



Date: 01/10/2020

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

Till date, 255 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.	ADT Biotech Sdn. Bhd. (ADT India Private Limited)	LyteStar 2019-nCoV RT-PCR Kit 2.0	nCoV-2008-01ST
5.	Advanced Molecular Diagnostics (AMD), UK (Diagnostic Biosystems)	Zena Max SARS-CoV-2 Direct qPCR Detection Kit	0011382
6.	Affigenix Biosolutions Pvt. Ltd, Bangalore	Affigenix Covid 19 test (ACT) kit	AFDX1000602
7.	Affigenix Biosolutions Pvt Ltd, Bangalore, India	AFFIGENIX COVID 19 TEST (ACT-1) (3 Genes MULTIPLEX KIT)	MX07/3G/08_MFG
8.	Agappe Diagnostics Ltd, Kerala, India	Agappe Real Time RT – LAMP COVID 19 Testing Kit	R008003
9.	Ajay Bio-Tech (India) Ltd.	PATHOFIND COVID-19 Realtime RT-PCR Kit	20200601
10.	AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited)	abTES™ COVID-19 qPCR I Kit	L141-57
11.	AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited)	abTES COVID-19 qPCR I Kit (v1.1)	L141-173
12.	Altona Diagnostics, Germany	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005 024628
13.	Angstrom Biotech Pvt. Ltd, Rajasthan	ANGPCR 2019-nCoV	COVP02
14.	Aspen Laboratories Pvt. Ltd, New Delhi (Deep Meditech Pvt Ltd)	Aspen SARS-CoV-2 Nucleic acid detection kit (PCR- Fluorescent probe method)	07020



Sl. No	Name of Company	Name of the Kit	*Batch Number
15.	Athenese-Dx Private Limited, Tamil Nadu	Aridia CoVid-19 Real Time PCR Detection Kit	AP1708201
16.	Aura Biotechnologies Private Limited, Chennai	Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT	LD12020005
17.	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
18.	BAG Diagnostics, Germany (Shiva Scientific Company, New Delhi)	ViroQ SARS-CoV-2 (E gene + RdRp)	002VM1
19.	BGI Genomics, China	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
20.	Bhat Biotech India Pvt Ltd	GENEASY COVID-19 RT-PCR Kit	COVID20200601
21.	Biogenix INC Pvt Ltd, Lucknow	Biogenix Covid-19 one step RT PCR	20200412
22.	BioGenomics Limited, Thane, India	BIO COVID ID/COVID-19 qualitative PCR detection kit version 2	BGL/IVD/COV/0420/004
23.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200331E
24.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Multiplex Real Time RT-PCR Kit	200231G
25.	Bioneer Corporation, South Korea (Effibar India Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200231E
26.	BioSewoom, South Korea	Real-Q 2019-nCoV Detection Kit	580L-008
27.	BioSystems Diagnostics Pvt. Ltd	Concepta COVID-19 Multiplex RT PCR Kit	P-T 01
28.	Cancer Rop Co. Ltd (Anjanajyoti Systems Private Limited)	Q Sens 2019-nCoV Detection Kit	Q-12C
29.	Cepheid, United States	Xpert Xpress SARS-CoV-2	1000191996 1000191998 1000191999
30.	Cepheid, United States (Cepheid India Private Limited)	Xpert Xpress SARS-CoV-2	1000206864
31.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENETM Corona Virus (2019 NCV) Test Kit	20C11PE-01
32.	Daan Gene Co. Ltd., China	Daan Gene Co. Ltd	2020007
33.	DiagSure nCOV 19 Detection assay (Multiplex Taqman)	GCC Biotech India Private Limited	20115K1310
34.	DNA technology Research & Production, LLC, Russia (365 Medical India)	SARS-CoV-2/SARS-CoV Multiplex Rteal-Time PCR detection kit	F2005S-2M
35.	DNA Xpert Pvt. Ltd, Noida, India	Xpert Covid19-Fast RT-PCR kit	XC19-01
36.	DNA Xpert Pvt. Ltd, Noida, India	Xperts Covid19 Multiplex RT-PCR kit	MP-20-01
37.	1Drop Inc, Korea (Nandan Exports & Imports Private Limited)	1copy COVID-19 qPCR Triplex Kit	M230H1900
38.	EUROIMMUN, UK (CPC Diagnostics Pvt Ltd)	EURO Real Time SARS CoV-2	I200428CF



