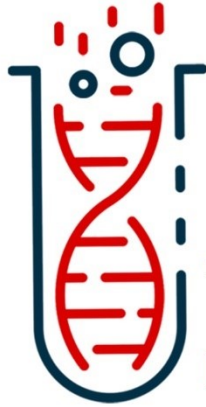




Ministry of Health & Family Welfare
Government of India



DEPARTMENT OF BIOTECHNOLOGY
Ministry of Science & Technology
Government of India



INDIAN IVDs INDUSTRY THROUGH THE PANDEMIC

FROM INSUFFICIENCY TO AATMANIRBHARTHA

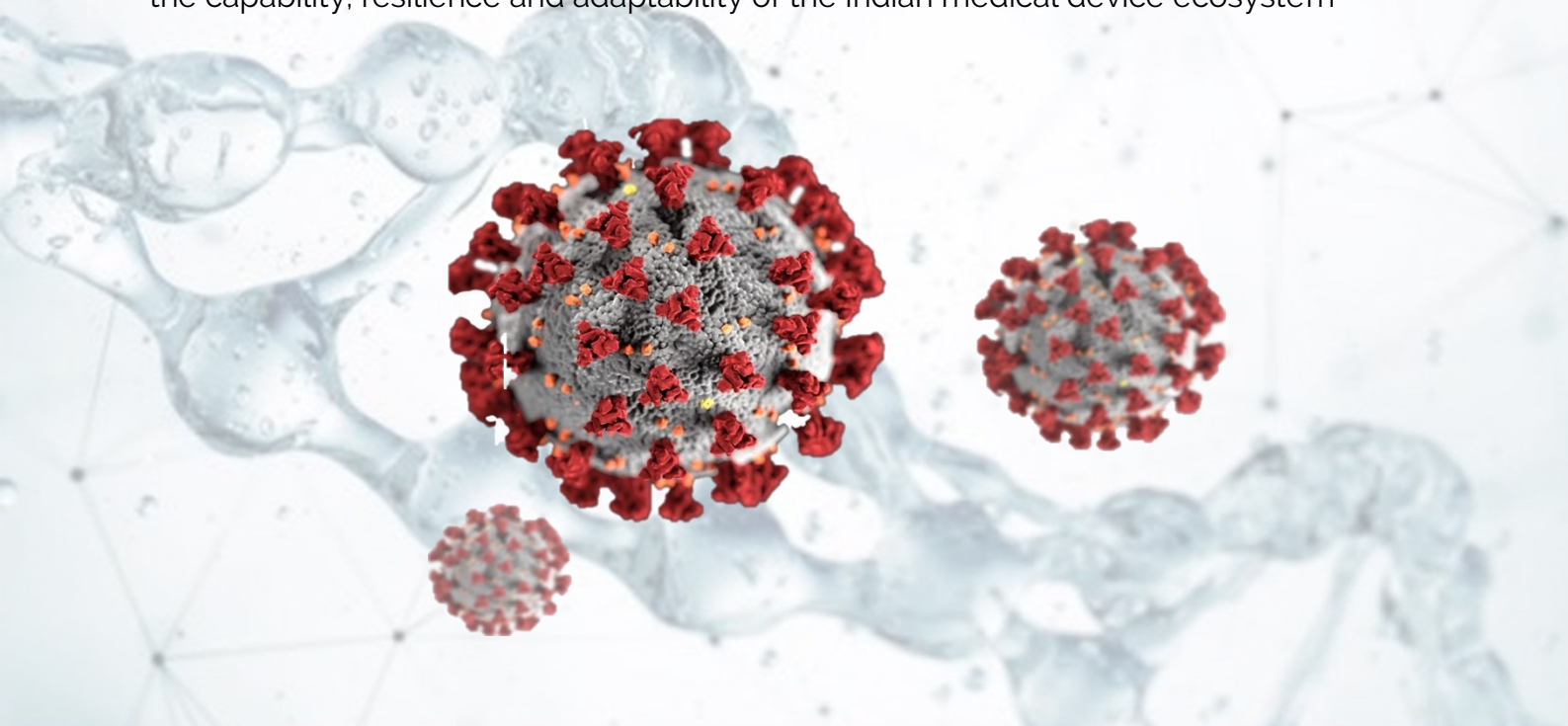


FOREWORD

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



HOW INDIA SCALED UP ITS LABORATORY TESTING CAPACITY FOR COVID-19

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).



ICMR Approved RT-PCR Kits

MADE IN INDIA COMMERCIAL COVID-19 DIAGNOSTIC KITS

RT-PCR Based Kit

Biogenix Inc. Pvt. Ltd

One Step RT-PCR

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



DNA Xperts Private Limited

Covid19 - Fast RT-PCR Kit

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



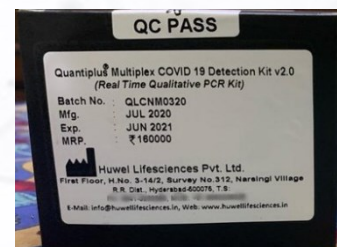
Huwel Lifesciences Pvt. Ltd.

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



Medsorce Ozone Biomedicals

RT PCR Covid Testing Kit

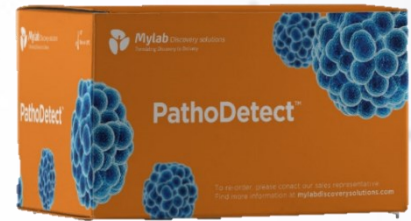
- Testing Time: 90 Mins
- 99% Specificity & 95% Sensitivity
- Production Capacity: 1 Mn per Month



Mylab Discovery Solutions Private Limited

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

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

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



Triviron Healthcare Pvt. Ltd.

