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

Point-of-Care Genedrive® COV19-ID Kit receives Coronavirus Test Device Approval ("CTDA")

genedrive plc (AIM: GDR), the near patient molecular diagnostics company, announces that the UK Medicines and Healthcare Products Regulatory Agency has granted a CTDA enabling the sale of the Genedrive® COV19-ID Kit in the United Kingdom. Genedrive's application for approval, under the requirements that came into force on 28 July 2021 via The Medical Devices (Coronavirus Test Device Approvals Regulations (2021)), was made on 21 December 2021.

Since submission for approval, the product has undergone positive external validation, commercial partners have been engaged in specific countries, and product claims have been expanded to include the testing of asymptomatic patients.

Information about the Genedrive® COV19-ID Kit can be found at https://www.genedrive.com/assays/cov19-id-assay.php

David Budd, CEO of genedrive plc, said: *"We are very pleased to have received a CTDA, which now allows the UK access to the fastest point-of-care COVID molecular test. The performance of the test has met CTDA standards in all regards, which positions genedrive well to engage in opportunities as they develop going forwards in the UK."*

The Genedrive® COV19-ID Kit is a rapid molecular diagnostic test that delivers positive results as quickly as 7.5 minutes and negative results at 17 minutes. It utilises Reverse-Transcription Loop Mediated Isothermal Amplification (RT-LAMP) and a proprietary buffer formulation to achieve rapid results without requirement for user viral extraction steps. Performed directly from a mid-turbinate nasal swab, the assay targets the ORF1ab and N genes of the SARS-CoV-2 genome, adding robustness against emerging SARS-CoV-2 variants.

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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, MT-RNR1 for Ototoxicity, certain military biological targets, and a high throughput SARS-CoV-2 assay.