



Date: 26.10.2020

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

Till date, 282 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.	Accurex Biomedical Pvt Ltd, Palghar, Maharashtra	Accurex SARS COVID-19 RT-PCR Assay	CRV1D001
4.	Accurex Biomedical Pvt Ltd, Palghar, Maharashtra	Novel Coronavirus (2019-nCoV) Nucleic Acid Detection Kit (Fluorescence PCR Method)	DCRPT001
5.	ADALTIS S.r.l, Italy (PUG Capital Private Limited)	MOLgen SARS CoV-2 Realtime RT-PCR kit	20167
6.	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
7.	ADT Biotech Sdn. Bhd. (ADT India Private Limited)	LyteStar 2019-nCoV RT-PCR Kit 2.0	nCoV-2008-01ST
8.	Advanced Molecular Diagnostics (AMD), UK (Diagnostic Biosystems)	Zena Max SARS-CoV-2 Direct qPCR Detection Kit	0011382
9.	Affigenix Biosolutions Pvt. Ltd, Bangalore	Affigenix Covid 19 test (ACT) kit	AFDX1000602
10.	Affigenix Biosolutions Pvt Ltd, Bangalore, India	AFFIGENIX COVID 19 TEST (ACT-1) (3 Genes MULTIPLEX KIT)	MX07/3G/08_MFG
11.	Agappe Diagnostics Ltd, Kerala, India	Agappe Real Time RT – LAMP COVID 19 Testing Kit	R008003
12.	Ajay Bio-Tech (India) Ltd.	PATHOFIND COVID-19 Realtime RT-PCR Kit	20200601
13.	AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited)	abTESTM COVID-19 qPCR I Kit	L141-57

Sl. No	Name of Company	Name of the Kit	*Batch Number
14.	AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited)	abTES COVID-19 qPCR I Kit (v1.1)	L141-173
15.	Altona Diagnostics, Germany	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005 024628
16.	Angstrom Biotech Pvt. Ltd, Rajasthan	ANGPCR 2019-nCoV	COVP02
17.	Aspen Laboratories Pvt. Ltd, New Delhi (Deep Meditech Pvt Ltd)	Aspen SARS-CoV-2 Nucleic acid detection kit (PCR- Fluorescent probe method)	07020
18.	Athenese-Dx Private Limited, Tamil Nadu	Aridia CoVid-19 Real Time PCR Detection Kit	AP1708201
19.	Aura Biotechnologies Private Limited, Chennai	Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT	LD12020005
20.	Avience Biomedicals Pvt Ltd, Delhi	AvienBio COVID-19 RT PCR Assay	AV-000001
21.	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
22.	BAG Diagnostics, Germany (Shiva Scientific Company, New Delhi)	ViroQ SARS-CoV-2 (E gene + RdRp)	002VM1
23.	BGI Genomics, China	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
24.	Bhat Biotech India Pvt Ltd	GENEASY COVID-19 RT-PCR Kit	COVID20200601
25.	Biogenix INC Pvt Ltd, Lucknow	Biogenix Covid-19 one step RT PCR	20200412
26.	BioGenomics Limited, Thane, India	BIO COVID ID/COVID-19 qualitative PCR detection kit version 2	BGL/IVD/COV/0420/004
27.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200331E
28.	Bioneer Corporation, South Korea (Wevio Global Private Limited)	AccuPower SARS-CoV-2 Multiplex Real Time RT-PCR Kit	200231G
29.	Bioneer Corporation, South Korea (Effibar India Private Limited)	AccuPower SARS-CoV-2 Real Time RT-PCR Kit	200231E
30.	BioSewoom, South Korea	Real-Q 2019-nCoV Detection Kit	580L-008
31.	BioSystems Diagnostics Pvt. Ltd	Concepta COVID-19 Multiplex RT PCR Kit	P-T 01
32.	Cancer Rop Co. Ltd (Anjanajyoti Systems Private Limited)	Q Sens 2019-nCoV Detection Kit	Q-12C
33.	Cepheid, United States	Xpert Xpress SARS-CoV-2	1000191996 1000191998 1000191999
34.	Cepheid, United States (Cepheid India Private Limited)	Xpert Xpress SARS-CoV-2	1000206864
35.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENE COVID-19 V.2 Real Time PCR Test Kit	20K12PE-01
36.	CoSara Diagnostics Pvt. Limited, Ahmedabad, India	SARAGENE™ Corona Virus (2019 NCV) Test Kit	20C11PE-01

