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Thermo Fisher receives FDA EUA nod for high-throughput COVID-19 test

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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 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 modular solution processes samples in a four-step process requiring minimum hands-on time, laboratory space and staffing resources. It was introduced as an automated real-time PCR test that can analyze up to 8,000 COVID-19 samples in a single day. It empowers clinical and public healthcare laboratories to scale gold standard PCR testing with minimal staffing needs and a secured supply of kits, reagents and consumables to meet the rising testing demands.

"India is experiencing a more intense second wave of COVID-19. This has compelled the country to take rigorous measures of ramping up testing capacity and adopt a nationwide testing regime. While a lab-based PCR test is the most suitable technology in terms of reliability, quick turnaround time and scalability, it still lacks the adequate testing volume to satisfy the status quo. With the approval of Amplitude Solution, Thermo Fisher can help to quickly double or even triple the country's testing capacity", said Amit Chopra, managing director, India and South Asia, Thermo Fisher Scientific.

The Amplitude Solution uses Thermo Fisher's Applied Biosystems TaqPath COVID-19 Combo Kit, a quick, highly sensitive multiplex diagnostic test that contains the assays and controls needed for the qualitative detection of nucleic acid from SARS-CoV-2, the virus responsible for causing COVID-19. The kit's multi-gene target design and updated interpretive software may help labs detect SARS-CoV-2 variants.

Speaking on the matter, Kapil Sood, senior director, life sciences solutions, Thermo Fisher Scientific, said, "With the onset of vaccination, there continues to be demand for frequent routine testing to control the outbreak. While each state conducts testing on different capacities, a new approach for scaling the testing volume is essential to safeguard human life. Our high-yielding, automated solution can help laboratories quickly scale COVID-19 testing to volumes needed to help reduce the spread of disease and restore economies and communities."