Luminex Receives FDA Emergency Use Authorization and CE Mark for Expanded NxTAG® Respiratory Panel Test Including SARS-CoV-2

March 4, 2021

Provides labs with high throughput, syndromic respiratory testing capabilities

AUSTIN, Texas, March 4, 2021 /PRNewswire/ -- Luminex Corporation (NASDAQ: LMNX) today announced that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for a new expanded version of its NxTAG® Respiratory Pathogen Panel (RPP) that includes the SARS-CoV-2 virus for high-throughput respiratory testing. The new test is a combination of the company's original NxTAG RPP, an FDA-cleared in vitro diagnostic for syndromic respiratory infection testing, and SARS-CoV-2.

Respiratory infections such as COVID-19 and influenza can be challenging to differentiate and diagnose because they often have overlapping symptoms. NxTAG RPP is a multiplex, high-throughput test designed to enable simultaneous detection of the most common respiratory pathogens for a fast, syndromic testing approach. Following the addition of the SARS-CoV-2 virus target, the panel now includes 19 viral and 2 bacterial targets, combining the most common respiratory pathogens in one panel to help facilitate the rapid identification of various individual and co-occurring infectious pathogens.

NxTAG RPP provides scalable throughput, allowing clinical labs to run up to 96 samples at a time—generating results in approximately four hours with minimal hands-on time. The test runs on Luminex's easy-to-use, compact MAGPIX® System and is designed for use in high-complexity molecular laboratories.

Importantly, the NxTAG RPP + SARS-CoV-2 Assay is expected to detect new variants of the coronavirus. An in silico analysis of molecular probes used in the assay compared to SARS-CoV-2 sequences available in the GISAID database as of February 11, 2021, determined that key sequences still match and should yield a positive result. The analysis included variants originally detected in the United Kingdom (B.1.1.7), South Africa (B.1.351 or 20H/501Y.V2), Brazil (P.1 lineage or 20J/501Y.V3), and California (one of five reoccurring mutations that constitute the B.1.429 lineage and CAL20C).

"Given the emergence of new respiratory pathogens and new variants of these pathogens, it will be increasingly challenging to identify and distinguish the presence and co-existence of SARS-CoV-2, influenza, and other common respiratory pathogens. As a highly accurate, low-cost, multiplex test, our NxTAG RPP + SARS-CoV-2 test delivers an ideal solution for this challenge," said Nachum "Homi" Shamir, Chairman, President and CEO of Luminex. "Clinical laboratories using the assay will be able to scale-up their testing for both COVID-19 and the flu with one high-capacity diagnostic platform that can provide much-needed information for appropriate patient treatment. This is especially important given that the symptoms for the flu, COVID-19, and other respiratory illnesses can be very similar, but their treatment may be very different."

A version of the assay, which also detects *Legionella pneumophila* and the 2009 H1N1 Flu A subtype, also just received a CE Mark, and was commercialized last month in Europe.

Since the COVID-19 pandemic began, Luminex has expanded capacity for SARS-CoV-2 testing across all of its molecular platforms. The company previously launched the NxTAG CoV Extended Panel under an EUA from the FDA and an Authorization for Import or Sale with Conditions from Health Canada, and also received FDA EUA for its ARIES® SARS-CoV-2 Assay. In August, the company announced it received an EUA from the FDA for its xMAP® SARS-CoV-2 Multi-Antigen Immunoglobulin G (IgG) Assay, a new serology test that can be run on any of Luminex's xMAP-based, high-throughput, gold-standard multiplex platforms. The test detects IgG antibodies, which are an important component of an adaptive immune response and typically reflect sustained immunity to a given pathogen.

The NxTAG CoV Extended Panel and the ARIES® SARS-CoV-2 Assay have each been funded with $642,450 of Federal funds, approximately 36% each of the expected overall cost of development, from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, Division of Research Innovation and Ventures under Contract Nos. 75A50120C00037 (NxTAG CoV Extended Panel) and 75A50120C00043 (ARIES® SARS-CoV-2 Assay). Luminex financed the remaining $1,118,663 of each program, constituting 64% each of the total program costs.

About Luminex Corporation
At Luminex, our mission is to empower labs to obtain reliable, timely, and actionable answers, ultimately advancing health. We offer a wide range of solutions applicable in diverse markets including clinical diagnostics, pharmaceutical drug discovery, biomedical research, genomic and proteomic research, biodefense research, and food safety. We accelerate reliable answers while simplifying complexity and deliver certainty with a seamless experience. To learn more about Luminex, please visit us at luminexcorp.com.

Cautionary Statement Regarding Forward-Looking Statements
This press release contains forward-looking statements relating to Luminex's business outlook for the first quarter, as well as other statements that refer to future plans and expectations, particularly around the development of products to address the novel coronavirus. Such statements involve a number of risks and uncertainties. Words such as "can," "will," "allowing," and variations of such words and similar expressions are intended to identify forward-looking statements. Statements that refer to or are based on estimates, forecasts, projections, uncertain events or assumptions, and anticipated trends in our businesses or the markets relevant to them, also identify forward-looking statements. Such statements are based on management's expectations as of the date they were first made and, except as required by law, Luminex disclaims any obligation to update these statements to reflect future events or circumstances. Forward-looking statements involve many risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from the company's expectations include changes in market conditions, supply constraints and other disruptions, changes in capital requirements, and other

factors set forth in Luminex's most recent Annual Report on Form 10-K filed with the SEC and available at Luminex's website at luminexcorp.com and the SEC's website at sec.gov.

Investor Contact:
Harriss Currie
Sr. Vice President of Finance and CFO
hcurrie@luminexcorp.com
512-219-8020

Media Contact:
Michele Parisi
Bioscribe
mparisi@bioscribe.com
925-864-5028

View original content to download multimedia:http://www.prnewswire.com/news-releases/luminex-receives-fda-emergency-use-authorization-and-ce-mark-for-expanded-nxtag-respiratory-panel-test-including-sars-cov-2-301240142.html

SOURCE Luminex Corporation