Sl. No	Name of Company	Name of the Kit	*Batch Number
37.	Daan Gene Co. Ltd., China	Daan Gene Co. Ltd	2020007
38.	DiagSure nCOV 19 Detection assay (Multiplex Taqman)	GCC Biotech India Private Limited	20115K1310
39.	DNA technology Research & Production, LLC, Russia (365 Medical India)	SARS-CoV-2/SARS-CoV Multiplex Rreal-Time PCR detection kit	F2005S-2M
40.	DNA Xpert Pvt. Ltd, Noida, India	Xpert Covido 19-Fast RT-PCR kit	XC19-01
41.	DNA Xpert Pvt. Ltd, Noida, India	Xperts Covido19 Multiplex RT-PCR kit	MP-20-01
42.	1Drop Inc, Korea (Nandan Exports & Imports Private Limited)	1copy COVID-19 qPCR Triplex Kit	M230H1900
43.	EUROIMMUN, UK (CPC Diagnostics Pvt Ltd)	EURO Real Time SARS CoV-2	I200428CF
44.	Equine Biotech, Karnataka (EBT PVT LTD)	Global COVID 19 Kit	EBT002
45.	GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India	DiagSure nCOV-19 Detection assay (Taqman based)	20115K1278 20115k1251
46.	GeneMatrix, South Korea	NeoPlex COVID-19 detection kit	NR05A
47.	Gene Path Diagnostics, Pune, India	GenePath CoVIDx One RT-qPCR v2.1.1	20200504A
48.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 Screening PCR kit	2025671 2025455
49.	Gene Proof, Czech Republic	Gene Proof SARS-CoV-2 PCR kit	2025500
50.	GeneReach Biotechnology Corporation, Taiwan (Padmanabha Labs Pvt. Ltd.)	IQ Real SARS-CoV-2 Qualitative System	031320
51.	General Biologicals Corporation, Taiwan (Innvolution Limited, New Delhi)	GB SARS-CoV-2 Real Time PCR (E + ORF1ab gene + IC)	PVT6068
52.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT II Multiplex real time RT-PCR for COVID-19	G2M2001
53.	Genes2me Pvt Ltd, Gurugram, Haryana	VIRALDTECT Multiplex Real-Time PCR kit	G2M1001
54.	Genestore, France	Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit	DII.31519.3.0000001
55.	Genetix Biotech Asia Pvt Ltd, New Delhi, India	COVISure COVID-19 Real Time PCR Kit	G1T20.G.101
56.	Genetix Biotech Asia Pvt Ltd, New Delhi, India	COVISure (Lyo Mix) COVID19 Real Time PCR Kit	PDT1T20.I.301
57.	Genome Diagnostics Pvt. Ltd., New Delhi, India	Genosens nCOV 2019 Real time PCR kit	CoV-002/20

