



Date: 10.7.2020

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

Till date, 154 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. | Ajay Bio-Tech (India) Ltd. | PATHOFIND COVID-19 Realtime RT-PCR Kit | 20200601 |
| 5. | Altona Diagnostics, Germany | RealStar SARS-CoV-2 RT-PCR kit 1.0 | 023005 024628 |
| 6. | Angstrom Biotech Pvt. Ltd, Rajasthan | ANGPCR 2019-nCoV | COVP02 |
| 7. | Aura Biotechnologies Private Limited, Chennai | Aura's CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT | LD12020005 |
| 8. | BAG Diagnostics, Germany (Shiva Scientific Company, New Delhi) | ViroQ SARS-CoV-2 (E gene + RdRp) | 002VM1 |
| 9. | BGI Genomics, China | Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV | 6020200107 |
| 10. | Bhat Biotech India Pvt Ltd | GENEASY COVID-19 RT-PCR Kit | COVID20200601 |
| 11. | Biogenix INC Pvt Ltd, Lucknow | Biogenix Covid-19 one step RT PCR | 20200412 |
| 12. | BioGenomics Limited, Thane, India | BIO COVID ID/COVID-19 qualitative PCR detection kit version 2 | BGL/IVD/COV/0420/004 |
| 13. | BioSewoom, South Korea | Real-Q 2019-nCoV Detection Kit | 580L-008 |
| 14. | Cepheid, United States | Xpert Xpress SARS-CoV-2 | 1000191996 1000191998 1000191999 |
| 15. | CoSara Diagnostics Pvt. Limited, Ahmedabad, India | SARAGENE™ Corona Virus (2019 NCV) Test Kit | 20C11PE-01 |
| 16. | Daan Gene Co. Ltd., China | Daan Gene Co. Ltd | 2020007 |
| 17. | DNA technology Research & Production, LLC, Russia (365 Medical India) | SARS-CoV-2/SARS-CoV Multiplex Real-Time PCR detection kit | F2005S-2M |



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| 18. | DNA Xpert Pvt. Ltd, Noida, India | Xpert Covido 19-Fast RT-PCR kit | XC19-01 |
| 19. | EUROIMMUN, UK (CPC Diagnostics Pvt Ltd) | EURO Real Time SARS CoV-2 | I200428CF |
| 20. | GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India | DiagSure nCOV-19 Detection assay (Taqman based) | 20115K1278 20115k1251 |
| 21. | GeneMatrix, South Korea | NeoPlex COVID-19 detection kit | NR05A |
| 22. | Gene Path Diagnostics | GenePath CoViDx One RT-qPCR v2.1.1 | 20200504A |
| 23. | General Biologicals Corporation, Taiwan (Innvolution Limited, New Delhi) | GB SARS-CoV-2 Real Time PCR (E + ORF1ab gene + IC) | PVT6068 |
| 24. | Genes2me Pvt Ltd, Gurugram, Haryana | VIRALDTECT II Multiplex real time RT-PCR for COVID-19 | G2M2001 |
| 25. | Genes2me Pvt Ltd, Gurugram, Haryana | VIRALDTECT Multiplex Real-Time PCR kit | G2M1001 |
| 26. | Genestore, France | Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit | DII.31519.3.0000001 |
| 27. | Genome Diagnostics Pvt. Ltd., New Delhi, India | Genosens nCOV 2019 Real time PCR kit | CoV-002/20 |
| 28. | Gland Pharma Ltd., Hyderabad | RT PCR SARS-CoV-2 | 20200406 |
| 29. | Helini Biomolecules, Chennai, India | Helini Coronavirus [COVID-19] Real time-PCR Kit | 01/2020 MFD: 04/20 |
| 30. | Helini Biomolecules, Chennai | Helini Coronavirus Real-Time PCR kit [RdRp & ORF gene – Dual target-single tube assay] | 01/2020, 02/2020, 03/2020 |
| 31. | Huwel Lifesciences Pvt. Ltd., Hyderabad, India | Quantiplus CoV detection KIT Ver 2.0 | QLCNV0620 QLCNV0920 |
| 32. | Huwel Lifesciences Pvt. Ltd., Hyderabad, India | Quantiplus Multiplex COVID-19 detection kit | QLCNM0120.2 |
| 33. | JN Medsys Pte Ltd, Singapore | Protect COVID-19 RT-qPCR Kit | RD 202004-001 |
| 34. | KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India) | TRUPCR SARS-CoV-2RT-qPCR kit version 2 | CoV-19/V2/2020/01 |
| 35. | Kogene Biotech, Seoul, Korea | Power Check 2019 nCoV Real Time PCR Kit | R6900TD200423 |
| 36. | Kogene Biotech Co. Ltd, Seoul, Korea (Kin Diagnostics) | Powercheck SARS CoV-2 RT PCR Kit | 1R6902200602 |
| 37. | Indian Institute of Technology, Delhi, India | Covid 19 Probe-free Real Time PCR Diagnostic Kit | 09042020 |
| 38. | InnoDx Solutions Pvt. Ltd | InnoDetect COVID-19 RT-PCR kit Version 1 | COV-21-JU-20 |



