

Siemens Healthineers Releases Test Kit for Coronavirus COVID-19

- **Siemens Healthineers test kit will help detect SARS-CoV-2, the cause of COVID-19**
- **Company is pursuing Emergency Use approvals from WHO and FDA for clinical use**

Siemens Healthineers announced today the availability of its molecular Fast Track Diagnostics (FTD) SARS-CoV-2 Assay test kit used to aid in the diagnosis of infection by the SARS-CoV-2 virus that causes the COVID-19 disease. Test kits are already being shipped within the European Union for research use only (RUO) to expedite availability while the company continues to pursue Emergency Use Assessment and Listing (EUAL) from the World Health Organization (WHO) for clinical use. In addition, Siemens Healthineers has begun discussions with the U.S. Food and Drug Administration (FDA) for release of the test under Emergency Use Authorization (EUA). Both applications are in progress. While the controlled roll-out of the assay for research use is continuing, Siemens Healthineers is simultaneously expanding its production capacity.

“With this molecular diagnostic assay, we want to make a contribution to fight the current COVID-19 global pandemic by delivering fast and accurate SARS-CoV-2 testing,” said Sebastian Kronmueller, Head of Molecular Diagnostics at Siemens Healthineers. “The Siemens Healthineers assay is designed to help researchers positively identify the virus in less than three hours so that healthcare professionals can proceed as quickly as possible with the necessary next steps on their patients’ triage paths.”

Many molecular assays detect the presence of viral ribonucleic acid (RNA), determining the presence of the targeted virus directly in the patient sample. In this way, molecular testing is effective early in the lifecycle of the virus and is thus efficient in urgent testing situations, such as global pandemics. After regulatory approval, the commercial roll-out of the assay is intended in the U.S. and Europe.

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The FTD SARS-CoV-2 Assay has been optimized on the Biomerieux EasyMag Extraction System and the Applied Biosystems 7500 Real-time PCR Thermocycler* and utilizes the same workflow, including PCR profile, as other FTD Respiratory Disease kits from Siemens Healthineers. It can be run in laboratories simultaneously with FTD Respiratory Pathogens 21**, a molecular syndromic testing panel from Siemens Healthineers that identifies 21 different upper respiratory pathogens that can cause acute respiratory infections.

The FTD SARS-CoV-2 Assay was developed by Fast Track Diagnostics, a Siemens Healthineers Company, in Esch-sur-Alzette, Luxembourg. Fast Track Diagnostics was acquired by Siemens Healthineers at the end of 2017.

For more information, visit: siemens-healthineers.com/ftd-sars-cov-2-assay

**For research use [for more information on FTD assays](#)*

***CE-IVD labelled for diagnostic use in the EU.*

Product availability varies by country and is subject to local regulatory requirements.

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Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostic, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers' ability to provide high-quality, efficient care to patients. In fiscal 2019, which ended on September 30, 2019, Siemens Healthineers, which has approximately 52,000 employees worldwide, generated revenue of €14.5 billion and adjusted profit of €2.5 billion. Further information is available at www.siemens-healthineers.com.