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ASIA EDITION

Singapore submits Coronavirus Diagnostic Test to FDA for EUA clearance

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Singapore's Vela Diagnostics has developed a new diagnostic test that will be able to detect and differentiate the Wuhan Coronavirus from other closely related coronaviruses and is expected to be officially available by end-February

Vela Diagnostics has developed the ViroKeyTM SA201 COVID-19 RT-PCR-PCR Test, a new diagnostic test for the detection of the COVID-19.

Vela Diagnostics is currently in discussions with the U.S Food and Drug Administration (FDA) for clearance of the test under the emergency use authorization (EUA). The EUA will allow the emergency use of FDA unapproved medical products in qualified labs, thereby facilitating widespread access to the diagnostic test.

The ViroKeyTM SA201 COVID-19 RT-PCR Test will be officially available by end-February with the facility to pre-order now.

The COVID-19 Coronavirus was first identified in mid-December 2019 in Wuhan, China. Human-to-human transmission has been confirmed by China's health ministry. According to Chinese health agencies, there are more than 40,000 confirmed cases with at least 900 fatalities in China, while over 200 cases have been confirmed in more than 20 other countries. These numbers are expected to increase. There is an urgent need for a fast, high-throughput and accurate diagnostic method to provide timely treatment for those infected and to prevent the spread of the virus.

The ViroKey™ SA201 COVID-19 RT-PCR Test will be able to detect and differentiate the Wuhan Coronavirus from other closely related coronaviruses such as SARS and MERS. To enable high-throughput processing of 96 samples in 4 hours, the test is configured for an automated workflow consisting of the *Sentosa*™ SX101 instrument, in conjunction with the Applied Biosystems 7500 Fast Dx Real-Time PCR instrument (ABI 7500 Fast Dx) or the *Sentosa*™ SA201. The *Sentosa*™ SA201 platform also supports other tests such as the *Sentosa*™ SA201 HSV-1/2 PCR Test (U.S. FDA cleared) and the *Sentosa*™ SA201 ZIKV RT-PCR Test (for use under Emergency Use Authorization from the U.S. FDA). As time-to-market is critical to address the urgent need for the test, a manual kit will also be made available to facilitate the fast adoption of the test by laboratories with existing ABI 7500 Fast Dx PCR instruments.

Concurrently, Vela Diagnostics and Great Basin Scientific are co-developing a COVID-19 assay for use on Great Basin's sample-to-result diagnostic system. The Great Basin system utilizes a disposable cartridge with fully integrated reagents and internal controls. The Great Basin automated bench-top analyzer performs all steps in the assay, visually interprets the results, and provides a digital report of the results. Great Basin is targeting to deliver a diagnostic result in under 90 minutes for the COVID-19 assay.