



COMPENDIUM OF INSTRUCTIONS FOR COVID-19 TESTING LABORATORY

Medical Education and Drugs Department
Government of Maharashtra

**SECOND EDITION
VOLUME 2**

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COMPENDIUM OF INSTRUCTIONS FOR COVID-19 TESTING LABORATORY

SECOND EDITION VOLUME 2

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FOREWORD

As you are aware, COVID – 19 is widely spreading across the country, rising beyond 600000 positive cases in the 23rd week. In order to manage and contain the spread of COVID – 19 any further, both Centre and State Government and Associated Departments have come out with Guidelines and Instructions for COVID-19 Testing to be adopted across the country and in each state. This Compendium is a compilation of instructions & guidelines for operating a Covid-19 Testing Laboratory issued by Ministry of Health & Family Welfare, Indian Council of Medical Research, Government of India and instructions issued by Public Health Department and Medical Education and Drugs Department of Government of Maharashtra. All the information provided in this Compendium is available in publicly available sources.

We hope that this compilation helps Laboratory In-charges, Administrators and all people involved in Testing of COVID – 19 cases.

This Compendium is updated with the information issued till 6th July, 2020. The Editorial Board shall be updating this on a regular basis.

We thank you all.

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**INDIAN COUNCIL OF MEDICAL RESEARCH
DEPARTMENT OF HEALTH RESEARCH**

Strategy for COVID19 testing in India (Version 5, dated 18/05/2020)

1. All symptomatic (ILI symptoms) individuals with history of international travel in the last 14 days.
2. All symptomatic (ILI symptoms) contacts of laboratory confirmed cases.
3. All symptomatic (ILI symptoms) health care workers / **frontline workers involved in containment and mitigation of COVID19.**
4. All patients of Severe Acute Respiratory Infection (SARI).
5. Asymptomatic direct and high-risk contacts of a confirmed case to be tested once **between day 5 and day 10 of coming into contact.**
6. All symptomatic ILI within hotspots/containment zones.
7. **All hospitalised patients who develop ILI symptoms.**
8. **All symptomatic ILI among returnees and migrants within 7 days of illness.**
9. **No emergency procedure (including deliveries) should be delayed for lack of test. However, sample can be sent for testing if indicated as above (1-8), simultaneously.**

NB:

- *ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.*
- *SARI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough AND requiring hospitalization.*
- *All testing in the above categories is recommended by real time RT-PCR test only.*
- **All changes incorporated in these guidelines as compared to the previous version have been indicated in bold.**

ICMR Specimen Referral Form for COVID-19 (SARS-CoV2)

INTRODUCTION

This form is for collection centres/ labs to enter details of the samples being tested for Covid-19. It is mandatory to fill this form for each and every sample being tested. It is essential that the collection centres/ labs exercise caution to ensure that correct information is captured in the form.

INSTRUCTIONS:

- ⊙ Inform the local / district / state health authorities, especially surveillance officer for further guidance
- ⊙ Seek guidance on requirements for the clinical specimen collection and transport from nodal officer
- ⊙ This form may be filled in and shared with the IDSP and forwarded to a lab where testing is planned
- ⊙ Fields marked with asterisk (*) are mandatory to be filled

SECTION A – PATIENT DETAILS

A.1 TEST INITIATION DETAILS

* Doctor Prescription: Yes No

(If yes, attach prescription; If No, test cannot be conducted)

* Follow up Sample: Yes No

If Yes, Patient ID:

A.2 PERSONAL DETAILS

* Patient Name:

* Age: Years/Months age <1 yr, pls. tick months checkbox)

* Patient in quarantine facility: Yes No

* Gender: Male Female Others

* Present Village or Town:

* Mobile Number:

* District of Present Residence:.....

* Mobile Number belongs to: Self Family

* State of Present Residence:.....

* Nationality:

* Present patient address:

* Downloaded Aarogya Setu App: Yes No

.....

(These fields to be filled for all patients including foreigners)

Pincode:

Aadhar No. (For Indians):

Passport No. (For Foreign Nationals):

* A.3 SPECIMEN INFORMATION FROM REFERRING AGENCY

* Specimen type Throat Swab Nasal Swab BAL ETA Nasopharyngeal swab

* Collection date

* Sample ID (Label)

* A.4 PATIENT CATEGORY (PLEASE SELECT ONLY ONE)

Cat 1: Symptomatic international traveller in last 14 days.....

Cat 2: Symptomatic contact of lab confirmed case.....

Cat 3: Symptomatic Healthcare worker / Frontline workers

Cat 4: Hospitalized SARI (Severe Acute Respiratory Illness) patient.....

Cat 5a: Asymptomatic direct and high risk contact of lab confirmed case - family member

Cat 5b: Asymptomatic healthcare worker in contact with confirmed case without adequate protection.....

Cat 6: Symptomatic Influenza like Illness (ILI) in Hospital.....

Cat 7: Pregnant woman in / near labour.....

Cat 8: Symptomatic (ILI) among returnees and migrants (within 7 days of illness).....

Cat 9: Symptomatic Influenza Like Illness(ILI) patient in Hotspot / Containment zones.....

Other: (please specify) * (Select "other" only if the patient doesn't belong to category 1-8)

SECTION B- MEDICAL INFORMATION

B.1 CLINICAL SYMPTOMS AND SIGNS

Symptoms: Yes NO If No please go to B.2 section

Symptoms	Yes	Symptoms	Yes	Symptoms	Yes	Symptoms	Yes	Symptoms	Yes
Cough	<input type="checkbox"/>	Diarrhoea	<input type="checkbox"/>	Vomiting	<input type="checkbox"/>	Fever at evaluation	<input type="checkbox"/>	Abdominal pain	<input type="checkbox"/>
Breathlessness	<input type="checkbox"/>	Nausea	<input type="checkbox"/>	Haemoptysis	<input type="checkbox"/>	Body ache	<input type="checkbox"/>		
Sore throat	<input type="checkbox"/>	Chest pain	<input type="checkbox"/>	Nasal discharge	<input type="checkbox"/>	Sputum	<input type="checkbox"/>		

Which of the above mentioned was First Symptom:..... Date of onset of First Symptom: (dd/mm/yy)

.....

B.2 PRE-EXISTING MEDICAL CONDITIONS

Condition	Yes	Condition	Yes	Condition	Yes	Condition	Yes
Chronic lung disease	<input type="checkbox"/>	Malignancy	<input type="checkbox"/>	Heart disease	<input type="checkbox"/>	Chronic liver disease	<input type="checkbox"/>
Chronic renal disease	<input type="checkbox"/>	Diabetes	<input type="checkbox"/>	Hypertension	<input type="checkbox"/>		
Immunocompromised condition: YES <input type="checkbox"/> NO <input type="checkbox"/>				Other underlying conditions:			

B.3 HOSPITALIZATION DETAILS

Hospitalized: Yes <input type="checkbox"/> No <input type="checkbox"/>	Hospital State:
Hospital ID / number <input type="text"/>	Hospital District:
Hospitalization Date: <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> (dd/mm/yy)	Hospital Name:

B.4 REFERRING DOCTOR DETAILS

*Name of Doctor:	Doctor Mobile No.:
	Doctor Email ID:

* Fields marked with asterisk are mandatory to be filled

TEST RESULT (To be filled by Covid-19 testing lab facility)

Date of sample receipt(dd/mm/yy)	Sample accepted/ Rejected	Date of Testing (dd/mm/yy)	Test result (Positive / Negative)	Repeat Sample required (Yes / No)	Sign of Authority (Lab in charge)

**Specimen Referral Form (SRF) ID information
for COVID-19 (SARS-CoV2), in RT-PCR app**

SRF ID

Patient Name _____

Phone number

Lab Name _____

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Date: 09/05/2020

Advisory for use of Cartridge Based Nucleic Acid Amplification Test (CBNAAT) using Cepheid Xpert Xpress SARS-CoV2

1. Cepheid Xpert Xpress SARS-CoV2 is a FDA approved Cartridge Based Nucleic Acid Amplification Test (CBNAAT) for use under an emergency use authorization (EUA) only
<https://www.fda.gov/media/136314/download>.
2. Specimen collection and transfer of sample for CBNAAT must be performed using appropriate PPE and following all applicable biosafety requirements.
3. ICMR recommends that any testing with the Cepheid Xpert Xpress SARS CoV-2 is carried under Biosafety 2 level (BSL-2) conditions and with appropriate biosafety precautions.
4. Any laboratory which is already functional for SARS CoV2 testing by real-time PCR with the appropriate BSL-2 setup may initiate testing using Cepheid Xpert Xpress SARS- CoV2 without any further approval from ICMR. The results of the testing need to be entered on the ICMR COVID-19 portal.
5. Any new Government laboratory seeking to initiate CBNAAT must satisfy the following minimum requirements:
 - a. **Availability of a BSL-2 level laboratory facility including a molecular biology setup for virological diagnosis and a functioning and calibrated Biosafety cabinet type 2A/2B in the laboratory.**
 - b. Staff Requirements:
 - i. Availability of following minimum staff: trained microbiologist for handling Molecular Virology work.
 - ii. Technicians – At least 2-3 with experience of work on respiratory pathogens.
 - iii. Multi-Task Staff – 1 or more for washing / cleaning
 - c. Desired expertise of the staff:
 - i. Good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis
 - ii. Experience of work in virology and handling clinical specimens, especially respiratory samples.
 - d. **A robust Institutional policy on biomedical waste management of human origin.**
 - e. **Well defined arrangement for segregation and discarding of biomedical waste.**
6. In addition to the above, private laboratories which intend to initiate testing using CBNAAT should have NABL accreditation for molecular detection of RNA viruses either by Real Time PCR or by CBNAAT.
7. ICMR guidelines and testing strategy for testing may be strictly followed.
8. Since the guidance evolves periodically, the latest revised version should be followed. Testing laboratories to ensure immediate/ real-time reporting to State officials of IDSP (Integrated Disease Surveillance Program of Govt. of India) for timely initiation of contact tracing. Additionally, as mandated by PMO, a report should also be uploaded on the online portal of ICMR. Each laboratory initiating COVID-19 testing should essentially register on the ICMR portal and get a username and password. Data entry should be ensured on a daily real-time basis.
9. All applications may be submitted by email at: arvind.nccs@gmail.com

Guideline for RT-PCR based pooled sampling for migrants/returnees from abroad/green zones

The following guideline is in pursuance of letter of Secretary, MoHFW dated 12th May 2020 on the subject.

A decision has been taken to use one time RT-PCR based pooled sampling for surveillance purposes for migrant workers in institutional quarantine facilities, international passengers in institutional quarantine facilities/hotels ear-marked for quarantine and for surveillance purposes in green zones (districts with no case/no case reported in last 21 days).

The following guidelines would be followed for pooling of samples:

1. A cohort of 25 people will be identified
2. Throat/nasal swab will be collected following laid down protocol by trained laboratory personnel under appropriate protective gear (apron, hand glove, face-shield/goggles, N-95 mask), as per ICMR protocol (available at:
https://www.mohfw.gov.in/pdf/5Sample%20collection_packaging%20%202019-nCoV.pdf)
3. Proper labelling (name/age/gender/specimen ID) needs to be done on specimen container.
4. 25 such samples of such cohort would be packed in triple layer packaging and will be transported to the identified laboratory under cold-chain as per ICMR guidelines, link of which is provided under para -2. The outer container mentioning “be tested for SARS-CoV-2” will also bear the details of sender (name/address/phone number).
5. The samples will be aliquoted and thereafter pooled samples from 25 specimens shall be tested in the laboratory by RT-PCR method.
6. The report will be conveyed to the quarantine/concerned facility within 24 hours.
7. If any of the pooled samples tests positive, individual samples would be tested from the aliquoted samples preserved in the laboratory.



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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 19/05/2020

Revised Guidelines for TrueNat testing for COVID-19

The TrueNat system is now a comprehensive assay for screening and confirmation of COVID-19 cases.

- 1) The sample is collected in viral lysis buffer and hence biosafety and biosecurity requirements for use of TrueNat machines are minimal.
- 2) Assay: The assay comprises of following two steps.
 - A) **Step 1:** This is E gene screening assay. All samples of suspect COVID-19 should be first tested by this assay. All negatives are to be considered as **true negatives**. All positive samples should be subjected to confirmation by step 2 assay.
 - B) **Step 2:** RdRp gene confirmatory assay. All samples that test positive by this assay must be considered as **true positive**.
- 3) No further RT-PCR based confirmation is required for samples that are positive after step 2 of the assay above.
- 4) All positive and negative results must be reported to ICMR portal in real time manner.



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 22/05/2020

Advisory for the DBT, DST, CSIR, DAE, ICAR, DRDO Labs

It is hereby notified that ICMR has no objection to initiation of COVID19 testing in Government laboratories operational under the Department of Biotechnology (DBT), Department of Science & Technology (DST), Council of Scientific & Industrial Research (CSIR), Department of Atomic Energy (DAE), Indian Council of Agricultural Research (ICAR) and Defence Research and Development Organisation (DRDO).

Since these research Institutes are of eminence under other research organizations, ICMR will not conduct any site assessment nor accord approval for initiation of testing at these laboratories. Secretary to the Government of India of the concerned Departments may accord approval for initiation of testing as deemed appropriate. Responsibility of these laboratories will lie with the concerned departments and not ICMR.

Caution: SARS-CoV-2 is a high-risk pathogen with high transmissibility and infectivity. Sample handling at too many points and by inadequately trained staff can lead to spills and laboratory outbreaks.

ICMR hereby advises the DBT, DST, CSIR, DAE, ICAR and DRDO laboratories to ensure the following safeguards before initiation of COVID19 testing:

- Availability of BSL-2 level laboratory including a molecular biology setup for virological diagnosis.
- Availability of a functioning and calibrated Biosafety cabinet type 2A/2B in the laboratory.
- Availability of cold centrifuge/microfuge for RNA extraction
- Availability of a functioning and calibrated real-time PCR machine.
- Availability of staff with good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis, RNA extraction and realtime PCR.
- Available staff with experience of work in virology and handling clinical specimens, especially respiratory samples.
- A robust Institutional policy on biomedical waste management of human origin.
- Well defined arrangement for segregation and discarding of biomedical waste.

