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Vela Diagnostics receives CE-IVD approval for automated COVID-19 detection test

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Received Provisional Authorisation from the Health Sciences Authority in Singapore



Singapore based Vela Diagnostics has announced that an automated version of its COVID-19 detection test, the ViroKey™ SARS-CoV-2 RT-PCR Test v2.0, has received the CE mark for *in vitro* diagnostic use as well as Provisional Authorisation from the Health Sciences Authority in Singapore.

The ViroKey™ SARS-CoV-2 RT-PCR Test v2.0 is a probe-based reverse transcription PCR Test that detects SARS-CoV-2 by targeting conserved regions of the SARS-CoV-2 genome, specifically the *ORF1a* and *N* genes. The automated 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.

The automated workflow enables high throughput testing with significantly reduced hands-on time. Up to 48 tests, including controls, can be performed in a single run. "Receiving CE certification and Provisional Authorisation from the Health Sciences Authority in Singapore for our automated test facilitates efficient testing of SARS-CoV-2 in patients suspected of COVID-19 in Europe, Africa, Middle East and Asia, where there is an urgent need to identify individuals infected with SARS-CoV-2 for effective management of the global pandemic," said Managing Director, Andreas Goertz.

In April this year, an earlier version of the test, the ViroKey™ SARS-CoV-2 RT-PCR Test, also received the CE mark and Provisional Authorisation from the Health Sciences Authority in Singapore.