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PERFORMANCE EVALUATION OF COMMERCIAL KITS FOR REAL TIME PCR FOR COVID-19 BY ICMR IDENTIFIED VALIDATION CENTRES

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

Sl. No	Name of Company	Name of the Kit	*Batch Number
1.	ABI (Applied bio-systems), United States	TaqMan 2019-nCoV Control Kit v1	47532-020720
2.	Accelerate Technologies Pte.ltd (DxD Hub), Singapore	A*STAR FORTITUDE KIT 2.0	200304 200402
3.	ADT India Ltd, New Delhi, India	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
4.	Altona Diagnostics, Germany	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
5.	BGI Genomics, China	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
6.	BioGenomics Limited, Thane, India	BIO COVID ID/ COVID-19 qualitative PCR detection Kit version 2	BGL/IVD/COV/0420/004
7.	Cepheid, United States	Xpert Xpress SARS-CoV-2	1000191996 1000191998 1000191999
8.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENE™ Corona Virus (2019 NCV) Test Kit	20C11PE-01
9.	Daan Gene Co. Ltd., China	Daan Gene Co. Ltd	2020007
10.	GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
11.	GeneMatrix, South Korea	NeoPlex COVID-19 detection kit	NR05A
12.	Genome Diagnostics Pvt. Ltd., New Delhi, India	Genosens nCOV 2019 Real time PCR kit	CoV-002/20
13.	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
14.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus CoV detection KIT Ver 2.0	QLCNV0620

Sl. No	Name of Company	Name of the Kit	*Batch Number
15.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
16.	KILPEST (3B BlackBio Biotech India Ltd.) Bhopal, India	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
17.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
18.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
19.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402
20.	LabGenomics , South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
21.	Medsorce Ozone Biomedicals, Faridabad, India	COVID-19 RT-PCR kit	20200433
22.	Meril Diagnostics, Vapi, Gujarat, India	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
23.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
24.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
25.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
26.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015
27.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01
28.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009

*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 can be used directly after due marketing approval from Drug Controller General of India (DCGI). 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/>).