

Guidelines for use of commercial kits for nasal/throat swab based diagnosis of COVID-19 in India, 28 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 **17** 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 negative (%)	Concordance among true positive (%)
1. Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	100%	100%
2. MY LAB	Patho Detect	100%	100%
3. BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	100%	90%
4. Krishgen Bio System	SARS-CoV-2 Coronavirus Real Time RT-PCR (RT-qPCR) Detection Kit v1	100%	80%
5. ABI	TaqMan 2019-nCoV Control Kit v1	100%	90%
6. HIMEDIA	Hi –PCR Corona Virus (CoViD-19) Probe PCR Kit	100%	5%
7. HUWEL	Quantiplus Coronavirus (2019nCoV) detection kit	100%	40%
8. IIT-Delhi	SYBR Green based one step QRT-PCR	98%	10%
9. KILPEST (BLACKBIO)	TRUPCR	100%	75%
10. Genesig	Coronavirus (COVID19) genesig Real Time PCR Assay	100%	84%
11. Roche	LightMix Modular SARS and Wuhan CoV E gene	91%	100%
12. Roche	LightMix Modular SARS and Wuhan CoV N gene	93%	67%
13. Roche	LightMix Modular Wuhan RdRp gene	100%	60%
14. Seegene	Allplex 2019-nCoV assay	100%	100%
15. SD Biosensor	nCoV Real-Time Detection kit	100%	100%
16. AmpliGene India Biotech	AmpEZ Covid -19 using real-time PCR machine	Inconclusive results. Needs further product development	
17. AmpliGene India Biotech	AmpEZ Covid -19 using Ampligene device	Inconclusive results. Needs further product development	

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

- ICMR recommends these results and the Central Drugs Standard Control Organization (CDSCO) has been intimated.