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Roche obtains CE mark for SARS-CoV-2 Rapid Antigen Test Nasal

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Roche has announced that it has obtained the CE mark for its new SARS-CoV-2 Rapid Antigen Test Nasal. The test will be available in countries accepting the CE mark by mid-February, 2021.

In comparison to the existing Roche SARS-CoV-2 Rapid Antigen Test, the SARS-CoV-2 Rapid Antigen Test Nasal collects the sample from the front area of the nose instead of the nasopharynx, resulting in a simplified and faster testing procedure. This testing method can help reduce overall patient discomfort, particularly in sensitive individuals such as children, elderly people and/or people with disabilities.

Besides being less invasive, the test also provides patients with the option to self-collect their nasal sample under the supervision of a healthcare professional. Through reduced physical contact, this method of testing can help to decrease the risk of exposure to the virus for healthcare professionals. Whether the test could also be used without supervision of a healthcare professional will depend on local regulatory requirements.

“Rapid testing continues to play an important role in the fight against COVID-19, especially in places when laboratory testing

is not available and quick results are needed, such as nursing homes, healthcare facilities, and schools." said Thomas Schinecker, CEO, Roche Diagnostics. "The SARS-CoV-2 Rapid Antigen Test Nasal provides patients with a more comfortable testing experience."

The launch is a partnership with SD Biosensor Inc, with whom Roche has also launched a SARS-CoV-2 Rapid Antibody Test in July and a SARS-CoV-2 Rapid Antigen Test in September 2020. SD Biosensor, is currently preparing to submit an Emergency Use Authorisation (EUA) to the US Food and Drug Administration (FDA).