FDA expands EUA for TaqPath COVID-19 combo kit

April 14, 2021–Thermo Fisher Scientific announced the FDA has expanded emergency use authorization for the Applied Biosystems TaqPath COVID-19 Combo Kit to include the high-throughput Thermo Fisher Scientific Amplitude solution.

The Amplitude solution is a molecular diagnostic testing system that aims to help clinical labs expand their testing capacity by combining the company's extraction and real-time PCR instruments with liquid-handling products from the Tecan Group. The modular system uses a high-throughput version of Thermo Fisher's Applied Biosystems TaqPath COVID-19 Combo Kit, which received emergency use authorization in March 2020, to process samples in four steps. The platform can process up to 8,000 samples per day.

"While COVID-19 cases globally may be decreasing in some areas as vaccines become more widely available, there continues to be a demand for frequent routine testing to control future outbreaks," Mark Stevenson, executive vice president and chief operating officer of Thermo Fisher Scientific, said in a press release. "For population-wide testing programs, lab-based PCR is the best fitting technology, providing confidence in results, capacity to process thousands of samples a day, and consistent, reliable turnaround times. The Amplitude solution can help support a systematic testing strategy by enabling labs to quickly scale their testing and begin processing high-volume samples, even with limited personnel."

Testing with the Amplitude solution and the TaqPath COVID-19 combo kit is limited to CLIA-certified laboratories to perform high-complexity tests or by similarly qualified non-U.S. laboratories.