The disease COVID-19 caused by the SARS Coronavirus 2 (known as SARS-CoV-2) emerged in late 2019 and quickly turned into a worldwide pandemic. While India reported its first cases in January 2020, the number of cases quickly started rising across the country. In response to the rising number of cases and the measures initiated by the Government of India, it was evident that India would require a large number of diagnostic tests to screen, identify, diagnose, isolate and treat the infected individuals to contain the spread of the infection.

Initially, the country depended on imported kits as there were no approved kits from Indian manufacturers for COVID-19 diagnosis. However, the diagnostic industry quickly rose to the challenge facing the country. In parallel to the rapid spreading of the disease, the industry responded with greater measures to not only fulfill the need of the country, but to make India an overall export-oriented destination. Today, more than 100 kits from Indian manufacturers representing different technologies (RT-PCR, LAMP, ELISA, Rapid tests) for detection of viral RNA, antigens and antibodies are approved for use and sale in India.

This success story of the developers and manufacturers has been ably supported by various Government initiatives such as grants, activation of testing centers, regulatory facilitation etc. coming together in a synergistic manner. DBT and BIRAC in collaboration with NBM initiated the COVID-19 Research Consortium to facilitate the holistic development of the diagnostic ecosystem of Country. Their N-BRIC initiative targeted towards the long pending demand of the country of domestic manufacturing diagnostics components/ reagents for making India self-reliant. We are hopeful that this progress and co-operation will become a shining example of the capability, resilience and adaptability of the Indian medical device ecosystem.
India has been calibrating its testing strategy as per the changing paradigm, and taking into account the scope, need and capacity to rapidly scale up tests performed each day across the country. Over a period, the number of laboratories in the country rose from 14 in February to more than 1596 in August. The testing rate has been ramped up significantly over the last few months with the introduction of the rapid antigen detection test in addition to the molecular tests, which remain the mainstay of diagnosis.

Technology landscaping, leveraging resources and optimizing the processes to increase efficiency were the key approaches that the Indian Council of Medical Research (ICMR), Ministry of Health & Family Welfare (MoHFW), Government of India undertook to expand the scale of testing. The government took a quantum leap by consolidating its resources, investing in infrastructure, forging public-private partnerships, and training human resource to cater to the need for increased tests per day.

As the country moves through different stages of the pandemic, the government is working towards continually evolve its testing strategy. The ICMR along with the Ministry of Health and Family Welfare (MoHFW) is expanding and diversifying testing capacity by leveraging technology such as use of automated PCR and RNA extraction platforms. India’s Prime Minister Shri Narendra Modi launched three high throughput COVID-19 testing facilities to further ramp up testing capacity and thus strengthen early detection and treatment. Indigenous vendors and manufacturers have been provided support to produce swabs and Viral Transport Medium (VT M) for sample collections, RNA extraction and RT-PCR kits, and other diagnostic material to align with the vision of “Atmanirbhar Bharat” (self-reliant India).
MADE IN INDIA COMMERCIAL COVID-19 DIAGNOSTIC KITS

RT-PCR Based Kit

Biogenix Inc. Pvt. Ltd  www.biogenixinc.com

One Step RT-PCR

- Testing Time: 60 mins
- 95% Specificity & 95% Sensitivity
- Production Capacity: 10000/Day

DNA Xperts Private Limited  www.dnaxperts.com

Covid19 - Fast RT-PCR Kit

- Testing Time: 57 mins
- 98.6% Specificity & 98.8% Sensitivity
- Units Sold: 25k Tests / Day

Huwel Lifesciences Pvt. Ltd.  www.huwellifesciences.in

1. Quantiplus Multiplex COVID detection kit
   - Testing Time: 80 Mins
   - 99% Specificity & 100% Sensitivity
   - Production Capacity: 12000 tests per day

2. Quantiplus COVID-19 detection kit
   - Testing Time: 80 Mins
   - 100% Specificity & 100% Sensitivity
   - Production Capacity: 8000 tests per day

Medsource Ozone Biomedicals  www.ozonebio.com

RT PCR Covid Testing Kit

- Testing Time: 90 Mins
- 99% Specificity & 95% Sensitivity
- Production Capacity: 1 Mn per Month
**Mylab Discovery Solutions Private Limited**  
www.mylabdiscoversolutions.com

