

2022

Enabling one million indigenous tests per day for COVID-19 in India

A step towards Atmanirbhar Bharat for Molecular Diagnostics

GUIDED BY



SUPPORTED BY





FUNDED BY

COVID-19 PANDEMIC AND INDIGENISATION OF DIAGNOSTICS

In March 2020, as the world was beginning to battle COVID-19, India grappled with its preparedness to manage the pandemic. There was 80% dependence on global markets for diagnostic kits, their components, and reagents. It was imperative that the country's molecular diagnostics community step up to manufacture affordable, accessible, and high-quality indigenous diagnostic kits. In the early days of the pandemic, the cost of each RT-PCR test was about INR 5000. This was not affordable, hence not accessible to a majority of population in a scenario where controlling the pandemic was highly dependent on test-track-isolate approach.

As the virus continued to mutate and spread across the country, more than 30 million cases were reported in India alone till June 2021. In this context, building a support system for indigenous diagnostic manufacturers became a vital step towards developing self-reliance in a range of diagnostic kits. This would facilitate identification and testing of new variants, assuring safety in workplaces.

The CCAMP-InDx programme was conceptualised as a response to the need to support Indian diagnostic manufacturers. The programme was flagged off to establish a strong supply chain network of Indian Micro, Small and Medium Enterprises (MSMEs) and work side by side with them to ensure that international standards of quality were met and capacities scaled up. The goal was to reach a stage where these manufacturers would be able to produce, supply, and execute one million indigenous diagnostic kits per day.

This programme is funded by The Rockefeller Foundation and executed by the Centre for Cellular and Molecular Platforms (C-CAMP), Bangalore, India, and constitutes a governance team offering strategic directions, a programme management unit with a functional team with operational responsibilities, and the Centres of Excellence (CoEs) for scientific and technical support.

With the onset of the pandemic in India, the first phase was dominated by multiple challenges responsible for falling short of meeting the demands for COVID testing across the country. The four dimensions of the key challenges outlined below were the primary focus areas for the programme.



Cost

Diagnostic kits for SARS CoV2 detection were exorbitant, making them unaffordable for general public. This was largely due to high dependency on global imports as indigenous manufacturers did not have the requisite capacities.



Access

Extraction

India, with its vast hinterland and population, had severe challenges in offering access to COVID testing. RT-PCR machines and laboratory infrastructure were in short supply when the pandemic started. Increasing capacities for RT-PCR-based tests and creating access was paramount, but alternate point-of-care (POC) testing was also the need of the hour.

Quality

High demand in the country led to an onslaught of imported kits from multiple countries offering competitive pricing. Meeting the testing needs came with major quality issues. As unbroken cold chains were far and few in between, temperature surges would impact the quality of the testing kits, increasing the risk of false negatives.



Availability

Diagnostic kits were in high demand due to the pandemic. Supply chain issues arose due to an erratic supply of imported kits, compounded by quality challenges. Hence, the unequivocal call for the programme was to support indigenous manufacturers to build their capacities to quality to meet the countrywide demands.

SURVEILLANCE

ELISA/CLIA

Rapid Antibody Tests

TEST, TRACK, ISOLATE. BUT HOW? The current cohort of COVID-19 tests include: NP/OP Swabs, Saliva, Sputum NP/OP Swabs, Saliva, Sputum VTM, MTM (Transport Media) RNA ExtractionBased Methods RNA ExtractionFree Methods RNA Blood/Serum Collection

SCREENING

Diagnostic Platforms

RT-PCR LAMP CRISPR /Cas9 Nucleic acid-based methods

COVID-19 Report

CONFIRMATORY

GAPS IDENTIFIED AND ADDRESSED BY CCAMP-InDx

High-quality components and reagents for molecular diagnostic kits that Indian manufacturers depend on the global markets for:

