

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

Validation by ICMR Institutes

Till date, 71 RT-PCR kits have been validated by ICMR validation centres, and the following were found to be satisfactory.

Sl. 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-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
3.	Seegene	Allplex 2019-nCoV assay	RP4520A01
4.	SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
5.	KILPEST (BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
6.	Huwel Lifesciences Pvt. Ltd.	Quantiplus CoV detection KIT Ver 2.0	QLCNP0620
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	HeliniCoronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
11.	ADT India Ltd, New Delhi,	LyteStar 2019-nCoV RT PCR Kit 1.0	nCOV-2003-06; nCOV-2004-02 nCOV-2004-03 SARS-2004-01 SARS-2004-02 SARS-2004-03
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 version 2	BGL/IVD/COV/0420/004
15.	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098
16.	GeneMatrix	NeoPlex COVID-19 detection kit	NR05A

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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-19 One-step RT-pCR kit	RPCR200401 RPCR200402
20.	POCT services private Limited	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
21.	GCC Biotech Pvt Ltd, WB	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
22.	Roche Diagnostics India Pvt Ltd	LightMix Modular SARS-CoV-2 (COVID19) RdRp	48492015
23.	Genosens	Genosens nCOV 2019 Real time PCR kit	CoV-002/20
24.	Accelerate Technologies pte.ltd (DxD Hub)	A*STAR FORTITUDE KIT 2.0	200304 200402
25.	JN Medsys Pte Ltd Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
26.	LabGenomics Co. Ltd.	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
27.	Daan Gene Co. Ltd	Daan Gene Co. Ltd	2020007

*Above listed kits are validated with the mentioned batch number only. The tests have been performed as per the manufacturer's 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.