Eurofins Announces the launch of an At-Home COVID-19 PCR Test kit available direct to consumers, without prescription

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Eurofins's Clinical Enterprise, Inc. announces that it has received US Food and Drug Administration Emergency Use Authorization (EUA) for a direct-to-consumer (DTC) version of its EmpowerDX COVID-19 Home Collection Kit.

The Eurofins at-home COVID-19 nasal PCR kit is among the first over-the-counter at-home test kits for SARS-CoV-2 to receive EUA. With this authorization, Eurofins is able to sell the test kit directly to consumers without prescription.

The kit is currently available through Eurofins' subsidiary, empowerDX. The at-home test kits can be easily ordered online for $99 at empowerdxlab.com, and are also available in pharmacies across the U.S.

The at-home COVID-19 test kit includes step-by-step instructions, a shallow nasal swab, test tube and a pre-paid FedEx package for the easy return of samples. Customers will receive their results to a secure patient portal within 48 hours.

This test was developed by Eurofins Viracor, a leading infectious disease testing laboratory, and is based on its FDA EUA authorized SARS-CoV-2 RT-PCR assay. That assay is ranked one of the most sensitive of the 117 tests evaluated by the FDA SARS-CoV-2 Reference Panel[1].

Eurofins' CEO, Gilles Martin commented: "This product has the potential to significantly increase population testing rates and help build confidence to accelerate the return of everyday life. We are also working very closely with European authorities for the approval of similar direct-to-consumer products."

This home-collection kit has not been FDA cleared or approved; rather it has been authorized by FDA under an EUA only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, and not for any other viruses or pathogens, and only for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Notes to Editors:

For more information, please visit empowerdxlab.com, eurofins.com **or contact:**

Annemarie Watson
ir@eurofins.com

[1] https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data#results

About Eurofins – the global leader in bio-analysis

Eurofins is Testing for Life. Eurofins is the global leader in food, environment, pharmaceutical and cosmetic product testing and in agroscience Contract Research Organisation services. Eurofins is one of the market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, advanced material sciences and in the support of clinical studies, as well as having an emerging global presence in Contract Development and Manufacturing Organisations. The Group also has a rapidly developing presence in highly specialised and molecular clinical diagnostic testing and in-vitro diagnostic products.

With over 50,000 staff across a decentralised and entrepreneurial network of more than 800 laboratories in over 50 countries, Eurofins offers a portfolio of over 200,000 analytical methods to evaluate the safety, identity, composition, authenticity, origin, traceability and purity of a wide range of products, as well as providing innovative clinical diagnostic testing services and in-vitro diagnostic products.

The Group's objective is to provide its customers with high-quality services, innovative solutions and accurate results on time. Eurofins is ideally positioned to support its clients' increasingly stringent quality and safety standards and the increasing demands of regulatory authorities as well as the requirements of healthcare practitioners around the world.

In 2020, Eurofins reacted quickly to meet the global challenge of COVID-19, by creating the capacity to help over 20 million patients monthly who may have been impacted by the pandemic with our testing products and our services and directly supporting healthcare professionals working on the front line to fight the virus. The Group has established widespread PCR testing capabilities and has carried out over 15 million tests in its own laboratories, is supporting the development of a number of vaccines and has established its SAFER@WORK™ testing, monitoring and consulting programmes to help ensure safer environments during COVID-19.

Eurofins has grown very strongly since its inception and its strategy is to continue expanding its technology portfolio and its geographic reach. Through R&D and acquisitions, the Group draws on the latest developments in the field of biotechnology and analytical chemistry to offer its clients unique analytical solutions.

Shares in Eurofins Scientific are listed on the Euronext Paris Stock Exchange (ISIN FR0014000MR3, Reuters EUFI.PA, Bloomberg ERF FP).

Until it has been lawfully made public widely by Eurofins through approved distribution channels, this document contains inside information for the purpose of Regulation (EU) 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, as amended.

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