RT-PCR, LAMP - Master mixes, dNTPs, Primers/Probes, Amidites CRISPR/Cas9 - Paper strips, Enzymes Rapid Antigen/Antibody Test - LFA strips, Antigens/Antibodies Additional focus areas - Sample collection devices, RNA Extractionfree methods, alternate sample formats like saliva CCAMP-InDx is helping fill these gaps through:

- 1) Indigenisation
- 2) Optimisation
- 3) Commercialisation
- 4) Scale-up

CCAMP-InDx: **VOCAL FOR LOCAL**

In building the country's self-reliance in molecular diagnostics, CCAMP-InDx is at the forefront uniting local manufacturers, service providers, regulators, government agencies, and, most importantly, research institutions to leverage knowledge and expertise in building quality and capacity for molecular diagnostics.

Impediments to indigenous manufacturing are being removed. Collaborations across the country are being nurtured and Indian companies are beginning to make a global impact.

BOTTLENECKS



Marketplace

Lack of a consortium to bring together all stakeholders in Indian diagnostic space to interact, collaborate, and innovate



Supply chain

Gaps in supply chain for reagents and components, scale-up, and partnering options



Service providers

Absence of an independent agency to provide technical support for quality testing and process development

CCAMP-InDx is addressing these needs and problems with a rigorously formulated three-pronged approach to further the mission of manufacturing globally competitive products.

THREE-PRONGED CCAMP-InDx APPROACH



DIGITAL MARKETPLACE

- Establishing supply chain network of indigenous diagnostic ecosystem
- Facilitating negotiation, buying, and selling of products and services





OUTREACH

- Reaching out to and onboarding diagnostics manufacturers and service providers into the programme
- Facilitating networking through discussions and round table meetings





CENTRES OF EXCELLENCE

- Bringing together subject matter expertise, academic excellence, and state-of-the-art cutting-edge technologies
- Offering scientific and technical support to enhance quality, manufacturing capacities, and clinical validations





GOAL

Enable Indian manufacturers to develop diagnostic kits that would be used in executing 1 million COVID-19 tests per day

CCAMP-InDx DIGITAL PLATFORM

Connecting everyone within the diagnostic ecosystem

What is CCAMP-InDx Digital Platform?

CCAMP-InDx Digital Platform is an online marketplace for indigenous diagnostic kits, reagents, ancillary products, and supporting services needed by indigenous companies. Tata Consultancy Services (TCS) has developed this platform pro bono.

WHAT CAN IT DO?



Create an integrated supply chain



Identify needs and challenges



Present options for indigenous ingredients



CCAMP-InDx Ecosystem





Provide visibility to capacities



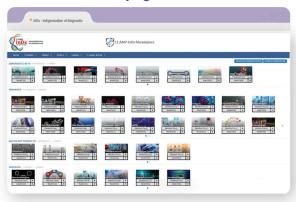
Powered by

Access to new technologies

TATA CONSULTANCY SERVICES

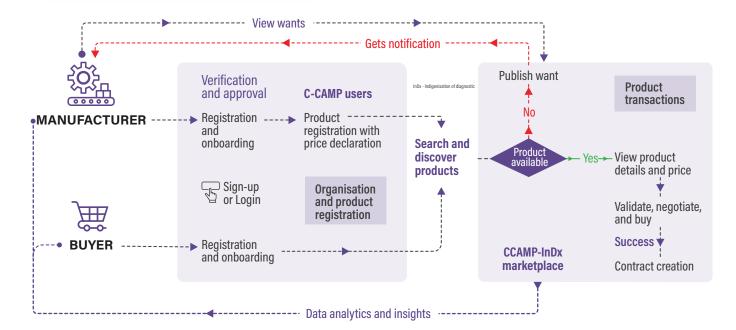
HOW DOES IT WORK?

View of the Homepage



Product/Service Listing







UNITED WE STAND, STRIVE, AND SUCCEED

Bringing institutional expertise, world-class infrastructure, and regulatory rigour to every single indigenous manufacturer to drive affordability, accessibility, and global-quality diagnostics in India.

