



Dated: 10/09/2020

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

Till date, 235 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<br>200402  |
| 3.     | ADT India Ltd, New Delhi, India                                     | LyteStar 2019-nCoV RT PCR Kit 1.0   | nCoV-2003-06;<br>nCov-2004-02<br>nCov-2004-03<br>SARS-2004-01<br>SARS-2004-02<br>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.     | Ajay Bio-Tech (India) Ltd.  | PATHOFIND COVID-19 Realtime RT-PCR Kit                                      | 20200601  |
| 8.     | AITbiotech Pte Ltd, Singapore (Hiddenite Beverages Private Limited) | abTES™ COVID-19 qPCR I Kit  | L141-57   |
| 9.     | Altona Diagnostics, Germany   | RealStar SARS-CoV-2 RT-PCR kit 1.0  | 023005<br>024628  |
| 10.    | Angstrom Biotech Pvt. Ltd, Rajasthan                                | ANGPCR 2019-nCoV  | COVP02  |
| 11.    | Aspen Laboratories Pvt. Ltd, New Delhi (Deep Meditech Pvt Ltd)      | Aspen SARS-CoV-2 Nucleic acid detection kit (PCR- Fluorescent probe method) | 07020   |
| 12.    | Athenese-Dx Private Limited, Tamil Nadu                             | Aridia CoVid-19 Real Time PCR Detection Kit                                 | AP1708201   |
| 13.    | Aura Biotechnologies Private Limited, Chennai                       | Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT                   | LD12020005  |
| 14.    | 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   |
| 15.    | BAG Diagnostics, Germany (Shiva Scientific Company, New Delhi)      | ViroQ SARS-CoV-2 (E gene + RdRp)  | 002VM1  |



| Sl. No | Name of Company   | Name of the Kit   | *Batch Number                       |
|--------|---|---|-------------------------------------|
| 16.    | BGI Genomics, China   | Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV      | 6020200107                          |
| 17.    | Bhat Biotech India Pvt Ltd  | GENEASY COVID-19 RT-PCR Kit                                   | COVID20200601                       |
| 18.    | Biogenix INC Pvt Ltd, Lucknow   | Biogenix Covid-19 one step RT PCR                             | 20200412                            |
| 19.    | BioGenomics Limited, Thane, India                                     | BIO COVID ID/COVID-19 qualitative PCR detection kit version 2 | BGL/IVD/COV/0420/004                |
| 20.    | Bioneer Corporation, South Korea (Wevio Global Private Limited)       | AccuPower SARS-CoV-2 Real Time RT-PCR Kit                     | 200331E                             |
| 21.    | Bioneer Corporation, South Korea (Wevio Global Private Limited)       | AccuPower SARS-CoV-2 Multiplex Real Time RT-PCR Kit           | 200231G                             |
| 22.    | Bioneer Corporation, South Korea (Effibar India Private Limited)      | AccuPower SARS-CoV-2 Real Time RT-PCR Kit                     | 200231E                             |
| 23.    | BioSewoom, South Korea  | Real-Q 2019-nCoV Detection Kit                                | 580L-008                            |
| 24.    | BioSystems Diagnostics Pvt. Ltd                                       | Concepta COVID-19 Multiplex RT PCR Kit                        | P-T 01                              |
| 25.    | Cancer Rop Co. Ltd (Anjanajyoti Systems Private Limited)              | Q Sens 2019-nCoV Detection Kit                                | Q-12C                               |
| 26.    | Cepheid, United States  | Xpert Xpress SARS-CoV-2                                       | 1000191996 1000191998<br>1000191999 |
| 27.    | Cepheid, United States (Cepheid India Private Limited)                | Xpert Xpress SARS-CoV-2                                       | 1000206864                          |
| 28.    | CoSara Diagnostics Pvt. Limited, Ahmedabad, India                     | SARAGENETM Corona Virus (2019 NCV) Test Kit                   | 20C11PE-01                          |
| 29.    | Daan Gene Co. Ltd., China   | Daan Gene Co. Ltd   | 2020007                             |
| 30.    | DiagSure nCOV 19 Detection assay (Multiplex Taqman)                   | GCC Biotech India Private Limited                             | 20115K1310                          |
| 31.    | DNA technology Research & Production, LLC, Russia (365 Medical India) | SARS-CoV-2/SARS-CoV Multiplex Real-Time PCR detection kit     | F2005S-2M                           |
| 32.    | DNA Xpert Pvt. Ltd, Noida, India                                      | Xpert Covido 19-Fast RT-PCR kit                               | XC19-01                             |
| 33.    | DNA Xpert Pvt. Ltd, Noida, India                                      | Xperts Covido19 Multiplex RT-PCR kit                          | MP-20-01                            |
| 34.    | 1Drop Inc, Korea (Nandan Exports & Imports Private Limited)           | 1copy COVID-19 qPCR Triplex Kit                               | M230H1900                           |
| 35.    | EUROIMMUN, UK (CPC Diagnostics Pvt Ltd)                               | EURO Real Time SARS CoV-2                                     | I200428CF                           |
| 36.    | Equine Biotech, Karnataka (EBT PVT LTD)                               | Global COVID 19 Kit   | EBT002                              |
| 37.    | GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India                 | DiagSure nCOV-19 Detection assay (Taqman based)               | 20115K1278<br>20115K1251            |
| 38.    | GeneMatrix, South Korea   | NeoPlex COVID-19 detection kit                                | NR05A                               |
| 39.    | Gene Path Diagnostics, Pune, India                                    | GenePath CoViDx One RT-qPCR v2.1.1                            | 20200504A                           |
| 40.    | Gene Proof, Czech Republic  | Gene Proof SARS-CoV-2 Screening PCR kit                       | 2025671<br>2025455                  |



