

Thermo Fisher Scientific Receives CE Mark for its Diagnostic Test to Detect COVID-19

**Test will now be available for qualified laboratories across the European Union
Company provides update on other designated approvals received to date**

WALTHAM, Mass., March 26, 2020 /PRNewswire/ -- Thermo Fisher Scientific Inc. (NYSE:TMO), the world leader in serving science, today announced that it has received the CE mark in the European Union for its diagnostic test to detect nucleic acid from SARS-CoV-2, the virus that causes COVID-19.

"The CE mark certification is an important step in combatting the outbreak of COVID-19 across Europe," said Marc N. Casper, chairman, president and chief executive officer of Thermo Fisher Scientific. "We are committed to fighting this disease and we will continue to work with regulatory authorities and customers around the world to expand the availability of diagnostic testing and stem the spread of the coronavirus."

The Thermo Fisher test, which uses Applied Biosystems TaqPath Assay and real-time PCR technology, is designed to provide patient results within four hours of a sample being received by a lab. The estimated time-to-result also includes time for sample preparation and instrument analysis.

This CE mark represents Thermo Fisher's assurance that its test complies with the European Union's *In vitro* Diagnostic Directive, which applies to products that are manufactured in or designed to be sold in the European Economic Area¹.

For more information about the CE-marked test, visit www.thermofisher.com/covid19ceivd

Update on Other Designated Approvals

Thermo Fisher Scientific received Emergency Use Authorization by the U.S. Food and Drug Administration for its COVID-19 test on March 13, 2020. This authorization was amended on March 24, 2020, to include additional instruments, such as the company's Applied Biosystems 7500 Fast Real-Time PCR System. This expands testing capabilities in the U.S. from approximately 1,000 instruments to more than 3,000 instruments on which Thermo Fisher's diagnostic test can be run. The expansion also includes manual sample extraction using the MagMax Viral/Pathogen Nucleic Acid Isolation Kit as well as Applied Biosystems COVID-19 Interpretive Software.

In addition to receiving the designated approvals in the U.S. and E.U., Thermo Fisher's diagnostic test has received the designated approvals in Canada, Singapore, India, Australia and New Zealand.

Thermo Fisher has created an online resource to make it easier to find up-to-date information about its response to the COVID-19 pandemic, including availability of its diagnostic test kits. Please refer to <https://corporate.thermofisher.com/en/COVID-19.html> for current news, information and frequently asked questions about COVID-19-related products and services that are vital to researchers, labs, healthcare workers and first responders worldwide.

About Thermo Fisher Scientific

Thermo Fisher Scientific Inc. is the world leader in serving science, with annual revenue exceeding \$25 billion. Our Mission is to enable our customers to make the world healthier, cleaner and safer. Whether our customers are accelerating life sciences research, solving complex analytical challenges, improving patient diagnostics and therapies or increasing productivity in their laboratories, we are here to support them. Our global team of more than 75,000 colleagues delivers an unrivaled combination of innovative technologies, purchasing convenience and pharmaceutical services through our industry-leading brands, including Thermo

Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services and Patheon. For more information, please visit www.thermofisher.com.

1 The European Economic Area includes the EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the following countries: UK, Norway, Iceland, Liechtenstein, Switzerland and Turkey.

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