HOW?

CCAMP-InDx assembled a stellar team of subject matter experts from various areas of science and technology. These teams, spread across eight Centres of Excellence, offer their expertise and laboratory capabilities to support manufacturers in ensuring high-quality materials to produce diagnostic kits.

CAPABILITIES OF THE CCAMP-InDx CENTRES OF EXCELLENCE (CoEs)



Enhance the **quality** of indigenously manufactured reagents and components



Support with **clinical** development of diagnostic kits



Offer **scale-up** process technologies for enzymes of diagnostic importance



Evaluate
interchangeability of
reagents and
components from
indigenous sources



Adopt **best practices** in quality and manufacturing to meet global standards

CCAMP-InDx CoEs





CoE for Chemistry
CoE Lead: Prof Seergazhi G Srivatsan
Performs chemical characterisation and
qualification of reagents for development and
commercialisation of diagnostic kits





CoE for Clinical Studies
CoE Lead: Prof Colin Jamora
Conducts clinical studies for the
development and commercialisation of
diagnostic kits









CoE for Antigen/Antibody
CoE Leads: Dr Nalam Madhusudhana Rao,
Dr Feroz Musthafa
Design and development of high-quality antigen-and
antibody-based diagnostics





CoE for Biologics
CoE Lead: Dr Saravanan Palani
Process development for high-quality enzymes
and biologics for molecular diagnostics





CoE for Business Analytics
CoE Lead: Rashmi (Rohini) Pimpale
Provides business plans for molecular diagnostics
enterprises, formulates pricing strategy, and
builds economic cases to attract funds





CoE for Quality
CoE Lead: Dr Mitali Samaddar
Designs quality control strategy and offers quality testing, interchangeability, analytical validation, and benchmarking studies