Additional advice is as follows:

- ICMR advisory on use of commercial kits may also be accessed at www.icmr.gov.in. SoPs available with ICMR will be shared on request.
- Laboratory test should be only offered when the sample is referred by the State health officials or State IDSP.
- ICMR guidelines for testing (available at www.icmr.gov.in) may be strictly followed. Since the guidance evolves periodically, the latest revised version should be followed.
- Testing laboratories to ensure immediate/ real-time reporting to State officials of IDSP (Integrated Disease Surveillance Program of Govt. of India) for timely initiation of contact tracing. Additionally, as mandated by PMO, a report should also be uploaded on the online portal of ICMR. Each laboratory initiating COVID-19 testing should essentially register on the ICMR portal and get a username and password. Data entry should be ensured on a daily real-time basis. Contact points for registration at ICMR are:

support.dmu@bmi.icmr.gov.in

(Kindly note that all data has to be reported to IDSP and ICMR)



Dated: 11/06/2020

Revised guidelines for positive sample storage by ICMR approved private labs that are doing COVID-19 testing by Real time RT-PCR/CB-NAAT/TrueNat

1. All private labs that are doing COVID-19 testing by Real time RT-PCR/CB-NAAT/TrueNat are to send all positive samples to NIV, Pune as per earlier guidelines (Order no Z 28015/23/2020-EMR, dated 21st March 2020).
2. With the surge in testing across the country, the total number of positive samples has gone up considerably. Keeping this in view, ICMR advises of the following.
 - a) Labs that have been mapped with ICMR validation centres should periodically (on a regular basis) seek the requirements of these centres. The validation centres will tell labs that are mapped with them, to send the required number of positive and negative samples to help such centres validate different kits that become available for validation.
 - b) All labs will send 10 random positive and 5 random negative samples per month to QC labs. ICMR has mapped testing private labs to different QC labs (Annexure I). All testing labs will liaise with the recommended QC labs and will ensure regular participation in QC activity.
 - c) All testing labs will ensure storage of samples at -80C (or at least at -20C) and will ensure regular monthly transfer to QC labs. Don't forget to include your lab name and sample ID. While shipping, place samples in screw capped vials and proper Biosafety and Biosecurity precautions should be followed as per IATA.
 - d) In case of any discordance, additional 5 positive and 3 negative samples will need to be sent for QC check.
 - e) If QC results are concordant, all the samples will be destroyed and labs will keep record of destruction.
 - f) There is no need to send all positive samples to NIV, Pune.



Annexure I

QC lab	All private testing labs in
RMRC, Dibrugarh Contact: Dr. Biswa Borkakoty, Email: biswaborkakoty@gmail.com	Assam
SVMS, Tirupati Contact: Dr. Usha Kalawat, Email: ukalawat@yahoo.com	Andhra Pradesh and Puducherry
RMRIMS, Patna Contact: Dr. Pradeep das, Email: drpradeep.das@gmail.com	Bihar
AIIMS, New-Delhi Contact: Dr. Lalit Dar, Email: lalitdaraiims@gmail.com	Delhi
BJMC, Ahmedabad Contact: Dr. M.M. Vegad, Email: mahendravegad@rediffmail.com	Gujarat
BPS, Sonapat Contact: Dr. Sarita Yadav, Email: yadav78sarita@yahoo.com	Haryana
RIMS, Ranchi Dr. Manoj Kumar, Email: icmrvirologyrim@gmail.com	Jharkhand
AIIMS, Bhopal Dr. Debasis Biswas, Email: debasis.microbiology@aiimsbhopal.edu.in	Madhya Pradesh
NIV Field unit, Bengaluru Contact: Dr. Ashok Email: ashokmniv@gmail.com	Karnataka
NIV Field unit, Allapuzha Contact: A.P. Sugunan, Email: apsugunan@gmail.com	Kerala
Kasturba Hospital for Infectious Diseases, Mumbai. Contact: Dr. Jayanthi Shastri, Email: jsshastri@gmail.com	Mumbai
NIV, Pune Contact: Dr. Varsha Potdar Email: potdarvarsha9@gmail.com	Rest of Maharashtra



QC lab	All private testing labs in
RMRC, Bhubaneswar Contact: Dr. Jyoti Turuk Email: drjyotirmayuturuk@gmail.com	Odisha
PGI, Chandigarh Contact: Dr. Mini Singh Email: minipsingh@gmail.com	Punjab
GMC, Haldwani Contact: Dr. Vinita Rawat, Email: drvinitarawat@gmail.com	Uttarakhand
SMS Medical College, Jaipur Contact: Dr. Bharti Malhotra, Email: drbhartimalhotra@gmail.com	Rajasthan
KIPM, Chennai Contact: Dr. K. Kaveri, Email: kaveri_raj1967@yahoo.com	Tamilnadu
GMC, Secunderabad Contact: Dr. K. Nagamani, Email: nagamaniy2k03@rediffmail.com	Telangana
KGMU, Lucknow Contact: Dr. Amita Jain, Email: amita602002@yahoo.com	UP
NICED, Kolkata Contact: Dr. Shanta Dutta Email: shanta1232001@yahoo.co.in,	West Bengal



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

ADVISORY

Newer Additional Strategies for COVID-19 Testing

Dated: 23/06/2020

Existing strategies for COVID-19 testing:

- Real Time RT-PCR** is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. In view of the specialized laboratory requirements, this test cannot be performed at every district level lab which do not have molecular virology facilities. However, wherever available, it is advised to use real time RT-PCR as the frontline test for diagnosis of SARS-CoV-2.
- The TrueNat and CBNAAT** systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges. These platforms have widespread availability even at district and primary health center level as these platforms are widely used for diagnosis of Tuberculosis and other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day only. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.
- All COVID-19 tests conducted through RT-PCR, TrueNat and CBNAAT are reported on ICMR data entry portal which helps in drawing the National estimates on numbers of tests conducted, numbers of positives, tests conducted per million population etc. This data portal is the single National source of data entry which is accessed by all relevant Ministries / Departments for defining National strategies for COVID-19. ICMR urges all the laboratories to continue entering data into the ICMR portal <https://cvstatus.icmr.gov.in/login.php> to help in guiding the National strategies appropriately.
- In an effort to ramp up testing capacity, ICMR has approved a total of 1000 COVID-19 testing labs in both public (730) and private sector (270). This includes RT-PCR labs (557); TrueNat Labs (363) and CBNAAT Labs (80). However, inspite of these developments, access to testing still remains a huge challenge in a large country like India. There is a definite need to increase the outreach of testing by introducing rapid point of care diagnostic tests. Also, there is value in conducting serosurveys with IgG based antibody tests in certain situations. In view of this, it is now suggested to include additional testing methods to improve the access and availability of testing in various parts of the country.



Newer additional strategies for COVID-19 Testing:

1. Rapid Point-of-Care (PoC) Antigen Detection Test (for diagnosis along with RT-PCR):

5. Since the entire public health machinery is focused to test, track and treat COVID-19 patients, it is imperative to explore the existing antigen-based assays as point-of-care tests for early detection of SARS-CoV-2. Such tests, if reliable would be valuable at field level for early detection of infection and quick containment. Availability of antigen-based detection tests is very limited all across the world. Most of such tests have relatively **moderate sensitivity but high specificity**. However, manufacturers of all antigen-based tests are encouraged to approach ICMR for validation and inclusion of their test in the wider testing approach of the country. A positive test should be considered as a true positive whereas all symptomatic individuals testing negative through the rapid antigen test should be confirmed with a real-time PCR test.
6. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay which **does not require a specialized machine** and can be interpreted with a naked eye. The test is a promising tool for quick diagnosis of SARS-CoV-2 in field settings. The assay is known as **Standard Q COVID-19 Ag kit** and has been developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. On validation, the test has been found to have a very high specificity with moderate sensitivity. It is now recommended to use Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020 in this regard, which may be accessed at: [https://www.icmr.gov.in/pdf/covid/strategy/Advisory for rapid antigen test 14062020.pdf](https://www.icmr.gov.in/pdf/covid/strategy/Advisory%20for%20rapid%20antigen%20test%2014062020.pdf). The recommended use of the rapid antigen PoC as per the ICMR advisory is enclosed at **Annexure 1**.
7. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor.
Contact details are as follows:
Dr. CS Bedi.
Mobile No: +919810426069; Email: drbedi@icloud.com

For any technical assistance /clarifications, details of the ICMR contact point are given below:
Dr. Sidhartha Giri
Mobile No: +918754617892; Email: sidhartha.g@icmr.gov.in

ICMR recommends deployment of the rapid antigen PoC test in the following settings:

- i) All containment zones identified by the State Governments,
- ii) All Central & State Government Medical Colleges and Government hospitals
- iii) All private hospitals approved by National Accreditation Board for Hospitals & Healthcare (NABH).
- iv) All private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs.



Rapid antigen PoC test is recommended for use subject to the following conditions:

- i) All hospitals, labs, State Govts intending to perform the **PoC antigen test need to register with ICMR to obtain the login credentials for data entry. Interested Institutions may send their request on the following email id's:**

ag-pvthosp-nabh@icmr.gov.in

ag-govthosp@icmr.gov.in

- ii) All data of testing needs to be entered into the ICMR portal on a real time basis. The ICMR portal has been modified to include a component on antigen testing. Detailed video is available on ICMR website at http://www.icmr.gov.in/video/Data_Entry_Antigen_v4.mp4.
- iii) **All labs/hospitals initiating testing** through the rapid antigen PoC test need to ensure that **all symptomatic negative patients should be essentially referred to a real-time RT-PCR test for COVID-19**. This is particularly essential as the rapid antigen PoC test has a moderate sensitivity.
- iv) All the entities using antigen PoC test are expected to tie up with the nearest RT-PCR COVID-19 testing lab to ensure that all symptomatic who are negative by the rapid antigen test get tested at the nearest facility.
- v) The data of individuals tested by RT-PCR will need to be entered through the lab performing the RT-PCR test.

II. IgG Antibody test for COVID-19 (Only for surveillance and not diagnosis):

8. IgG antibodies generally start appearing after two weeks of onset of infection, once the individual has recovered after infection and last for several months. Therefore, the IgG test is not useful for detecting acute infection. However, detection of IgG antibodies for SARS-CoV-2 may be useful in the following situations:
- Serosurveys to understand the proportion of population exposed to infection with SARS-CoV-2 including asymptomatic individuals. Depending upon the level of seroprevalence of infection, appropriate public health interventions can be planned and implemented for prevention and control of the disease. Periodic serosurveys are useful to guide the policy makers.
 - Survey in high risk or **vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc)** to know who has been infected in the past and has now recovered. The groups of individuals who should be prioritized for such serosurveys is enclosed at **Annexure 2**.
9. It is strictly advised to use IgG based ELISA and CLIA assays only for conduct of serosurveys. ICMR has validated and approved IgG ELISA kits for COVID-19. In addition, USFDA approved IgG ELISA and CLIA kits are also available and can be used. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf. It is advised to enable all **Government and Private Hospitals, Offices, Public Sector Units etc. to perform the antibody-based testing**. This will help in allaying the fear and anxiety of health care workers, office employees etc. As the apex research organization of the country, ICMR is mandated to review and



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conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, it is advised to share the comprehensive report of antibody testing with ICMR at the email id given below: mmurhekar@gmail.com.

10. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to **all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened**. ICMR advises all concerned State Governments, Public and Private Institutions to take required steps to scale up testing for COVID-19 by deploying combination of various tests as advised above.



Annexure 1:

Use of Standard Q COVID-19 Ag a point of care diagnostic assay is recommended in the following settings in combination with the gold standard RT-PCR test:

- A. Containment zones or hotspots** (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):
- All symptomatic Influenza Like Illness (ILI).
 - Asymptomatic direct and high-risk contacts with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.
- B. Healthcare settings** (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):
- All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
 - Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:
 - Patients undergoing chemotherapy
 - Immunosuppressed patients including those who are HIV+;
 - Patients diagnosed with malignant disease;
 - Transplant patients;
 - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
 - Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
 - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures etc.
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis etc.

****ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- Should be interpreted between 15 to 30 minutes with a naked eye. No interpretation should be made before 15 minutes or after 30 minutes.
- Symptomatic individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.**
- Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.
- The test should be conducted **onsite** under strict medical supervision and within one hour of sample collection in extraction buffer.



Annexure 2:

Possible groups/ community/ population based on specific requirement for sero-survey by using IgG ELISA test.

- i.) **Immuno-compromised patients:** PLHIV, patients on immuno-suppressive treatment, TB, SARI, COPD, patients on dialysis to be considered for testing;
- ii.) **Individuals in containment zones:** In identified containment zones and buffer zones where large number/ cluster of cases have been identified as demarcated geographical areas with residential, commercial structures;
- iii.) **Health Care Workers:** Specifically, all doctors including specialists, nursing staff, support staff, sanitary and other staff including the staff at registration, pharmacists, client facing desk clerks etc. Those workers in health care settings who either faces patients (whether known COVID 19 +ve or not), involved in their care or are in environment of potentially shared spaces or handling fomites;
- iv.) **Security personnel:** All security personnel facing the visitors, conducting their security screening, physical checking and thermal screening. This includes CISF personnel involved in security especially of offices;
- v.) **Police and paramilitary personnel civil defense & volunteers:** police personnel and volunteers involved in duties facing large number of individuals or those coming in contact with potentially infected individuals, fomites or settings/ places;
- vi.) **Press corps:** Press reporters covering field, interviews, press briefings, etc. and support staff;
- vii.) **Rural, tribal population (after reverse migration):** Migrant workers who have travelled back from urban and peri-urban areas to rural, tribal, hard to reach areas in the country as well as natives after coming in contact with returned migrants.
- viii.) **Industrial workers or labour force:** industry workers, daily wagers, migrant workers, temporary travel related workers, hospitality related works, service sector who are in large number or groups and has potential to spread transmission rapidly in workplace settings;
- ix.) **Farmers, vendors visiting large markets:** Farmers, sellers, brokers, purchasing vendors, distributors and other persons including drivers and labor by virtue of visiting crowded places like main markets where large exchange of materials happen between farmers and vendors during purchase and sell of vegetables etc.;
- x.) **Staff in municipal bodies:** Municipal staff working in areas like sanitation, water supply, electricity, etc. where interactions with citizens is expected; and
- xi.) **Drivers:** Drivers of hospital ambulances, hearse, buses, auto, taxies, etc. who have been on work front faced large number of individual previously or going to face in future. Bus conductors, cleaners and helping staff also should be included;
- xii.) **Banks, post, couriers, telecom offices:** public or private banks, small or large branches of banks and post, telecom offices as well as couriers;



