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Thermo Fisher's new Bengaluru facility to produce COVID-19 diagnostic solutions for India

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Applied Biosystems CoviPath COVID-19 RT-PCR Kit is approved for in vitro diagnostic use by ICMR and DCGI

A new state-of-the-art Thermo Fisher Scientific manufacturing facility in Bengaluru will produce COVID-19 testing kits and diagnostic solutions that are made in India for use in India. CoviPath COVID-19 RT-PCR Kit, which contains the assays and controls for Thermo Fisher's gold standard RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in individuals suspected of COVID-19.

The CoviPath COVID-19 RT-PCR Kit has been approved under MDR 2017 rules for in vitro diagnostic use by the Indian Council for Medical Research (ICMR) and Drug Control General of India (DCGI) in all authorised laboratories. Testing with the kit can be done on Applied Biosystems real-time PCR instruments with FAM dye, VIC dye, and JUN dye or any RT-PCR platform with three dye channels in molecular biology laboratories approved for testing. Samples are collected from nasopharyngeal swab, nasopharyngeal aspirate and bronchoalveolar lavage (BAL) specimens.

"The new facility is equipped with the capacity to manufacture up to 10 million tests every month. This facility will be instrumental in ensuring access to affordable testing kits while maintaining global quality standards," said Amit Chopra, Managing Director, India and South Asia, Thermo Fisher Scientific.

The CoviPath COVID-19 RT-PCR Kit is designed to detect viral targets with low mutations and offers more than 99.5 per cent sensitivity and 99.5 per cent specificity. The kit is packaged in a user- friendly and convenient pack size of 200 reactions.

"Thermo Fisher's local production facility will augment accessibility of testing kits across the country.", said Kapil Sood, Senior Director, Life Sciences Solutions, Thermo Fisher Scientific, India.

The Applied Biosystems CoviPath COVID-19 RT-PCR Kit is for use in India only.