**PathoDetect CVD-19 Qualitative PCR Kit. CoVID-19**
- Testing Time: 2 Hrs
- 100% Specificity & 100% Sensitivity
- Units Sold: 6 Mn per Month

**Nucleus Diagnosys LLP**  
www.nucleusdiagnosy.com

**SARS COV-2 TRIPLEX RTPCR KIT**
- Testing Time: 1.5 hrs
- 100% Specificity & 97% Sensitivity
- Production Capacity: 40000 tests per day

**POCT Services Private Limited**  
www.poctservices.com

**Q-Line n CoV -19 RT-PCR Kit**
- Testing Time: 60-90 Mins
- 100% Specificity & 98.7% Sensitivity
  Production Capacity: 2 Mn tests per month

**Trivitron Healthcare Pvt. Ltd.**  
www.trivitron.com

1) **COVIDsure Multiplex Real Time RT PCR Tests**
- Testing Time: <60 mins
- 98.9% Specificity & 98.8% Sensitivity
- Units Sold: 80 lac per month

2) **COVIDsure Pro Multiplex RT PCR Tests**
- Testing Time: <60 mins
- 100% Specificity & 100% Sensitivity
- Units Sold: 40 Lac per month
Molbio Diagnostics Private Limited  www.molbiodiagnostics.com

1) Truenat Beta Cov
- Testing time: 1 Hour
- 100% Specificity & 100% Sensitivity
- Units Sold: 20,000 equipment & 100 million tests per year

2) Truenat Sars Cov 2
- Testing time: 1 Hour
- 100% Specificity & 100% Sensitivity
- Units Sold: 20,000 equipment & 100 million tests per year

3) Truenat Covid 19
- Testing time: 1 Hour
- 100% Specificity & 100% Sensitivity
- Units Sold: 20,000 equipment & 100 million tests per year

Mylab Discovery Solutions Private Limited  www.mylabdiscoverysolutions.com

1) Compact X
- Testing time: 35-40 minutes for 8 samples
- 100% Specificity & 100% Sensitivity
- Units Sold: 60 per month

2) Compact xL
- Testing time: 35-40 minutes for 32 samples
- 100% Specificity & 100% Sensitivity
- Units Sold: 60 per month
Advy Chemical Private Limited.  www.advychemical.com

**EzDx™ Covid-19 IgG/IgM rapid antibody test**
- Testing time: 15 Mins
- 97.7% Specificity & 95.5% Sensitivity
- Units Sold: 20-25 Lac Tests/Month

Biogenix Inc. Pvt. Ltd.  www.biogenixinc.com

1) **SARS CoV-2 Antibody Rapid Test**
   - Testing time: 10-15 Mins
   - 98% Specificity & 98% Sensitivity
   - Production Capacity: 40000/Day

2) **SARS CoV-2 Antigen Rapid Test**
   - Testing time: 10-15 Mins
   - 99% Specificity & Sensitivity 99%
   - Production Capacity: 40000/Day

Lab-Care Diagnostics (India) Pvt. Ltd  www.labcarediagnostics.com

1) **Accucare COVID-19 IgG/IgM Ab Card Test**
   - Testing time: 15 - 20 Mins
   - >95% Specificity & >90% Sensitivity
   - Units Sold: 1 lac Tests / Day

2) **Accucare COVID-19 Antigen Card Test**
   - Testing time: 15 - 20 Mins
   - >100% Specificity & >80% Sensitivity
   - Units Sold: 1 lac Tests / Day

Medsource Ozone Biomedicals  www.ozonebio.com

**Covid IgM Rapid test**
- Testing time: 20 Mins
- >99% Specificity & >99% Sensitivity
- Production Capacity: 2 Mn tests per month
1. **PathoCatch COVID-19 Ag Lateral Flow Card test**
   - Testing Time - 15-20 Mins
   - 92% Specificity & 100% Sensitivity
   - Units Sold - 12 Mn Per month