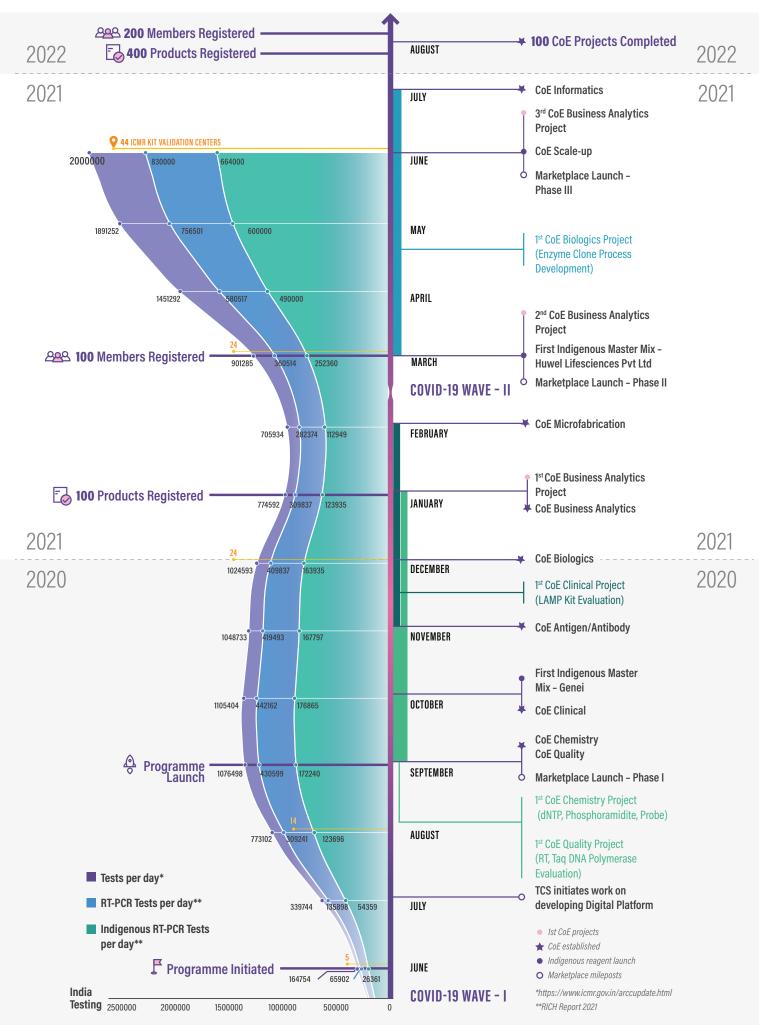


CoE for Scale-up
CoE Lead: Dr Vinothkumar Kutti Ragunath
Scale-up process development for enzymes, antibodies,
antigens, and other proteins



CoE for Informatics
Strengthens, validates, and integrates informatics solution components developed by InDx stakeholders

THE JOURNEY SO FAR



SMALL CHANGE, BIG IMPACT

CCAMP-InDx PARTNERS

90+ diagnostic kit manufacturers 8+ academic technology developers 35+ reagent manufacturers 55+ service providers 35+ ancillary products



CCAMP-InDx PROJECTS

100 CoE projects, diagnostic kits, master mixes, enzymes, primers/probes, dNTPs, amidites, **30** tech transfers

CCAMP-InDx has created history as an enabler of change by providing a platform for suppliers, MSMEs, and developers to avail local, indigenous products for the manufacture of RT-PCR and other molecular diagnostic kits. This, in turn, has increased the capacity for daily testing.



CCAMP-InDx PORTFOLIO

100+ diagnostic kits

100+ reagents

150+ ancillary products

50+ services



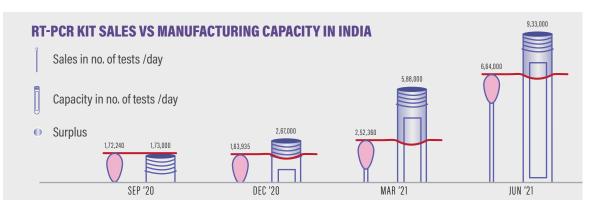
THE ECOSYSTEM IS GROWING

90 indigenous RT-PCR Kit manufacturers are associated with CCAMP-InDx programme from around 100 diagnostic kit manufacturers in the country.

- Indigenous RT-PCR kit manufacturers
- No of indigenous RT-PCR kit manufacturers partnering with CCAMP-InDx







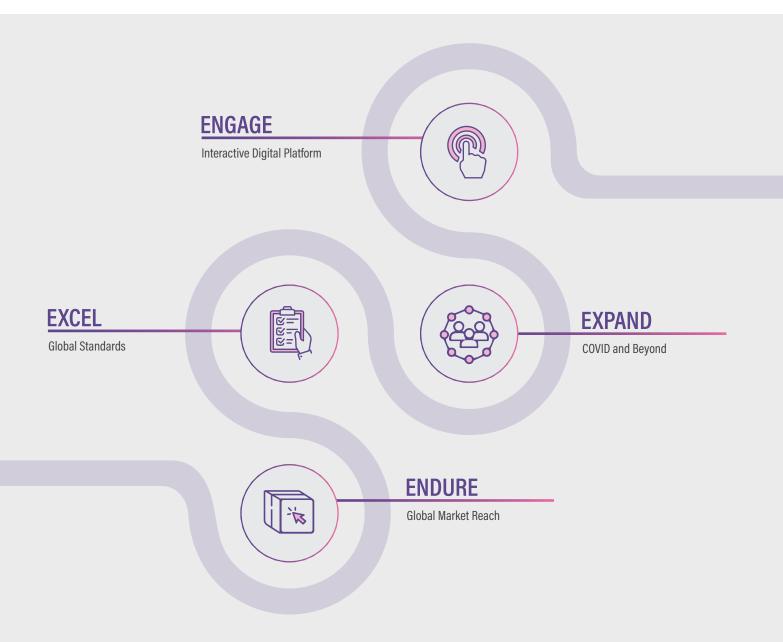
THE WAY FORWARD

Catalysing sustainable growth for future preparedness

India, with a high prevalence of infectious and chronic diseases, needs to build a strong ecosystem of indigenous diagnostics with a sustainable balance of quality, affordability, and access. Combining the country's prowess in creating scalable, large informatics and digital solutions with the foundation of predictive and preventive diagnostics companies can usher in an era of democratisation of healthcare.

