



Date: 25/08/2020

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

Till date, 215 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.	Affigenix Biosolutions Pvt. Ltd, Bangalore	Affigenix Covid 19 test (ACT) kit	AFDX1000602
5.	Ajay Bio-Tech (India) Ltd.	PATHOFIND COVID-19 Realtime RT-PCR Kit	20200601
6.	AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited)	abTES™ COVID-19 qPCR I Kit	L141-57
7.	Altona Diagnostics, Germany	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005 024628
8.	Angstrom Biotech Pvt. Ltd, Rajasthan	ANGPCR 2019-nCoV	COVP02
9.	Aspen Laboratories Pvt. Ltd (Deep Meditech Pvt Ltd)	Aspen SARS-CoV-2 Nucleic acid detection kit (PCR- Fluorescent probe method)	07020
10.	Aura Biotechnologies Private Limited, Chennai	Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT	LD12020005
11.	3B Black Bio Biotech India Ltd., Bhopal, India	TRUPCR SARS-CoV-2 RT-qPCR Kit (V-3.2) (Single Tube Multiplex format)	CoV-19/V3.2/2020/02
12.	BAG Diagnostics, Germany (Shiva Scientific Company, New Delhi)	ViroQ SARS-CoV-2 (E gene + RdRp)	002VM1
13.	BGI Genomics, China	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
14.	Bhat Biotech India Pvt Ltd	GENEASY COVID-19 RT-PCR Kit	COVID20200601
15.	Biogenix INC Pvt Ltd, Lucknow	Biogenix Covid-19 one step RT PCR	20200412



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16.	BioGenomics Limited, Thane, India	BIO COVID ID/COVID-19 qualitative PCR detection kit version 2	BGL/IVD/COV/0420/004
17.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200331E
18.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Multiplex Real Time RT-PCR Kit	200231G
19.	Bioneer Corporation, South Korea (Effibar India Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200231E
20.	BioSewoom, South Korea	Real-Q 2019-nCoV Detection Kit	580L-008
21.	BioSystems Diagnostics Pvt. Ltd	Concepta COVID-19 Multiplex RT PCR Kit	P-T 01
22.	Cancer Rop Co. Ltd (Anjanajyoti Systems Private Limited)	Q Sens 2019-nCoV Detection Kit	Q-12C
23.	Cepheid, United States	Xpert Xpress SARS-CoV-2	1000191996 1000191998 1000191999
24.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENE™ Corona Virus (2019 NCV) Test Kit	20C11PE-01
25.	Daan Gene Co. Ltd., China	Daan Gene Co. Ltd	2020007
26.	DiagSure nCOV 19 Detection assay (Multiplex Taqman)	GCC Biotech India Private Limited	20115K1310
27.	DNA technology Research & Production, LLC, Russia (365 Medical India)	SARS-CoV-2/SARS-CoV Multiplex Rreal-Time PCR detection kit	F2005S-2M
28.	DNA Xpert Pvt. Ltd, Noida, India	Xpert Covido 19-Fast RT-PCR kit	XC19-01
29.	EUROIMMUN, UK (CPC Diagnostics Pvt Ltd)	EURO Real Time SARS CoV-2	I200428CF
30.	GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
31.	GeneMatrix, South Korea	NeoPlex COVID-19 detection kit	NR05A
32.	Gene Path Diagnostics	GenePath CoViDx One RT-qPCR v2.1.1	20200504A
33.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 Screening PCR kit	2025671 2025455
34.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 PCR kit	2025500
35.	General Biologicals Corporation, Taiwan (Innvolution Limited, New Delhi)	GB SARS-CoV-2 Real Time PCR (E + ORF1ab gene + IC)	PVT6068
36.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT II Multiplex real time RT-PCR for COVID-19	G2M2001
37.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT Multiplex Real-Time PCR kit	G2M1001



Sl. No	Name of Company	Name of the Kit	*Batch Number
38.	Genestore, France	Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit	DII.31519.3.0000001
39.	Genetix Biotech Asia Pvt Ltd	COVISure COVID-19 Real Time PCR Kit	G1T20.G.101
40.	Genome Diagnostics Pvt. Ltd., New Delhi, India	Genosens nCOV 2019 Real time PCR kit	CoV-002/20
41.	Gland Pharma Ltd., Hyderabad	RT PCR SARS-CoV-2	20200406
42.	Guangdong Ardent Biomed Co., Ltd, Hong Kong (Biotime Healthcare Private Limited)	Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (PCR- Fluorescent Probe)	V20200609
43.	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
44.	Helini Biomolecules, Chennai	Helini Coronavirus Real-Time PCR kit [RdRp & ORF gene – Dual target-single tube assay]	01/2020, 02/2020, 03/2020
45.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus CoV detection KIT Ver 2.0	QLCNV0620 QLCNV0920
46.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus Multiplex COVID-19 detection kit	QLCNM0120.2
47.	iNtRON Biotechnology, Inc., Korea (Loften India Pvt Ltd)	LiliF COVID-19 Multi Real-time RT-PCR Kit	H215060553
48.	JITM Skills Private Limited	JITM COVID-19 Detection Kit	JJ15052003
49.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
50.	Karwa Enterprises Private Limited, Delhi	Karwa SARS-CoV-2 Nucleic Acid Detection Kit	20200213
51.	KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
52.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
53.	Kogene Biotech Co. Ltd, Seoul, Korea (Kin Diagnostics)	Powercheck SARS CoV-2 RT PCR Kit	1R6902200602
54.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
55.	InnoDx Solutions Pvt. Ltd	InnoDetect COVID-19 RT-PCR kit Version 1	COV-21-JU-20
56.	Intron Biotechnology, Korea (Loften India Pvt Ltd)	LiliF COVID-19 Real Time RT-PCR kit	H215051153
57.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402