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58.	Genores Biotech Pvt Ltd, Maharashtra, India	GenoCoV	G/GC/20/0006
59.	Gland Pharma Ltd., Hyderabad	RT PCR SARS-CoV-2	20200406
60.	Guangdong Ardent Biomed Co., Ltd, Hong Kong (Biotime Healthcare Private Limited)	Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (PCR- Fluorescent Probe)	V20200609
61.	HA Tech Biopharma & Diagnostics, Australia (RLT Group Services)	SARS-CoV-2 RT-PCR Multiplex Diagnostic Kit	NAT-01-200901
62.	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID-19] Real time-PCR Kit	01/2020 MFD: 04/20
63.	Helini Biomolecules, Chennai	Helini Coronavirus Real-Time PCR kit [RdRp & ORF gene – Dual target-single tube assay]	01/2020, 02/2020, 03/2020
64.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus CoV detection KIT Ver 2.0	QLCNV0620 QLCNV0920
65.	Huwel Lifesciences Pvt. Ltd., Hyderabad, India	Quantiplus Multiplex COVID-19 detection kit	QLCNM0120.2
66.	iNtRON Biotechnology, Inc., Korea (Loften India Pvt Ltd)	LiliF COVID-19 Multi Real-time RT-PCR Kit	H215060553
67.	JITM Skills Private Limited, New Delhi, India	JITM COVID-19 Detection Kit	JJ15052003
68.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
69.	Karwa Enterprises Private Limited, Delhi	Karwa SARS-CoV-2 Nucleic Acid Detection Kit	20200213
70.	KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
71.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
72.	Kogene Biotech Co. Ltd, Seoul, Korea (Kin Diagnostics)	Powercheck SARS CoV-2 RT PCR Kit	1R6902200602
73.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
74.	InnoDx Solutions Pvt. Ltd	InnoDetect COVID-19 RT-PCR kit Version 1	COV-21-JU-20
75.	Intron Biotechnology, Korea (Loften India Pvt Ltd)	LiliF COVID-19 Real Time RT-PCR kit	H215051153
76.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402
77.	LabGenomics, South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006

Sl. No	Name of Company	Name of the Kit	*Batch Number
78.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun COVID-19 Assay plus	CVA 20E001
79.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun™ COVID-19 ExoFast RT- PCR Kit	CVF20G001
80.	Lifespan Biotech Pvt Ltd, Madhya Pradesh, India	LS COVID-19 RT-qPCR kit	VLC20002
81.	Lifespan Biotech Pvt Ltd, Madhya Pradesh, India	LS COVID-19 RT-qPCR Multiplex Kit	LSMX20200621
82.	Lipomic Healthcare Pvt. Ltd., New Delhi	Lipomic COVID-19 multiplex Realtime RT-PCR Kit	LIPO-001
83.	LLC Art Biotech	Art Test COVID-19 kit	C19300320
84.	Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)	SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR)	0420131
85.	Med Achievers Private Limited, Noida, Uttar Pradesh, India	Genome Analyst SARS-CoV-2 detection kit	Lot No. GA0306-20-A, Batch No. MGA202003006
86.	Medical and Biological Laboratories (MBL) Co. Ltd, Japan (OSB Agencies Pvt Ltd)	MEBRIGHT SARS-CoV-2 Kit	01FA
87.	Medsorce Ozone Biomedicals, Faridabad, Haryana	COVID-19 RT-PCR kit	20200433
88.	Medsorce Ozone Biomedicals, Faridabad, Haryana	OZOFIND SARS COV2 RT PCR KIT	TLPCOV040920
89.	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
90.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q COVID-19 Multiplex Detection Kit	M2243a20DN1FA
91.	Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)	Veri-Q nCOV-QM COVID-19 Multiplex Detection Kit	M224320EN1HB
92.	M.J.Biopharm Pvt. Ltd	MJ Coronavirus (COVID-19) RT-qPCR Kit	RTPCR0520AB21
93.	Molbio Diagnostics Private Limited, India	Truemix Covid 19	ETMXCD01
94.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
95.	Mylab Discovery solutions, Pune, India	Pathodetect (Two tube assay)	PP00005-C-0520003
96.	Mylab Discovery solutions, Pune, India	Pathodetect Coronavirus (COVID-19) Qualitative PCR Kit	PP00005-C-070001E