- xiii.) **Shops:** Vendors and/ or owners as well as staff working in shops for essential goods, groceries, vegetables, milk, bread, chemists working at pharmacies, eateries and take away restaurants, etc.;
- xiv.) **Air travel related staff:** All ground staff, security staff, janitors, sanitation staff, flight captains and crew for domestic and international as well as cargo may be considered;
- xv.) **International operations:** All members of overseas operations for evaluation;
- xvi.) **Congregate settings:** People staying or working in slums with very high population density with poorly ventilated building, structures. Persons staying in institutional settings like old age homes, orphanage, asylums, shelters for homeless, hostels, etc. may also be considered;
- xvii.) **Prisons:** All prisoners with or without symptoms whenever there is a batch transfer or reported symptomatic;



Dated: 25/06/2020

Guidelines for storage of respiratory specimens collected for COVID-19 diagnosis by RT PCR platforms in Government laboratories

1. In the ongoing laboratory testing for COVID-19 diagnosis by molecular diagnostic methods, clinical specimens or a subset of the clinical specimens may need to be retained for various purposes such as performing additional tests, for quality control purposes or for use as control materials to assess newer diagnostic tests. In addition, a laboratory may need to store specimens for projects aimed at studying genomic epidemiology of the SARS CoV2 virus across regions and over time.
2. All samples being stored for a long-term must be appropriately labelled indicating laboratory identifiers, date of sample collection and must be stored in properly functioning -80°C deep freezers. A proper inventory (preferably electronic) of stored samples should be essentially maintained.
3. With the surge in testing across the country, the total number of tested samples has gone up considerably. Keeping this in view, ICMR advises of the following.
 - a) Laboratories that are serving as validation centres for COVID-19 diagnostic kits are advised to preserve adequate numbers of positive and negative samples to prepare appropriate panels for validation etc.
 - b) At a minimum, all samples testing positive for SARS CoV2 must be retained for at least 30 days from the date of testing before being destroyed. Depending on the freezer space availability in a particular laboratory, one or more aliquots of the positive specimen may be retained for the period.
 - c) A government laboratory may decide on the number of positive / negative samples to retain in the long term based on the availability of freezer space as well as perceived research agenda of the laboratory for COVID-19 in the future.
 - d) If the number of samples tested positive at a laboratory is considerably large and the laboratory is unable to retain all positive samples beyond 30 days, a minimum of 10% of all positives detected at the laboratory in a month or 40-50 positives preferably with equal numbers of high, moderate and low viral load should be stored for a period of 1 year at the least. A single aliquot of a positive sample may be retained taking into account freezer space availability at the laboratory.



- e) Considering that the number of samples tested negative at each laboratory will vary depending on the sample load and testing capacity of the laboratory, a minimum of 50 samples or 1-2% of all negative tested samples over a month, whichever is smaller should be retained at the testing laboratory for a period of 1 year. A single aliquot of a negative sample may be retained taking into account freezer space availability at the laboratory.
- f) All labs will send 5 random positive and 5 random negative samples per month to QC labs. ICMR has mapped COVID-19 testing labs to different QC labs (Annexure I). All testing labs should liaise with the recommended QC labs and will ensure regular participation in QC activity.
- g) All testing labs will ensure storage of samples at -80°C and will ensure regular monthly transfer to QC labs. Don't forget to include your lab name and sample ID. While shipping, place samples in screw capped vials and proper Biosafety and Biosecurity precautions should be followed as per IATA guidelines.
- h) In case of any discordance, additional 5 positive and 3 negative samples will need to be sent for QC check.
- i) If QC results are concordant, all the QC samples may be destroyed and labs will keep record of destruction.
- j) Appropriate procedures to disinfect all samples prior to disposal must be followed.



Annexure I

QC lab	Government Testing Labs
RMRC, Dibrugarh Contact: Dr. Biswa Borkakoty, Email: biswaborkakoty@gmail.com	Assam, Manipur, Mizoram, Meghalaya, Nagaland, Tripura
SVMS, Tirupati Contact: Dr. Usha Kalawat, Email: ukalawat@yahoo.com	Andhra Pradesh, Telangana
RMRC, Port Blair Contact: Dr. Paluru Vijayachari Email: vijayacharipaluru@gmail.com	Andaman and Nicobar Islands
RMRIMS, Patna Contact: Dr. Pradeep Das, Email: drpradeep.das@gmail.com	Bihar
AIIMS, Raipur Contact: Dr. Anudita Bhargava, Email: anuditabhargava@gmail.com	Chhattisgarh
AIIMS, New-Delhi Contact: Dr. Lalit Dar, Email: lalitdaraiims@gmail.com	Delhi
BJMC, Ahmedabad Contact: Dr. M.M. Vegad, Email: mahendravegad@rediffmail.com	Gujarat
BPS, Sonipat Contact: Dr. Sarita Yadav, Email: yadav78sarita@yahoo.com	Haryana
RIMS, Ranchi Dr. Manoj Kumar, Email: icmrvirologyrim@gmail.com	Jharkhand
SKIMS, Jammu and Kashmir Dr. Bashir Fomda Email: bashirfomda@gmail.com	Jammu and Kashmir, Ladakh
AIIMS, Bhopal Dr. Debasis Biswas, Email: debasis.microbiology@aiimsbhopal.edu.in	Madhya Pradesh
NIV Field unit, Bengaluru Contact: Dr. Ashok Email: ashokmniv@gmail.com	Karnataka



QC lab	Government Testing Labs
NIV Field unit, Allapuzha Contact: A.P. Sugunan, Email: apsugunan@gmail.com	Kerala, Lakshadweep
Kasturba Hospital for Infectious Diseases, Mumbai. Contact: Dr Jayanthi Shastri, Email: jsshastri@gmail.com	Mumbai
NIV, Pune Contact: Dr. Varsha Potdar Email: potdarvarsha9@gmail.com	Rest of Maharashtra, Goa, Dadra and Nagar Haveli
RMRC, Bhubaneswar Contact: Dr. Jyoti Turuk Email: drjyotirmayuturuk@gmail.com	Odisha
PGI, Chandigarh Contact: Dr. Mini Singh Email: minipsingh@gmail.com	Chandigarh, Punjab, Himachal Pradesh
JIPMER, Puducherry Contact: Dr. Rahul Dhodapkar Email: rahuldhodapkar@gmail.com	Puducherry
GMC, Haldwani Contact: Dr. Vinita Rawat, Email: drvinitarawat@gmail.com	Uttarakhand
SMS Medical College, Jaipur Contact: Dr. Bharti Malhotra, Email: drbhartimalhotra@gmail.com	Rajasthan
KIPM, Chennai Contact: Dr. K. Kaveri, Email: kaveri_raj1967@yahoo.com	Tamil Nadu
KGMU, Lucknow Contact: Dr. Amita Jain, Email: amita602002@yahoo.com	Uttar Pradesh
NICED, Kolkata Contact: Dr. Shanta Dutta Email: shanta1232001@yahoo.co.in,	West Bengal, Sikkim



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 06/07/2020

Total Operational (initiated independent testing) Laboratories reporting to ICMR:

Government laboratories : 793

Private laboratories : 322

- Real-Time RT PCR for COVID-19 : 598 (Govt: 372 + Private 226)
- TrueNat Test for COVID-19 : 423 (Govt: 388 + Private: 35)
- CBNAAT Test for COVID-19 : 94 (Govt: 33 + Private: 61)

Total No. of Labs : 1115

*CSIR/DBT/DST/DAE/ICAR/DRDO/MHRD/ISRO Laboratories.

#Laboratories approved for both Real-Time RT-PCR and TrueNat/CBNAAT

\$Laboratories approved for both TrueNAT and CBNAAT

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
1.	Andhra Pradesh (65) Govt: 58 Private: 7	RT-PCR	1. Sri Venkateswara Institute of Medical Sciences, Tirupati 2. Sri Venkateswara Medical College, Tirupati	1. Manipal Hospital, Tadepalli, Guntur 2. PathGene Health Care Pvt Ltd#2nd Floor, Srinivasapuram, Tiruchanoor Road, Opp LV kayanamandapam, Tirupathi



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			<ol style="list-style-type: none">3. Rangaraya Medical College, Kakinada4. #Sidhartha Medical College, Vijaywada5. Govt. Medical College, Ananthpur6. Guntur Medical College, Guntur7. Rajiv Gandhi Institute of Medical Sciences, Kadapa8. Andhra Medical College, Visakhapatnam9. Govt. Kurnool Medical College, Kurnool10. Govt. Medical College, Srikakulam11. AIIMS, Mangalagiri	<ol style="list-style-type: none">3. Apollo Health and Lifestyle Ltd, Vijayawada Diagnostics Lab, 40-5-6, Parmeshwara Complex, Tikkle Road, Vijayawada4. Vijaya Diagnostic Centre Pvt. Ltd., Plot No: 43/198, Old Rainbow Hospital Lane, N R Peta, Kurnool5. Maharaja Institute of Medical Sciences, Vizianagaram6. Asram Medical College, Eluru7. Vijaya Medical Centre, 14G, Health City, Chinagadhili, Visakhapatnam
		TrueNat	<ol style="list-style-type: none">12. Damien TB Research Centre, Nellore13. SVRR Govt. General Hospital, Tirupati14. Community Health Centre, Gadi Veedhi Saluru, Vizianagaram15. Community Health Centre, Bhimavaram, West Godavari District16. Community Health Centre, Patapatnam17. Community Health Center, Nandyal, Banaganapalli, Kurnool18. GSL Medical College & General Hospital, Rajahnagam, East Godavari District	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			19. District Hospital, Madnapalle, Chittoor District	
			20. District Hospital, APVVP, Pulivendula, Kadapa District	
			21. District Hospital, Rajahmundry, East Godavari District	
			22. District Hospital, Noonepalli, Nandyal, Kurnool	
			23. District Hospital, Anakapalli, Vishakhapatnam	
			24. District Hospital, Hindupur, Anantpur	
			25. District Hospital, Proddatur	
			26. District Hospital, Machlipatnam	
			27. District Hospital, Atmakur	
			28. District Hospital, Markapur	
			29. District Hospital, Tekkali	
			30. Area Hospital, Rampachodavaram, East Godavari District	
			31. Area Hospital, Palamaner, Chittoor	
			32. Area Hospital, Amalapuram, East Godavari District	
			33. Area Hospital, Adoni, Kurnool	
			34. Area Hospital, Chirala	
			35. Area Hospital, Kandukuru	
			36. Area Hospital, Narsipatnam	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			37. Area Hospital, Parvathipuram 38. Area Hospital, Tadepalligudem 39. Area Hospital, Kavali 40. Area Hospital, Tenali 41. Area Hospital, Narasaraopet, Guntur 42. Area Hospital, Macheria, Guntur 43. Area Hospital, Kadiri 44. Area Hospital, Gandhinagar, Nuzividu 45. ACSR Govt. Medical College, Nellore 46. Rural Development Trust, Bathalpalli 47. Govt. General Hospital, Guntur 48. Govt. General Hospital/ RIMS, Ongole 49. DST Lab Govt. Chest Hospital, Vishakhapatnam 50. District Hospital, Vizianagram 51. District Hospital, Chittoor 52. District Hospital, Eluru 53. *SHAR Hospital, Sriharikota, Nellore 54. Area Hospital, Srikalahasthi 55. CHC, Sundipeta 56. CHC, Pathikonda 57. CHC, Narasapuram 58. CHC, Kovvuru	
2.	Arunachal Pradesh (4)	RT-PCR	59. Tomo Riba Institute of Health & Medical Sciences, Naharlagun	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
	Govt: 4			
		TrueNAT	60. Intermediate Reference Laboratory, Directorate of Health Sciences, Naharlagun 61. Bakin Pertin General Hospital and Training Centre, Pasighat, East Siang District 62. KDS District Hospital, Tawang	
3.	Assam (18) Govt: 13 Private: 5	RT-PCR	63. Gauhati Medical College, Guwahati 64. ICMR-Regional Medical Research Center, Dibrugarh 65. Jorhat Medical College, Jorhat 66. Silchar Medical College, Silchar 67. Fakkhruddin Ali Ahmed Medical College, Barpeta 68. Tezpur Medical College, Tezpur 69. Assam Medical College, Dibrugarh 70. *CSIR North East Institute of Science and Technology (NEIST), Jorhat 71. *Defence Research Laboratory, Tezpur 72. Diphu Medical College, Karbi Anglong	8. Ultracare Diagnostic Centre, Dept of Lab Services, Ashok Path, Survey, Beltola, Guwahati
		TrueNat	73. State Cancer Institute, Guwahati Medical College, Guwahati 74. B Borooah Cancer Institute, Gopinath Nagar, Guwahati	9. Molecular Testing LAb, GNRC Lab services, GNRC Hospitals, Dispur 10. Dept of Lab Medicine, North-East Health City Pvt Ltd, Koinadhara, Guwahati



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				11. Dispur Clinical Lab, Dispur Hospital Campus, Ganeshguri, Kamrup Metro, Guwahati
		CB NAAT	75. 151 Base Hospital, Guwahati	12. Department of Laboratory Medicine, Apollo Personalised Health Chek Centre, A Unit of Apollo Hospitals, Guwahati
4.	Bihar (44) Govt: 41 Private: 3	RT-PCR	76. ICMR-Rajendra Memorial Research Institute of Medical Sciences, Patna 77. Indira Gandhi Institute Medical Sciences, Patna 78. Patna Medical College, Patna 79. Darbhanga Medical College, Darbhanga 80. SKMCH, Muzaffarpur 81. All India Institute of Medical Sciences, Patna 82. #Anugrah Narayan Magadh Medical College (ANMMC), Gaya	13. Narayan Medical College, Sasaram 14. #Saral Pathlab Pvt. Ltd, 55B, Sector O, Sachiwalaya Colony, Kankarbagh, Patna
		TrueNAT	83. Vardhman Institute of Medical Sciences, Pawapuri, Nalanda 84. District Hospital, Siwan 85. District Hospital, Rohtas 86. JanNayak Karpoori Thakur Medical College and Hospital, Madhepura 87. Govt. Medical College, Bettiah	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			88. District Hospital, Purnia	
			89. District Hospital, Katihar	
			90. District Hospital, East Champaran	
			91. District Hospital, Madhubani	
			92. District Hospital, Buxar	
			93. District Hospital, Khagaria	
			94. District Hospital, Begusarai	
			95. District Hospital, Banka, Bihar	
			96. District Hospital, Gopalganj, Bihar	
			97. District Hospital, Aurangabad, Bihar	
			98. District Hospital, Jehanabad, Bihar	
			99. District Hospital, Nawada, Bihar	
			100. District Hospital, Arwal	
			101. District Hospital, Saharsa, Bihar	
			102. District Hospital, Supaul, Bihar	
			103. District Hospital, Kaimur, Bihar	
			104. District Hospital, Saran, Bihar	
			105. District Hospital, Bhojpur, Bihar	
			106. District Hospital, Kishanganj, Bihar	
			107. District Hospital, Jamui, Bihar	
			108. District Hospital, Lakhisarai, Bihar	
			109. District Hospital, Munger	
			110. District Hospital, Sheikhpura	
			111. District Hospital, Vaishali	
			112. District Hospital, Araria	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			113. District Hospital, Samastipur 114. District Hospital, Sheohar 115. District Hospital, Sitamarhi	
		CB-NAAT	116. Jawaharlal Nehru Medical College, Bhagalpur	15. \$ Sen Diagnostics Pvt. Ltd., Budh Marg, Patna
5.	Chandigarh (4) Govt: 3 Private: 1	RT-PCR	117. Post Graduate Institute of Medical Education & Research, Chandigarh 118. Govt. Medical College, Chandigarh 119. *Institute of Microbial Technology, Chandigarh	
				16. Atulaya Healthcare, H No 11, Sector 11 A, Chandigarh
6.	Chhattisgarh (7) Govt: 5 Private: 2	RT-PCR	120. All India Institute of Medical Sciences, Raipur 121. Late Baliram Kashyap M Govt. Medical College, Jagdalpur 122. JNM Medical College, Raipur 123. Late Shri Lakhi Ram Agrawal Memorial Govt. Medical College, Raigarh	
		TrueNat	124. Intermediate Reference Laboratory, Lalpur, Raipur	17. Dept of Lab services, Balco Medical Centre (Vedanta Medical Research Foundation), Sector-36, Naya Raipur, PO: Uparwara, Raipur



