

Lowndes Advises Applied DNA on EUA Amendment for Its COVID-19 Diagnostic Assay Kit Delivering Increased Accessibility and Turnaround Time to Customers

News Release

08.04.2020

Orlando, FL – Lowndes, a Florida-based law firm, advised Applied DNA Sciences Inc. (Applied DNA) on its recent Emergency Use Authorization (EUA) amendment which both expands the installed base of PCR equipment platforms that can process the company's Linea™ COVID-19 Assay Kit and introduces automation to significantly increase the throughput of the assay by use of robotic RNA extraction.

According to a company release, the amendment, which was granted by the FDA on July 30, 2020, can greatly enhance the efficiency of laboratories who adopt the diagnostic kit and also significantly expand the targeted installed base of authorized RT-PCR equipment. In response to the COVID-19 infection spikes throughout the country, Applied DNA is increasing diagnostic kit production to meet the potential demand.

Lowndes attorney Clay D. Shorrock advised Applied DNA through both the initial EUA approval and the amendment processes, including drafting FDA submissions and representing Applied DNA in FDA interactions, as well as preparing necessary patent applications.

An EUA is an authorization from the FDA for the use of an unapproved medical product 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.

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.
