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ASIA EDITION

Thermo Fisher Amplitude Solution receives EUA from FDA

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The Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit enables laboratories to rapidly scale high-sensitivity PCR testing capacity



Thermo Fisher Scientific Inc. has announced on April 12, 2021 that the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorization (EUA) for the Thermo Fisher Scientific Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit.

The Amplitude Solution enables clinical and public health laboratories to scale gold standard PCR testing and process up to 8,000 samples in a single day with minimal staffing resources and a secured supply of kits, reagents and consumables to meet their testing needs. The Amplitude Solution has been implemented globally including labs in Europe and Japan.

Mark Stevenson, executive vice president and chief operating officer of Thermo Fisher Scientific. "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."

The Amplitude Solution is a molecular diagnostic testing system that helps clinical labs expand testing capacity by combining Thermo Fisher's extraction and real-time PCR instruments with liquid handling products from Tecan Group. The modular system utilizes a high-throughput version of Thermo Fisher's Applied Biosystems TaqPath COVID-19 Combo Kit, which received EUA in March 2020, to process samples in four steps with minimal hands-on time and laboratory space requirements. The kit's multi-gene target design and updated interpretive software may help labs detect SARS-CoV-2 variants.

The Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit has not been FDA cleared or approved and is only authorized for the duration of the EUA grant.