22 December 2021

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

UK CTDA application for Point-of-Care Genedrive® COV19-ID kit

Sensitivity and specificity data submitted meets MHRA requirements
Performance data supports successful Omicron detection

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that, further to the announcement on 29 November 2021 confirming submission for CE-IVD certification for the Genedrive® COV19-ID Kit, expanded product validation requirements have now been completed and the Company has filed for approval to sell the product in the United Kingdom under the new Coronavirus Test Device Approvals (CTDA) regulations[1]. CTDA regulations came into effect on 1 Nov 2021 and place specific registration, review and performance requirements on suppliers of COVID-19 diagnostic products into the United Kingdom.

The expanded clinical validation sample cohort required for CTDA approval was referenced against the Thermo Fisher TaqPath COVID-19 RT-PCR test. In the 264 samples, specificity was 98%, and sensitivity was 98% in samples with viral load >500 copies per ml. This cohort included samples of confirmed Omicron variant, all of which were successfully detected. The sensitivity and specificity of the Genedrive® COV19-ID assay on the entire cohort met the current requirements of the UK's MHRA Target Product Profile for SARS-CoV-2 Point-of-Care molecular diagnostic tests.

Potential commercial partners, testing suppliers, or clinical professionals interested in the new Genedrive® COV19-ID Kit can contact the Company via info@genedrive.com. Information about the new Genedrive® COV19-ID Kit can be found at https://www.genedrive.com/assays/cov19-id-assay.php

David Budd, CEO of genedrive plc, said: *"CTDA performance data builds on the data already generated for CE certification, and demonstrates that the product meets the expanded UK requirements for Point-of-Care COVID-19 molecular tests. The next milestone is approval by the Department of Health and Social Care, however, no assured timeline is provided on how long the review under CTDA regulations will take, given a current backlog in their reviews. We have confidence in our data and the application is another positive step that allows us now to progress UK focused commercial discussions."*

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 - 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 a high throughput SARS-CoV-2 assay. The Company has also recently released a test to help in the prevention of hearing loss (Genedrive® MT-RNR1 Kit) caused by specific antibiotics in neonates.

[1]https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/covid-19-test-approval-step-2-process-for-desktop-review#overview-of-the-process