Indigenous molecular diagnostics, an emerging industry in the country, requires sustained scientific and technical support across the product development value chain to catalyze growth and global competitiveness. The CCAMP-InDx programme will continue to play a significant role as outlined here.

- Supporting exploratory research, development, analytical/clinical validations, and commercialization of:
 - 1. Next generation of COVID-19 diagnostics
 - 2. SARS CoV2 variant specific tests
 - 3. Biomarkers in COVID-19 disease management
- Postering innovative technologies and point-of-care devices to the market
- Evolving assurance testing methods for resuming schools, physical workplaces, and travel
- Envisaging to build a quality framework to ensure harmonisation and consistency of diagnostic kit performance



CCAMP-InDx is by far the largest effort ever undertaken for advancing the molecular diagnostics industry in India. It has brought about a paradigm shift in this industry by building autonomy in terms of capability and capacity for not only COVID-19 diagnostics but also for mitigating future pandemics.

CCAMP-InDx programme is a firm foundation built to bring affordable and accessible diagnostics across many disease areas. CCAMP-InDx will herald a self-reliant, innovative molecular diagnostic industry in India.

BUILDING A SELF-RELIANT DIAGNOSTICS ECOSYSTEM



Mr Hasmukh Rawal Managing Director Mylab Discovery Solutions Pvt Ltd



"CCAMP-InDx is a brilliant example of the platform, infrastructure, and network needed to build large-scale, global diagnostics companies from India. The centers of excellence, the digital marketplace, and the network of suppliers and service providers will go a long way in establishing solid foundations for molecular diagnostics in India. We are truly proud to be associated with the effort. More power to C-CAMP."



Dr Rachana Dr ShesheerDirectors
Huwel Lifesciences Pvt Ltd





"CCAMP-InDx is an excellent idea; this idea needs to be extended to all molecular diagnostics platforms. It will help in making India a global hub for diagnostics."



Dr Prabhakar Kulkarni Co-Founder, Director NeoDx Biotech Labs Pvt Ltd



"CCAMP-InDx has been a hub for indigenisation and clinical testing for us. We finally have a diagnostics platform in India that will catapult us to global markets."



Mr Harkaran Dhingra Director DSS TAKARA Bio India Pvt Ltd



"A truly remarkable effort that brings together so many companies actively working in the diagnostics area. The weekly round table meets are a great opportunity to network, learn, and find partners."



Dr Sudeshna Adak CEO & Founder OmiX Research and Diagnostics Laboratories Pvt Ltd



"We developed a novel LAMP-based detection platform for COVID-19 that combines easy-to-use kits with a colorimetric detection device. This reduces both the requirement for skilled manpower and cost.

CCAMP-InDx's support has been essential in the development of our novel LAMP platform and we look forward to their support in ensuring the kits can be manufactured at low cost with indigenisation of its components."



Dr S Chandrashekaran Managing Director GeNei Laboratories Pvt Ltd



"Genei is working with CCAMP-InDx on the characterisation of enzymes – Taq DNA Polymerase, Reverse Transcriptase, and Bst. We have successfully launched an indigenous master mix with support from CCAMP-InDx and are looking forward to launching a 100% indigenous RT-PCR Kit. The process and performance at InDx are truly of global standards. This is the kind of effort that will help indigenise and globalise Indian diagnostics."



Dr Paidi Yella Reddy President, CEO Sapala



"It is our pleasure to be part of Atmanirbhar Bharat. The CCAMP-InDx programme is a great initiative by C-CAMP for promoting indigenous sourcing of materials for diagnostic purposes and we are proud to be a part of it.

