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

Genedrive® 96 SARS-CoV-2 Kit verified with Beckman Coulter Life Sciences RNA extraction chemistry

genedrive plc (LSE: GDR), the near patient molecular diagnostics company, announces that the Company has completed initial testing of Beckman Coulter Life Sciences’ RNAdvance Viral RNA extraction chemistry on respiratory swabs in conjunction with its COVID-19 PCR test. The sensitivity in using the Genedrive Kit with samples from upper respiratory swabs is equivalent to the existing Genedrive SARS-CoV-2 Kit specification claim, indicating the Beckman product is suitable for use in the Genedrive testing workflow. The Beckman RNAdvance kit has now been added to the Genedrive 96 SARS-CoV2 Instruction for Use as a validated extraction protocol for swabs. This is an important technical milestone in transitioning the Genedrive® 96 SARS-CoV-2 Kit to a fully automated workflow using Beckman’s RNA extraction and Biomek automated workstation.

The Genedrive Beckman collaboration seeks to fully automate the entire laboratory PCR testing process for COVID-19 PCR. The two companies are continuing to validate the Genedrive® 96 SARS-CoV-2 Kit on the Biomek i7 automated workstation with both saliva and respiratory swab specimens extracted using Beckman Coulter Life Sciences’ RNAdvance viral extraction chemistry. While saliva is potentially a more difficult sample type compared to upper respiratory swabs, work completed to date has been very promising and the Company remains confident that it could be validated with clinically acceptable performance.

David Budd, Chief Executive Officer of genedrive plc, said *“We have a collaboration agreement with Beckman Coulter which includes genedrive validating the analytical parameters of the combined companies’ offerings, and Beckman Coulter establishing the mechanics and automation of the overall workflow. Once our product performance is established, we plan to introduce the overall solution in stages, beginning with swab-based claims and then transitioning to saliva claims thereafter. The FDA places specific prospective clinical performance requirements on validation of saliva samples, which will take additional time. Our initial US evaluation site is currently being installed following the completion of our internal validation studies, after which they will validate the end-to-end solution as required. We will obtain regulatory approvals prior to a final solution release.”*

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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.

Disclaimer - BEC Products are for research use and not validated for use in diagnostic procedures.