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The information contained within this Announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this Announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.

genedrive plc
(“genedrive” or the “Company”)

Beckman Coulter collaboration to automate high throughput SARS-CoV-2 PCR testing

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that it has entered into a collaboration with Beckman Coulter Life Sciences (“Beckman Coulter”) to fully automate the entire laboratory PCR testing process for COVID-19. The two companies are working to combine and validate the Genedrive® 96 SARS-CoV-2 Kit on the Biomek i7 automated workstation with saliva samples extracted using Beckman Coulter’s RNAdvance viral extraction chemistry.

The freeze dried bead chemistry of the Genedrive® 96 SARS-CoV-2 test is ideally suited for use on high throughput robotic platforms like the Biomek i7. Stable at room temperature for 4 hours after unsealing, many Genedrive® 96 SARS-CoV-2 Kit 96-well plates can be left arrayed and open in the laboratory environment during the set-up process. The ready-to-go nature of the test bead also removes the fluid dispensing steps required in other assays, increasing the overall throughput of the Biomek i7 compared to using a liquid based test set-up. Accordingly, once validated, Beckman Coulter estimates that this new turnkey solution could process circa 1,000 PCR samples per Biomek installed during a standard 8-hour working day, using just a 0.5 full-time-equivalent in technician time for processing.

Genedrive has already completed initial evaluation of Beckman Coulter’s RNA extraction chemistry to confirm compatibility with the Genedrive 96 SARS-CoV-2 test. Further work is ongoing to validate clinical saliva samples which are a very relevant sample type for applications such as high volume occupational screening. Beckman’s RNAdvance Viral XP has already been listed as an extraction method for swab samples for use with the Centers for Disease Control’s EUA-authorized COVID-19 test in FDA’s FAQ on testing for SARS-CoV-2.

Greg Milosevich, President at Beckman Coulter Life Sciences, said *“The integration of Beckman Coulter Life Sciences’ and genedrive’s technologies produces a formidable workhorse solution for specialized laboratories looking to establish new or next level laboratory automation with labor cost reduction. Our ability to fully integrate the RNA extraction process on the Biomek while simultaneously preparing the plates for analysis is a critical step forward in advancing COVID testing workflows. Speed up the testing workflow, reduce labor time and costs. This is the goal of our collaboration with Genedrive and we are excited to be bringing this solution forward to the market.”*

David Budd, Chief Executive Officer of genedrive plc, said *“We are very pleased to have the opportunity to work with Beckman Coulter in delivering an innovative high throughput COVID-19 PCR solution. It’s been our focus to work with a top tier, high throughput lab automation partner like Beckman to drive uptake of our test and further differentiate our unique capabilities in the market. The combination of our ready to use chemistry with robotics and on-board RNA extraction would give laboratories a unique and rapid workflow that can achieve impressive throughput and result turnaround times. We are both working to have the ongoing validation completed in approximately 6 weeks, with initial introduction in the USA at an already identified clinical laboratory.”*

The integrated Genedrive/Beckman Coulter solution will be introduced in selected, relevant geographies subject to validation and any required regulatory approvals.

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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.

About Beckman Coulter Life Sciences <https://www.beckman.com/>

Beckman Coulter Life Sciences has helped establish test sites globally for a broad range of customer sizes and testing requirements. We are dedicated to advancing and optimizing the laboratory. For more than 80 years, we have been a trusted partner for laboratory professionals, helping to advance scientific research and patient care. We have a vital role: our focus on innovation, reliability and efficiency has led us to become the partner of choice for clinical, research and industrial customers around the globe.

RNAAdvance Viral XP is listed as an extraction method for use with the Centers for Disease Control's EUA-authorized COVID-19 test referenced in FDA's FAQ on testing for SARS-CoV-2. Other than this designation, RNAAdvance Viral XP is for research use, and not intended for diagnostic purposes