

ICMR sets fast track approvals for COVID-19 testing kits

24 March 2020 | News

This is in addition to the US FDA approved kits that are currently being in use



Indian Council of Medical Research (ICMR) has recommended two RT-PCR (Reverse transcription polymerase chain reaction) test kits for use in ICMR approved government and private laboratories.

These test kits have been found to have 100% concordance among true positive and true negative samples.

ICMR has established a fast-track mechanism for validation of non-US FDA EUA/CE IVD approved kits at ICMR NIV Pune.

ICMR NIV Pune has completed evaluation of 9 non-US FDA EUA/CE IVD kits. Only test kits with 100% concordance among true positive and true negative samples have been recommended for commercial use in India.

In addition to the above US FDA EUA/CE IVD approved kits can be used directly after due approval from DCGI and intimation to ICMR.

List of testing kits-

Altona Diagnostics - RealStar SARS-CoV-2 RT-PCR kit

MY LAB - Patho Detect

BGI - Real Time detecting 2019-nCoV

Krishgen Bio System - SARS-CoV-2 (RT-qPCR) Detection

ABI - TaqMan 2019-nCoV Control Kit

HIMEDIA - Hi -PCR Corona Virus (CoVId-19) Probe PCR

HUWEL - Quantiplus detection kit

IIT-Delhi SYBR Green based one step QRT-PCR

KILPEST (BLACKBIO) - TRUPCR