

Vela Diagnostics Receives BARDA Funding to Develop COVID-19 Tests

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The partnership will support verification and clinical validation of RT-PCR tests to detect the COVID-19 virus.



Vela Diagnostics has been awarded a \$225,000 contract by the Biomedical Advanced Research and Development Authority (BARDA) part of the office of the Assistant Secretary for Preparedness and Response at the U.S. Department of Health and Human Services, to develop manual and automated tests to detect SARS-CoV-2, the virus that causes COVID-19.

The ViroKey™ SARS-CoV-2 RT-PCR Test is a probe-based reverse transcription PCR test that detects the virus by targeting conserved regions of the SARS-CoV-2 genome.

Under the agreement, Vela Diagnostics will perform verification and clinical validation of the ViroKey™ SARS-CoV-2 RT-PCR Test to be used on automated and manual workflows for Emergency Use Authorization (EUA) submission to the U.S. Food and Drug Administration (FDA). Support from BARDA is expected to accelerate the progress toward EUA submission.

The automated ViroKey™ SARS-CoV-2 RT-PCR Test is performed on a workflow consisting of the *Sentosa*™ SX101 instrument, in conjunction with the Applied Biosystems 7500 Fast Dx Real-Time (ABI 7500 Fast Dx) PCR instrument or the *Sentosa*™ SA201 instrument.

Up to 48 samples (including positive and negative controls) can be processed per run on the automated workflow. The manual assay was developed to enable flexible sample processing and quick adoption of the test by laboratories with existing ABI 7500 Fast Dx instruments.

High volume testing of SARS-CoV-2 is also critical in mitigating the rapidly evolving COVID-19 pandemic. The CDC recommends COVID-19 testing for individuals with symptoms associated with COVID-19 such as fever and acute respiratory illness.

“High throughput detection of SARS-CoV-2 using our automated workflow will provide rapid and valuable information to save lives,” said Sam Dajani, acting CEO and chairman of the Board. “The funding from BARDA will enable Vela Diagnostics to increase the domestic and global testing capacity for COVID-19 to curb further spread of the virus.”

“Rapid diagnostic tests put essential information into the hands of healthcare providers and patients to manage patient care safely and appropriately. Data gathered from high-throughput testing aids public health officials in making decisions about community mitigation to combat the pandemic,” said BARDA Director Rick Bright, Ph.D.

To date, COVID-19 has affected 199 countries and territories around the world, with total cases exceeding a million in US, Europe and China combined and at least 100,000 fatalities worldwide. On March 11, the World Health Organization declared COVID-19 to be a pandemic.

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