2. **PathoCatch COVID-19 Antibody Lateral Flow Card test**
   - Testing time: 15-20 mins
   - 92% Specificity & 100% Sensitivity
   - Units Sold: 12 Mn/month

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**Covid-19 IgG/IgM rapid test**
- Testing Time: 15 Mins
- 99% Specificity & 98% Sensitivity
- Production Capacity: 10000 Tests / Day

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**Q-Line COVID-19 IgG Antibody Test**
- Testing Time: 20 Mins
- 96% Specificity & 83% Sensitivity
- Production Capacity: 1.5 Mn tests / Month

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**Biocard Pro COVID-19 Rapid Antigen**
- Testing time: <10 Mins
- 100% Specificity & 92% Sensitivity
- Units Sold: 45 lac per month

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**Sensit: COVID 19 IgG/IgM Rapid Test**
- Testing Time: 10-15 Mins
- 96% Specificity & 92% Sensitivity
- Production Capacity: 80000 Tests / Day
**VoxEL Covid 19 IgG Antibody Detection ELISA Test kit**

- **Testing Time:** 10 Mins
- **Most accurate test, with excellent Specificity & Sensitivity**
- **Production Capacity:** 2 lac Tests / Day

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**Genuine Biosystem Pvt Ltd**  
[www.genuinebiosystem.com](http://www.genuinebiosystem.com)

1) **GB PURE SPIN - RNA Extraction Kit**
   - **Testing time:** 20 Mins
   - **Production Capacity:** 1 Mn tests per month

2) **GB AURAPURE - RNA Extraction Kit**
   - **Testing time:** 20 Mins
   - **Production Capacity:** 2 Mn tests per month

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**HiMedia Laboratories Pvt. Ltd.**  
[www.himedialabs.com](http://www.himedialabs.com)

1) **HiPurA® Viral RNA Purification Kit**
   - **Testing time:** 20 Mins
   - **>97% Specificity & >97% Sensitivity:**
   - **Units Sold:** 1 Lac Tests / Day

2) **HiPurA® Viral RNA Purification Kit (Magnetic Bead Based)**
   - **Testing time:** 12 Mins
   - **>97% Specificity & Sensitivity >97%**
   - **Units Sold:** 1 Lac Tests / Day

3) **Pre-filled Plates for Insta NX® Mag 32/Pre-filled Plates for Insta NX® Mag 96**
   - **Testing time:** 12-27 Mins
   - **>97% Specificity & Sensitivity >97%**
   - **Units Sold:** 1 Lac Tests / Day
Extraction Kit

- >95% Specificity & Sensitivity >95%
- Production Capacity: 400000 per month

Mylab Discovery Solutions Private Limited

1) Maverick Magnetic Bead Based Nucleic Acid Extraction Kit
   - Testing time: 35-45 Mins
   - 100% Specificity & 100% Sensitivity
   - Units Sold: 6 Mn/month

2) Maverick Column-Based Nucleic Acid Extraction Kit
   - Testing time: 30 Mins
   - 100% Specificity & 100% Sensitivity
   - Units Sold: 6 Mn/month

4) Insta NX® Mag96/Mag32
   - Testing time: 12-27 Mins
   - >97% Specificity & Sensitivity >97%

5) Insta NX® Automated DNA/RNA Extraction System
   - Testing time: 20 Mins
   - >97% Specificity & Sensitivity >97%

POCT Services Private Limited

1) Q-Line RNA Extraction Kit (Spin Column)
   - Testing time: 30 samples / Hr
   - 100% Specificity & 100% Sensitivity
   - Production Capacity: 2 Mn Tests / month

2) Q-Line RNA Extraction Kit (Magnetic Bead)
   - Testing time: 60 samples / Hr
   - 100% Specificity & 100% Sensitivity
   - Production Capacity: 2 Mn Tests / month
HiMedia Laboratories Pvt. Ltd.  
**EliSafe**
- Testing Time: 3 Hrs
- 100% Specificity & 100% Sensitivity
- Units Sold: 1.5 Mn test per Month

J.MITRA CO. PVT. LTD  
1) **COVID 19 (IgM+IgG+IgA) MICROLISA**
- Testing Time: 90 min
- 100% Specificity & 94% Sensitivity
- Production Capacity: 70 lakh test per month