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
7.	Delhi (51) Govt: 21 Private: 30	RT-PCR	125. All India Institute Medical Sciences 126. Lady Hardinge Medical College 127. National Centre for Disease Control 128. Ram Manohar Lohia Hospital 129. Institute of Liver & Biliary Sciences 130. Army Hospital Research & Referral 131. Maulana Azad Medical College 132. Vardhman Mahavir Medical College & Safdarjung Hospital 133. University College of Medical Sciences, New Delhi 134. Army Base Hospital, New Delhi 135. *IGIB, CSIR, New Delhi 136. Rajiv Gandhi Super Speciality Hospital, Taharpur, Delhi 137. Vallabhbhai Patel Chest Institute (VPCI), Delhi 138. *Defence Institute of Physiology & Allied Sciences (DIPAS), DRDO, Delhi 139. *Institute of Nuclear Medicine & Allied Sciences (INMAS-DRDO), New Delhi	18. MMI Narayana Superspeciality Hospital, New Dhamtari Road, Lalpur, Raipur 19. Lal Path Labs, Block -E, Sector 18, Rohini, Delhi 20. #Dr Dangs Lab, C-2/1, Safadarjung Development Area, New-Delhi 21. Laboratory Services, Indraprastha Apollo Hospitals, Sarita Vihar, New Delhi 22. Max Lab, Max Super Speciality Hospital, Saket, New-Delhi 23. Sir Ganga Ram Hospital Clinical Lab Services, Sir Ganga Ram Hospital, Delhi 24. Oncquest Labs Ltd, 3-Factory Road, New-Delhi 25. Prognosis Laboratories, 515-16, Sector 19, Dwarka 26. City X-Ray & Scan Clinic Pvt Ltd, 4B/18, Tilak Nagar, New-Delhi 27. Lifeline Laboratory, H-11, Green Park Extension, New-Delhi 28. Dept of Lab Services, Dr. B.L. Kapur Memorial Hospital, 5, Pusa Road, New-Delhi



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				29. Dept of Laboratory Services, Action Cancer Hospital, A-4, Paschim Vihar (East), New-Delhi 30. Star Imaging & Path Lab Pvt Ltd, 4B/4, Tilak Nagar, New Delhi 31. Genestrings Diagnostic Centre Pvt Ltd, 3, MMTC, Geetanjali Enclave, New Delhi 32. Sterling Accuris Diagnostics, A division of Sterling Accuris Wellness Pvt Ltd, C-65, Block C, Phase I, Okhla, New Delhi 33. CRL Diagnostics Pvt Ltd, Plot No 10, Avtar Enclave, Opposite Metro Pillar 227, Paschim Vihar, Rohtak Road, New Delhi 34. Dept of Lab Medicine, HCMCT, Manipal Hospital, Main Road, Sector 6, Dwarka, New Delhi 35. Gen-X Diagnostics, 2/6, Sarvapriya Vihar, New Delhi 36. Noble Diagnostic Centre, WZ-409C, Janak Park, Hari Nagar, Opposite DDU Hospital, New Delhi 37. Mahajan Imaging Pvt Ltd, E-19, Defence Colony, New-Delhi



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				38. #Dept of Lab Sciences, Rajiv Gandhi Cancer Institute & Research Centre, Sector 5, Rohini, New-Delhi 39. Metropolis Healthcare Ltd. E21, Block-B1, Mohan Cooperative Industrial Estate, South East Delhi 40. Gagan Pathology & Imaging Pvt Ltd F-26/21-22, Near Ayodhya Chowk, Sector 7, Rohini, Delhi 41. Saral Diagnostics, 2&3, Shakti Vihar, Pitampura 42. Unipath Diagnostics, C-4, Green Park Extension, New Delhi
		TrueNat	140. ESIC Hospital, Basaidarapur 141. State TB Training and Demonstration Laboratory, New Delhi 142. Gobind Balabh Panth Institute of Postgraduate Medical Education and Research, New Delhi	43. Aakash Path Lab, Aakash Healthcare & Super speciality Hospital, Road No 201, Sector 3, Dwarka, New Delhi 44. Ganesh Diagnostic And Imaging Centre Pvt Limited 109 Pkt A-1 Sector 8 Rohini, Delhi
		CB NAAT	143. State TB Training and Demonstration Centre, Jawaharlal Nehru Marg, Delhi Gate	45. Dr P Bhasin Path Labs (P) Ltd, S 13 Greater Kailash Part 1, New Delhi 46. Venkateshwar Hospital, sector- 18A, Dwarka, New Delhi- 110075



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			144. Department of Microbiology, National Institute of TB and Respiratory Diseases (NITRD), New Delhi 145. Northern Railway Central Hospital, New Delhi	47. HAHC & HIMSR, Jamia Hamdard Campus, Guru Ravidas Marg, BLock D, Hamdard Nagar, New Delhi 48. Dept of Laboratory Medicine, Batra Hospital & Medical Research Centre, 1, Tughlakabad Institutional Area, M.B. Road, New Delhi
8.	Gujarat (54) Govt: 33 Private: 21	RT-PCR	146. BJ Medical College, Ahmedabad 147. MP Shah Govt Medical College, Jamnagar 148. Govt. Medical College, Surat 149. Govt. Medical College, Bhavnagar 150. Govt. Medical College, Vadodara 151. Govt. Medical College, Rajkot 152. NHL Medical College, Ahmedabad 153. GMERS Medical College, Ahmedabad 154. GMERS Medical College, Gandhinagar 155. GMERS Medical College, Valsad 156. ICMR-National Institute of Occupational Health, Ahmedabad 157. Gujarat Cancer & Research Institute, Ahmedabad 158. Surat Municipal Institute of Medical Education & Research (SMIMER), Surat 159. GMERS Medical College and Hospital, Dharpur-Patan, Gujarat	49. Unipath Specialty laboratory limited, 102, Sanoma Plaza, Opposite Parimal Garden, Besides JMC House, Ellisbridge, Ahmedabad 50. Supratech Micropath Laboratory & Research Institute Pvt Ltd, Kedar, Ahmedabad 51. SN GeneLab Pvt Ltd, President Plaza -A, Near Mahavir Hospital, Nanpura, Surat 52. Pangenomics International Pvt Ltd, Ellis Bridge, Ahmedabad 53. #Dept of Lab Medicine, Zydus Hospitals & Healthcare Research Pvt Ltd, Zydus Hospital Road, Hebatpur, Off S.G. Highway, Thaltej, Ahmedabad 54. #Toprani Advanced Lab Systems, Suflam, 10, Haribhakti Colony, Race Course, Vadodra 55. Dept of Lab Medicine, Apollo Hospitals International Ltd, 1, Bhat, GIDC Estate, Ahmedabad



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			160. Gujarat Adani Institute of Medical Sciences, Bhuj 161. Gujarat Biotechnology Research Center, Gandhinagar 162. Gujarat Forensic Sciences University, Gandhinagar 163. GMERS Medical College, Gotri, Vadodara 164. GMERS Medical College, Himmatnagar 165. Dr. H.L. Trivedi Institute of Transplantation Services, Ahmedabad 166. #GMERS Medical College, Junagadh 167. GMERS Medical College, Vadnagar	56. Divine lab, B 201/202, Mangalkirti Apartment, Fatehgunj, Vadodra 57. Green Cross Genetics Lab Pvt Ltd, 104, Sears Towers, Ahmedabad 58. #Sunflower Laboratory, Helmet Circle, Rudra Arcade, Drive In Road, Manav Mandir, MemNagar, Ahmedabad 59. Parul Institute of Medical Sciences & Research (PIMSR), Vadodara 60. Dhiraj Hospital, Smt. B.K. Shah Medical Institute & Research Centre, Vadodara 61. Gujarat Pathology Lab & Diagnostic Centre, 101/102, Span Trade Centre, Paldi, Ahmedabad 62. Scientific Diagnostic Centre Pvt.Ltd, 3,Venunand Raw House, Gulbai Tekra Road, Ellisebridge, Ahmedabad 63. #Salvus Bioresearch Solutions, 2nd Floor, Earth Retail, Science City Circle, S.P. Ring Road, Ahmedabad 64. Sterling Accuris Diagnostics, 201 & 404, Ayush Doctor House, Station - Lal Darwaja Road, Behind Param Doctor House, Surat
		TrueNat	168. Shantaba Medical College and General Hospital, Amreli	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			169. Banas Medical College, Palanpur 170. District Hospital, Navsari 171. District Hospital, Vyara 172. District Hospital, Porbandar 173. District Hospital, Jamkhambhaliya 174. District Hospital, Rajpipla 175. General Hospital, Ahwa 176. General Hospital, Veraval	
		CB NAAT	177. GCS Medical College and Hospital, Ahmedabad 178. AMC MET Medical College and Hospital, Ahmedabad	65. Dept of Lab Medicine, Bhailal Amin Gen Hospital, Alembic Road, Gorwa, Vadodra 66. Microcare Lab & TRC, 105, Manthan Point, Unapani Road, Surat 67. Speciality Microtech Laboratory, 121 Akshar Arcade, Navrangpura, Ahmedabad 68. Sterling Accuris Diagnostics, Sterling Hospital, Phase 2, 1st Floor, Race Course Circle (West), Vadodra 69. Care Institute of Medical sciences (CIMS hospital), Department of Microbiology, Opp shukan mall, Science city road, Ahmedabad
9.	Goa (5)	RT-PCR	179. #Goa Medical College, Goa	
		TrueNat	180. North District Hospital, Mapusa 181. Subdistrict Hospital, Ponda 182. South Goa District Hospital (Hospicio Hospital), Margao	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			183. Sub- District Hospital, Chicalim, Vasco Da Gama	
10.	Haryana (25) Govt: 16 Private: 9	RT-PCR	184. Pt. B.D. Sharma Post Graduate Inst. Of Med. Sciences, Rohtak 185. Command Hospital, Chandimandir 186. BPS Govt. Medical College, Sonipat 187. ESIC Hospital, Faridabad 188. Kalpana Chawla Govt. Medical College, Karnal 189. Govt. Civil Hospital, Panchkula 190. *ICAR-National Research Centre on Equines, Hisar 191. *Translational Health Science & Technology Institute, Faridabad 192. #SHKM, Govt. Medical College, Mewat 193. #District Civil Hospital, Ambala 194. Civil Hospital, Gurugram 195. #Maharaj Agrasen Medical College, Agroha, Hisar	70. Strand Life Sciences, A-17, Sector 34, Gurugram 71. SRL Limited, GP26, Sector 18, Gurugram 72. Modern Diagnostic & Research Centre-Lab, 363-364/4, JAwarah Nagar. Gurgaon 73. Core Diagnostics Pvt Ltd, Udyog Vihar Phase-3, Gurgaon 74. MolQ Laboratory, Plot 28,29; Sector 18(P), Electronic city, Udyog Vihar, Phase IV, Gurgaon 75. Pathkind Diagnostics Pvt Ltd, Plot 55-56, Phase 4, Udyog Vihar, Sec 18, Gurugram 76. Department of Pathology and Laboratory Medicine, Medanta-The Medicity, Sector 38, Gurugram 77. SGT Medical College, Hospital and Research Institute, Gurugram
		TrueNat	196. Civil Hospital, Sirsa 197. Civil Hospital, Faridabad 198. Civil Hospital, Fatehabad	78. Apex Diagnostics - 12 Jacaranda Marg , Dlf City Phase - 2 , Gurgaon
		CB NAAT	199. IRL, Haryana Govt. Public Health Laboratory, Karnal	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
11.	Himachal Pradesh (11) Govt: 11	RT-PCR	200. Indira Gandhi Medical College, Shimla 201. Dr. Rajendra Prasad Govt. Medical College, Tanda 202. Central Research Institute, Kasauli 203. Shri Lal Bahadur Shastri Govt. Medical College, Mandi 204. *CSIR Institute of Himalayan Bioresource Technology, Palampur 205. #Dr. Yashwant Singh Parmar Government Medical College, Nahan 206. #Pt. JLN Government Medical College and Hospital, Chamba 207. #Dr. Radhakrishnan Government Medical College, Hamirpur	
		TrueNat	208. Zonal Hospital, Mandi 209. Regional Hospital, Una 210. Civil Hospital, Nurpur, Kangra District	
12.	Jammu & Kashmir (9) Govt: 8 Private: 1	RT-PCR	211. Govt. Medical College, Jammu 212. Command Hospital (NC) Udhampur 213. Sher-i-Kashmir Institute of Medical Sciences, Srinagar 214. Govt. Medical College, Srinagar 215. Sheri Kashmir Institute of Medical Science Medical College, Bemina, Srinagar	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			216. *CSIR Indian Institute of Integrative Medicine (IIIM), Jammu	
		TrueNat		79. Swastik Diagnostic Lab, Dr. Modi Market, Dogra Hall, Jammu Tawi
		CB NAAT	217. Intermediate Reference Laboratory, Chest Disease Hospital, Dalgate, Srinagar 218. 92 Base Hospital, Badami Bagh Cantonment, Srinagar	
13.	Jharkhand (32) Govt: 30 Private: 02	RT-PCR	219. MGM Medical College & Hospital, Jamshedpur 220. #Rajendra Institute of Medical Sciences, Ranchi 221. Patliputra Medical College & Hospital, Dhanbad 222. Itki Aarogyashala, Ranchi	80. Tata Main Hospital (Dept of Pathology), Tata Steel, Bistupur, Jamshedpur 81. MicroPraxis Labs, 2nd floor, New Building, Guru Nanak Hospital & Research Centre, Station Road, Ranchi
		TrueNat	223. District Hospital, Bokaro 224. District Hospital, Chatra 225. District Hospital, Deoghar 226. District Hospital, Dumka 227. District Hospital, Garhwa 228. District Hospital, Giridih 229. District Hospital, Godda 230. District Hospital, Hazaribag 231. District Hospital, Kodarma	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			232. District Hospital, Lathehar 233. District Hospital, Pakur 234. District Hospital, Palamu 235. District Hospital, Pashchimi Singhbhum 236. District Hospital, Ranchi 237. District Hospital, Sahibganj 238. District Hospital, Dhanbad 239. District Hospital, Gumla 240. District Hospital, Jamtara 241. District Hospital, Khunti 242. District Hospital, Lohardaga 243. District Hospital, Purbi Singhbhum 244. District Hospital, Ramgarh 245. District Hospital, Saraikela Kharsawan 246. District Hospital, Simdega 247. Central Hospital, CCL, Gandhinagar, Ranchi	
		CB NAAT	248. Military Hospital, Namkum, Ranchi	
14.	Karnataka (81) Govt: 44 Private: 37	RT-PCR	249. Hassan Inst. Of Med. Sciences, Hassan 250. #Mysore Medical College & Research Institute, Mysore 251. Shivamogga Institute of Medical Sciences, Shivamogga	82. Neuberg Anand Reference Laboratory, Anand Tower, #54, Bowring Hospital Road, Bengaluru 83. Cancyte Technologies Pvt Ltd, Sri Shankara Research Centre, Bengaluru