Sl. No	Name of Company	Name of the Kit	*Batch Number
97.	NeoDx Biotech Labs Private Limited, India (DSS Imagetech Pvt Ltd)	CoviDx mPlex-4R SARS-CoV-2 RT-PCR Detection Kit	CM4R-030820
98.	NeoDx Biotech Labs Private Limited, India	CoviDx mPlex-3NC SARS-CoV-2 RT-PCR Detection Kit	CM3NC-140820
99.	NeoDx Biotech Labs Private Limited, India	CoviDxTM mPlex-3NR SARS-CoV-2 RT-PCR Detection Kit	CM3NR-120820
100.	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
101.	NovaTec Immunodiagnostica, Germany (Eurofins Amar Immunodiagnosics Pvt. Ltd)	GSD NovaPrime SARS-COV-2 (COVID-19) RT-PCR	PCOV6030-005G, PCOV6030-005-1, PCOV6030-006
102.	Nucleus Diagnosys LLP, Gujarat, India	SARS CoV-2 Triplex PCR Kit	RD2762001
103.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
104.	Oscar Medicare Pvt. Ltd., New Delhi, India	COVID-19 RT-PCR Kit	OSCOV-003 Catalog No. OSCOV-96
105.	Perkin Elmer, Finalnd	SARS-CoV-2 RT-qPCR Reagent Kit	680613 680415 680694
106.	Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited)	COVID-19 One-step RT-PCR kit	99001
107.	POCT Services Private Limited	Q-Line Molecular ER nCOV-19 RT-PCR Kit	M200702
108.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
109.	Primer Design, UK	Z-Path Covid-19C (Genesig)	JN-02780-0011
110.	Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi)	RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene)	RC1405
111.	Promea Therapeutics, Telangana	ProPCR COVID-19 RT-qPCR	TRCV 2001
112.	QuantuMdx, United Kingdom (Ally-Bio Private Limited)	QuantuMDx SARS-CoV-2 RT PCR Detection Assay	P01090
113.	Reliance Industries Limited, India	'R-Green Kit (SARS CoV-2 realtime PCR)	1-2
114.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015
115.	Shambhav Medical, Uttar Pradesh	ViroDetect COVID-19 Real-Time PCR Kit	95001001
116.	Sansure Biotech Inc., Changsha, China	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	2020029/S3102E

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117.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01 RP4520D34 RP4520D47 RP4520D50 RP4520D51 RP4529D70
118.	Sentinel Diagnostics, Italy	STAT-NAT COVID-19 B Realtime RT-PCR Kit	00310 00324 00365
119.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
120.	Shanghai ZJ Bio-Tech Co., Ltd (Life Technologies (India) Pvt Ltd)	LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit	20200601
121.	Shenzen Uni-Medica Technology Co. Ltd (Vishat Diagnostics Pvt Ltd)	Real Time PCR Kit for Novel Coronavirus 2019-nCoV (ORF1ab, N)	20200602
122.	SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd)	COVID-19 Real Time PCR kit v1	2006R2
123.	Stellence Pharmsciences Pvt Ltd	Stellence Covid-19 RT-qPCR Kit	027032
124.	TranScience Innovative Technologies, Chennai	TrueScreen COVID-19 Multiplex Real Time PCR Detection Kit	TS0820-01
125.	Trivitron healthcare Pvt Ltd	Covidsure Pro Multiplex RT-PCR kit	COVID-M-001
126.	Trivitron healthcare Pvt Ltd	COVIDsure Multiplex Realtime RT-PCR kit	COVID-C-T-004
127.	uBio Biotechnology Systems Private Limited	ViraGEN Molecular Diagnostics Covid-19 Real- Time RT-PCR kit	UBMD0072001
128.	Vitane Biologics Pvt Ltd, Telangana	CovTect COVID-19 Qualitative PCR Kit	VBRT004
129.	Vitro S.A., Spain (DSS Imagetech Private Ltd.)	SARS-CoV-2 RT-PCR Kit	COVP006
130.	Wuhan Easy Diagnosis Biomedicine Co. Ltd	COVID-19 (SARS-CoV-2) Nucleic acid test kit	200401HW
131.	YD Diagnostics Corp., Korea (POCT Services Private Limited)	MolecuTech Real time COVID-19 RT-PCR kit	M2042011
132.	YOUSEQ, UK	COVID19 E,N,RdRp & S gene Multiplex qPCR kit	YSM1641
133.	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/>).