2) **COVID Kawach IgG MICROLISA**
- Testing Time: 130 min
- 100% Specificity & 96.33% Sensitivity
- Production Capacity: 70 lakh test per month

Lab-Care Diagnostics (India) Pvt. Ltd  
**Accucare COVID-19 IgG ELISA**
- Testing Time: 180 min
- 100% Specificity & 100% Sensitivity
- Units Sold: 30,000 kits per month
POCT Services Private Limited  www.poctservices.com

Q-LISA COVID-19 Antibody Elisa Kit

- Testing time: 2 Hrs
- 99% Specificity & 100% Sensitivity
- Production Capacity: 1 Mn Tests/ month

Trivitron Healthcare Pvt Ltd  www.trivitron.com

1) COVIDscreen PLUS ELISA Kit

- 99% Specificity & 100% Sensitivity
- Units Sold: 5 lacs
- Production Capacity: 15 lac per month

2) COVID KAVACH ANTI-SARS CoV-2 HUMAN IgG ELISA

- 100% Specificity & 98% Sensitivity
- Unit Sold 12 Lacs
- Production Capacity: 15 lac per month

Transasia Biomedical  www.transasia.co.in

Erbalisa CoVID-19 IgG

- Testing Time: 2 Hrs
- 98% Specificity & 97% Sensitivity
- Units Sold: 50,000 test per Day

Voxtur Bio Ltd.  www.voxturbio.com

VoxEL Covid 19 IgG Antibody Detection ELISA Test kit

- Testing time: 2 Hrs
- Under direct technology transfer from ICMR
- Production Capacity: 20000 Tests/Day
Viral Transport Media (VTM) Kits

DNA Xperts Pvt Ltd.  www.dnaxperts.com

Xperts Viral Transport Medium Kit

- Production Capacity: 5 Lacs per month

HiMedia Laboratories Pvt. Ltd.  www.himedialabs.com

1) Viral Transport Media VTM

- Units Sold: 5 Lakh Tests / Day
- Production Capacity: Over 100 Million tests

2) CovidSafe

- Units Sold: 5 Lakh Tests / Day
- Production Capacity: 1 Million tests

Lab-Care Diagnostics (India) Pvt. Ltd  www.labcarediagnostics.com

Accucare Viral Transport Medium

- Units Sold: 1 Lac Tests / Day
- Production Capacity: 5 Lacs test

Mylab Discovery Solutions Private Limited  www.mylabdiscoverysolutions.com

Virotrap VTM/MTM kits

- Units Sold: 21 Mn
- Production Capacity: 4 Mn per month
Q-Line VTM Kit

- Units Sold: > 1.5 Mn
- Production Capacity: 1 Million tests/month

ViSure - VIRAL TRANSPORT KIT

- Units Sold: 30 Lac per Month
- Production Capacity: 75 Lacs

1) VDx-Viral Transport Kit

- Units Sold: 3.3 Million Tubes of 3.0 ml each.
- Production Capacity: 2 Million Tubes of 3.0 ml each.

2) VDx-Viral Lysis Transport Kit

- Units Sold: 0.2 Mn Tubes of 3.0 ml each
- Production Capacity: 1 Million Tubes of 3.0 ml each.
### Target Genes

- **E** = envelope protein of SARS-CoV-2;
- **RdRp** = RNA-225 dependent RNA polymerase of SARS-CoV-2;
- **N** = nucleocapsid protein of SARS-CoV-2;
- **ORF1ab** = open reading frame 1a and b 226 of SARS-CoV-2, includes the RdRp, RNA-dependent RNA polymerase of SARS-CoV-2, part of ORF1ab;
- **S** = spike protein of SARS-228 CoV-2;
- **E-gene PCR** = these E-gene assays are specific.

### Sensitivity & Specificity

Key performance parameters like sensitivity and specificity are assessed by CENTRAL MEDICAL DEVICE TESTING laboratories under rule 83 of Drugs & Cosmetics act or by Certified competent laboratories approved as per ISO 17025:2017.