| Sl. No | Name of Company  | Name of the Kit  | *Batch Number             |
|--------|--|--|---------------------------|
| 41.    | Gene Proof, Czech Republic   | Gene Proof SARS-CoV-2 PCR kit  | 2025500                   |
| 42.    | GeneReach Biotechnology Corporation, Taiwan (Padmanabha Labs Pvt. Ltd.)          | IQ Real SARS-CoV-2 Qualitative System  | 031320                    |
| 43.    | General Biologicals Corporation, Taiwan (Innovation Limited, New Delhi)          | GB SARS-CoV-2 Real Time PCR (E + ORF1ab gene + IC)                                     | PVT6068                   |
| 44.    | Genes2me Pvt Ltd, Gurugram, Haryana  | VIRALDTECT II Multiplex real time RT-PCR for COVID-19                                  | G2M2001                   |
| 45.    | Genes2me Pvt Ltd, Gurugram, Haryana  | VIRALDTECT Multiplex Real-Time PCR kit   | G2M1001                   |
| 46.    | Genestore, France  | Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit                                  | DII.31519.3.0000001       |
| 47.    | Genetix Biotech Asia Pvt Ltd, New Delhi, India                                   | COVISure COVID-19 Real Time PCR Kit  | G1T20.G.101               |
| 48.    | Genome Diagnostics Pvt. Ltd., New Delhi, India                                   | Genosens nCOV 2019 Real time PCR kit   | CoV-002/20                |
| 49.    | Gland Pharma Ltd., Hyderabad   | RT PCR SARS-CoV-2  | 20200406                  |
| 50.    | Guangdong Ardent Biomed Co., Ltd, Hong Kong (Biotime Healthcare Private Limited) | Novel Coronavirus (COVID-19) Nucleic Acid Detection Kit (PCR- Fluorescent Probe)       | V20200609                 |
| 51.    | Helini Biomolecules, Chennai, India  | Helini Coronavirus [COVID-19] Real time-PCR Kit  | 01/2020<br>MFD: 04/20     |
| 52.    | Helini Biomolecules, Chennai   | Helini Coronavirus Real-Time PCR kit [RdRp & ORF gene – Dual target-single tube assay] | 01/2020, 02/2020, 03/2020 |
| 53.    | Huwel Lifesciences Pvt. Ltd., Hyderabad, India                                   | Quantiplus CoV detection KIT Ver 2.0   | QLCNV0620<br>QLCNV0920    |
| 54.    | Huwel Lifesciences Pvt. Ltd., Hyderabad, India                                   | Quantiplus Multiplex COVID-19 detection kit  | QLCNM0120.2               |
| 55.    | iNtRON Biotechnology, Inc., Korea (Loften India Pvt Ltd)                         | LiliF COVID-19 Multi Real-time RT-PCR Kit  | H215060553                |
| 56.    | JITM Skills Private Limited, New Delhi, India                                    | JITM COVID-19 Detection Kit  | JJ15052003                |
| 57.    | JN Medsys Pte Ltd, Singapore   | Protect COVID-19 RT-qPCR Kit   | RD 202004-001             |
| 58.    | Karwa Enterprises Private Limited, Delhi   | Karwa SARS-CoV-2 Nucleic Acid Detection Kit  | 20200213                  |
| 59.    | KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)                          | TRUPCR SARS-CoV-2RT-qPCR kit version 2   | CoV-19/V2/2020/01         |
| 60.    | Kogene Biotech, Seoul, Korea   | Power Check 2019 nCoV Real Time PCR Kit  | R6900TD200423             |





