Luminex Submits Joint SARS-CoV-2 and Flu/RSV Respiratory Panel to FDA for Emergency Use Authorization

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AUSTIN, Texas, March 10, 2021 /PRNewswire/ -- Luminex Corporation (NASDAQ: LMNX) today announced that it has submitted an Emergency Use Authorization application to the U.S. Food and Drug Administration for the company's new multi-analyte respiratory panel combining Flu A/B and respiratory syncytial virus (RSV) targets with the SARS-CoV-2 target. The ARIES® Flu A/B & RSV+SARS-CoV-2 Assay can be run on all Luminex ARIES® Systems. This submission represents completion of a key milestone in a Luminex funding award from the Biomedical Advanced Research and Development Authority (BARDA), which helped support the rapid development and validation of the assay.

Respiratory infections such as COVID-19 and influenza can be challenging to differentiate and diagnose because they often have overlapping symptoms. Luminex designed the combined assay to quickly deliver clear answers about these infections from a single test and, thereby, help clinical-care teams treat patients more effectively. The ARIES® Flu A/B & RSV+SARS-CoV-2 Assay can be run on six-unit and 12-unit ARIES® Systems with minimal hands-on time, producing results in approximately two hours. The ARIES® System is an FDA-cleared, sample-to-answer, automated molecular diagnostics platform designed for use in moderate and high complexity labs.

Importantly, the ARIES® Flu A/B & RSV+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).

"We are grateful to BARDA for supporting development of this important new assay, and are pleased to have fulfilled our commitment to file for EUA so quickly," said Nachum "Homi" Shamir, Chairman, President and CEO of Luminex. "It is critical to continue expanding the number of FDA-authorized assays that include SARS-CoV-2 detection for a broad range of clinical uses, and we're proud to have developed a single assay that provides answers about some of the most common respiratory infections – including SARS-CoV-2 - in just two hours."

BARDA is part of the US Department of Health and Human Services and is tasked with protecting the country against emerging infectious diseases and other threats. Through public-private partnerships, BARDA supports the development of vaccines, drugs, and diagnostics. Luminex developed the original ARIES® SARS-CoV-2 Assay with financial support from BARDA earlier this year.

Since the COVID-19 pandemic began, Luminex has expanded capacity for SARS-CoV-2 testing across its diagnostic 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. It also received an EUA from the FDA for its xMAP® SARS-CoV-2 Multi-Antigen Immunoglobulin G (IgG) Assay, a serology test that can be run on any of Luminex's xMAP-based, high-throughput, gold-standard multiplex platforms.

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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. To learn more about Luminex's COVID-19 Testing and Research Solutions, please visit: https://www.luminexcorp.com/solutions/.

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," "designed" 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 www.luminexcorp.com and the SEC's website at sec.gov.

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