present in the novel B.1.1.529 Omicron SARS-CoV-2 variant: VirSNip SARS Spike ins214EPE (RUO), VirSNiP SARS-CoV-2 Spike S371L S373P (RUO), VirSNip SARS Spike E484A (RUO). The World Health Organization (WHO) has classified the recently emerged SARS-CoV-2 variant, Omicron (B.1.1.529), as a COVID-19 variant of concern (VOC).

The VirSNiP variant kits allow differentiation between unique mutations present within the Omicron variant compared to other SARS-CoV-2 variants and are for use on LightCycler® and cobas® z 480 analysers. Using a technology called qPCR (quantitative polymerase chain reaction) they can help researchers with improved variant detection and viral research, and are among the first to address the number of unique mutations of the Omicron variant.

“The COVID-19 pandemic continues to be an evolving and complex situation, and Roche is committed to responding to healthcare’s biggest challenges. The teams at TIB Molbiol have worked around the clock since the new variant emerged, and today we are able to offer a test that can specifically identify the novel B.1.1.529 Omicron SARS-CoV-2 variant to help better understand its spread and behaviour,” said Thomas Schinecker, CEO Roche Diagnostics. “There is still much to learn about Omicron. It's critical to identify Omicron quickly and accurately, which will help inform ongoing research - including the further development of therapeutics and vaccines - and potentially stop or slow down the advance of this new variant.”

The test kits have been developed by TIB Molbiol, with Roche announcing the legal completion of the purchase agreement of the Berlin-based company on 1 December 2021. This has enabled Roche to deliver an agile response to the evolving variant situation. TIB Molbiol’s researchers work in collaboration with their academic contacts to continually screen for new variants and emerging diseases allowing a fast and effective response to emerging healthcare needs. At the onset of the COVID-19 pandemic, TIB Molbiol and Roche provided the first research use only SARS-CoV-2 detection test in January 2020, only days after the new coronavirus was first sequenced.

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## About the assays

TIB Molbiol offers a broad range of VirSNiP variant kits for the detection of key spike protein mutations. TIB Molbiol has now added three additional research use only (RUO) VirSNiP kits for the detection of mutations present in the novel B.1.1.529 Omicron SARS-CoV-2 variant: VirSNip SARS Spike ins214EPE (RUO), VirSNiP SARS-CoV-2 Spike S371L S373P (RUO), VirSNip SARS Spike E484A (RUO). They can be used for SARS-CoV-2 virus research as well as detecting mutations of SARS-CoV-2 variants. VirSNiP kits are for research use only, not for diagnostic procedures. The mutations in the Omicron variant do not affect the performance of the LightMix® Modular SARS-CoV-2 (COVID19) N-gene, E-gene, nor RdRP-gene kits. These kits are launched globally (excluding the USA).

Roche also offers in vitro diagnostic (IVD) tests to accurately diagnose COVID-19 and the cobas® SARS-CoV-2 Variant Set 1 test (RUO) for use on the cobas® 6800/8800 Systems, which is an automated, multiplex, real-time reverse transcription polymerase chain reaction (RT-PCR) assay for the rapid in vitro qualitative detection and discrimination of selected SARS-CoV-2 mutations E484K, N501Y and deletion HV-69/70 in e.g. nasal and nasopharyngeal swab specimens collected viral transport media (VTM). The test is designed to be used with known SARS-CoV-2 positive samples and to support the understanding of variant epidemiology for Population Health Management.

Based on initial analysis, the cobas® SARS-CoV-2 Variant Set 1 test (RUO) is predicted to detect one of the Omicron variant mutations known as del 69-70 in the spike protein, the region that enables the virus to attach to and enter the human cell. It can therefore be used as a tool to presumptively identify Omicron. Roche is currently working to generate additional data to supplement our analysis around this test.

## About TIB Molbiol

TIB Molbiol is a subsidiary of Roche Diagnostics that has supplied the global market with reagents for research and medical diagnostics for over 30 years. As a manufacturer of custom oligonucleotides the company partnered in the development of molecular diagnostics and built a broad portfolio of diagnostic assays, in particular for inherited genetic as well as somatic mutation testing, quantitative assays for haematology and transplantation medicine. The majority of assays are used to test for infectious diseases. They are available as modular kits, enabling the creation of symptomatic panels by combining assays, including emerging pathogens. To support customers performing human genotyping, TIB Molbiol provides custom-made LightSNiP assays for SNP analysis. TIB Molbiol is headquartered in Berlin (Germany).

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

## 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.

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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

## 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, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

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. In recent years, the company has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

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 thirteenth consecutive year, Roche has been recognised as one of the most sustainable companies in the pharmaceutical 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.



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