| Sl. No | Name of Company   | Name of the Kit   | *Batch Number                                    |
|--------|---|---|--|
| 61.    | Kogene Biotech Co. Ltd, Seoul, Korea (Kin Diagnostics)                          | Powercheck SARS CoV-2 RT PCR Kit                        | 1R6902200602                                     |
| 62.    | Indian Institute of Technology, Delhi, India                                    | Covid 19 Probe-free Real Time PCR Diagnostic Kit        | 09042020   |
| 63.    | InnoDx Solutions Pvt. Ltd   | InnoDetect COVID-19 RT-PCR kit Version 1                | COV-21-JU-20                                     |
| 64.    | Intron Biotechnology, Korea (Loften India Pvt Ltd)                              | LiliF COVID-19 Real Time RT-PCR kit                     | H215051153                                       |
| 65.    | Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India                           | Accucare COVID-19 One-step RT-pCR kit                   | RPCR200401<br>RPCR200402                         |
| 66.    | LabGenomics , South Korea   | LabGun Real Time PCR Kit                                | COV20D001<br>COV20D002<br>COV20D004<br>COV20D006 |
| 67.    | Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)     | LabGun COVID-19 Assay plus                              | CVA 20E001                                       |
| 68.    | Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)     | LabGun™ COVID-19 ExoFast RT- PCR Kit                    | CVF20G001  |
| 69.    | Lifespan Biotech Pvt Ltd, Madhya Pradesh, India                                 | LS COVID-19 RT-qPCR kit                                 | VLC20002   |
| 70.    | Lifespan Biotech Pvt Ltd, Madhya Pradesh, India                                 | LS COVID-19 RT-qPCR Multiplex Kit                       | LSMX20200621                                     |
| 71.    | Lipomic Healthcare Pvt. Ltd., New Delhi   | Lipomic COVID-19 multiplex Realtime RT-PCR Kit          | LIPO-001   |
| 72.    | LLC Art Biotech   | Art Test COVID-19 kit                                   | C19300320  |
| 73.    | Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)                      | SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR) | 0420131  |
| 74.    | Med Achievers Private Limited, Noida, Uttar Pradesh, India                      | Genome Analyst SARS-CoV-2 detection kit                 | Lot No. GA0306-20-A,<br>Batch No. MGA202003006   |
| 75.    | Medical and Biological Laboratories (MBL) Co. Ltd, Japan (OSB Agencies Pvt Ltd) | MEBRIGHT SARS-CoV-2 Kit                                 | 01FA   |
| 76.    | Medsources Ozone Biomedicals, Faridabad, Haryana                                | COVID-19 RT-PCR kit                                     | 20200433   |
| 77.    | Meril Diagnostics   | Meril COVID-19 One-step RT-PCR Kit                      | MRD091<br>MRD097<br>MRD098<br>M1052007           |
| 78.    | Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)                               | Veri-Q COVID-19 Multiplex Detection Kit                 | M2243a20DN1FA                                    |
| 79.    | Micobiomed Co. Ltd, Korea (POCT Services Pvt Ltd)                               | Veri-Q nCOV-QM COVID-19 Multiplex Detection Kit         | M224320EN1HB                                     |
| 80.    | M.J.Biopharm Pvt. Ltd   | MJ Coronavirus (COVID-19) RT-qPCR Kit                   | RTPCR0520AB21                                    |



