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Vela Diagnostics to offer manual ViroKey SARS-CoV-2 RT-PCR Test

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After test validation (targetted to April 2020) Vela Diagnostics will offer the assay immediately in accordance with Section IV.C. of FDA's policy for Diagnostic Tests for COVID-19



Ahead of Emergency Use Authorization (EUA) and in accordance with the U.S. Food and Drug Administration (FDA) Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency guidance document issued on March 16, 2020, Vela Diagnostics will offer the manual ViroKey™ SARS-CoV-2 RT-PCR Test when validation is completed. Validation is targeted to be completed by early April 2020. After validating the test, Vela Diagnostics will offer the assay immediately in accordance with Section IV.C. of FDA's policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency, dated March 16, 2020.

Vela Diagnostics is currently working with the FDA for authorization of the manual test under the February 4, 2020 existing public health emergency authorizing EUA of *in vitro* diagnostics for detection and / or diagnosis of the virus that causes COVID-19. The manual ViroKey™ SARS-CoV-2 RT-PCR Test is also on track to receive CE-IVD approval by the end of March.

In February 2020, Vela Diagnostics announced the development of the ViroKey™ SARS-CoV-2 RT-PCR Test for the detection of SARS-CoV-2, the virus that causes COVID-19. The ViroKey™ SARS-CoV-2 RT-PCR Test detects and differentiates the SARS-CoV-2 from other respiratory pathogens such as influenza. The manual assay was developed to facilitate quick adoption of the test by laboratories with existing Applied Biosystems 7500 Fast Dx Real-Time (ABI 7500 Fast Dx) PCR instruments. The Research Use Only (RUO) test is configured for an automated workflow consisting of the *Sentosa* ™ SX101 instrument, in conjunction with the ABI 7500 Fast Dx or the *Sentosa*™ SA201 instruments.

To date, COVID-19 has affected 199 countries and territories around the world, with more than 240 000 cases in US, Europe and China combined and at least 27 000 fatalities worldwide. On 11 March 2020, the World Health Organization declared COVID-19 a pandemic.