### LOD, LOQ


### Certifications

COVID-19 test kits manufactured in India adhere to Guidelines as per CDSCO MDR 2017, QMS as per ISO 13485:2016 and approved certifications by ICMR.
NBRIC is a ‘A Make in India’ initiative for Biomedical research and innovative products, towards promoting import substitution and exports.

National Biomedical Resource Indigenisation Consortium, NBRIC, was constituted by the Department of Biotechnology, Ministry of Science and Technology, Government of India as a Public Private Partnership. Hosted and led by the Centre for Cellular and Molecular Platforms - C-CAMP, NBRIC serves as a nation-wide collaborative platform for convergence of research, product resources and services towards developing reagents, diagnostics, vaccines and therapeutics across India for COVID-19 response.

In a span of six months, the consortium identified and assessed the nation’s need for research/innovation in biomedical resources, specifically in RT-PCR diagnostics kits along with current capabilities and capacity so as to work towards self-reliance.

**RT-PCR Diagnostics Kit - For RNA Isolation and cDNA Synthesis**

<table>
<thead>
<tr>
<th>Consumables</th>
<th>No. of Manufacturers</th>
<th>Manufacturing Capacity/month (Supply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trizol</td>
<td>21</td>
<td>14,659,000 Units, 10,372.2 L &amp; 35,00,000 Tests</td>
</tr>
<tr>
<td>Chloroform</td>
<td>13</td>
<td>11,61,496.55 L</td>
</tr>
<tr>
<td>DEPC Treated water</td>
<td>19</td>
<td>1,11,51,435.5 L &amp; 10,000 tests</td>
</tr>
<tr>
<td>Isopropanol/Ethanol</td>
<td>14</td>
<td>11,77,912.6 L</td>
</tr>
<tr>
<td>Rnase/Dnase free water</td>
<td>21</td>
<td>1,12,34,723.11 L &amp; 5,20,000 tests</td>
</tr>
<tr>
<td>cDNA synthesis Enzyme</td>
<td>19</td>
<td>10,99,19,507 Units</td>
</tr>
</tbody>
</table>

**RT-PCR Diagnostics Kit - For Nucleic Acid detection**

<table>
<thead>
<tr>
<th>Consumables</th>
<th>No. of Manufacturers</th>
<th>Manufacturing Capacity/month (Supply)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taqman Probe</td>
<td>18</td>
<td>2,43,85,600 Units, 20,010 micromole, 135 grams, &amp; 10,000 ml</td>
</tr>
<tr>
<td>SyBr Green based</td>
<td>22</td>
<td>1,00,80,002 Units, 22.4506 L &amp; 100 gm</td>
</tr>
<tr>
<td>Master Mix</td>
<td>16</td>
<td>17,56,000 Units, 8,8251.1 L &amp; 41.66 gms</td>
</tr>
<tr>
<td>dNTPs</td>
<td>25</td>
<td>7,73,18,000 Units &amp; 12.5251 L</td>
</tr>
<tr>
<td>Taq DNA Polymerase</td>
<td>25</td>
<td>1,17,48,000 Units, 0.5 L &amp; 10,000 gm</td>
</tr>
<tr>
<td>Bst 2 Enzyme</td>
<td>11</td>
<td>13273548 L &amp; 1500000 tests</td>
</tr>
<tr>
<td>Buffers</td>
<td>19</td>
<td>2,40,52,33,000 Units &amp; 10000.005 grams</td>
</tr>
<tr>
<td>Positive &amp; Negative Controls</td>
<td>11</td>
<td></td>
</tr>
</tbody>
</table>
State of the art Medical Diagnostic Equipments

Serology Testing Section
This section equipped with high-end automated ELISA systems, analyses blood samples for the presence of viral antigens and antibodies (IgG and IgM)

Molecular biology Laboratory for virological diagnosis with BSL-2 facilities.
This section provides Immunogenetics and Molecular testing facilities for genetic screening and detection of various infectious diseases along with DNA isolation and banking.
Make In India Facilitation Cell for Biotechnology,
Biotechnology Industry Research Assistance Council
1st Floor, MTNL Building, 9 CGO Complex, Lodhi Road, New Delhi-110003

Weblink:https://birac.nic.in/mii/index.php