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			252. Command Hospital (Air Force), Bengaluru	84. Central Diagnostic Lab, Vydehi Institute of Medical Sciences and Research Centre, #82, E.P.I.P. Area, Whitefield, Bengaluru
			253. Bangalore Medical College & Research Institute, Bengaluru	85. Syngene International Limited, Biocon Park, SEZ, Bommasandra Industrial Area, Phase IV, Bommasandra-Jigani Link Road, Bengaluru
			254. ICMR-National Institute of Virology, Bangalore Field Unit, Bengaluru	86. #Department of Lab Medicine, Narayana Hrudayalaya Ltd, 258/A, Bommasandra Industrial Area, Hosur Road, Bengaluru
			255. *Indian Institute of Science, Bengaluru (Department of Biochemistry, Centre for Infectious Disease Research)	87. Aster Clinical Lab LLP, No 24, Venkatappa Road, Tasker Town, Vasanthanagar, Bangalore
			256. Gulbarga Institute of Medical Sciences, Gulbarga	88. Microbiological Lab, 22-D 3, KIADB Industrial Area, 1st Phase, Kumbalagidu, Bengaluru
			257. Vijaynagar Institute of Medical Sciences, Bellary	89. Yenepoya Medical College Hospital Lab, Nithyananda Nagar, Derlakatte, Mangaluru
			258. National Institute of Mental Health and Neuro-Sciences, Bangalore	90. Hybrinomics Life Science and diagnostics LLP, Site No 50, Maruthi Township, B. Hanumanthanagar, Bileshivale, Doddagubbi Post, Bengaluru
			259. Wenlock District Hospital, Mangalore	91. Shamanur Shivashankarappa Institute of Medical Sciences and Research Centre (SSIMSRC), Davangere
			260. Karnataka Institute of Medical Sciences, Hubli	92. XCyton Diagnostics Pvt Ltd - Molecular Diagnostic Services, #449, 10th Cross, 4th phase, Peenya, Bengaluru
			261. National Institute of Traditional Medicine, Belagavi	
			262. Dharwad Institute of Mental Health & Neurosciences, Dharwad	
			263. Kidwai Memorial Institute of Oncology, Bengaluru	
			264. *Instem, Bengaluru	

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			265. Mandya Institute of Medical Sciences (MIMS), Mandya	93. St. Johns Medical College and Hospital, Bangalore
			266. Chamarajanagar Institute of Medical Sciences (CIMS), Chamarajanagar District	94. Kasturba Medical College Manipal
			267. #Gadag Institute of Medical Sciences, Gadag	95. Father Muller's Medical College, Mangalore
			268. Kodagu Institute of Medical Sciences (KOIMS), Kodagu District	96. JJM Medical College (JJMMC), Davangere
			269. Government Virus Diagnostic Laboratory, Shimoga District	97. Manipal Hospital, Bangalore
			270. #Raichur Institute of Medical Sciences, Raichur	98. #Sakra World Hospital Lab Services, Devarabeesanahalli VArthur Hobli, Bengaluru
			271. #Bidar Institute of Medical Sciences, Bidar	99. Kasturba Medical College, Mangalore
			272. #Koppal Institute of Medical Sciences, Koppal	100. KS Hegde Medical Academy (KSHEMA), Mangalore
			273. #Karwar Institute of Medical Sciences, Karwar	101. Narayana Nethralaya, Department of Molecular Diagnostics, Bangalore
			274. #Tumkur District Hospital, Tumkur	102. #Lab Services, Apollo Hospitals, 154/11, Bannerghatta Road, Bengaluru
			275. #Bowring Lady Curzon Medical College and Research Institute (BLCMRI), Bangalore	103. Kempegowda Institute of Medical Sciences, Bangalore
			276. SNR District Hospital, Kolar	104. United Hospitals, Kalburgi
				105. Medicluc Diagnostics, Bangalore
				106. Sri Devaraj Urs Medical College, Kolar
				107. JSS Medical College, Mysore
				108. JN Medical College, Belgaum
				109. Eurofins Clinical Genetics India Pvt Ltd, Eurofins, #21 & #22, Peenya II Phase, Peenya, Bengaluru



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			277. Chigateri District Hospital, Davangere District 278. Yadgir Institute of Medical Sciences, District Hospital, Yadgir 279. District Hospital, Haveri 280. #Belgaum Institute of Medical Sciences, Belgaum 281. #District Public Health Laboratory, Ramanagara District	110. East Point College of Medical Sciences and Research Centre, Bangalore 111. Adichunchanagiri Institute of Medical Sciences, B.G.Nagara, Mandya District
		TrueNAT	282. Public health Laboratory, Chikkaballapur District Hospital, Chikkaballapur 283. Public Health Laboratory, Chikmagalur District Hospital, Chikmagalur 284. Udupi District Hospital, Udupi 285. Yadgiri District Hospital, Yadgiri 286. Chitradurga District Hospital, Chitradurga 287. District Public Health Laboratory, Kolar District 288. District Public Health Laboratory, Chamarajanagar District 289. Bangalore Bruhat Mahanagara Palike (BBMP) Health Centre (Fever Clinic), Adugodi, Bangalore	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			290. Jayadeva Institute of Cardiac Sciences, Bangalore	
		CB NAAT	291. Vijayapura District Hospital, Vijayapura 292. Bagalkot District Hospital, Bagalkot	112. KLES Dr Prabhakar Kore Hospital & MRC Hi Tech Lab, NehruNagar, Belgaum, Belagavi 113. Dept of Pathology & Lab Medicine, Aster CMI Hospital, #43/2, NH 7, International Airport Rd, Sahakar Nagar, Bengaluru 114. Dept of Lab Medicine, Vikram Hospital Pvt Ltd, No 71/1, Millers Road, Bengaluru 115. Department of Laboratory Medicine and Pathology, Columbia Asia Referral Hospital, Yeshwantpur, #26/4, Brigade Gateway, Malleshwaram West, Bengaluru 116. SRL Limited at Fortis hospitals, 154/9, Bannerghatta Main Road, Bengaluru 117. Trident Diagnostics & Healthcare Pvt.Ltd, #313, 2nd main Jagajyothi Nagara, 80 feet outer Ring Road, Kenchanapura Cross bus stop, Nagadevanahalli, Bengaluru 118. NMR Diagnostics Pvt. Ltd, Maratha Mandal Building, P.B.Road, Dharwad
15.	Kerala (46) Govt: 27 Private: 19	RT PCR	293. National Institute of Virology, Field Unit, Allapuzha 294. Govt. Medical College, Thiruvananthapuram	119. DDRC SRL Diagnostics Pvt Ltd, Panampilly Nagar, Ernakulam 120. MIMS Lab Services, Govindapuram, Kozhikode



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			295. Govt. Medical College, Kozhikode 296. Govt. Medical College, Thrissur 297. *Rajiv Gandhi Center for Biotechnology, Thiruvananthapuram 298. Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram 299. State Public Health Laboratory, Trivandrum 300. Inter University, Kottayam 301. Malabar Cancer Center, Thalassery 302. Central University of Kerala, Periyar, Kasaragod 303. Govt. Medical College, Ernakulam 304. Govt. Medical College, Manjeri 305. Govt. Medical College, Kottayam 306. Govt. Medical College, Kannur 307. *Indian Institute of Science Education and Research (IISER), Thiruvananthapuram 308. Government Medical College, Palakkad	121. Lab Services of Amrita Institute of Medical Sciences & Research Centre, AIMS-Ponekkara, Kochi 122. Dane Diagnostics Pvt Ltd, 18/757 (1), RC Road, Palakkad 123. Medivision Scan & Diagnostic Research Centre Pvt Ltd, Sreekandath Road, Kochi 124. MVR Cancer Centre & Research Institute, CP 13/516 B, C, Vellalaserri NIT (via), Poolacode, Kozhikode 125. Aza Diagnostic Centre, Stadium Puthiyara Road, Kozhikode
		TrueNat	309. Regional Public Health Laboratory, Pathanamthitta 310. Government Medical College Hospital, Kollam	126. Department of Laboratory Medicine, Avitis Super Specialty Hospitals Private Limited, XX/882, Thrissur-Pollachi Main Road, Nemmara, Palakkad



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			311. Government TD Medical College, Alappuzha 312. District Public Health Laboratory, Wayanad 313. District TB Centre, Palakkad 314. INHS Sanjivani, Kochi 315. District Public Health Laboratory, Kollam 316. Government Medical College, Idukki 317. District Hospital Palakkad	127. Jubilee Mission Medical College & RI, Thrissur 128. Aswini Diagnostic Services, Ramnath Building, Jail Road, Kozhikode 129. Laboratory Medicine, Premium Medical and Healthcare providers Private Limited. Meitra Hospital, 38/2208-B, Karaparamba Kunduparamba MiniBypass, Kozhikode 130. Dept of Molecular Biology, Valluvanad Hospital Complex Limited, Ottapalam
		CB NAAT	318. Regional Cancer Centre, Thiruvananthapuram 319. District TB Centre, Kottayam	131. Dept of Pathology and Lab Medicine, Aster Medcity, Aster DM Healthcare Ltd, Kutty Sahib Road, Kothad, Cochin 132. NIMS Medicity, Department of Laboratory Medicine, Aralumoodu, Neyyattinkara, Thiruvananthapuram 133. Rajagiri Hospital Laboratory Services, Rajagiri Hospital, Chunangamvely, Aluva 134. \$ Micro Health LABs, MPS Tower, Kozhikode 135. \$Microbiology Section, Department Of Laboratory Medicine, Kerala Institute Of Medical Sciences, Anamukham, Anayara P.O. Thiruvananthapuram

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				136. \$ Believers Church Medical College Laboratory, St Thomas Nagar, Kuttapuzha P.O., Thiruvalla
				137. AI Salama Diagnostic Centre, Thalakkadathur, Tirur
16.	Maharashtra (116) Govt: 68 Private: 48	RT-PCR	320. ICMR-National Institute of Virology, Pune 321. Seth GS Medical College & KEM Hospital, Mumbai 322. Kasturba Hospital for Infectious Diseases, Mumbai 323. National Institute of Virology Field Unit, Mumbai 324. Armed Forces Medical College, Pune 325. BJ Medical College, Pune 326. Command Hospital (SC), Pune 327. Indira Gandhi Govt. Medical College, Nagpur 328. All India Institute of Medical Sciences, Nagpur 329. Govt. Medical College, Nagpur 330. Nagpur Veterinary College, MAFSU, Nagpur 331. #Intermediate Reference Laboratory, Nagpur	138. Thyrocare Technologies Limited, D37/1, TTC MIDC, Turbhe, Navi Mumbai 139. Suburban Diagnostics (India) Pvt. Ltd., 306, 307/T, 3rd Floor, Sunshine Bld., Andheri (W), Mumbai 140. Metropolis Healthcare Ltd, Unit No. 409-416, 4th Floor, Commercial Building-1, Kohinoor Mall, Mumbai 141. Sir H.N. Reliance Foundation Hospital and Research Centre, Molecular Medicine, Reliance Life Sciences Pvt. Ltd., R-282, TTC Industrial Area, Rabale, Navi Mumbai 142. SRL Limited, Prime Square Building, Plot No 1, Gaiwadi Industrial Estate, SV Road, Goregaon, Mumbai 143. A.G. Diagnostics Pvt Ltd, Nayantara Building, Pune 144. Kokilaben Dhirubhai Ambani Hospital Laboratory, Four Bungalows, Mumbai

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			332. Grant Medical College & Sir JJ Hospital, Mumbai	145. InfeXn Laboratories Private Limited, A/131, Therelek Compound, Road No 23, Wagle Industrial Estate, Thane (W)
			333. Govt. Medical College, Aurangabad	146. iGenetic Diagnostics Pvt Ltd, Krislon House, Andheri East, Mumbai
			334. V. M. Govt. Medical College, Solapur	147. Sahyadri Speciality Labs, Plot No 54, S.No. 89-90, Lokmanya Colony, Kothrud, Pune
			335. Haffkine Institute, Mumbai	148. Metropolis Healthcare Limited, Construction House, 796/189-B, Bhandarkar Institute Road, Pune
			336. Shree Bhausheb Hire Govt. Medical College, Dhule	149. # SRL Diagnostics - Dr. Avinash Phadke (SRL Diagnostics Pvt Ltd), Mahalaxmi Engineering Estate, 2nd Floor, L.J. Cross Road No 1, KJ Khilnani High School, Mahim (West), Mumbai
			337. Govt. Medical College, Miraj	150. Department of Laboratory Medicine - P.D. Hinduja National Hospital and Medical Research Centre, Veer Savarkar Marg, Mahim, Mumbai
			338. Govt. Medical College, Akola	151. Vaidya Lab Thane, Unit of Millenium Special Lab Pvt Ltd, Odyssey Park, 2nd Floor, 201, Raghunath Nagar, Wagle Estate, Thane
			339. National Institute for Research on Reproductive Health, Mumbai	152. Genepath Diagnostics India Pvt Ltd, 4th Floor, Above Phadke Hospital, Pune
			340. Rajiv Gandhi Medical College & CSM Hospital, Kalwa, Thane, Mumbai	
			341. ICMR-National AIDS Research Institute, Pune	
			342. Swami Ramanand Teerth Marathwada University, Nanded	
			343. Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha	
			344. Vilasrao Deshmukh Govt. Institute of Medical Sciences, Latur	
			345. INHS Ashvini, Mumbai	
			346. *Tata Memorial Centre ACTREC, Mumbai	
			347. *Tata Memorial Hospital, Mumbai	



