Eurofins' empowerDX at-home COVID-19 testing kit receives EUA for children three years and older

21 May 2021

Clinical Enterprise Inc., d/b/a empowerDX, a Eurofins Scientific company, announces its at-home COVID-19 testing kit has received FDA-emergency use authorization for children three years and older. The direct-to-consumer company is the first to receive an EUA for an at-home nasal PCR test for young children. empowerDX launched its FDA-authorized at-home COVID test in Q3 of 2020 to consumers 18 years and older. The company's tests are now available without a prescription on empowerdxlab.com, Amazon, RiteAid as well as via Uber's on-demand delivery service.

Easy, convenient, and painless testing options for children remain a crucial part of monitoring and slowing the spread of the virus – especially for those kids attending schools, summer camps, and indoor sports facilities.

The empowerDX test is one of the most sensitive at-home COVID tests on the market [1]. Eurofins Viracor, an infectious disease testing laboratory for more than 35 years, developed the empowerDX test based on its own FDA emergency-use authorized SARS-CoV-2 RT-PCR assay.

The Eurofins U.S. Clinical Diagnostics group of companies has been at the forefront of COVID-19 testing – launching its first RT-PCR assay for SARS-CoV-2 on March 13, 2020. The Eurofins' SARS-CoV-2 assay menu now includes diagnostic tests, as well as environmental monitoring assays, such as wastewater, air, and saliva tests.

This at-home testing kit not been FDA cleared or approved, but has been authorized by the FDA under an Emergency Use Authorization; it has been authorized 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.

For further information, please visit empowerDXlab.com or contact:
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About empowerDX

empowerDX is the online shop for easy at-home health testing. empowerDX specializes in FDA-authorized COVID-19 testing, women's health, men's health, sexual health and general wellness testing. Along with its affiliated CLIA-certified clinical laboratories in the U.S., empowerDX is positioned to lead the market for cutting edge, self-collected diagnostic and non-diagnostic testing.

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

Welcome to health clarity with just a few clicks. The company is based outside of Boston, in Framingham, MA. To learn more, please visit empowerDXlab.com.

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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