Sl. No	Name of Company	Name of the Kit	*Batch Number
39.	Equine Biotech, Karnataka (EBT PVT LTD)	Global COVID 19 Kit	EBT002
40.	GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
41.	GeneMatrix, South Korea	NeoPlex COVID-19 detection kit	NR05A
42.	Gene Path Diagnostics, Pune, India	GenePath CoViDx One RT-qPCR v2.1.1	20200504A
43.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 Screening PCR kit	2025671 2025455
44.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 PCR kit	2025500
45.	GeneReach Biotechnology Corporation, Taiwan (Padmanabha Labs Pvt. Ltd.)	IQ Real SARS-CoV-2 Qualitative System	031320
46.	General Biologicals Corporation, Taiwan (Innvolution Limited, New Delhi)	GB SARS-CoV-2 Real Time PCR (E + ORF1ab gene + IC)	PVT6068
47.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT II Multiplex real time RT-PCR for COVID-19	G2M2001
48.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT Multiplex Real-Time PCR kit	G2M1001
49.	Genestore, France	Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit	DII.31519.3.0000001
50.	Genetix Biotech Asia Pvt Ltd, New Delhi, India	COVISure COVID-19 Real Time PCR Kit	G1T20.G.101
51.	Genetix Biotech Asia Pvt Ltd, New Delhi, India	COVISure (Lyo Mix) COVID19 Real Time PCR Kit	PDT1T20.I.301
52.	Genome Diagnostics Pvt. Ltd., New Delhi, India	Genosens nCOV 2019 Real time PCR kit	CoV-002/20
53.	Genores Biotech Pvt Ltd, Maharashtra, India	GenoCoV	G/GC/20/0006
54.	Gland Pharma Ltd., Hyderabad	RT PCR SARS-CoV-2	20200406
55.	Guangdong Ardent Biomed Co., Ltd, Hong Kong (Biotime Healthcare Private Limited)	Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (PCR- Fluorescent Probe)	V20200609
56.	HA Tech Biopharma & Diagnostics, Australia (RLT Group Services)	SARS-CoV-2 RT-PCR Multiplex Diagnostic Kit	NAT-01-200901



Sl. No	Name of Company	Name of the Kit	*Batch Number
57.	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
58.	Helini Biomolecules, Chennai	Helini Coronavirus Real-Time PCR kit [RdRp & ORF gene – Dual target-single tube assay]	01/2020, 02/2020, 03/2020
59.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus CoV detection KIT Ver 2.0	QLCNAV0620 QLCNAV0920
60.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus Multiplex COVID-19 detection kit	QLCNM0120.2
61.	iNtRON Biotechnology, Inc., Korea (Loften India Pvt Ltd)	LiliF COVID-19 Multi Real-time RT-PCR Kit	H215060553
62.	JITM Skills Private Limited, New Delhi, India	JITM COVID-19 Detection Kit	JJ15052003
63.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
64.	Karwa Enterprises Private Limited, Delhi	Karwa SARS-CoV-2 Nucleic Acid Detection Kit	20200213
65.	KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
66.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
67.	Kogene Biotech Co. Ltd, Seoul, Korea (Kin Diagnostics)	Powercheck SARS CoV-2 RT PCR Kit	1R6902200602
68.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
69.	InnoDx Solutions Pvt. Ltd	InnoDetect COVID-19 RT-PCR kit Version 1	COV-21-JU-20
70.	Intron Biotechnology, Korea (Loften India Pvt Ltd)	LiliF COVID-19 Real Time RT-PCR kit	H215051153
71.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402
72.	LabGenomics, South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
73.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun COVID-19 Assay plus	CVA 20E001
74.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun™ COVID-19 ExoFast RT- PCR Kit	CVF20G001



Sl. No	Name of Company	Name of the Kit	*Batch Number
75.	Lifespan Biotech Pvt Ltd, Madhya Pradesh, India	LS COVID-19 RT-qPCR kit	VLC20002
76.	Lifespan Biotech Pvt Ltd, Madhya Pradesh, India	LS COVID-19 RT-qPCR Multiplex Kit	LSMX20200621
77.	Lipomic Healthcare Pvt. Ltd., New Delhi	Lipomic COVID-19 multiplex Realtime RT-PCR Kit	LIPO-001
78.	LLC Art Biotech	Art Test COVID-19 kit	C19300320
79.	Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)	SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR)	0420131
80.	Med Achievers Private Limited, Noida, Uttar Pradesh, India	Genome Analyst SARS-CoV-2 detection kit	Lot No. GA0306-20-A, Batch No. MGA202003006
81.	Medical and Biological Laboratories (MBL) Co. Ltd, Japan (OSB Agencies Pvt Ltd)	MEBRIGHT SARS-CoV-2 Kit	01FA
82.	Medsorce Ozone Biomedicals, Faridabad, Haryana	COVID-19 RT-PCR kit	20200433
83.	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
84.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q COVID-19 Multiplex Detection Kit	M2243a20DN1FA
85.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q nCOV-QM COVID-19 Multiplex Detection Kit	M224320EN1HB
86.	M.J.Biopharm Pvt. Ltd	MJ Coronavirus (COVID-19) RT-qPCR Kit	RTPCR0520AB21
87.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
88.	Mylab Discovery solutions, Pune, India	Pathodetect (Two tube assay)	PP00005-C-0520003
89.	Mylab Discovery solutions, Pune, India	Pathodetect Coronavirus (COVID-19) Qualitative PCR Kit	PP00005-C-070001E
90.	NeoDx Biotech Labs Private Limited, India (DSS Imagetech Pvt Ltd)	CoviDx mPlex-4R SARS-CoV-2 RT-PCR Detection Kit	CM4R-030820
91.	NeoDx Biotech Labs Private Limited, India	CoviDx mPlex-3NC SARS-CoV-2 RT-PCR Detection Kit	CM3NC-140820
92.	NeoDx Biotech Labs Private	CoviDxTM mPlex-3NR SARS-CoV-2 RT-	CM3NR-120820



