8 December 2021

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

CE-IVD certification for Point-of-Care Genedrive® COV19-ID kit

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that further to the announcement of 29 November 2021, its rapid point of care Genedrive® COV19-ID Kit has received CE-IVD certification under the European Communities Council Directive 98/79.

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 viral extraction. 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. In the case of the new Omicron variant of concern, there were approximately 650 Omicron (B.1.1.529) genome sequences identified within the global reference database as of 7 December 2021, and the Genedrive® COV19-ID Kit was 100% inclusive in detection.

Sensitivity and specificity of the Genedrive® COV19-ID Kit was 98.2% and 98.9% respectively in its clinical validation cohort of 149 samples (58 positives at greater than 500 copies per ml) which were referenced against the Thermo Fisher TaqPath COVID-19 RT-PCR test. The Genedrive® COV19-ID molecular test offers several orders of magnitude improvement in sensitivity compared to antigen lateral flow devices. The clinical cohort included five confirmed SARS-COV2 Delta variants, which were all detected by the Genedrive® COV19-ID test. The sensitivity and specificity of the assay on the entire cohort met the current requirements of the UK's MHRA Target Product Profile for a SARS-CoV-2 Point of Care molecular diagnostic test.

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

As detailed in the announcement on 29 November, the product is being provided for review and evaluation to a range of potential commercial partners who have actively expressed interest in the product with regards to European opportunities.

David Budd, CEO of genedrive plc, said: *"This is an important milestone in the development of our new rapid molecular COVID19-ID test and we can now move forward with our commercial plans. We have developed a very fast and easy to use Point of Care system that will allow immediacy and convenience in molecular testing, rather than waiting many hours or days for results from a central laboratory. The newest Variant of Concern highlights that COVID is an ongoing and long-term global health issue and our ability to manage it better can be aided by rapid detection to prevent ongoing transmissions, using innovative products like the new Genedrive COV19-ID kit."*

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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 caused by certain antibiotics in neonates.