

Siemens Healthineers Starts Delivery of Test Kit for Corona virus SARS-CoV-2, Now CE-IVD Registered

- **Test Kit Registered and Available for Diagnostic Use in EU**
- **CE labelling allows for molecular diagnostic test kit to be used in clinical practice**
- **Test has shown 100% (91.8-100, 95% CI) diagnostic sensitivity and 100% (93.8-100, 95% CI) diagnostic specificity¹.**

Siemens Healthineers registered its molecular Fast Track Diagnostics (FTD) SARS-CoV-2 Assay² test kit for diagnostic use with the Luxembourg Ministry of Health. This registration of the kit, which was released for research use only (RUO) on April 2, 2020, allows for immediate rollout of the testing kit for diagnostic use in Europe.

The test has shown 100% (91.8-100, 95% CI) diagnostic sensitivity and 100% (93.8-100, 95% CI) diagnostic specificity¹. Sample-to-answer time, including extraction and generating the result, takes 2-3 hours, depending on the molecular system and lab resources employed. Up to 32 patient samples can be analyzed per kit.

The company plans to ship more than 1.3 million tests per month worldwide as production capacity increases in May 2020. The FTD SAR-CoV-2 Assay can be run in laboratories simultaneously with FTD Respiratory Pathogens 21³ and FTD FLU/HRSV³, molecular syndromic testing panels from Siemens Healthineers that identify a wide range of pathogens that can cause acute respiratory infections.

“Having our molecular assay available for diagnostic use throughout the European Union is a major step forward in our contribution to the fight against the global pandemic,” said Deepak Nath, PhD, President, Laboratory Diagnostics, Siemens Healthineers. “I am grateful for the work and achievement of our Siemens Healthineers teams under difficult

circumstances, and I hope our clinical test will help the healthcare professionals who are working on the frontlines of the pandemic and those affected by COVID-19.”

The company is also working to expand its infectious disease testing capabilities to address the COVID-19 pandemic in other areas of diagnostics. On April 23, the company announced it is developing a SARS-CoV-2 serology assay⁴ to detect IgM and IgG antibodies in blood, helping indicate whether a person has developed immunity against SARS-CoV-2. An antibody test can reveal if a person had COVID-19 even if they were asymptomatic or never diagnosed with the disease.

¹ In method comparison studies, FTDSARS-CoV-2 has shown 100% (91.8-100, 95% CI) diagnostic sensitivity and 100% (93.8-100, 95% CI) diagnostic specificity when tested in Copan eSwab nasopharyngeal and oropharyngeal swabs.

² CE-IVD labelled for diagnostic use in the EU. For research use only (RUO) in the U.S. Pursuing FDA emergency use authorization (EUA) and WHO emergency use listing (EUL).

³ CE-IVD labelled for diagnostic use in the EU. For research use only (RUO) in the U.S.

⁴ Under development. Not available for sale. Future availability cannot be guaranteed.

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

This press release and a press picture is available at <https://www.siemens-healthineers.com/press-room/press-releases/test-kit-for-coronavirus-covid-19-ce-ivd.html>.

For further information, please see

<https://www.siemens-healthineers.com/molecular-diagnostics>.

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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.