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| 39. | Intron Biotechnology, Korea (Loften India Pvt Ltd) | LiliF COVID-19 Reqaal Time RT-PCR kit | H215051153 |
| 40. | Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India | Accucare COVID-19 One-step RT-pCR kit | RPCR200401 RPCR200402 |
| 41. | LabGenomics , South Korea | LabGun Real Time PCR Kit | COV20D001 COV20D002 COV20D004 COV20D006 |
| 42. | Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited) | LabGun COVID-19 Assay plus | CVA 20E001 |
| 43. | Lifespan Biotech Pvt Ltd | LS COVID-19 RT-qPCR kit | VLC20002 |
| 44. | Lipomic Healthcare Pvt. Ltd., New Delhi | Lipomic COVID-19 multiplex Realtime RT-PCR Kit | LIPO-001 |
| 45. | LLC Art Biotech | Art Test COVID-19 kit | C19300320 |
| 46. | Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd) | SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR) | 0420131 |
| 47. | Med Achievers Private Limited, Noida, Uttar Pradesh, India | Genome Analyst SARS-CoV-2 detection kit | Lot No. GA0306-20-A, Batch No. MGA202003006 |
| 48. | Medsorce Ozone Biomedicals | COVID-19 RT-PCR kit | 20200433 |
| 49. | Meril Diagnostics | Meril COVID-19 One-step RT-PCR Kit | MRD091 MRD097 MRD098 M1052007 |
| 50. | Micobiomed Co. Ltd (POCT Services Pvt Ltd) | Veri-Q COVID-19 Multiplex Detection Kit | M2243a20DN1FA |
| 51. | Mylab Discovery Solutions, Pune, India | Patho Detect | PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002 |
| 52. | Mylab Discovery solutions, Pune, India | Pathodetect (Two tube assay) | PP00005-C-0520003 |
| 53. | Mylab Discovery solutions, Pune, India | Pathodetect Coronavirus (COVID-19) Qualitative PCR Kit | PP00005-C-070001E |
| 54. | OSANG Health Care, South Korea | Gene Finder COVID-19 | 2003-R45-22 |
| 55. | Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited) | COVID-19 One-step RT-PCR kit | 99001 |
| 56. | POCT Services Pvt. Limited, | Q-line Molecular Coronavirus (COVID-19) | P200401 |



| Sl. No | Name of Company | Name of the Kit | *Batch Number |
|--------|---|---|--|
| | Lucknow, India | RT-PCR kit | |
| 57. | Primer Design, UK | Z-Path Covid-19C (Genesig) | JN-02780-0011 |
| 58. | Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi) | RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene) | RC1405 |
| 59. | Roche Diagnostics , Switzerland | Light Mix Modular SARS-CoV-2 (COVID19) RdRp | 48492015 |
| 60. | Sansure Biotech Inc., Changsha, China | Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing) | 2020029/S3102E |
| 61. | Seegene, South Korea | Allplex 2019-nCoV assay | RP4520A01 RP4520D34 RP4520D47 RP4520D50 RP4520D51 RP4529D70 |
| 62. | Sentinel Diagnostics, Italy | STAT-NAT COVID-19 B Realtime RT- PCR Kit | 00310 00324 00365 |
| 63. | SD Biosensor, South Korea | nCoV Real-Time Detection kit | MNCO 0120004 MNCO0120009 |
| 64. | SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd) | COVID-19 Real Time PCR kit v1 | 2006R2 |
| 65. | Triviron healthcare Pvt Ltd | Covidsure Pro Multiplex RT-PCR kit | COVID-M-001 |
| 66. | Triviron healthcare Pvt Ltd | COVIDsure Multiplex Realtime RT-PCR kit | COVID-C-T-004 |
| 67. | Oscar Medicare Pvt. Ltd., New Delhi, India | COVID-19 RT-PCR Kit | OSCOV-003 Catalog No. OSCOV-96 |
| 68. | 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 |
| 69. | YOUSEQ, UK | COVID19 E,N,RdRp & S gene Multiplex qPCR kit | YSM1641 |
| 70. | 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/>).