

miDiagnostics launches its CE-IVD certified ultra-fast COVID-19 PCR test

LEUVEN, BELGIUM, May 2, 2022

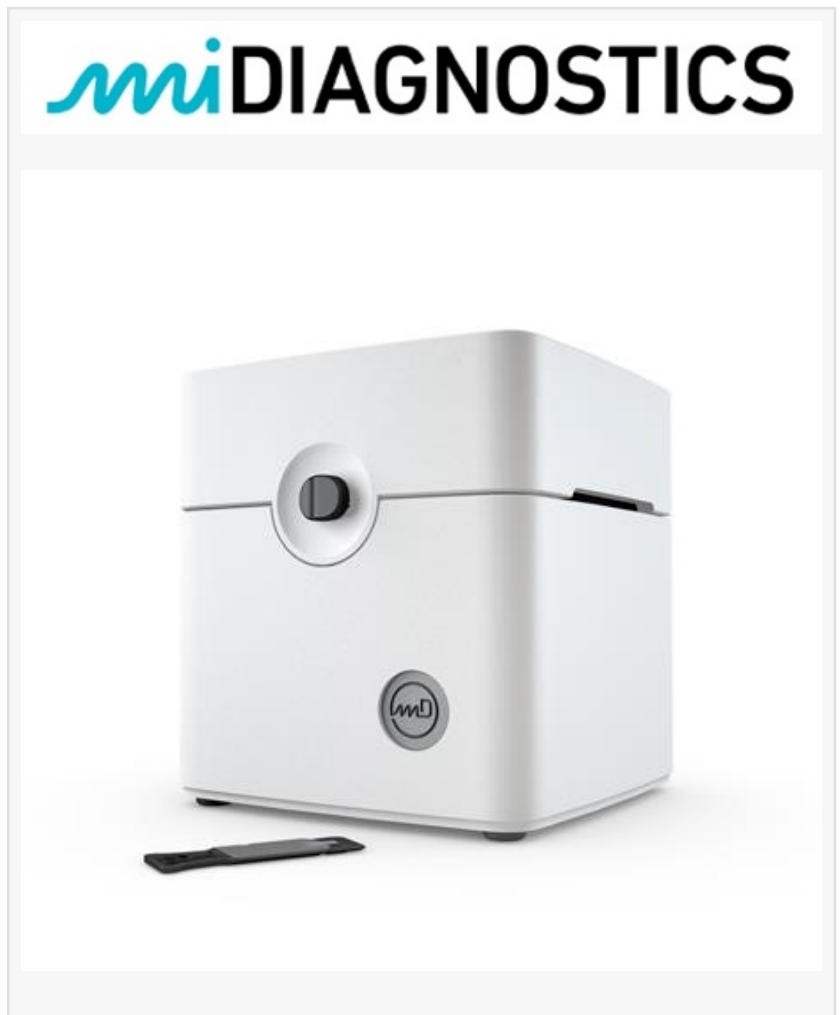
/EINPresswire.com/ -- miDiagnostics, a fast-growing POC diagnostics company announces the launch of its CE-IVD certified ultra-fast COVID-19 PCR test. The test is now available for use across Europe and other countries that accept CE-IVD marking, providing a powerful pandemic and endemic management tool in industries where fast and reliable decentralized testing is crucial. With the launch of its first product, miDiagnostics enters the commercial phase, marking an important milestone in the company's development.

Ultra-fast and reliable COVID testing on a micro-chip

miDiagnostics' COVID-19 PCR test is based on unique silicon chip technology from imec (Leuven, Belgium) and developed in close

collaboration with Johns Hopkins University. The miniaturization of the RT-qPCR process makes it possible to diagnose COVID-19 infections with the accuracy, sensitivity, and reproducibility of a traditional PCR test, but with the convenience and speed of an antigen test. Within 30 minutes of registering on site, patients receive their result, with the real-time PCR itself taking less than 15 minutes.

