



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 05.06.2020

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

Till date, 97 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 024628
5.	Angstrom Biotech Pvt. Ltd, Rajasthan	ANGPCR 2019-nCoV	COVP02
6.	Aura Biotechnologies Private Limited, Chennai	Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT	LD12020005
7.	BGI Genomics, China	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
8.	Biogenix INC Pvt Ltd, Lucknow	Biogenix Covid-19 one step RT PCR	20200412
9.	BioGenomics Limited, Thane, India	BIO COVID ID/COVID-19 qualitative PCR detection kit version 2	BGL/IVD/COV/0420/004
10.	Cepheid, United States	Xpert Xpress SARS-CoV-2	1000191996 1000191998 1000191999
11.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENE™ Corona Virus (2019 NCV) Test Kit	20C11PE-01
12.	Daan Gene Co. Ltd., China	Daan Gene Co. Ltd	2020007
13.	DNA Xpert Pvt. Ltd	Xpert Covido 19-Fast RT-PCR kit	XC19-01
14.	GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
15.	GeneMatrix, South Korea	NeoPlex COVID-19 detection kit	NR05A



Sl. No	Name of Company	Name of the Kit	*Batch Number
16.	Gene Path Diagnostics	GenePath CoViDx One RT-qPCR v2.1.1	20200504A
17.	Genome Diagnostics Pvt. Ltd., New Delhi, India	Genosens nCOV 2019 Real time PCR kit	CoV-002/20
18.	Gland Pharma Ltd., Hyderabad	RT PCR SARS-CoV-2	20200406
19.	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
20.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus CoV detection KIT Ver 2.0	QLCNAV0620 QLCNAV0920
21.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
22.	KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
23.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
24.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
25.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402
26.	LabGenomics , South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
27.	Medsource Ozone Biomedicals, Faridabad, India	COVID-19 RT-PCR kit	20200433
28.	Meril Diagnostics, Vapi, Gujarat, India	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
29.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
30.	Mylab Discovery solutions, Pune, India	Pathodetect (Two tube assay)	PP00005-C-0520003
31.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
32.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
33.	Primer Design, UK	Z-Path Covid-19C (Genesig)	JN-02780-0011
34.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015



Sl. No	Name of Company	Name of the Kit	*Batch Number
35.	Sansure Biotech Inc., Changsha, China	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	2020029/S3102E
36.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01 RP4520D34 RP4520D47 RP4520D50 RP4520D51 RP4529D70
37.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
38.	Oscar Medicare Pvt. Ltd.	COVID-19 RT-PCR Kit	OSCOV-003 Catalog No. OSCOV-96
39.	3B Black Bio Biotech India Ltd.	TRUPCR SARS-CoV-2 RT-qPCR Kit (V-3.2) (Single Tube Multiplex format)	CoV-19/V3.2/2020/02
40.	ZyBio Inc, China (Biodx healthcare)	Zybio SARS-CoV-2 NA detection kit	200201

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