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Thermo Fisher collaborates with WuXi Diagnostics

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Response to COVID-19 Expands to Include New Serology Test

Thermo Fisher Scientific Inc., the world leader in serving science, announced it will expand its response to the COVID-19 pandemic by developing a total antibodies test in collaboration with WuXi Diagnostics and Mayo Clinic.

The new test is the result of ongoing collaboration between all three organizations, including clinical evaluation and support from Mayo Clinic. Thermo Fisher will seek U.S. FDA Emergency Use Authorization (EUA) and international regulatory authorizations for the test over the next few weeks.

Once approved for use, the Thermo Scientific OmniPath COVID-19 Total Antibody ELISA test will detect Immunoglobulin M (IgM) and Immunoglobulin G (IgG) to help clinicians determine if a patient has been exposed to SARS-CoV-2. The test is designed to run on an open instrument platform, and the determination of antibody status will aid in the diagnosis of the disease during the acute and recovery stages of infection.

"Since the outbreak was first detected, we have mobilized our scientific, regulatory and commercial teams to support virus analysis, identification, deployment of personal protective equipment as well as development of therapies and vaccines," said Marc N. Casper, chairman, president and chief executive officer of Thermo Fisher Scientific. "Stopping the spread of COVID-19 requires comprehensive testing solutions, and we are very pleased to join forces with WuXi Diagnostics and Mayo Clinic to respond to the widespread need for antibody-based tests. Working together, we will now be able to provide governments, healthcare systems and communities with yet another important tool to aid in the fight against the pandemic."

The global call to ramp up testing requires a combination of both PCR-based molecular tests and serological tests. Molecular tests, such as Thermo Fisher's Applied Biosystems TaqPath Combo Kit, are considered the gold standard for determining if a patient has an active infection. Serological tests determine if a patient has antibodies to SARS-CoV-2 that indicate whether they have had – or still have – the virus and have built up an immune response. When used in combination, these tests provide greater clinical efficacy, support contact tracing and enhance epidemiological efforts to stop the spread of the virus.

Thermo Fisher will begin manufacturing the Thermo Scientific OmniPath COVID-19 Total Antibody ELISA test at its sites in

the U.S. and Europe in the next few weeks as it prepares to submit for EUA.

Jason Liu, Ph.D., chief executive officer of WuXi Diagnostics, said, "We are pleased to join forces with Thermo Fisher and Mayo Clinic in the battle against the pandemic. This global collaboration of R&D, clinical expertise, manufacturing and commercialization capability will significantly advance serological testing for COVID-19. WuXi Diagnostics offers an open-access platform for innovative diagnostic solutions. By collaborating with our partners, we're dedicated to supporting healthcare professionals and their patients around the world."