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Vela Diagnostics receives CE mark for COVID-19 test

April 30, 2020 | News

Vela Diagnostics ViroKeyÃ¢â??Â¢ SARS-CoV-2 RT-PCR Test receives CE-IVD marking



Singapore headquartered Vela Diagnostics announced that the manual version of the ViroKey™ SARS-CoV-2 RT-PCR Test has received the CE mark for *in vitro* diagnostic use. The test detects SARS-CoV-2 in patients suspected of COVID-19 by their healthcare providers.

The ViroKey™ SARS-CoV-2 RT-PCR Test is a probe-based reverse transcription PCR Test that detects SARS-CoV-2 by targeting conserved regions of the SARS-CoV-2 genome. The manual version of the assay enables quick adoption of the test by laboratories with existing Applied Biosystems 7500 Fast Dx (ABI 7500 Fast Dx) instruments.

“The CE mark enables Vela Diagnostics to expand COVID-19 testing capacity in Europe, where there is an urgent need to identify individuals infected with SARS-CoV-2,” said Sam Dajani, acting CEO and Chairman of the Board.

Vela Diagnostics has also developed an automated version of the test which is slated for CE-IVD registration in April 2020. The automated ViroKey™ SARS-CoV-2 RT-PCR Test is optimized for a workflow consisting of the *Sentosa*™ SX101 instrument, in conjunction with the *Sentosa*™ SA201 instrument or the ABI 7500 Fast Dx.