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

Till date, 123 RT-PCR kits have been evaluated by ICMR validation centres, and the following were found to be satisfactory.

<table>
<thead>
<tr>
<th>Sl. No</th>
<th>Name of Company</th>
<th>Name of the Kit</th>
<th>*Batch Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>ABI (Applied bio-systems), United States</td>
<td>TaqMan 2019-nCoV Control Kit v1</td>
<td>47532-020720</td>
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<td>2.</td>
<td>Accelerate Technologies Pte Ltd (DxD Hub), Singapore</td>
<td>A*STAR FORTITUDE KIT 2.0</td>
<td>200304; 200402</td>
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<td>3.</td>
<td>ADT India Ltd, New Delhi, India</td>
<td>LyteStar 2019-nCoV RT PCR Kit 1.0</td>
<td>nCoV-2003-06; nCoV-2004-02; nCoV-2004-03; SARS-2004-01; SARS-2004-02; SARS-2004-03</td>
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<td>4.</td>
<td>Altona Diagnostics, Germany</td>
<td>RealStar SARS-CoV-2 RT-PCR kit 1.0</td>
<td>023005; 024628</td>
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<td>5.</td>
<td>Angstrom Biotech Pvt. Ltd, Rajasthan</td>
<td>ANGPCR 2019-nCoV</td>
<td>COVP02</td>
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<td>6.</td>
<td>Aura Biotechnologies Private Limited, Chennai</td>
<td>Aura’s CORONAVIRUS (COVID-19) Real Time PCR DETECTION KIT</td>
<td>LD12020005</td>
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<td>7.</td>
<td>BGI Genomics, China</td>
<td>Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV</td>
<td>6020200107</td>
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<td>8.</td>
<td>Biogenix INC Pvt Ltd, Lucknow</td>
<td>Biogenix Covid-19 one step RT PCR</td>
<td>202000412</td>
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<td>10.</td>
<td>Cepheid, United States</td>
<td>Xpert Xpress SARS-CoV-2</td>
<td>1000191996; 1000191998; 1000191999</td>
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<td>12.</td>
<td>Daan Gene Co. Ltd., China</td>
<td>Daan Gene Co. Ltd.</td>
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<td>13.</td>
<td>DNA technology Research &amp; Production, LLC, Russia (365 Medical India)</td>
<td>SARS-CoV-2/SARS-CoV Multiplex Real-Time PCR detection kit</td>
<td>F2005S-2M</td>
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<td>14.</td>
<td>DNA Xpert Pvt. Ltd</td>
<td>Xpert Covido 19-Fast RT-PCR kit</td>
<td>XC19-01</td>
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<td>15.</td>
<td>EUROIMMUN (CPC Diagnostics Pvt Ltd)</td>
<td>EURO Real Time SARS CoV-2</td>
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<td>16.</td>
<td>GCC Biotech Pvt. Ltd, 24 Parganas, West Bengal, India</td>
<td>DiagSure nCOV-19 Detection assay (Taqman based)</td>
<td>20115K1278; 20115K1251</td>
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<td>17.</td>
<td>GeneMatrix, South Korea</td>
<td>NeoPlex COVID-19 detection kit</td>
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<td>Company / Organization / Location</td>
<td>Test Details</td>
<td>Code / Batch Details</td>
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<td>18</td>
<td>Gene Path Diagnostics</td>
<td>GenePath CoViDx One RT-qPCR v2.1</td>
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<td>19</td>
<td>Genes2me Pvt Ltd</td>
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<td>Genes2me Pvt Ltd</td>
<td>VIRALDTTECT Multiplex Real-Time PCR kit</td>
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<td>21</td>
<td>Genestore</td>
<td>Detection Expert 1S © SARS CoV-2 One Step rRT-PCR Kit</td>
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<td>Genome Diagnostics Pvt. Ltd., New Delhi, India</td>
<td>Genosens nCOV 2019 Real time PCR kit</td>
<td>CoV-002/20</td>
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<td>23</td>
<td>Gland Pharma Ltd., Hyderabad</td>
<td>RT PCR SARS-CoV-2</td>
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<td>24</td>
<td>Helini Biomolecules, Chennai, India</td>
<td>Helini Coronavirus [COVID-19] Real time-PCR Kit</td>
<td>01/2020 MFD: 04/20</td>
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<td>26</td>
<td>Huwel Lifesciences Pvt. Ltd., Hyderabad, India</td>
<td>Quantiplus CoV detection KIT Ver 2.0</td>
<td>QLCNV0620 QLCNV0920</td>
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<td>27</td>
<td>JN Medsys Pte Ltd., Singapore</td>
<td>Protect COVID-19 RT-qPCR Kit</td>
<td>RD 202004-001</td>
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<td>28</td>