Sl. No	Name of Company	Name of the Kit	*Batch Number
58.	LabGenomics , South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
59.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun COVID-19 Assay plus	CVA 20E001
60.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun™ COVID-19 ExoFast RT- PCR Kit	CVF20G001
61.	Lifespan Biotech Pvt Ltd	LS COVID-19 RT-qPCR kit	VLC20002
62.	Lifespan Biotech Pvt Ltd	LS COVID-19 RT-qPCR Multiplex Kit	LSMX20200621
63.	Lipomic Healthcare Pvt. Ltd., New Delhi	Lipomic COVID-19 multiplex Realtime RT-PCR Kit	LIPO-001
64.	LLC Art Biotech	Art Test COVID-19 kit	C19300320
65.	Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)	SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR)	0420131
66.	Med Achievers Private Limited, Noida, Uttar Pradesh, India	Genome Analyst SARS-CoV-2 detection kit	Lot No. GA0306-20-A, Batch No. MGA202003006
67.	Medical and Biological Laboratories (MBL) Co. Ltd, Japan (OSB Agencies Pvt Ltd)	MEBRIGHT SARS-CoV-2 Kit	01FA
68.	Medsorce Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
69.	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
70.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q COVID-19 Multiplex Detection Kit	M2243a20DN1FA
71.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q nCOV-QM COVID-19 Multiplex Detection Kit	M224320EN1HB
72.	M.J.Biopharm Pvt. Ltd	MJ Coronavirus (COVID-19) RT-qPCR Kit	RTPCR0520AB21
73.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
74.	Mylab Discovery solutions, Pune, India	Pathodetect (Two tube assay)	PP00005-C-0520003



Sl. No	Name of Company	Name of the Kit	*Batch Number
75.	Mylab Discovery solutions, Pune, India	Pathodetect Coronavirus (COVID-19) Qualitative PCR Kit	PP00005-C-070001E
76.	NeoDx Biotech Labs Private Limited, India (DSS Imagetech Pvt Ltd)	CoviDx mPlex-4R SARS-CoV-2 RT-PCR Detection Kit	CM4R-030820
77.	NeoDx Biotech Labs Private Limited, India	CoviDx mPlex-3NC SARS-CoV-2 RT-PCR Detection Kit	CM3NC-140820
78.	NeoDx Biotech Labs Private Limited, India	CoviDx TM mPlex-3NR SARS-CoV-2 RT-PCR Detection Kit	CM3NR-120820
79.	NovaTec Immunodiagnostica, Germany (Eurofins Amar Immunodiagnosics Pvt. Ltd)	GSD NovaPrime SARS-COV-2 (COVID-19) RT-PCR	PCOV6030-005G, PCOV6030-005-1, PCOV6030-006
80.	Nucleus Diagnosys LLP, Gujarat, India	SARS CoV-2 Triplex PCR Kit	RD2762001
81.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
82.	Oscar Medicare Pvt. Ltd., New Delhi, India	COVID-19 RT-PCR Kit	OSCOV-003 Catalog No. OSCOV-96
83.	Perkin Elmer, Finalnd	SARS-CoV-2 RT-qPCR Reagent Kit	680613 680415 680694
84.	Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited)	COVID-19 One-step RT-PCR kit	99001
85.	POCT Services Private Limited	Q-Line Molecular ER nCOV-19 RT-PCR Kit	M200702
86.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
87.	Primer Design, UK	Z-Path Covid-19C (Genesig)	JN-02780-0011
88.	Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi)	RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene)	RC1405
89.	QuantuMdx, United Kingdom (Ally-Bio Private Limited)	QuantuMDx SARS-CoV-2 RT PCR Detection Assay	P01090
90.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015
91.	Sansure Biotech Inc., Changsha, China	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	2020029/S3102E
92.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01 RP4520D34 RP4520D47 RP4520D50

Sl. No	Name of Company	Name of the Kit	*Batch Number
			RP4520D51 RP4529D70
93.	Sentinel Diagnostics, Italy	STAT-NAT COVID-19 B Realtime RT-PCR Kit	00310 00324 00365
94.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
95.	Shanghai ZJ Bio-Tech Co., Ltd (Life Technologies (India) Pvt Ltd)	LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	20200601
96.	Shenzen Uni-Medica Technology Co. Ltd (Vishat Diagnostics Pvt Ltd)	Real Time PCR Kit for Novel Coronavirus 2019-nCoV (ORF1ab, N)	20200602
97.	SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd)	COVID-19 Real Time PCR kit v1	2006R2
98.	TranScience Innovative Technologies, Chennai	TrueScreen COVID-19 Multiplex Real Time PCR Detection Kit	TS0820-01
99.	Trivitron healthcare Pvt Ltd	Covidsure Pro Multiplex RT-PCR kit	COVID-M-001
100.	Trivitron healthcare Pvt Ltd	COVIDsure Multiplex Realtime RT-PCR kit	COVID-C-T-004
101.	uBio Biotechnology Systems Private Limited	ViraGEN Molecular Diagnostics Covid-19 Real- Time RT-PCR kit	UBMD0072001
102.	Vitro S.A., Spain (DSS Imagetech Private Ltd.)	SARS-CoV-2 RT-PCR Kit	COVP006
103.	Wuhan Easy Diagnosis Biomedicine Co. Ltd	COVID-19 (SARS-CoV-2) Nucleic acid test kit	200401HW
104.	YOUSEQ, UK	COVID19 E,N,RdRp & S gene Multiplex qPCR kit	YSM1641
105.	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 can be used directly after due marketing approval from DCGI. The complete list of US-FDA SARS-CoV-2 real time PCR kits is available at (<https://www.finddx.org/covid-19/pipeline/>).