



## LumiraDx Five-Minute SARS-CoV-2 Ag Ultra Test Achieves CE Marking

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- Results in just 5 minutes from sample application, aids in fast clinical decision-making at point of care (POC), helping to inform treatment decisions and prevent the further spread of infection, while also increasing testing throughput
- Run on the multi-assay LumiraDx Platform, the Ultra Test's innovative strip design builds on the company's microfluidic immunofluorescence technology enabling faster reaction times without sacrificing sensitivity
- Available on the same POC Platform as LumiraDx's high sensitivity SARS-CoV-2 Antigen, Flu A/B, SARS-CoV-2 Antibody, SARS-CoV-2 Antigen Pool as well as INR, D-dimer and CRP tests\*

LONDON, May 19, 2022 /PRNewswire/ -- LumiraDx Limited (Nasdaq: LMDX), a next-generation point of care diagnostics company, today announced its [SARS-CoV-2 Ag Ultra Test](#) achieved CE Marking. The Ultra test provides digital and connected results in just five minutes with high sensitivity, making it one of the fastest and most sensitive COVID-19 antigen tests available. The reduced time allows clinicians to treat patients much faster, and increases throughput on the LumiraDx Platform, now enabling users to complete up to 80 SARS-CoV-2 Antigen tests per eight-hour day, or up to 10 per hour, on a single LumiraDx Instrument.



Advancements made with the Ultra test strip design reflect the company's continued innovation of its microfluidic immunofluorescence technology, allowing for higher sample volumes to enter the test strip chambers to increase detection levels, achieve faster reaction times and even greater precision. This new technology is run on the existing LumiraDx Platform and can be applied to future Platform tests.

The LumiraDx SARS-CoV-2 Ag Ultra Test matches the same high-performance of the LumiraDx SARS-CoV-2 Ag 12 min test. The test has a positive percent agreement of 92.7% and a negative percent agreement of 100% versus RT-PCR in symptomatic individuals, based on clinical data collected 0-12 days since symptom onset. Within this cohort, The LumiraDx SARS-CoV-2 Ag Ultra test showed high sensitivity of 97.4% up to a CT of 35 indicating high coverage of potentially infectious individuals.

In addition, the LumiraDx SARS-CoV-2 Ag Ultra Test demonstrated 95.7% positive agreement versus RT-PCR in samples collected from asymptomatic individuals. With the Omicron variant showing a much higher rate of asymptomatic carriage compared to other variants, the high sensitivity of the LumiraDx SARS-CoV-2 Ag Ultra Test can be an important tool in breaking the chain of transmission.<sup>1</sup>

Ron Zwanziger, LumiraDx's Chief Executive Officer explained, "Our SARS-CoV-2 Ag Ultra Test exemplifies our mission to increase access to testing and provide rapid diagnostics without sacrificing accuracy. Now, clinicians, pharmacies and other providers can use a single platform and significantly

increase throughout, making a profound impact on patient workflow supported by our Platform. This innovation and advancement of our Microfluidic technology can also be applied to other tests on our Platform which we look forward to rolling out in the coming year."

Professor Jean-Paul Cristol, Head of the Division of Biology Pathology at Montpellier University Hospital Center commented, "The LumiraDx SARS-CoV-2 Ag Test has been integrated in testing strategy in our institution's adult, pediatric, obstetric and neurology emergency departments since this January. The clinical accuracy allows us to detect symptomatic and non-symptomatic patients and the traceability of the results is ensured by the connection to our middleware. In the emergency department, time is everything and being able to provide these results in a shortened time can be critical. A high-sensitivity, good traceability, and faster test will be an optimal option to screen patients in emergency departments."

The [SARS-CoV-2 Ag Ultra](#) test follows the successful launch of LumiraDx's SARS-CoV-2 Antigen test which has been commercially available for nearly two years.

### **About LumiraDx**

LumiraDx (Nasdaq: LMDX) is a next-generation point of care diagnostics company that is transforming community-based healthcare. Founded in 2014, LumiraDx manufactures and commercializes an innovative diagnostic Platform that supports a broad menu of tests with lab comparable performance at the point of care. LumiraDx diagnostic testing solutions are being deployed by governments and leading healthcare institutions across laboratories, urgent care, physician offices, pharmacies, schools, and workplaces to screen, diagnose, and monitor wellness as well as disease. LumiraDx has, on the market and in development, 30+ tests covering infectious diseases, cardiovascular diseases, diabetes, and coagulation disorders, all on the LumiraDx Platform. In addition, LumiraDx has a comprehensive portfolio of fast, accurate, and cost-efficient COVID-19 testing solutions from the lab to point of need.

LumiraDx is based in the UK with more than 1600 employees worldwide. Further information on LumiraDx and the LumiraDx Platform is available at [www.lumiradx.com](http://www.lumiradx.com)

### **Cautionary Note Regarding Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, including statements regarding the performance and benefits of the SARS-CoV-2 Ag Ultra test. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements, including, among others, general economic, political and business conditions; the effect of COVID-19 on LumiraDx's business and financial results; maintaining CE marking for the SARS-CoV-2 Ag Ultra test and those factors discussed under the header "Risk Factors" in the Annual Report on Form 20-F for the year ended December 31, 2021, which was filed by LumiraDx with the Securities and Exchange Commission ("SEC") on April 13, 2022, and other filings made by LumiraDx with the SEC. Although LumiraDx believes that it has a reasonable basis for each forward-looking statement contained in this press release, LumiraDx cautions you that these statements are based on a combination of facts and factors currently known by it and its projections of the future, about which it cannot be certain. LumiraDx undertakes no obligation to update or revise the information contained in this press release, whether as a result of new information, future events or circumstances or otherwise.

\* Not all tests are available in all countries and regions. For additional detail on product availability please visit [www.lumiradx.com](http://www.lumiradx.com).

1 Garrett N, Tapley A, Andriesen J, et al. High Rate of Asymptomatic Carriage Associated with Variant Strain Omicron. Preprint. *medRxiv*. 2022;2021.12.20.21268130. Published 2022 Jan 14. doi:10.1101/2021.12.20.21268130

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