The CCAMP-InDx programme has helped in disseminating our capabilities and strengths to the Indian scientific community. It has helped us in supplying key nucleic acid reagents to promote the global cause for indigenous diagnostic kits to meet our country's needs."

DIAGNOSTIC KIT MANUFACTURERS







Aakaar Biotechnologies



AbGenics Life Sciences



Accurex Biomedical



Acrannolife Genomics



Aditum LifeSciences



Advanced Microdevices



Advy Chemical



Affigenix Biosolutions



Agappe Diagnostics



AMMAGEN



Aps Lifetech



Aura Biotechnologies



Azooka Labs



Bhat Biotech



Biobharati LifeScience



BioGenomics



Biosensika



Bogar Bio Bee Stores



Chimera Translational Research Fraternity



Chromous Biotech



CLAMBio



Cosara Diagnostics



DNA xperts



D-NOME



DSS Takara Bio India



Enhanced Innovations



Epygen Biotech



Equine Biotech



GCC Biotech



geneOmbio Technologies



GenePath Diagnostics



Genes2me



Genetix Biotech Asia



Genexis Biotech



Genotypic Technology



Grace Lifetech



Gunasutraa Healthcare



HELINI Biomolecules



HiMedia Laboratories



Huwel Lifesciences



Igneus Life Science



InnoDx Solutions



Iota Design & Innovations



J. Mitra & Co.



Karwa Enterprises



Krishgen Biosystems



Kriya Medical Technologies



Lab-Care Diagnostics



Levram Lifesciences











Livgen Biotechnologies



Medsource Ozone

Mylab Discovery Solutions

NeoDx Biotech Labs











Neuome Technologies

NextGen Invitro Diagnostics

OmicsGen LifeSciences

OmiX Research and **Diagnostics Laboratories**

Oncosimis Biotech











Papyrus Diagnostics

Pathkits Healthcare

Primordia



Prantae Solutions

Premier Medical Corporation

Primordia Lifesciences











Promea Therapeutics

Q-Line Biotech

Saffron Naturele Products

SciGenom Labs













γ∫spotsense





Shrimpex Biotech

Siemens Healthineers

SpotSense

Stellar Diagnostics India

Strumed Solutions







Swagene



Swemed Diagnostics



Synteny Lifesciences

TATA MD

Tata Medical and Diagnostics



Theranosis Life Sciences



TranScience



Trivitron Healthcare



UBIO Biotechnology



Unigene



Vanguard Diagnostics



Vitane Biologics



Voxtur Bio



Yaathum Biotech



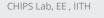
Yaazh Xenomics

DIAGNOSTIC TECHNOLOGIES FROM ACADEMIA











CSIR - National **Environmental Engineering** Research Institute



Indian Institute of Technology, Kharagpur

Arati Ramesh Lab, NCBS, Bangalore

Centre For Human Genetics, Bangalore

REAGENT MANUFACTURERS







Applied Bioscience



BioArtis Life Sciences



Bioserve Biotechnologies



CisGen Biotech Discoveries



Cytiva



Edna Biolabs



GeNei Laboratories



GenetoProtein Pvt Ltd



GeNext Genomics



HELINI Biomolecules



IMGENEX India Pvt Ltd



Indigenese Biotechnologies Innovassynth Technologies





Premas Biotech



ProCyto Labs



Protein Design



Recdesprot



Rubizon Pvt Ltd - (Dxbidt)