Sl. No	Name of Company	Name of the Kit	*Batch Number
	Limited, India	PCR Detection Kit	
93.	Ningbo Health Gene Technologies Co., Ltd. (The Rising Medicare Private Limited)	SARS-CoV-2 Virus detection Diagnostic Kit (RT-qPCR Method) Version 1.0	200522006
94.	NovaTec Immunodiagnostica, Germany (Eurofins Amar Immunodiagnosics Pvt. Ltd)	GSD NovaPrime SARS-COV-2 (COVID-19) RT-PCR	PCOV6030-005G, PCOV6030-005-1, PCOV6030-006
95.	Nucleus Diagnosys LLP, Gujarat, India	SARS CoV-2 Triplex PCR Kit	RD2762001
96.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
97.	Oscar Medicare Pvt. Ltd., New Delhi, India	COVID-19 RT-PCR Kit	OSCOV-003 Catalog No. OSCOV-96
98.	Perkin Elmer, Finalnd	SARS-CoV-2 RT-qPCR Reagent Kit	680613 680415 680694
99.	Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited)	COVID-19 One-step RT-PCR kit	99001
100.	POCT Services Private Limited	Q-Line Molecular ER nCOV-19 RT-PCR Kit	M200702
101.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
102.	Primer Design, UK	Z-Path Covid-19C (Genesig)	JN-02780-0011
103.	Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi)	RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene)	RC1405
104.	Promea Therapeutics, Telangana	ProPCR COVID-19 RT-qPCR	TRCV 2001
105.	QuantuMdx, United Kingdom (Ally-Bio Private Limited)	QuantuMDx SARS-CoV-2 RT PCR Detection Assay	P01090
106.	Reliance Industries Limited, India	'R-Green Kit (SARS CoV-2 realtime PCR)	1-2
107.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015
108.	Shambhav Medical, Uttar Pradesh	ViroDetect COVID-19 Real-Time PCR Kit	95001001
109.	Sansure Biotech Inc., Changsha, China	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	2020029/S3102E



Sl. No	Name of Company	Name of the Kit	*Batch Number
110.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01 RP4520D34 RP4520D47 RP4520D50 RP4520D51 RP4529D70
111.	Sentinel Diagnostics, Italy	STAT-NAT COVID-19 B Realtime RT-PCR Kit	00310 00324 00365
112.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
113.	Shanghai ZJ Bio-Tech Co., Ltd (Life Technologies (India) Pvt Ltd)	LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	20200601
114.	Shenzen Uni-Medica Technology Co. Ltd (Vishat Diagnostics Pvt Ltd)	Real Time PCR Kit for Novel Coronavirus 2019-nCoV (ORF1ab, N)	20200602
115.	SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd)	COVID-19 Real Time PCR kit v1	2006R2
116.	Stellence Pharmsciences Pvt Ltd	Stellence Covid-19 RT-qPCR Kit	027032
117.	TranScience Innovative Technologies, Chennai	TrueScreen COVID-19 Multiplex Real Time PCR Detection Kit	TS0820-01
118.	Triviron healthcare Pvt Ltd	Covidsure Pro Multiplex RT-PCR kit	COVID-M-001
119.	Triviron healthcare Pvt Ltd	COVIDsure Multiplex Realtime RT-PCR kit	COVID-C-T-004
120.	uBio Biotechnology Systems Private Limited	ViraGEN Molecular Diagnostics Covid-19 Real- Time RT-PCR kit	UBMD0072001
121.	Vitane Biologics Pvt Ltd, Telangana	CovTect COVID-19 Qualitative PCR Kit	VBRT004
122.	Vitro S.A., Spain (DSS Imagetech Private Ltd.)	SARS-CoV-2 RT-PCR Kit	COVP006
123.	Wuhan Easy Diagnosis Biomedicine Co. Ltd	COVID-19 (SARS-CoV-2) Nucleic acid test kit	200401HW
124.	YD Diagnostics Corp., Korea (POCT Services Private Limited)	MolecuTech Real time COVID-19 RT-PCR kit	M2042011
125.	YOUSEQ, UK	COVID19 E,N,RdRp & S gene Multiplex qPCR kit	YSM1641
126.	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/>).