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ASIA EDITION

Roche COVID-19 at-home test receives emergency use approval from US FDA

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To expand access to rapid self-testing solutions in the United States

Roche has announced that the US Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for its COVID-19 At-Home Test.

The test uses a simple anterior nasal swab sample that can be conveniently self-collected and self-tested by individuals aged 14 years and older, and by an adult for children aged 2-13 years old.

The test is able to produce accurate, reliable and quick results in as few as 20 minutes for SARS-CoV-2 and all known variants of concern, including Omicron.

The FDA's EUA decision stems from Roche's participation in the National Institutes of Health (NIH) Rapid Acceleration of Diagnostics' (RADx) Independent Test Assessment Programme (ITAP), which aims to accelerate the regulatory review and availability of high-quality, accurate and reliable OTC tests to the American public.

The COVID-19 At-Home Test was prioritised by the FDA based on Roche and SD Biosensor's ability to deliver large quantities of high-quality tests and ramp up manufacturing to meet future demands. The launch will be in partnership with South Korean firm SD Biosensor Inc., with whom Roche has a global distribution agreement.