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			348. *National Centre for Cell Sciences, Pune	153. Daignostic Molecular Laboratory, Dept of Microbiology, Dr. Vasantao Pawar Medical College Hospital & Research Centre, Vasantdada Nagar, Adgaon, Nashik
			349. *National Environmental Engineering Research Institute, Nagpur	154. Dept of Lab Medicine, Dr. Balabhai Nanavati Hospital, Swami Vivekananda Road, Mumbai
			350. Sant Gadge Baba Amravati University, Amravati	155. Krsnaa Diagnostics Pvt Ltd, Lt. Jayabai Nanasaheb Sutar Maternity Home, Pune
			351. #RCSM Govt. Medical College, Kolhapur	156. Dhruv Pathology and Molecular Diagnostic Lab, Third Floor, Aditya Enclave, Central Bazaar Road, Ramdaspath, Nagpur
			352. Model Rural Health Research Unit (MRHRU), Sub District Hospital, Agar, Dahanu, Palghar	157. Dept of Molecular Biology & Genetics, Krishna Institute of Medical Sciences, Karad, Satara
			353. *Indian Institute of Science Education and Research (IISER), Pune	158. Lab Services, Ayugen Biosciences Pvt Ltd, 562/1, Shivajinagar, Pune
			354. Govt. Medical College, Jalgaon	159. MGM Medical College and Hospital, Navi Mumbai
			355. District General Hospital, Ahmednagar	160. #Ruby Hall Clinic, Dept of Laboratory, Grant Medical Foundation, 40, Sassoon Road, Pune
			356. Government Medical College, Baramati	161. D. Y. Patil Medical College, Kolhapur
			357. #Govt. Medical College, Chandrapur	
			358. #Govt. Medical College, Yavatmal	
			359. Swami Ramanand Teerth Rural Government Medical College, Ambajogai	
			360. Government Medical College, Gondia	
			361. Agharkar Research Institute, Pune	
			362. District General Hospital, Ratnagiri	
			363. Dr. Shankarrao Chavan Govt. Medical College, Nanded	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			364. YCM Hospital, Pimpri 365. Babasaheb Ambedkar Marathwada University, Aurangabad	162. Metropolis Healthcare Limited, Shop No. 1, Ground Floor, Ahilya Building, Savarkar Marg, Thane West, Thane 163. Molecular Diagnostic Laboratory, Department of Pathology, LMMF's Deenanath Mangeshkar Hospital and Research Center, Erandwane, Pune 164. Datar Cancer Genetics Ltd, F-8, D-Road, Ambad MIDC, Nashik 165. Apoorva Diagnostic and Health Care, Bhaktivedanta Hospital and Research Institute, Bhaktivedanta Swami MArg, Sector 1, Mira Bhayandar 166. Dr. DY Patil Medical College Hospital and Research Centre, Pimpri, Pune 167. Molecular Laboratory, Jaslok Hospital and Research Centre, 15, Dr Deshmukh Marg, Peddar Road, Mumbai 168. NM Medical, Harchandrai House, Above Axis Bank, 2nd Floor, Maharshi Karve Road, Marine Lines (E), Mumbai 169. Bharati Vidyapeeth (Deemed to be University) Medical College, Pune



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				170. Lifecare Diagnostic & Research Centre Pvt. Ltd. 206, Cosmos Plaza, J P Road, Andheri West 171. Aditya Birla Memorial Hospital - Laboratory, Aditya Birla Marg, Chinchwad, Pune
		TrueNat	366. Civil Surgeon, District Hospital, Parbhani 367. District Hospital, Satara 368. Daga Memorial Government Women Hospital, Nagpur 369. Navi Mumbai Municipal Corporation General Hospital, F.R.U. Vashi 370. District General Hospital, Gadchiroli 371. Darasha Maternity Home, Solapur Municipal Corporation, Solapur 372. District Hospital, Amravati 373. Sub district Hospital, Shahapur, Thane 374. RCH Room, N.N. Wadia Hospital, Malegaon, Nashik, Maharashtra 375. Dr. Zakir Hussain Hospital, Kathda, Municipal Corporation Nashik 376. Sub District Hospital, Gadhinglaj, Kolhapur	172. Qualilife Diagnostics, Balaji Arcade, 1st Floor, 544/A, Netaji Subhash Road, Mulund (W), Mumbai 173. Rural Medical College, Pravara Institute of Medical Sciences, Loni, Ahmednagar 174. Clinicare Speciality Laboratory Pvt. Ltd., Lata Mangeshkar Hospital, Nagpur



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			377. Late Indira Gandhi Memorial Hospital, Bhiwandi 378. Rural Hospital, Sangamner, Ahmednagar 379. Sub- District Hospital, Panvel, Raigad 380. UHCC Shivajinagar Hospital, Nanded Waghala, City Municipal Corporation, Nanded 381. District Women Hospital, Akola 382. Agrawal Hospital Isolation Centre, Vasai Virar Municipal Corporation, Dist. Palghar	
		CB NAAT	383. Intermediate Reference Laboratory, Pune 384. Govt. Medical College, Baramati 385. Lokmanya Tilak Municipal General Hospital and Medical College, Mumbai 386. \$ Molecular Diagnostic Laboratory, District Hospital, Sindhudurg 387. Gokuldas Tejpal Hospital, Mumbai	175. Sunflower Lab & Diagnostic Center, Keshav Kunj, Marve Road, Malad West, Mumbai 176. Dr. Jariwala Lab & Diagnostics LLP, 1st Floor, Rasraj Heights, Rokadia Lane, Off Mandpeshwar Road, Borivli (W), Mumbai 177. Su-Vishwas Diagnostic Lab, 1st floor Midas height, Ramdaspath, Nagpur 178. \$Jupiter Lifeline Hospitals Limited, Pune 179. Kingsway Hospitals ((A Unit of SPANV Medisearch Lifesciences Pvt Ltd), 44, Kingsway Road, Nagpur



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				180. \$ Jupiter Hospital, Eastern Express Highway, Thane West 181. Dr Ajay Shah's Pathology Lab & Microbiology Reference Center, 1st Floor, Amidrashti, Opposite Manav Kalyan Kendra, S V Road, Dahisar East. Mumbai 182. Dr. Lal Pathlabs Ltd. Dadar, Add: Shop no 2 to 6, Shilpa Apartment, Shankar ghanekar marg, off Ghokale road, Prabhadevi, Dadar west, Mumbai 183. Kamalnayan Bajaj Hospital Pathology Laboratory, Gut no.43, Satara Parisar, Bajaj marg, Beed bypass road, Aurangabad 184. SRCC Children's Hospital ,1-1A, Keshavrao Khadye Marg, Haji Ali, Mahalakshmi, Mumbai 185. MGM New Bombay Hospital, Vashi Pathology Lab, Plot no 35, sector 3 , Vashi, Navi Mumbai
17.	Madhya Pradesh (79) Govt: 70 Private: 8	RT-PCR	388. All India Institute of Medical Sciences, Bhopal 389. ICMR-National Institute for Research on Tribal Health, Jabalpur 390. Mahatma Gandhi Memorial Medical College, Indore	186. Chirayu Medical College & Hospital, Bhopal Indore Highway, Bhaisakhedi, Bhopal 187. #Central Research Lab, R D Gardi Medical College, Surasa, Ujjain



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			391. Gandhi Medical College, Bhopal 392. Bhopal Memorial Hospital & research Centre, Bhopal 393. Gajra Raja Medical College, Gwalior 394. Bundelkhand Medical College, Sagar 395. SS Medical College, Rewa 396. *Defence Research & Development Organization, Gwalior 397. *ICAR-NIHSAD, Bhopal 398. Govt. Medical College, Ratlam 399. Netaji Subhash Chandra Bose Medical College, Jabalpur 400. Govt. Medical College, Khandwa 401. Atal Bihari Vajpayee Government Medical College (ABVGMC), Vidisha 402. *IISER, Bhopal	188. CentraPath Labs Private Ltd, MZ 117-118, Yeshwant Plaza, Indore 189. Lab Medicine, Bansal Hospital, A unit of Ayushman Medical Diagnostics Pvt Ltd, C-sector Shahpura, Bhopal 190. Sri Aurobindo Institute of Medical Sciences, Indore 191. L. N. Medical College & J. K. Hospital, Bhopal 192. Amaltas Institute of Medical Sciences, Dewas
		TrueNAT	403. District Tuberculosis Centre, Bhopal 404. District Hospital Gwalior 405. District Hospital Morena 406. District Hospital Chhatarpur 407. District Hospital Damoh 408. District Hospital Sagar 409. District Hospital Tikamgarh 410. District Hospital, Mandasaur 411. District Hospital, Neemuch	193. Sampurna Sodani Diagnostic Clinic, LG-1, Morya Centre, 16/1, Race Course Road, Indore 194. Central Pathology Laboratory, People's Hospital, Bhanpur, Bhopal-462037



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			412. District Tuberculosis Centre, Indore 413. District Hospital Chhindwara 414. District Hospital, Jabalpur 415. District Hospital, Shahdol 416. District Hospital, Burhanpur 417. District Hospital, Singrauli 418. District Tuberculosis Centre, Raisen 419. District Hospital, Bhind 420. District Hospital, Datia 421. District Hospital, Sheopur 422. District Hospital, Shivpuri 423. District Hospital, Alirazpur 424. District Hospital, Barwani 425. District Hospital, Dhar 426. District Hospital, Jhabua 427. District Hospital, Khargone 428. District Hospital, Agarmalwa 429. District Hospital, Shajapur 430. District Hospital, Ujjain 431. District Hospital, Dindori 432. District Tuberculosis Centre, Mandla 433. District Hospital, Seoni 434. District Hospital, Satna 435. District Hospital, Sidhi 436. District Hospital, Umaria	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			437. District Hospital, Panna 438. District Hospital, Rewa 439. District Hospital, Harda 440. JSR Hospital, Itarsi 441. CHC, Pipariya 442. District Hospital, Rajgarh 443. District Hospital, Sehore 444. District Hospital, Vidisha 445. District Hospital, Ashok Nagar 446. District Hospital, Dewas 447. District Hospital, Guna 448. District Hospital, Khandwa 449. District Hospital, Ratlam 450. District Government Hospital, Balaghat 451. District Hospital, Katni 452. MG Hospital, Dewas 453. JP Hospital, Bhopal 454. Government PC Sethi Hospital, Indore 455. District Hospital, Anuppur 456. District Hospital, Betul 457. Civil hospital, Gadarwara, Narsinghpur	
18.	Manipur (6) Govt: 6	RT-PCR	458. Jawaharlal Nehru Institute of Med. Sciences, Imphal-East, Manipur	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			459. Regional Institute of Medical Sciences, Imphal	
		TrueNat	460. Intermediate Reference Laboratory, Lamphelpat 461. District Hospital, Senapati 462. District Tuberculosis Centre (DTC), Ukhrul 463. District Hospital, Tamenglong	
19.	Meghalaya (12) Govt: 11 Private: 1	RT-PCR	464. North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences, Shillong, Meghalaya 465. #Civil Hospital, Tura	
		TrueNAT	466. Pasteur Institute, Shillong 467. Civil Hospital, Nongstoin 468. M.C.H. Hospital, Zowai 469. Civil Hospital, Nongpoh 470. Civil Hospital Shillong, East Khasi Hills District 471. Khliehriat CHC, East Jaintia Hills District 472. Civil Hospital Baghmara, South Garo Hills District 473. Civil Hospital Wiliamagar, East Garo Hills District	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			474. Resubelpara CHC, North Garo Hills District	
		CB NAAT		195. \$ Nazareth Hospital, Shillong
20.	Mizoram (2) Govt: 2	RT-PCR	475. Zoram Medical College, Falkawn	
		TrueNat	476. Civil Hospital, Lunglei	
21.	Nagaland (13) Govt: 13	RT-PCR	477. State Referral BSL-3 Laboratory, Naga Hospital, Kohima	
		TrueNat	478. Imkongliba Memorial District Hospital, Mokokchung 479. District Hospital, Mon 480. District Hospital, Dimapur, Nagaland 481. CHC, Jalunkie, Nagaland 482. District Hospital, Zunheboto 483. District Hospital, Wokha 484. District Hospital, Tuensang 485. District Hospital, Phek 486. District Hospital, Kiphire 487. District Hospital, Longleng 488. PHC Chumukedima, Dimapur 489. Naga Hospital Authority, Kohima	

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
22.	Odisha (26) Govt: 19 Private: 07	RT-PCR	490. ICMR-Regional Medical Research Centre, Bhubaneswar (High-throughput Laboratory) 491. All India Institute of Medical Sciences, Bhubaneswar 492. SCB Medical College and Hospital, Cuttack 493. MKCG Medical College, Berhampur 494. Ispat General Hospital, Rourkela 495. Veer Surendra Sai institute of Medical Science & Research, Sambalpur 496. *Institute of Life Sciences, Bhubaneswar 497. *ICAR- International Centre for Foot and Mouth Disease, Khordha, Odisha 498. *Indian Institute of Science Education and Research (IISER), Berhampur 499. #Bhima Bhoi Medical College and Hospital, Bolangir 500. #Pandit Raghunath Murmu Medical College, Baripada 501. #Fakir Mohan Medical College and Hospital, Balasore 502. #SLN Medical College and Hospital, Koraput	196. #Dept of Lab Services, Apollo Hospitals, Bhubaneswar 197. IMS & SUM Hospital, Bhubaneswar 198. InDNA Life Sciences Pvt Ltd, 2nd Floor, KIIT TBI, Bhubaneswar 199. GenX Diagnostics, A19, Maharshi College Road, Sahid Nagar, Bhubaneswar 200. #Central Lab, AMRI Hospitals, Plot No 1, Khandagiri, Bhubaneswar



