



## **Eurofins U.S. Clinical Diagnostic Laboratories Partner with Insurance Providers to Cover FDA-Authorized At-Home COVID-19 Test**

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Eurofins announces that its FDA-authorized At-Home COVID-19 Nasal PCR Test is now being covered by Medicare, Medicaid and commercial insurance providers. The Emergency Use Authorization (“EUA”) authorized self-collection kit gives consumers a minimally invasive, convenient and quick option to test from the comfort of their home. Results are provided via email link within 24 hours of sample receipt.

Available through the Eurofins at-home health testing company, Clinical Enterprise Inc., through its empowerDX business line, the At-Home test can be ordered online (<https://empowerdxc.com/>) and will ship to your home or business. After completing a questionnaire, qualified consumers will receive the sample collection kit via FedEx. Patients who are enrolled in Medicare, Medicaid, or other valid third-party health insurance and meet qualifying COVID-19 exposure and symptomatic criteria, may be eligible for full coverage with no out of pocket costs. EmpowerDX allows patients to input their insurance information online for a seamless ordering and payment experience, or they can alternatively choose the \$99.00 out-of-pocket option.

Eurofins’ infectious disease center for excellence, Viracor, developed the test based on its highly sensitive, FDA EUA-authorized SARS-CoV-2 RT-PCR assay. Viracor’s SARS-CoV-2 assay offers the best sensitivity of the 118 laboratories that have submitted results to FDA’s SARS-CoV-2 Reference Panel, with a limit of detection of 180 NAAT Detectable Units/mL<sup>1</sup>.

The Eurofins U.S. clinical diagnostics network has been at the forefront of COVID-19 testing – launching its first RT-PCR assay for SARS-CoV-2 on March 13. Since then, Eurofins has rolled out several highly sensitive and specific assays to thousands of clients nationwide, including hospitals, physicians’ offices, nursing homes, government entities, sports organizations and employers. At-Home COVID-19 testing adds additional capability, alongside pooled, antibody, wastewater, used-mask, saliva and combined COVID-19, Influenza and RSV tests.

Concurrent to ongoing COVID-19 assay innovation, Eurofins has increased capacity throughout its network of labs to ensure sufficient capacity is available for consistency of turnaround time should COVID-19 infections continue to increase in the upcoming weeks. Since March, Eurofins US clinical diagnostic testing capacity has ramped up to over 500,000 samples per week. Recent turnaround time for results has averaged less than 18 hours from specimen receipt in the lab.

This home-collection kit has not been FDA cleared or approved; rather it has been authorized by FDA under an EUA only for the self-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 in medical devices during the COVID-19 outbreak under Section 564(b)(1) of the Federal Food, Drug and Cosmetic

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<sup>1</sup> <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data>

Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The At-Home COVID-19 Nasal PCR Test is currently not available for those patients residing in the States of New York, New Jersey, Rhode Island, and Maryland.

#### Notes to Editors:

For more information, please visit [www.eurofins.com](http://www.eurofins.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. Armed with an exclusive consortium of CLIA-certified and CDC-regulated clinical laboratories in the US, empowerDX is positioned to lead the market for cutting edge, self-collected diagnostic and non-diagnostic testing. All clinical tests are reviewed by their licensed ordering physician to eliminate the need for a phlebotomist or a telemedicine-observed sample collection. 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](http://empowerdxlab.com).

#### About Eurofins – the global leader in bio-analysis

Eurofins Scientific, through its subsidiaries (hereinafter "Eurofins" or "the Group"), believes it is the global leader in food, environmental, pharmaceutical and cosmetics products testing and in agrosience CRO services. It is also one of the global independent market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, CDMO, advanced material sciences and in the support of clinical studies. In addition, Eurofins is one of the leading global emerging players in esoteric and molecular clinical diagnostic testing. With over **50,000 staff** across a network of more than 900 independent companies in over **50 countries** generally specialised by end client markets and operating more than **800 laboratories**, 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. The Group's objective is to provide its customers with high-quality and innovative services, accurate results on time and, when requested, expert advice by its highly-qualified staff.

Eurofins is committed to pursuing its dynamic growth strategy by expanding both 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 and a very large range of testing methods.

As one of the most innovative and quality-oriented international groups in its industry, Eurofins is ideally positioned to support its clients' increasingly stringent quality and safety standards and the increasing demands of regulatory authorities and healthcare practitioners around the world.

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