

Additional studies confirm Roche SARS-CoV-2 Rapid Antigen Tests' sensitivity against Omicron variant

- **New internal studies and emerging data from independent studies show that Roche's Rapid Antigen Tests are able to detect the Omicron variant**

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In [December 2021](#), Roche in collaboration with our partner SD Biosensor conducted in-silico ('dry lab') analyses of the publicly available sequences of the SARS-CoV-2 Omicron variant (B.1.1.529) and compared them to the design of the Roche SARS-CoV-2 Rapid Antigen Test. Based on these initial computational investigations, we concluded that the Roche SARS-CoV-2 Rapid Antigen Tests are able to detect Omicron without any impact on assay performance.

These conclusions have now been confirmed in further studies, conducted by SD Biosensor. In these studies, the nucleocapsid protein of 29 variants, including Omicron, was synthesized and used as a positive sample. The cut-off concentration, i.e. the concentration of virus in the sample at which the tests did not detect the virus anymore, was 0.0078 μ g/ml across the original SARS-CoV-2 lineage and all tested variants. **This shows that the Omicron variant, when tested with recombinant protein, does not affect the performance of the following Roche SARS-CoV-2 Rapid Antigen Tests:**

- SARS-CoV-2 Rapid Antigen Test
- SARS-CoV-2 Rapid Antigen Test Nasal
- SARS-CoV-2 Antigen Self Test Nasal

These findings join additional emerging data from independent studies indicating that Roche's Rapid Antigen Tests are able to detect the Omicron variant.¹⁻⁵ In these studies, the performance of rapid tests was mainly evaluated using viral cultures. In a standardized approach, each test was assessed using between 2 and 4 replications per viral dilution. The sensitivity of the Roche Rapid Antigen Test for the Omicron variant was similar to the Delta variant across a number of studies.^{2,4,5}

Study author	Study country	Sample type (number of replications or samples)	Omicron detected
Bekliz M et al. ¹	Switzerland	Cultured virus (n = not published) & Clinical samples (n = 18)	Yes
Deerain J et al. ²	Australia	Cultured virus (n = 4)	Yes
Goderski G et al. ³	Netherlands	Cultured virus (n = 3)	Yes
Statens Serum Institute ⁴	Denmark	Cultured virus (n=2)	Yes
Molenkamp R & Igloi Z ⁵	Netherlands	Cultured virus (no data published)	Yes

The Roche SARS-CoV-2 Rapid Antigen Test (manufactured by SD Biosensor) has been developed in compliance with the strictest quality global standards and has been externally validated many times. Independent studies are important to get the best possible picture of the quality of the different rapid antigen tests and we are proud that Roche SARS-CoV-2 rapid antigen tests are among the most studied rapid antigen tests worldwide.

The reliable performance of the Roche SARS-CoV-2 Rapid Antigen Test was also confirmed by a Cochrane meta-analysis of 78 study cohorts with a total of 24,418 samples across a total of 16 rapid antigen tests.⁶ In this meta-analysis, the Roche rapid antigen test (SD Biosensor Standard Q) achieved the highest overall sensitivity (88.1%) of all tests evaluated. It was also one of the few tests that met WHO standards (sensitivity & specificity) for confirmation and exclusion of COVID-19 in individuals with signs and symptoms of COVID-19.

Since the start of the COVID-19 pandemic, Roche has continuously investigated the potential impact of the variants of concern on the portfolio as part of our commitment to help fight the pandemic. Further investigations will take place should new variants of concern emerge.

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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