

Thermo Fisher receives CE mark for COVID-19 test

26 March 2020 | News

Test will now be available for qualified laboratories across the European Union



Thermo Fisher Scientific Inc., the world leader in serving science, has 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 Area.