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Genedrive PLC
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genedrive plc
("genedrive" or the "Company")

Genedrive® 96 SARS-CoV-2 Kit receives CE-IVD Mark

New easy-to-use test PCR format to support increased high-throughput Coronavirus testing

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that the Genedrive® 96 SARS-CoV-2 Kit is now CE-IVD marked and is available for commercial sale across the European Union, including the UK, whilst also accelerating market access to countries that accept the CE-IVD mark.

The Genedrive® 96 SARS-CoV-2 Kit is a novel Polymerase Chain Reaction (PCR) assay designed to detect active infection in COVID-19 patients. genedrive's PCR bead format eliminates the need for the time consuming and error-prone reagent preparation required in all other open-platform test kits. The proprietary format streamlines laboratory workflow, allowing more tests to be performed in a day. Patient samples are simply mixed with the PCR beads, and are then analysed on a variety of existing third-party real time PCR platforms. During CE-IVD evaluations on 180 randomised specimens, the Genedrive® 96 SARS-CoV-2 Kit achieved 100% sensitivity and 98.2% specificity, placing it in a top tier performance table for COVID-19 PCR tests.

The test has been co-developed with Cytiva (formerly GE Healthcare Life Sciences). The scalable manufacturing process uses Cytiva's Lyo-Stable™ validated manufacturing method, capable of producing 10,000 PCR beads per hour. The Genedrive® 96 SARS-CoV-2 kit is stable at ambient temperatures which eliminates the need for cold storage, making the test very practical for global export markets.

Following CE-IVD marking, the Company can commence commercial sales in the UK and across the EU immediately. The Company will now begin distribution to potential customers for initial clinical evaluations, and aims to record first commercial sales in June.

The Company continues to develop a point-of care version of the SARS-CoV-2 test for use with its Genedrive® platform, which will enable decentralised testing.

David Budd, Chief Executive Officer of genedrive plc, said: *"The development teams at genedrive and at Cytiva have worked tirelessly over the past 2 months to develop our unique product that has the potential to streamline lab testing, improve quality, and ultimately allow more people to be tested. CE marking was achieved with performance studies and validations that will also support regulatory applications in other jurisdictions, such as Emergency Use Authorisation with the USA FDA and Emergency Use Assessment and*

Listing with the WHO. The temperature stable nature of the Genedrive® 96 SARS-CoV-2 kit means we have the potential to easily access these global markets, which are in urgent need of testing efficiency and volume."

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About genedrive plc (http://www.genedriveplc.com)
genedrive plc is a molecular diagnostics company developing and commercialising a low cost, rapid, versatile, simple to use and robust point of need molecular diagnostics platform for the diagnosis of infectious diseases and for use in patient stratification (genotyping), pathogen detection and other indications. The Company has assays on market for the detection of HCV, certain military biological targets, and has tests in development for tuberculosis (mTB). The Company recently announced the development of a high throughput SARS-CoV-2 assay and a Genedrive® Point of Care version of the assay, both based on Genedrive® PCR chemistry.

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