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Luminex Receives FDA EUA for ARIES SARS-CoV-2 Assay

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Luminex is now able to provide SARS-CoV-2 diagnostic tests for both high-complexity, high-throughput reference labs and moderate complexity, sample-to-answer testing facilities

US based Luminex Corporation has announced that the Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for its ARIES® SARS-CoV-2 Assay for rapid detection of the virus that causes COVID-19.

The assay runs on the ARIES® System, an FDA-cleared, sample-to-answer, automated, on-demand molecular diagnostic platform. The system is capable of running up to 144 tests per day, requiring no specialty training and minimal human interaction.

"The ARIES® SARS-CoV-2 Assay will allow hospital professionals to determine the appropriate course of treatment for patients suspected of having COVID-19 within approximately two hours," said Nachum "Homi" Shamir, President and CEO of Luminex. "We are grateful to the FDA for this Emergency Use Authorization, which allows us to bring another cost-effective SARS-CoV-2 test from Luminex to labs and patients in dire need of quick, accurate results. We are scaling up production of this assay over the next three weeks to support hundreds of labs across the US and the rest of the globe. These labs are already operating the ARIES® System and should be able to get up and running very quickly as we make this test broadly available."

Luminex also launched the NxTAG® CoV Extended Panel last week after receiving an EUA from the US FDA and Medical Device Authorization for importation or sale for Health Canada. The panel is a high-throughput, scalable, cost-effective option for detecting SARS-CoV-2 in as many as 96 samples in approximately four hours. To provide a more complete picture of a patient's respiratory health, the NxTAG CoV Extended Panel can also be run in parallel with the NxTAG Respiratory Pathogen Panel.

Luminex is actively supporting laboratories in the US, Asia, and Europe with their testing, and the company has expanded its manufacturing capacity to produce up to 200,000 ARIES® SARS-CoV-2 tests per month, in addition to 300,000 NxTAG tests per month, with the majority of this capacity focused on SARS-CoV-2.