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FDA issues EUA to Roche's SARS-CoV-2 Test

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Roche's cobas SARS-CoV-2 Test to detect novel coronavirus receives FDA Emergency Use Authorization (EUA) and is available in markets accepting the CE mark

Roche has announced that the U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the cobas SARS-CoV-2 Test. It is intended for the qualitative detection of SARS-CoV-2, the virus that causes COVID-19 disease, in nasopharyngeal and oropharyngeal swab samples from patients who meet COVID-19 clinical and/or epidemiological criteria for testing. Hospitals and reference laboratories can run the test on Roche's fully automated cobas 6800 and cobas 8800 Systems, which are widely available in the U.S. and around the world.

The CE-IVD test is also available in markets accepting the CE mark for patients with signs and symptoms of COVID-19 disease and living in affected areas where the SARS-CoV-2 virus is known to be present.

The widely available Roche's cobas 6800/8800 Systems, which are used to perform the cobas SARS-CoV-2 Test, provide test results in three and half hours and offer improved operating efficiency, flexibility, and fastest time-to-results with the highest throughput providing up to 96 results in about three hours and a total of 1,440 results for the cobas 6800 System and 4,128 results for the cobas 8800 System in 24 hours. The test can be run simultaneously with other assays provided by Roche for use on the cobas 6800/8800 Systems.