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Siemens Healthineers releases test kit for COVID-19

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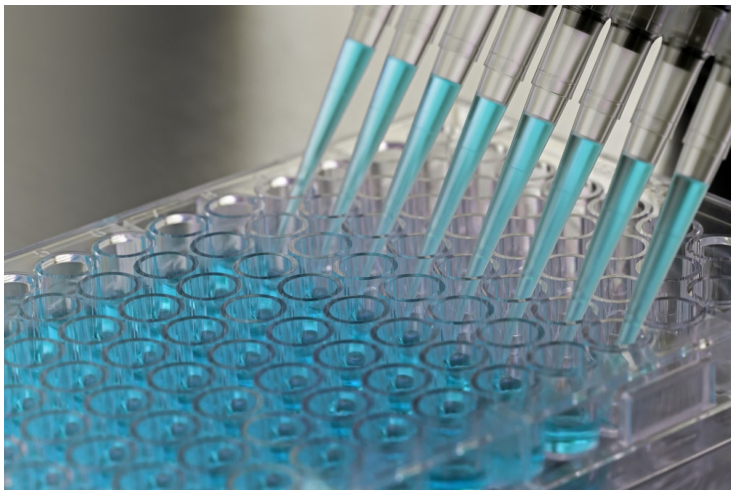
Company is pursuing Emergency Use approvals from WHO and FDA for clinical use



Siemens Healthineers has announced 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.

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.