BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

Fosun Pharma gets FDA EUA nod for COVID-19 detection kit

20 April 2020 | News

This kit can realize qualitative detection of novel coronavirus RNA targeting for its specific ORF1ab, N and E gene

Shanghai Fosun Pharmaceutical (Group) Co., Ltd has received emergency use authorization (EUA) from FDA for its COVID-19 RT-PCR detection kit.

The testing kit which was self-developed by Fosun Long March, a wholly-owned subsidiary of Fosun Pharma, has received the medical device registration certificate issued by the China National Medical Products Administration (NMPA) and granted CE certification from the European Union ("EU").

This kit can realize qualitative detection of novel coronavirus RNA targeting for its specific ORF1ab, N and E gene, and can complete the detection of 96 samples within two hours by supporting fast automatic nucleic acid extraction instrument and extraction reagents. In addition, automated testing will lower the risk of operator infection, reduce the probability of cross contamination in the clinical laboratory, and improve detection efficiency.