

Performance evaluation of commercial kits for detection of SARS-CoV-2 RNA by Real Time PCR**Validation by ICMR institutes**

Till date, 45 real-time PCR kits have been validated by ICMR validation centres, and the following were found to be satisfactory. 10 of these companies are from India.

S. No	Name of Company	Name of the Kit	*Batch number
1	Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
2	MY LAB	Patho Detect	PP00005-C-032001 PP00005-C-0420001 PP00005-C-0320002
3	Seegene	Allplex 2019-nCoV assay	RP4520A01
4	SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004
5	KILPEST (BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	COV-19/V2/2020/01
6	Huwel Lifesciences	Quantiplus CoV detection kit ver 2.0	QLCNAV0620
7	BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
8	ABI (Applied bio systems)	TaqMan 2019-nCoV Control Kit v1	47532-020720
9	Medsorce Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
10	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID 19] Real-time PCR kit	01/2020 MFD: 04/2020
11	ADT Biotech Sdn Bhd, Malaysia	LyteStar 2019 nCoV RT-PCR kit 1.0	nCoV-2003-06 nCoV-2004-02 nCoV-2004-03 SARS-2004-01 SARS-2004-02
12	OSANG Health Care	Gene Finder COVID-19	2003-R45-22
13	Cepheid	Xpert Xpress SARS-CoV-2	1000191996, 1000191998, 1000191999
14	Biogenomics (India)	BIO COVID ID/ COVID-19 qualitative PCR detection kit v. 2	BGL/IVD/COV/0420 /004
15	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098
16	Gene Matrix	NeoPlex COVID-19 detection kit	NR05A
17	IIT Delhi	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
18	Cosara Diagnostics	SARAGENE™ Corona Virus (2019 NCV) Test kit	20C11PE-01
19	Labcare Diagnostics	Accucare COVID One step RT-pCR kit	RPCR200401

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20	POCT services Pvt Ltd	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
21	GCC Biotech, West Bengal, India	DiAGSure nCov-19 Detection assay	20115K1278 20115K1251

*Above listed kits are validated with the mentioned batch number only. The tests have been performed as per the manufacturers' instructions. Responsibility for batch to batch consistency lies with the manufacturer.

Real-time PCR kits which are US-FDA and/or CE-approved

The complete list of US-FDA and/or CE-approved SARS-CoV-2 real-time PCR kits is available at (<https://www.finddx.org/covid-19/pipeline/>). US-FDA and/or CE-IVD approved kits can be used directly after due marketing approval from DCGI.