

Lowndes Advises Applied DNA on FDA Emergency Use Authorization for COVID-19 Diagnostic Assay Kit

Press Release

Lowndes

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Orlando, FL – Lowndes, a Florida-based law firm, advised Applied DNA Sciences Inc. (Applied DNA) on its recent Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for the clinical use of the company's patent-pending Linea™ COVID-19 RT-PCR test for COVID-19.

The FDA issued the EUA on May 14, and Applied DNA reports that clinical laboratories in the United States certified under Clinical Laboratory Improvement Amendments (CLIA) can immediately begin ordering and using the Linea™ COVID-19 assay kit to detect SARS-CoV-2, the virus that causes COVID-19. The machine that runs the assay can process testing results for up to 94 samples per hour, or more than 2,000 tests in 24 hours, which will help to meet the massive demand for COVID-19 testing.

"It's an incredible story," said Shorrock. "We're proud to have assisted Applied DNA in successfully navigating through the complex EUA approval. This achievement highlights Applied DNA's commitment to combating the COVID-19 pandemic."

An EUA is an authorization from the FDA for the use of an unapproved medical products during a public health emergency that may be effective in diagnosing, treating or preventing a disease or condition when there are no other adequate, approved or available alternatives. For an EUA, the FDA requires a lower burden of evidence than it does for a standard form of FDA approval. During the EUA approval process, flexibility is provided for the amount, type and quality of the evidence used to support an EUA application, utilizing a risk-benefit analysis based on the totality of the scientific evidence available.

About Applied DNA Sciences, Inc.

Applied DNA is a provider of molecular technologies that enable supply chain security, anti-counterfeiting and anti-theft technology, product genotyping, diagnostics and pre-clinical nucleic acid-based therapeutic drug candidates.

About Lowndes

Founded in Orlando, Florida in 1969, Lowndes, Drosdick, Doster, Kantor & Reed, P.A., is a multi-discipline business law firm. Our attorneys represent corporate, entrepreneurial and individual clients across a myriad of industries locally, nationally and beyond our borders, from offices in Orlando, Mount Dora and Melbourne, and through Meritas, an established global alliance of independent law firms offering local insight, local rates and world-class client service. LOCAL ROOTS. BROAD REACH.