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
		TrueNAT	503. Tribal Field Unit of ICMR-RMRC, Bhawanipatna, Kalahandi 504. Tribal Field Unit of ICMR-RMRC, Rayagada 505. Old District Headquarter Hospital, Jharsuguda 506. District Headquarters Hospital, Subarnapur 507. District Headquarters Hospital, Nabarangpur 508. District Headquarters Hospital, Deogarh	201. Shree Hospitals, 246, Lewis Road, Bhubaneswar
		CB NAAT		202. Kalinga Institute of Medical Science (KIMS), Dept. of Microbiology, Bhubaneswar
23.	Puducherry (5) Govt: 3 Private: 2	RT-PCR	509. #Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry 510. Indira Gandhi Medical College, Puducherry	203. Mahatma Gandhi Medical College and Research Institute, Puducherry
		TrueNat		204. Pondicherry Institute of Medical Sciences, Ganapathichettikulam, Kalapet, Puducherry
		CB NAAT	511. Intermediate Reference Laboratory, Govt. Hospital for Chest Diseases, Gorimedu, Puducherry	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
24.	Punjab (27) Govt: 20 Private: 7	RT-PCR	512. Govt. Medical College, Amritsar 513. Govt. Medical College, Patiala 514. Guru Gobind Singh Medical University, Faridkot	205. Tuli Diagnostic Centre, Majitha Road, Amritsar 206. Christian Medical College, Ludhiana 207. Sri Guru Ram Das Univ. of Health Sciences, Amritsar
		TrueNat	515. District Hospital, Barnala 516. District Hospital, Jalandhar 517. District Hospital, Ludhiana 518. District Hospital, Mansa 519. District Hospital, Pathankot 520. District Hospital, Bhatinda 521. District Hospital, Fazilka 522. District Hospital, Gurdaspur 523. District Hospital, Hoshiarpur 524. District Hospital, Kapurthala 525. District Hospital, Moga 526. District Hospital, Rupnagar 527. District Hospital, Sangrur 528. District Hospital, SBS Nagar 529. District Hospital, Muktsar Sahib	
		CB-NAAT	530. Intermediate Reference Laboratory, Patiala 531. Military Hospital, Jalandhar	208. Department of Microbiology, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				209. Dr Bhasin Path labs , A 96,97,98, Ranjit Avenue , Amritsar 210. Patel Hospital Pvt. Ltd. Laboratory, Civil Lines, Jalandhar 211. Department of Lab Medicine, Fortis Healthcare Limited, Phase VIII, Sector 62, Fortis Hospital, Mohali
25.	Rajasthan (30) Govt: 23 Private: 7	RT-PCR	532. Sawai Man Singh Medical College, Jaipur 533. Rajasthan University of Health Sciences Medical College, Jaipur 534. Dr. Sampurnan and Medical College, Jodhpur 535. Jhalawar Medical College, Jhalawar 536. RNT Medical College, Udaipur 537. SP Medical College, Bikaner 538. All India Institute of Medical Sciences, Jodhpur 539. JLN Medical College, Ajmer 540. Govt. Medical College, Kota 541. ICMR-National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur 542. RVRS Govt. Medical College, Bhilwara 543. Govt. Medical College, Dungarpur	212. Central Lab, The Mahatma Gandhi University of Medical Sciences and Technology, RIICO Institution Area, Sitapura, Tonk Road, Jaipur 213. Dr. B Lal Clinical Lab Pvt Ltd, 6-E, Malviya Industrial Area, Malviya Nagar, Jaipur 214. #Brig T.K. Narayanan Dept of Pathology, Santokaba Durlabhji Memorial Hospital Cum Medical Research Institute, Jaipur (TruNat and RTPCR) 215. Jaipur National University Institute for Medical Sciences and Research Centre, Jaipur 216. Krsnaa Diagnostics Pvt Ltd, National Institute of Ayurveda, Madhav Vilas Palace, Amer Road, Jaipur



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			544. Pandit Deendayal Upadhyaya Medical College, Churu 545. Govt. Medical College, Bharatpur 546. Govt. Medical College, Sikar 547. Govt. Medical College, Barmer 548. Govt. Medical College, Pali 549. Govt. BDK District Hospital, Jhunjhunu 550. Military Hospital, Jaipur 551. District Hospital, Sirohi 552. District Hospital, Jalore 553. Advanced Molecular Laboratory, MG Hospital, Banswara 554. Govt. JLN District Hospital, Nagaur	217. Suryam Diagnostic Center B 7, Ground Floor, Akshat Retreat, Sawai Ram Singh Road, Jaipur
		TrueNat		218. Goyal Hospital & Research Centre Pvt. Ltd., 961 Residency Road, Opp. Rotary Club, Jodhpur-342003
26.	Tamil Nadu (96) Govt: 50 Private: 46	RT-PCR	555. King Institute of Preventive Medicine & Research, Chennai 556. Madras Medical College, Chennai 557. Stanley Medical College, Chennai 558. Govt. Kilpauk Medical College, Chennai 559. ICMR-National Institute for Research in Tuberculosis, Chennai 560. State Public Health Laboratory, Chennai	219. Dept. of Clinical Virology, CMC, Vellore 220. #Department of Laboratory Services, Apollo Hospitals Enterprise Ltd, Chennai 221. Neuberg Ehrlich Lab Pvt Ltd, 46-48 Masilamani Road, Balaji Nagar, Chennai 222. Sri Ramachandra Medical College & Research Institute, Porur, Chennai 223. Microbiology Lab, Veerakeralam Road, Coimbatore



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			561. ICMR-National Institute of Epidemiology, Chennai	224. YRG CARE, Taramani, Chennai
			562. Dr. MGR Medical University, Chennai	225. Hitech Diagnostic Centre- A Unit of Dr. Ganesan's Hitech Diagnostic Centre Pvt Ltd, Poonamallee High Road, Chennai
			563. Dr. ALM PG Institute of Basic Medical Sciences, Chennai	226. PSG Hospitals Diagnostic Centre, Avinashi Road, Peelamedu, Coimbatore
			564. Govt. Medical College & Hospital, Omandurar Govt. Estate, Chennai	227. Medall Healthcare Pvt Ltd, 17, Race View Colony, 2nd street, Race Course Road, Guindy, Chennai
			565. Govt. Theni Medical College, Theni	228. Meenakshi Labs Madurai A unit of Sunmed Healthcare Pvt Ltd, 2nd Floor, Meenakshi Mission Hospital and Research Centre, Madurai
			566. Tirunelveli Medical College, Tirunelveli	229. Metropolis Healthcare Limited, No 3, Jaganathan Road, Nungambakkam, Chennai
			567. Govt. Medical College, Thiruvavur	230. #Clinical Lab Services, Dr. Rela Institute & Medical Centre, #7, CLC Works Rd, Shankar Nagar, Chennai
			568. Kumar Mangalam Govt. Medical College, Salem	231. Doctors' Diagnostic Centre, 123/1, Puthur High Road, Thiruchirapalli
			569. Coimbatore Medical College, Coimbatore	232. Molecular Testing, Institute of Lab Medicine, Kovai Medical Center & Hospital, 99, Avinashi Road, Coimbatore
			570. Govt. Medical College & ESIC Hospital, Coimbatore	
			571. Govt. Medical College, Villupuram	
			572. Madurai Medical College, Madurai	
			573. K A P Viswanatham Govt. Medical College, Trichy	
			574. Perundurai Medical College, Perundurai	
			575. Govt. Dharmapuri Medical College, Dharmapuri	
			576. Govt. Medical College, Vellore	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			577. Thanjavur Medical College, Thanjavur	233. Chettinad Hospital and Research Institute, Chengalpattu
			578. Kanyakumari Govt. Medical College, Nagercoil	234. Nu-Med Labs, 15A, Nellukara Street, Kanchipuram
			579. Govt. Thoothukudi Medical College, Thoothukudi	235. BioLine Laboratory, 43B-1, Cowley Brown Road, RS Puram, Coimbatore
			580. Institute of Vector Control & Zoonoses, Hosur	236. Premier Health Center, Crescent Court, Ground Floor No 963, Poonamallee High Road, Purasawalkam, Chennai
			581. Pasteur Institute of India, Coonoor	237. Dept of Lab Medicine, Royalcare Super Speciality Hospital Ltd, 1/520, L&T Road, Neelambur, Coimbatore
			582. Rajah Muthiah Medical College, Chidambaram	238. #VRR Diagnostics, #87, Burkit Road, T. Nagar, Chennai
			583. Govt. Medical College, Karur	239. Lab Services, Apollo Speciality Hospitals, P 3, KK Nagar East 1st Street, Madurai
			584. Govt. Tiruvannamalai Medical College & Hospital, Tiruvannamalai	240. Orbito Asia diagnostics, Puliyakulam road, Coimbatore
			585. Chengalpattu Govt. Medical College, Kancheepuram	241. Lifecell International Pvt Ltd, No 26, Vandalur - Kelambakkam Main Road, Keelakottaiyur, Chennai
			586. Govt. Medical College and Hospital, Pudukkottai	242. Vivek Laboratories, 1159, K.P. Road, Nagercoil, Kanniyakumari
			587. Govt. Shivagangai Medical College, Shivagangai	
			588. Govt. District Headquarters Hospital, Virrudhu Nagar	
			589. Govt. District Headquarters Hospital, Ramanathapuram	
			590. Govt. District Headquarters Hospital, Ariyalur	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			591. Govt. District Headquarters Hospital, Tiruppur	243. Krsnaa Diagnostics Pvt Ltd, Krsnaa Diagnostics Coimbatore Medical College & Hospital, No 1619 A, Trichy Road, Coimbatore
			592. Govt. Hospital, Kallakurichi	244. Central Laboratory, Sree Balaji Medical College and Hospital, Chennai
			593. Govt. District Headquarters Hospital, Tiruvallur	245. Aarthi Scans and Labs. No 60, 100 feet road, Vadapalani, Chennai
			594. Govt. District Headquarters Hospital, Namakkal	246. Balaji Medical Centre, Old No 18, New No 4, Jagadeeswaran Street, T.Nagar, Chennai
			595. *Central Leather Research Institute, Adyar, Chennai	247. Anderson Diagnostics and Labs, Kilpauk
			596. Government Headquarters Hospital, Dindigul	248. Aarthi Scans and Labs, No. 177(177A/22/1,177A/22/2), Trivandrum Road, Vannarpet, Tirunelveli, Tamilnadu
			597. C.D Hospital, Greater Chennai Corporation, Chennai	249. Velammal medical College Hospital & RI, Anuppanadi , Madurai
			598. Government District Head Quarters Hospital, Nagapattinam	250. PrimeGen Healthcare Laboratories Private Limited, Old no 7, New no 3, Inner ring road, 37th Street, Thillai Ganga Nagar, Nanaganallur, Chennai
			599. Government Hospital, Tirupattur	251. Meenakshi Medical College Hospital and Research Institute, Kanchipuram
			600. Government Head Quarters Hospital, Krishnagiri	252. Endocare Diagnostic Centre, No. 128, East 5th Street, K.K.Nagar, Madurai



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				253. Bharathi Diagnostics (A unit of Bharathi Hospitals), 95/1, Alagar Kovil Road, Madurai
		TrueNat	601. Government Hospital, Tiruchengodu, Namakkal District 602. Government District Head Quarters Hospital, Karaikudi Sivaganga District 603. Government Hospital, Padmanabapuram	254. Karpaga Vinayaga Institute of Medical Sciences, Madhuranthgam Chengalpet 255. Suriyaa Diagnostics, 81, Broadway main road, Chennai-600108 256. Meenakshi Hospital Lab Services, 244/2, Trichy Main Road, Thanjavur 257. Aara Clinical Laboratories, Old No 191 New No 251 Hamid Building, Annasalai, Chennai
		CB NAAT	604. Government Hospital of Thoracic Medicine, Sanatorium, Chennai Tambaram	258. MIOT Hospitals - Dept of Lab Medicine, 4/112, Mount Poonamallee Road, Manapakkam, Chennai 259. \$ Madras Medical Mission Clinical Lab Services, 4-A, Dr. J. Jayalalitha Nagar, Mogappair East, Chennai 260. \$Clinical Lab Services, Sundaram Medical Foundation, Dr. Rangarajan Memorial Hospital, 9C, 4th Avenue, Shanthi Colony, Anna Nagar, Chennai 261. VHS Lab Services, VHS Hospital, Rajiv Gandhi Salai, Taramani, Chennai



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				262. Laboratory Services, Sri Ramakrishna Hospital, 395, Sarojini Naidu Road, Sidhapudur, Coimbatore 263. Microbiology Lab, CSI, Scudder Memorial Hospital, Kelly's Road, Ranipet 264. SRM Institutes for Medical Sciences (SIMS Laboratory), No.1, Jawaharlal Nehru Salai (100 Feet Road), Vadapalani, Chennai
27.	Telangana (36) Govt: 14 Private: 22	RT-PCR	605. Gandhi Medical College, Secunderabad 606. Osmania Medical College, Hyderabad 607. Sir Ronald Ross of Tropical & Communicable Diseases, Hyderabad. 608. Nizam's Institute of Medical Sciences, Hyderabad 609. Institute of Preventive Medicine, Hyderabad 610. ESIC Medical College, Hyderabad 611. Kakatiya Medical College, Warangal 612. *Centre for Cellular & Molecular Biology, Hyderabad 613. *Centre for DNA Fingerprinting & Diagnostics, Hyderabad 614. Railway Hospital, Lallaguda, Secunderabad	265. #Laboratory Services, Apollo Hospitals, 6th Floor, Health Street Building, Jubilee Hills, Hyderabad 266. Vijaya Diagnostic Centre Pvt Ltd, Street No 19, Himayath Nagar, Hyderabad 267. Vimta Labs Ltd, Plot No 142, Phase 2, IDA Cherlapally, Hyderabad 268. Apollo Health and Lifestyle Limited, Diagnostic Laboratory, Bowenpally, Secunderabad 269. Dr. Remedies Labs Private Ltd, A3, Titus Plaza, Sharma Commercial Complex, Punjagutta, Hyderabad 270. Pathcare Labs Pvt Ltd, Medchal, Hyderabad