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



Automated NAAT testing

Molbio Diagnostics Private Limited

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

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



Rapid Diagnostic Tests (RDTs)

Advy Chemical Private Limited.

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.

1) SARS CoV-2 Antibody Rapid Test

- Testing time: 10-15 Mins
- 98% Specificity & 98% Sensitivity
- Production Capacity: 40000/Day



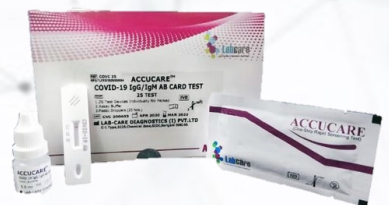
2) SARS CoV-2 Antigen Rapid Test

- Testing time: 10-15 Mins
- 99% Specificity & Sensitivity 99%
- Production Capacity: 40000/Day

Lab-Care Diagnostics (India) Pvt. Ltd

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

Covid IgM Rapid test

- Testing time: 20 Mins
- >99% Specificity & >99% Sensitivity
- Production Capacity: 2 Mn tests per month



MyLab Discovery Solutions Private Limited

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

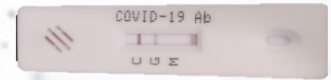
- Testing time: 15-20 mins
- 92% Specificity & 100% Sensitivity
- Units Sold: 12 Mn/month



Nucleus Diagnosys LLP

Covid-19 IgG/IgM rapid test

- Testing Time: 15 Mins
- 99% Specificity & 98% Sensitivity
- Production Capacity: 10000 Tests / Day



POCT Services Private Limited

Q-Line COVID-19 IgG Antibody Test

- Testing Time: 20 Mins
- 96% Specificity & 83% Sensitivity
- Production Capacity: 1.5 Mn tests / Month



Trivitron Healthcare

Biocard Pro COVID-19 Rapid Antigen

- Testing time: <10 Mins
- 100% Specificity & 92% Sensitivity
- Units Sold: 45 lac per month



ubio Biotechnology Systems Pvt . Ltd

Sensit: COVID 19 IgG/IgM Rapid Test

- Testing Time: 10-15 Mins
- 96% Specificity & 92% Sensitivity
- Production Capacity: 80000 Tests / Day



Voxtur Bio Ltd.

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



Nucleic Acid Extraction Kit

Genuine Biosystem Pvt Ltd

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



HiMedia Laboratories Pvt. Ltd.

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



Medsource Ozone Biomedicals

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



ELISA Based Kit

HiMedia Laboratories Pvt. Ltd.

EliSafe

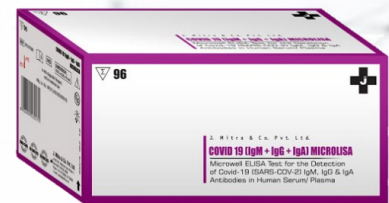
- Testing Time: 3 Hrs
- 100% Specificity & 100% Sensitivity
- Units Sold: 1.5 Mn test per Month



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

Q-LISA COVID-19 Antibody Elisa Kit

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



Triviron Healthcare Pvt Ltd

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 Anti-SARS CoV-2 Human IgG ELISA

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



Transasia Biomedical

Erbalisa CoVID-19 IgG

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



Voxtur Bio Ltd.

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.

Xperts Viral Transport Medium Kit

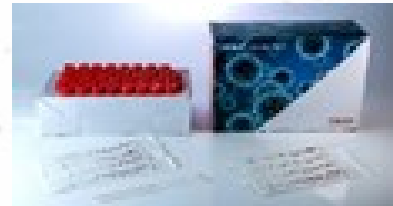
- Production Capacity: 5 Lacs per month



HiMedia Laboratories Pvt. Ltd.

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

Accucare Viral Transport Medium

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



Mylab Discovery Solutions Private Limited

Virotrap VTM/MTM kits

- Units Sold: 21 Mn
- Production Capacity: 4 Mn per month



POCT Services Private Limited

Q-Line VTM Kit

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



Triviron Healthcare

ViSure - VIRAL TRANSPORT KIT

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



Vanguard Diagnostics (P) Limited

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.



Key Characteristics for a COVID-19 Real Time PCR, ELISA & Rapid diagnostic test kits

Target Genes	<ul style="list-style-type: none">• E = envelope protein of SARS-CoV-2;• RdRp = RNA-225 dependent RNA polymerase of SARSCoV-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,	Technical Guidance Series - Principles of performance studies (TGS 3) & Technical Guidance Series (TGS 4) for Diagnostic Assessment Guidance on Test Method Validation of in vitro diagnostic medical devices
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.



NATIONAL BIOMEDICAL RESOURCE INDIGENIZATION CONSORTIUM

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

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

RT-PCR Diagnostics Kit - For Nucleic Acid detection

Consumables	No. of Manufacturers	Manufacturing Capacity/month (Supply)
Taqman Probe	18	2,43,85,600 Units, 20,010 micromole, 135 grams, & 10,000 ml
SyBr Green based Master Mix	22	1,00,80,002 Units, 22.4506 L & 100 gm
dNTPs	16	17,56,000 Units, 8.8251.1 L & 41.66 gms
Taq DNA Polymerase	25	7,73,18,000 Units & 12.5251 L
Bst 2 Enzyme	11	1,17,48,000 Units, 0.5 L & 10,000 gm
Buffers	19	13273548 L & 1500000 tests
Positive & Negative Controls	11	2,40,52,33,000 Units & 10000.005 grams



ANDHRA PRADESH MEDTECH ZONE LTD



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.



Our Partners

