



Press Release

Fast Track Approval for Indian COVID-19 testing kits for commercial use

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

New Delhi, March 23, 2020: 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. The *details in annexure includes all the kits tests as on date.*

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 09 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.

About ICMR: ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. ICMR's research agenda align with the National health priorities. These efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. ICMR promotes biomedical research in the country through intramural as well as extramural research. Visit us at <https://icmr.nic.in/>

For more details:

Subject Specific

Dr Priya Abraham,
Director, ICMR – NIV Pune
Email: priya.abraham@icmr.gov.in
Ph. +91-20-25880982

Media Coordinator

Dr Lokesh Sharma, Scientist E
Email: sharma.lk@icmr.gov.in
Mobile: +91-7567311014

Annexure

Name of Company	Name of the Kit	Concordance among true positive (%)	Concordance among true negative (%)
Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	100%	100%
MY LAB	Patho Detect	100%	100%
BGI	Real Time detecting 2019-nCoV	100%	90%
Krishgen Bio System	SARS-CoV-2 (RT-qPCR) Detection	100%	80%
ABI	TaqMan 2019-nCoV Control Kit	100%	90%
HIMEDIA	Hi –PCR Corona Virus (CoViD-19) Probe PCR	100%	5%
HUWEL	Quantiplus detection kit	100%	40%
IIT-Delhi	SYBR Green based one step QRT-PCR	98%	10%
KILPEST (BLACKBIO) (BLACKBIO)	TRUPCR	100%	75%