<td>KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)</td>
<td>TRUPCR SARS-CoV-2RT-qPCR kit version 2</td>
<td>CoV-19/V2/2020/01</td>
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<td>Kogene Biotech, Seoul, Korea</td>
<td>Power Check 2019 nCoV Real Time PCR Kit</td>
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<td>Indian Institute of Technology, Delhi, India</td>
<td>Covid 19 Probe-free Real Time PCR Diagnostic Kit</td>
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<td>31</td>
<td>InnoDx Solutions Pvt. Ltd</td>
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<td>COV-21-JU-20</td>
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<td>32</td>
<td>Intron Biotechnology, Korea (Loften India Pvt Ltd)</td>
<td>LilIF COVID-19 Reqal Time RT-PCR kit</td>
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<td>33</td>
<td>Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India</td>
<td>Accucare COVID-19 One-step RT-pCR kit</td>
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<td>34</td>
<td>LabGenomics , South Korea</td>
<td>LabGun Real Time PCR Kit</td>
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<td>Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)</td>
<td>LabGun COVID-19 Assay plus</td>
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<td>LLC Art Biotech</td>
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<td>37</td>
<td>Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)</td>
<td>SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR)</td>
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<td>38</td>
<td>Med Achievers Private Limited</td>
<td>Genome Analyst SARS-CoV-2 detection kit</td>
<td>Lot No. GA0306-20-A, Batch No. MGA202003006</td>
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<td>No.</td>
<td>Company Name</td>
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<td>Medsource Ozone Biomedicals, Faridabad, India</td>
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<td>40</td>
<td>Meril Diagnostics, Vapi, Gujarat, India</td>
<td>Meril COVID-19 One-step RT-PCR Kit</td>
<td>MRD091, MRD097, MRD098, M1052007</td>
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<td>Mylab Discovery Solutions, Pune, India</td>
<td>Patho Detect</td>
<td>PP00005-C-0320001, PP00005-C-0420001, PP00005-C-0320002, PP00005-C-0420002</td>
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<td>Mylab Discovery solutions, Pune, India</td>
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<td>OSANG Health Care, South Korea</td>
<td>Gene Finder COVID-19</td>
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<td>44</td>
<td>POCT Services Pvt. Limited, Lucknow, India</td>
<td>Q-line Molecular Coronavirus (COVID-19) RT-PCR kit</td>
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<td>Primer Design, UK</td>
<td>Z-Path Covid-19C (Genesig)</td>
<td>JN-02780-0011</td>
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<td>46</td>
<td>Roche Diagnostics , Switzerland</td>
<td>Light Mix Modular SARS-CoV-2 (COVID19) RdRp</td>
<td>48492015</td>
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<td>47</td>
<td>Sansure Biotech Inc., Changsha, China</td>
<td>Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)</td>
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<td>48</td>
<td>Seegene, South Korea</td>
<td>Allplex 2019-nCoV assay</td>
<td>RP4520A01, RP4520D34, RP4520D47, RP4520D50, RP4520D51, RP4529D70</td>
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<td>SD Biosensor, South Korea</td>
<td>nCoV Real-Time Detection kit</td>
<td>MNCO 0120004, MNCO0120009</td>
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<td>50</td>
<td>SNP Biotechnology R&amp;D Ltd, Turkey (Wockhardt Ltd)</td>
<td>COVID-19 Real Time PCR kit v1</td>
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<td>Oscar Medicare Pvt. Ltd.</td>
<td>COVID-19 RT-PCR Kit</td>
<td>OSCOV-003, Catalog No. OSCOV-96</td>
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<td>52</td>
<td>3B Black Bio Biotech India Ltd.</td>
<td>TRUPCR SARS-CoV-2 RT-qPCR Kit (V-3.2) (Single Tube Multiplex format)</td>
<td>CoV-19/V3.2/2020/02</td>
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<td>53</td>
<td>ZyBio Inc, China (Biodx healthcare)</td>
<td>Zybion SARS-CoV-2 NA detection kit</td>
<td>200201</td>
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</table>

*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/](https://www.finddx.org/covid-19/pipeline/).