| Sl. No | Name of Company   | Name of the Kit  | *Batch Number  |
|--------|---|--|--|
| 81.    | Mylab Discovery Solutions, Pune, India  | Patho Detect   | PP00005-C-0320001<br>PP00005-C-0420001<br>PP00005-C-0320002<br>PP00005-C-0420002 |
| 82.    | Mylab Discovery solutions, Pune, India  | Pathodetect (Two tube assay)   | PP00005-C-0520003  |
| 83.    | Mylab Discovery solutions, Pune, India  | Pathodetect Coronavirus (COVID-19) Qualitative PCR Kit                 | PP00005-C-070001E  |
| 84.    | NeoDx Biotech Labs Private Limited, India (DSS Imagetech Pvt Ltd)               | CoviDx mPlex-4R SARS-CoV-2 RT-PCR Detection Kit                        | CM4R-030820  |
| 85.    | NeoDx Biotech Labs Private Limited, India                                       | CoviDx mPlex-3NC SARS-CoV-2 RT-PCR Detection Kit                       | CM3NC-140820   |
| 86.    | NeoDx Biotech Labs Private Limited, India                                       | CoviDxTM mPlex-3NR SARS-CoV-2 RT-PCR Detection Kit                     | CM3NR-120820   |
| 87.    | 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  |
| 88.    | NovaTec Immunodiagnostica, Germany (Eurofins Amar Immunodiagnostics Pvt. Ltd)   | GSD NovaPrime SARS-COV-2 (COVID-19) RT-PCR                             | PCOV6030-005G,<br>PCOV6030-005-1,<br>PCOV6030-006                                |
| 89.    | Nucleus Diagnosys LLP, Gujarat, India   | SARS CoV-2 Triplex PCR Kit   | RD2762001  |
| 90.    | OSANG Health Care, South Korea  | Gene Finder COVID-19   | 2003-R45-22  |
| 91.    | Oscar Medicare Pvt. Ltd., New Delhi, India                                      | COVID-19 RT-PCR Kit  | OSCOV-003<br>Catalog No. OSCOV-96  |
| 92.    | Perkin Elmer, Finalnd   | SARS-CoV-2 RT-qPCR Reagent Kit   | 680613<br>680415<br>680694   |
| 93.    | Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited)                  | COVID-19 One-step RT-PCR kit   | 99001  |
| 94.    | POCT Services Private Limited   | Q-Line Molecular ER nCOV-19 RT-PCR Kit                                 | M200702  |
| 95.    | POCT Services Pvt. Limited, Lucknow, India                                      | Q-line Molecular Coronavirus (COVID-19) RT-PCR kit                     | P200401  |
| 96.    | Primer Design, UK   | Z-Path Covid-19C (Genesig)   | JN-02780-0011  |
| 97.    | Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi)   | RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene)                       | RC1405   |
| 98.    | Promea Therapeutics, Telangana  | ProPCR COVID-19 RT-qPCR  | TRCV 2001  |
| 99.    | QuantuMdx, United Kingdom (Ally-Bio Private Limited)                            | QuantuMDx SARS-CoV-2 RT PCR Detection Assay                            | P01090   |



| Sl. No | Name of Company   | Name of the Kit   | *Batch Number  |
|--------|---|---|--|
| 100.   | Roche Diagnostics , Switzerland                                     | Light Mix Modular SARS-CoV-2 (COVID19) RdRp   | 48492015   |
| 101.   | Shambhav Medical, Uttar Pradesh                                     | ViroDetect COVID-19 Real-Time PCR Kit   | 95001001   |
| 102.   | Sansure Biotech Inc., Changsha, China                               | Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | 2020029/S3102E   |
| 103.   | Seegene, South Korea  | Allplex 2019-nCoV assay   | RP4520A01<br>RP4520D34<br>RP4520D47<br>RP4520D50<br>RP4520D51<br>RP4529D70 |
| 104.   | Sentinel Diagnostics, Italy   | STAT-NAT COVID-19 B Realtime RT-PCR Kit   | 00310<br>00324<br>00365  |
| 105.   | SD Biosensor, South Korea   | nCoV Real-Time Detection kit  | MNCO 0120004<br>MNCO0120009  |
| 106.   | Shanghai ZJ Bio-Tech Co., Ltd (Life Technologies (India) Pvt Ltd)   | LifeRiver Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit              | 20200601   |
| 107.   | Shenzhen Uni-Medica Technology Co. Ltd (Vishat Diagnostics Pvt Ltd) | Real Time PCR Kit for Novel Coronavirus 2019-nCoV (ORF1ab, N)                       | 20200602   |
| 108.   | SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd)                   | COVID-19 Real Time PCR kit v1   | 2006R2   |
| 109.   | Stellence Pharmsciences Pvt Ltd                                     | Stellence Covid-19 RT-qPCR Kit  | 027032   |
| 110.   | TranScience Innovative Technologies, Chennai                        | TrueScreen COVID-19 Multiplex Real Time PCR Detection Kit                           | TS0820-01  |
| 111.   | Trivitron healthcare Pvt Ltd  | Covidsure Pro Multiplex RT-PCR kit  | COVID-M-001  |
| 112.   | Trivitron healthcare Pvt Ltd  | COVIDsure Multiplex Realtime RT-PCR kit   | COVID-C-T-004  |
| 113.   | uBio Biotechnology Systems Private Limited                          | ViraGEN Molecular Diagnostics Covid-19 Real- Time RT-PCR kit                        | UBMD0072001  |
| 114.   | Vitane Biologics Pvt Ltd, Telangana                                 | CovTect COVID-19 Qualitative PCR Kit  | VBRT004  |
| 115.   | Vitro S.A., Spain (DSS Imagetech Private Ltd.)                      | SARS-CoV-2 RT-PCR Kit   | COVP006  |
| 116.   | Wuhan Easy Diagnosis Biomedicine Co. Ltd                            | COVID-19 (SARS-CoV-2) Nucleic acid test kit   | 200401HW   |
| 117.   | YOUSEQ, UK  | COVID19 E,N,RdRp & S gene Multiplex qPCR kit  | YSM1641  |
| 118.   | 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/>).