The test's workflow is extremely simple: after a nasopharyngeal swab, the sample is dissolved in a buffer solution, mixed with detection mix, loaded onto a PCR card, and processed in a compact reader that performs ultra-fast temperature cycling and optical detection. The risk of cross-contamination is minimized thanks to the use of disposable PCR cards.



The performance of the new ultra-fast PCR test was confirmed in a large independent clinical study, led by Prof. Dr. Jan Verbakel of KU Leuven (Belgium). A total of 766 study subjects were tested for SARS-CoV-2 with both miDiagnostics' test and a traditional RT-PCR used in a centralized setting. Over 300 of these subjects were found to be SARS-CoV-2 positive, representing a broad range of viral loads (expressed as the Ct or "cycle threshold" value of the test). miDiagnostics' test showed excellent equivalence with the results obtained from the reference method.

A powerful tool for pandemic management

Since the start of the pandemic, testing has proven to be key to enabling restrictions to be eased. Even entering the endemic phase, routine testing and surveillance for SARS-CoV-2 will remain important. Traditional PCR tests performed in a central lab are very accurate, but take a long time to complete, and rapid antigen tests are fast but lack sensitivity and accuracy. This has driven the demand for rapid decentralized PCR testing, performed in satellite laboratories at the point of care or in locations where there is a need for on-demand testing, like airports, large corporations, UCI / ED settings in hospitals etc.

The current CE-IVD marking means miDiagnostics' COVID-19 test is now available for use by lab professionals in all countries that accept CE-IVD. Its optimized workflow, compact design, and ultra-fast and reliable results make it optimally suited for use in a decentralized testing approach. For example, its added value in the travel sector was demonstrated recently in the successful pilot study performed at Brussels Airport.

Katleen Verleysen, CEO of miDiagnostics: "The launch of our COVID-19 PCR test is a very important milestone as it marks the transition of miDiagnostics into a commercial organization. All attention and focus are now shifting towards the scale-up and production of enough tests to cater to the market demand as well as menu expansion, starting with the addition of influenza A/B and RSV."

Jan Verbakel, Professor at KU Leuven and Principal Investigator of the clinical study: "Molecular diagnostics has been essential in the global response to the COVID-19 pandemic. In our performance evaluation study, we found that this new point-of-care SARS-CoV-2 assay, which delivers a result in 12 minutes, has a diagnostic accuracy comparable to that of lab-grade equipment. This technology could aid the management of outbreaks in challenging settings, such as nursing homes and home care environments, allowing healthcare professionals to adjust their management decisions at the point of care. I would like to thank Dr David Bos and the rest of my team at KU Leuven for their support in conducting this study."

About miDiagnostics

miDiagnostics is a medical devices company with the mission to provide a comprehensive range of health screening tools that will eventually grant diagnostic access for everyone, everywhere, and at any time. This is achieved by miniaturizing and simplifying the diagnostics process using silicon chips, developed by imec (the Belgian world-leading R&D and innovation hub in nanoelectronics and digital technologies) in collaboration with Johns Hopkins University (the leading US research and medical centre).

The company is developing a molecular diagnostics pipeline, using its ultra-fast PCR technology for the diagnosis of SARS-CoV-2, with menu expansion possibilities towards other respiratory indications, sexual transmitted diseases and any other molecular test that could merit the benefits of decentralization, diagnostic accuracy, and ease of use. In parallel, portable cellular diagnostic devices are being developed, which could ultimately be used in the home setting (i.e., complete blood count monitoring). These include a nanofluidic processor for blood sample preparation and lens-free imaging for cell counting and characterization.

miDiagnostics is a privately held company based in Leuven (Belgium), founded in 2015. Follow miDiagnostics on LinkedIn, Twitter, Facebook and on [midiagnostics.com](https://www.midiagnostics.com).

Rita Prota

Turnstone Communications BV

+33 6 15 95 00 62

[email us here](#)

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