Saanvika Pharma



Sapala Organics



Sisco Research Laboratories



Tardigrade



VNIR Biotechnologies

ANCILLARY PRODUCT MANUFACTURERS



Accumax Lab Devices



ADIUVO Diagnostics



Biomoneta Research



Bionaltek Enterprises



Cambrian Bioworks



Chart Techno solutions



CosTheta Technologies



Docturnal



Enhanced Innovations



Genaxy Scientific



iHeal Innovations



Incumed



Inventigen Technologies



Invitreo Healthtech Ventures



Ishield



Livgen Biotechnologies



MagGenome Technologies



Route Biosciences



Scribetech Healthcare



ShanMukha Innovations



Shiv Dial Sud & Sons



Tapestry Labs



Tarsons Products Limited



TestRight Nanosystems



Valetude Primus Healthcare

SERVICE PROVIDERS



Achira Labs



Aequitas Consulting



Ameliorate Biotech



AmpliGene India Biotech



AshRin Bio LLP



BananalP Counsels



Biogenuix Medsystems



Bionivid Technology



Biosolutions India



Biotech Desk Pvt Ltd



Bird Electronics



Crisprbits



Denovo Biolabs



Dhiti Omics Technologies



Diponed biointelligence



EMPE Diagnostics



Gemni Electro Corporation



Genenest Biotech



Genworks Health



IIQ System



IMGENEX India Pvt Ltd



India Health Fund



Indra Chemical Manufacturing



Inte-e-Labs



Jaldhara and Company



Jehangir Clinical Development Centre



Karkhana.io



Link Biotech



Linq Therapeutics



Module Innovations



Movin Labs



OC India



Octosquare Business



Oneomics Pvt Ltd



Premas Life Sciences



Promiso Health



QTLomics Technologies



QA and Regulatory services consultant



Referral labs



regulatory1











Rivaara Labs Pvt Ltd



Sudarshan

Sinos Biotech & Consultants SperogenX Biosciences

ces Stella Polaris



Pharma

R RETTER HEALTHCARE SECUTIONS



© C-CAMP

Centre for Cellular and Molecular Platforms



Strand Life Sciences

Sudarshan Pharma Industries

Symbiorph Clinical Trialogy

Technology Platforms, C-CAMP

Vision Bio Science























CCAMP-InDx cohort's Regulatory approved Kits and Reagents

to leverage the capabilities and capacities of this cohort

ICMR-CDSCO Approved RT PCR Kits





















































Reagents

Master Mix and Enzymes























Primers and Probes









Phosphoramidites

dNTPs









For inquiries, write to indx-support@ccamp.res.in CCAMP-InDx Marketplace - https://indx.ccamp.res.in Website - https://www.ccamp.res.in/indx-indigenous-diagnostics

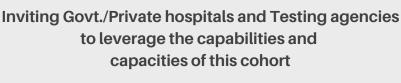






















CCAMP-InDx PROGRAM

CCAMP-InDx cohort's Regulatory Approved Kits

Inviting Govt./Private hospitals and Testing agencies to leverage the capabilities and capacities of this cohort

ICMR-CDSCO Approved Rapid Antigen Kits













Premier Medical Corporation Private Limited







ICMR-CDSCO Approved Rapid Antibody Kits













Premier Medical Corporation Private Limited



ICMR-CDSCO Approved ELISA Kits



















Reagents & Ancillary products







Antibodies





Nitrocellulose Paper





For inquiries, write to indx-support@ccamp.res.in CCAMP-InDx Marketplace - https://indx.ccamp.res.in Website - https://www.ccamp.res.in/indx-indigenous-diagnostics

















REGULATORY APPROVED RT PCR KITS FOR SARS COV2 INCLUDING RECENT SUBVARIANTS (BF.7, XBB) FROM C-CAMP InDx COHORT

Inviting Government/Private Hospitals and Testing agencies to leverage the capabilities and capacities of this cohort































