Guidelines for use of commercial kits for nasal/throat swab based diagnosis of COVID-19 in India, 23 March, 2020

- Currently, RT-PCR probes for diagnosis of COVID-19 are procured from USA by ICMR-NIV and are distributed to the testing laboratories across the country
- ICMR welcomes use of commercial kits for diagnosis of COVID-19
- US FDA EUA/CE IVD approved kits can be used directly after due approval from DCGI and intimation to ICMR.
- ICMR has established a fast-track mechanism for validation of non US FDA EUA/CE IVD approved kits at ICMR NIV. Test kits with 100% concordance among true positive and true negative samples will be approved for commercial use in India
- ICMR NIV has completed evaluation of 9 non- US FDA EUA/CE IVD kits. The results of the validation are summarized in the following table

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 Fluorescent RT-PCR Kit for detecting 2019-nCoV	100%	90%
Krishgen Bio System	SARS-CoV-2 Coronavirus Real Time RT-PCR (RT-qPCR) Detection Kit v1	100%	80%
ABI	TaqMan 2019-nCoV Control Kit v1	100%	90%
HIMEDIA	Hi –PCR Corona Virus (CoViD-19) Probe PCR Kit	100%	5%
HUWEL	Quantiplus Coronavirus (2019nCoV) detection kit	100%	40%
IIT-Delhi	SYBR Green based one step QRT-PCR	98%	10%
KILPEST (BLACKBIO)	TRUPCR	100%	75%

(Sensitivity and specificity of the kits could not be calculated since there were no false positive and false negative samples)

- RT-PCR kits from Altona Diagnostics and MY LAB are approved for use by ICMR recommended government and private laboratories