# Media & Investor Release

## Roche provides molecular testing solutions to identify and differentiate SARS-CoV-2 Omicron variants of concern

- **Roche and its subsidiary, Tib Molbiol, confirm that it has tests for research use that identify the SARS-CoV-2 subvariants of concern, Omicron: BA.1, BA.1.1, BA.2, BA.2.2, BA.3 and Delta**
- **The World Health Organization (WHO) has recently reported that the BA.2 subvariant is steadily increasing in prevalence, specifically in Denmark**
- **Use of these tests assess the spread of circulating variants and can help monitor the potential impact of therapeutics, vaccines and public health interventions**
- **All Roche SARS-Cov-2 tests correctly identify the virus including these new subvariants**

Basel, 16 March 2022 - Roche (SIX: RO, ROG; OTCQX: RHHBY) and TIB Molbiol, a subsidiary within the Roche Diagnostics division, today announced available testing solutions that can identify the SARS-CoV-2 B.1.1.529 variant and differentiate between the Omicron subvariants BA.1, BA.1.1, BA.2, BA.2.2, BA.3 and Delta.

“Roche is pleased to offer testing options addressing the ongoing COVID-19 healthcare crisis, specifically in response to the WHO’s recent recommendation that the Omicron BA.2 subvariant should continue to be monitored by public health authorities,” said Thomas Schinecker, CEO Roche Diagnostics. “In addition to detecting the SARS-CoV-2, irrespective of the variants, we are able to provide testing solutions identifying and differentiating between BA.1, BA.1.1, BA.2, BA.2.2,BA.3 and Delta. It's critical to quickly and accurately identify variants to inform ongoing research - including the ongoing development of therapeutics and vaccines. This can potentially stop or slow down the advancement of the disease.”

The available research use only tests - VirSNiP SARS-CoV-2 Spike S371L S373P and VirSNiP SARS-CoV-2 Spike S371L S373P 452R - add to the test kits previously developed by Roche and TIB Molbiol for the detection of the recent BA.1 and BA.2, as well as other mutations, present in the novel B.1.1.529 Omicron SARS-CoV-2 variant.

TIB Molbiol’s researchers work in collaboration with academic contacts to continually screen for new variants and emerging diseases. 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

VirSNiP Covid 19 variant kits are for research use only (RUO), not for diagnostic procedures.

TIB Molbiol offers a broad range of VirSNiP variant test kits for the detection of key spike protein mutations. The company launched eight RUO VirSNiP test kits for use on LightCycler® and cobas z 480 analyzers, for the detection of key spike protein mutations present in the novel B.1.1.529 Omicron SARS-CoV-2 variant. These kits can detect and differentiate between Omicron subvariants BA.1, BA.1.1, BA.2, BA.2.2, and BA.3, and Delta (https://www.tib-molbiol.de/covid-19).

To differentiate between the recent Omicron BA.1 & BA.2 subvariants, the following kits are recommended:

- VirSNiP SARS-CoV-2 Spike S371L S373P (RUO). Mutation S371L (only present in BA.1) Mutation S373P (present in both BA.1 and BA.2)
- VirSNiP SARS-CoV-2 Spike S371L S373P L452R (RUO). Same as above,in addition also differentiating Omicron vs. Delta Mutation L452R (Delta)
- VirSNiP SARS-CoV-2 NS3 H78Y (RUO). Mutation N78Y (present only in BA.2) within the NS3 gene

A mix of other assays in the portfolio can be combined to further differentiate BA1.1, BA2.2 and BA.3. The mutations in all Omicron variants do not affect the performance of the TIB Molbiol 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. In addition, the cobas® SARS-CoV-2 Variant Set 1 test (RUO) for use on the cobas® 6800/8800 Systems 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 . This assay is predicted to detect mutations in the Omicron variant del 69-70 and N501Y in the spike protein. It can therefore be used as a tool to presumptively identify Omicron. In addition BA.1 has both mutations (del 69-70 and N501Y) while BA.2 lacks the del 69-70 and therefore should produce different mutation patterns in this assay. Roche is currently working to generate additional data to supplement our analysis around this test. 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.

## 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.

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.

## About Roche

Founded in1896 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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