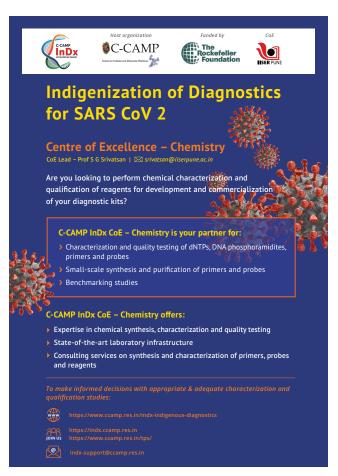


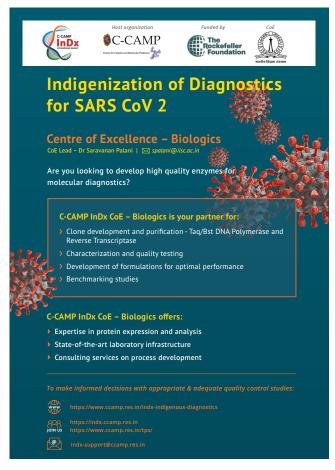




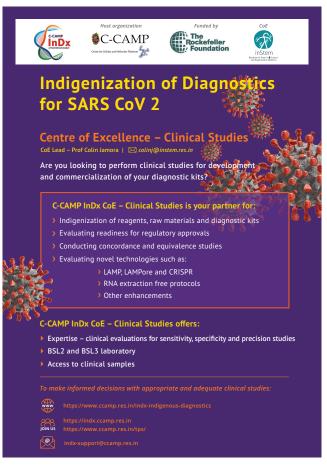
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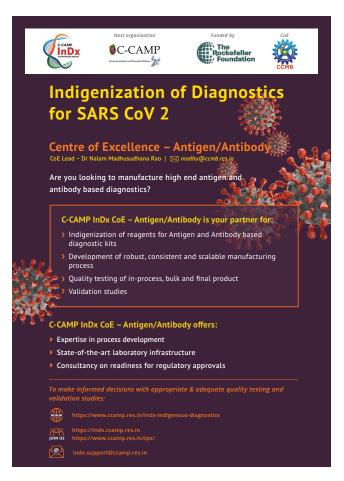




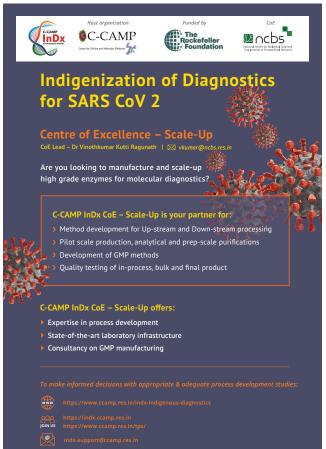
















ABOUT C-CAMP

C-CAMP – conceptualised by the Department of Biotechnology, Government of India in 2009 - is a catalyst of cutting-edge research and innovation in life sciences. We're an integral part of the Bangalore Life Sciences Cluster (BLiSC). Along with NCBS and inStem, we've been working towards enabling BLiSC to emerge as a centre of excellence.

We encourage researchers and entrepreneurs to develop homegrown scientific tools and solutions; our CCAMP-InDx programme is a major step in that direction.

THE MINDS BEHIND THE GROUND-BREAKING CCAMP-InDx INITIATIVE

GOVERNANCE TEAM



Dr Taslimarif Saiyed Principal Investigator, CCAMP-InDx, Bangalore



Prof Satyajit Mayor Director NCBS, Bangalore



Prof L S Sashidhara Professor, IISER, Pune

FUNCTIONAL TEAM



Lalith Kishore COO-InDx



Dr Mitali Samaddar Lead, Science and Technology



Nimisha Gupta Lead, Informatics



Richa Bohra Lead, Outreach



Dr Rituparna Tewari Lab Scientist and Coordinator



Gopal Das Application Scientist



G Puvaneswari **Application** Scientist



Dr Mayur Rajankar Application Scientist



Dr Suman Bhattacharya **Application** Scientist



Dr Manali Motghare Application Scientist



A N Shadakshari **Procurement**

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CCAMP-InDx Program



Engage with us: indx-support@ccamp.res.in



Register: https://indx.ccamp.res.in



Submit test request: https://www.ccamp.res.in/tps/



Highlight regulatory issues: indx-regulatory@ccamp.res.in