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

Genedrive notifies FDA of its intent to distribute to SARS-CoV-2 PCR test in the USA

Genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that it notified the Food and Drug Association (FDA) in the United States of its intention to import and distribute its Genedrive 96 SARS-CoV-2 Kit prior to an Emergency Use Authorization (EUA) determination, as described in the guidance on Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, Section IV.C.2.

Notification was made on 25 November and acknowledged on 15 December. The current claims of the product cover high throughput testing on a variety of third-party RT-PCR platforms for upper respiratory track specimens.

David Budd, CEO of genedrive plc, said: *"genedrive submitted its application to the FDA in May of this year but owing to the volume of applications received we are still waiting for EUA review. However, in order to support the Beckman Biomek system's transition into clinical use and exploit commercial opportunities, the product needs to be commercially available in the United States to end users. We are confident in the performance claims of our assay and have generated independent evaluation data in the United States at non-automated sites and our automated Biomek installations which confirm our product claims."*

In light of the increasing numbers of COVID-19 cases throughout the US and the need to expand capacity for COVID-19 testing during the public health emergency, the FDA has stated that it does not object to a commercial manufacturer's development and distribution of SARS-CoV-2 test kits for specimen testing for a reasonable period of time, where the test has been validated and while the manufacturer has made an Emergency Use Authorization request, where the manufacturer gives appropriate notification of validation to FDA, and where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website.

The product will bear a labelling stating that "validation of this test has not been reviewed by FDA. Review under the EUA program is pending".

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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 released a high throughput SARS-CoV-2 assay and has in development a Genedrive® Point of Care version of the assay, both based on Genedrive® chemistry.

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