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				<p>271. American Institute of Pathology And Lab Sciences Pvt Ltd, Citizens Hospital, Serilingampally, Hyderabad</p> <p>272. Medcis Pathlabs India Pvt Ltd, Plot No 16 & 17, Swathi Plaza, Anand Nagar, New Bowenpally, Secunderabad</p> <p>273. Department of Lab Medicine, Yashoda Hospital, 9th Floor, 1-1-156 & 157, Alexander Road, Secunderabad</p> <p>274. Biognosys Technologies (India) Pvt Ltd, #8-148/174/11, NRI Colony, Near Aleap Industrial Area, Medchal, Malkajgiri</p> <p>275. Tenet Diagnostics, Plot No 51, Kineta Towers, Journalist Colony, Road No 3, Banjara Hills, Hyderabad</p> <p>276. AIG Hospitals, Survey No 136, Plot No 2/3/4/5, 1, Mindspace Rd, Gachibowli, Hyderabad</p> <p>277. Cell Correct Diagnostics, Virinchi Hospitals, Road No 1, Banjara Hills, Hyderabad</p> <p>278. Krishna Institute of Medical Sciences Ltd, Dept of Lab Services, 1-8-31/1, Minister Road, Secunderabad</p>



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				279. MAPMYGENOME India Ltd, Royal Demeure, Plot No 12/2, Sector-1, HUDA TEchno Enclave, Madhapur, Hyderabad 280. LEpra Society-Blue Peter Public Health and Research Centre, Cherlapally, Near TEC Building, Hyderabad 281. Lucid Medical Diagnostics Pvt Ltd, Plot No 203,203A, Vasavi Nagar, Karkhana, Secunderabad 282. Chalmeda Anand Rao Institute of Medical Sciences, Karimnagar 283. Diagnostic Laboratory Services, Kamineni Hospitals Ltd., Unit D 4-7, Industrial Estate, Moula Ali, Hyderabad 284. MEGSAN Diagnostics Pvt Ltd, Survey No. 1, Pet Basheerabad, Kompally, Medchal Mandal, Hyderabad
		TrueNAT		285. Dept of Lab Medicine, Star Hospital, A Unit of UniMed Healthcare Pvt Ltd, 8-2-594/B, Road No 10, Banjara Hills, Hyderabad
		CB NAAT	615. Rajiv Gandhi Institute of Medical Sciences, Adilabad 616. Government General Hospital, Nizamabad, Telangana	286. Department of Laboratory Medicine, Gleneagles Global Hospital, Lakdi-kapul, Hyderabad 287. \$Continental Hospital Private Limited, Department of Advanced

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			617. Government General Hospital, Suryapet, Telangana 618. AH Hospital, Gadwal, Telangana	Diagnosics and Laboratory medicine, Plot No. 3, Road No.2, IT & Financial District, Nanakramguda, Hyderabad
28.	Tripura (1)	RT-PCR	619. Govt. Medical College, Agartala	
29.	Uttar Pradesh (132) Govt: 116 Private: 16	RT-PCR	620. # King George Medical University, Lucknow 621. Institute of Medical Sciences, Banaras Hindu University, Varanasi 622. Jawaharlal Nehru Medical College, Aligarh 623. Command Hospital, Lucknow 624. Lala Lajpat Rai Memorial Medical College, Meerut 625. #Sanjay Gandhi Post Graduate Institute, Lucknow 626. #MLN Medical College, Prayagraj 627. #Uttar Pradesh University of Medical Sciences (Formerly Uttar Pradesh RIMS), Saifai 628. #MLB Medical College, Jhansi 629. ICMR-Regional Medical Research Centre, Gorakhpur 630. #SN Medical College, Agra	288. RML Mehrotra Pathology Pvt Ltd, Nirala Nagar, Lucknow 289. Dept of Lab Medicine, Jaypee Hospital, Sector 128, Noida 290. Central Lab, Sharda Hospital, Plot no 32,34, Knowledge Park-III, Greater Noida 291. Medical Testing Lab, Yashoda Superspeciality Hospital, H-1, 24, 26-27, Kaushambi, Ghaziabad



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			631. #ICMR-National JALMA Institute for Leprosy & Other Mycobacterial Diseases, Agra	
			632. #RML Institute of Medical Sciences, Lucknow	
			633. #Govt. Institute of Medical Sciences, Noida	
			634. #GSVM Medical College, Kanpur	
			635. National Institute of Biologicals, Noida (High-throughput Laboratory)	
			636. #BRD Medical College, Gorakhpur	
			637. *Indian Institute of Toxicology Research, Lucknow	
			638. *Birbal Sahni Institute of Palaeosciences, Lucknow	
			639. *Central Drug Research Institute, Lucknow	
			640. *ICAR- Indian Veterinary Research Institute (IVRI), Izatnagar	
			641. #Super Specialty Pediatric Hospital and Postgraduate Teaching Institute (SSPHPGTI), Noida	
			642. College of Veterinary Sciences and Animal Husbandry, UP Pt. Deen Dayal Upadhyaya Pashu Chikitsa	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			Vishwavidyalaya evam Go Anusandhan Sansthan, Mathura 643. *CSIR - National Botanical Research Institute, Lucknow	
		TrueNat	644. District Combined Hospital, District Balrampur 645. District Combined Hospital, District Basti 646. Sarojani Naidu Samarak Hospital, District Firozabad 647. Babu Eswar Saran District Hospital, Gonda 648. Amar Shahid late Uma Nath Singh District Hospital, Jaunpur 649. District Hospital, Bahraich 650. District Male Hospital, Ayodhya 651. District Combined Hospital, Mahrajganj 652. District Femal Hospital, Muzaffarnagar 653. District Male Hospital, Pratapgarh 654. District Hospital, Ballia 655. Pt.Ramprasad Bismil, District Combined Hospital Shahjahanpur	292. Heritage Speciality Lab, Lanka, Varanasi 293. Central Lab, Subharti Medical College, Meerut 294. DR Chopra's Path Clinic, III F/8 Rakesh Marg, Nehru Nagar, Ghaziabad 295. Saral Diagnostics Classic Pvt. Ltd., E-1B, Sector 39, Gautam Budh Nagar, Noida 296. Medanta Lucknow, Sector A, Pocket 1, Sushant Golf City, Lucknow 297. Pathology Laboratory -Narinder Mohan Hospital & Heart Centre Mohan Nagar, Ghaziabad



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			656. Bairister Yusuf Emam, Divisional Hospital, Mirzapur	
			657. Mahatama Gandhi, District Combined Hospital, Siddharth Nagar	
			658. Balrampur Hospital, Lucknow	
			659. Malkhan Singh Joint District Hospital, Aligarh	
			660. District Hospital, Ambedkar Nagar	
			661. Pt. Din Dayal Upahadhy, District Combined Hospital, Moradabad	
			662. Motilal Nehru Divisional Hospital, Prayagraj	
			663. Divisional Hospital, Azamgarh	
			664. District Male Hospital, Budaun	
			665. Babu Mohan Singh, Joint District Hospital, Deoria	
			666. Bheemrao Ambedkar Multi Superspeciality District Hospital, G. B Nagar	
			667. Netaji Subhash Chandra Bose District Hospital, Gorakhpur	
			668. Rana Devi Madhav Singh, District Hospital, Raebareli	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			669. District Hospital, Sultanpur	
			670. Maharana Pratap Joint District Hospital, Bareilly	
			671. Rafi Ahmad Kidwai memorial District Hospital, Barabanki	
			672. District Hospital, Etah	
			673. M.M.G District Hospital, Ghaziabad	
			674. Joint District Hospital, Manjhanpur, Kaushambi	
			675. District Male Hospital, Sitapur	
			676. District Male Hospital, Kheri	
			677. Babu Banarasi Das govt. District Hospital, Bulandsahar	
			678. District Hospital, Agra	
			679. Joint District Hospital, Amethi	
			680. District Hospital, Baghpat	
			681. District Male & Eye Hospital, Padrauna, Kushinagar	
			682. U.H.M District Male Hospital, Kanpur Nagar	
			683. P.L. Sharma District Hospital, Meerut	
			684. Shadilal Memorial Community Health Centre, Shamli	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			685. Uma Shankar Dixit Joint District Hospital, Unnao	
			686. S.S.P.G District Hospital, Varanasi	
			687. 100 Bedded District Hospital, Auraiya	
			688. District Hospital, Banda	
			689. District Combined Hospital, Bijnor	
			690. Pt. Kamalapati Tripathi Joint District Hospital, Chandauli	
			691. Joint District Hospital, Chitrakoot	
			692. Dr. Bheemrao Ambedkar District Hospital, Etawah	
			693. Dr. Ram Manohar Lohia District Hospital, Farrukabad	
			694. District Hospital, Fatehpur	
			695. Dr. Mukhtar Ansari District Hospital, Ghazipur	
			696. Deewan Satrugghan District Hospital, Hamirpur	
			697. District Hospital, Hapur	
			698. Pt. Ramdayal Trivedi District Hospital, Hardoi	
			699. Bangla District Hospital, Hathras	
			700. Joint District Hospital, J.P Nagar	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			701. District Male Hospital, Jalaun 702. Divisional District Hospital, Jhansi 703. 100 Bedded District Hospital, Kannauj 704. Joint District Hospital, Akbarpur, Kanpur Dehat 705. Joint District Hospital, Kanshiram Nagar 706. Manywar Kanshiram Joint District Hospital, Lalitpur 707. District Hospital, Mahoba 708. Maharaja Tez Singh District Hospital, Mainpur 709. Mahrishi Dayanad Saraswati District Hospital, Mathura 710. District Hospital, Ghazipur Tiraha, Mau 711. Joint District Hospital, Pilibhit 712. District Hospital, Rampur 713. Seth Baldev Das District Hospital, Saharanpur 714. Joint District Hospital, Manjhanpur, Sambhal	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			715. Joint District Hospital, Sant Kabir Nagar	
			716. Maharaja Balwant District Hospital, Santravidas Nagar	
			717. Joint District Hospital, Bhinga, Shrawasti	
			718. Joint District Hospital, Robertsganj, Sonbhadra	
			719. 12 Air Force Hospital, Gorakhpur	
			720. Central Hospital, North Central Railway, Prayagraj	
			721. State Medical College, Banda	
			722. State Medical College, Saharanpur	
			723. State Medical College, Jalaun	
			724. State Medical College, Kannauj	
			725. State Medical College, Azamgarh	
			726. 11 Air Force Hospital, Hindon, Ghaziabad	
			727. Autonomous State Medical College, Ayodhya	
			728. Autonomous State Medical College, Shahjahanpur	
			729. Autonomous State Medical College, Badayun	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			730. Autonomous State Medical College, Basti 731. Autonomous State Medical College, Bahraich 732. Autonomous State Medical College, Firozabad 733. State Medical College, Ambedkarnagar 734. Dr. S.P.M. Hospital, Lucknow 735. L.B.R.N. Combined Hospital, Kanpur Road, Lucknow	
		CB NAAT		298. \$ Gian Life Care Ltd, 7/216(6), Swaroop Nagar, Kanpur 299. \$ Dept of Microbiology, Apollomedics Super Speciality Hospitals, KBC-31, Sector B, LDA Colony, Kanpur Road, Lucknow 300. Scientific Pathology Agra, Durga Commercial Complex, Hariparwat Delhi Gate, Agra 301. \$ Department of Lab Sciences, Regency Hospital, A-2, Sarvodaya Nagar, Kanpur 302. \$ Charakdhar Diagnostics Pvt. Ltd. Basement, 292/05 Tulsidas



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				Marg, Chowk, Near King George Medical University, Lucknow 303. \$ Life Diagnostic Center, Kasya Road, Betiyahata, Gorakhpur
30.	Uttarakhand (13) Govt: 11 Private: 2	RT-PCR	736. Govt. Medical College, Haldwani 737. All India Institute of Medical Sciences, Rishikesh 738. Doon Medical College, Dehradun 739. Veer Chandra Singh Garhwali Govt. Institute of Medical Science & Research, Srinagar, Pauri, Garhwal 740. *CSIR- Indian Institute of Petroleum, Dehradun 741. *ICAR- Indian Veterinary Research Institute (IVRI), Mukteswar	304. #Dr. Ahuja's Pathology and Imaging Centre, 7-B, Astley Hall, Dehradun 305. Himalayan Institute of Medical Sciences, Dehradun
		TrueNat	742. Mela Hospital, Haridwar 743. JLN Hospital, Rudrapur, USNagar 744. District Hospital, Pithoragarh, 745. District Hospital, Uttarkashi	
		CB NAAT	746. Military Hospital, Dehradun	
31.	West Bengal (54) Govt: 37 Private: 17	RT-PCR	747. ICMR-National Institute of Cholera & Enteric Diseases, Kolkata 748. Institute of Post Graduate Medical Education & Research, Kolkata 749. Midnapore Medical College, Midnapore	306. Apollo Gleneagles Hospitals, 58 Canal Circular Road, Kolkata 307. Tata Medical Center, Rajarhat, Kolkata 308. Suraksha Diagnostic Pvt Ltd (Dept of Lab Services), 12/1, Premises No 02/0327, DG

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			750. North Bengal Medical College, Darjeeling	Block (Newtown), Action Area 1D, Newtown, Kolkata
			751. School of Tropical Medicine, Kolkata	309. Dr. Lal Pathlabs Ltd - Kolkata Reference lab, Plot No CB-31/1, Premises No 031-0199, Street No 199, Action Area 1C, Newtown, Kolkata
			752. Malda Medical College & Hospital, Malda	
			753. Command Hospital, Kolkata	
			754. Chittaranjan National Cancer Institute, Kolkata	310. Dept of Lab Services, Medica Superspeciality Hospital, 127, Mukundpur, E.M. Bypass, Kolkata
			755. R.G. Kar Medical College & Hospital, Kolkata	311. Remedy Life Care, Plot 6, Nani Gopal Roy Chowdhury Avenue, Entally, Padmapukur On Main Road, Kolkata
			756. Murshidabad Medical College, Behrampore, Murshidabad	312. #Shri Ramkrishna Institute of Medical Sciences & Sanaka Hospitals, Malandighi, P.S. Kanksha, Durgapur
			757. Nil Ratan Sircar Medical College, Kolkata	313. #Laboratory Services, Peerless Hospitex Hospital & Research Centre, 360, Panchasayar, Kolkata
			758. Bankura Medical College, Bankura	314. Desun Reference Lab - A Unit of Desun Healthcare and Research Institute Limited (Department of Laboratory Services), S-16, Kasba Industrial Estate, Phase III, Kolkata
			759. Suri Sadar Hospital, Birbhum	315. # IICS Laboratory Services, Rabindranath Tagore International Institute of Cardiac
			760. #Medical College, Kolkata	
			761. College of Medicine and JNM Hospital, Kalyani, Nadia	
			762. ESI-Postgraduate Institute of Medical Science and Research (PGIMSR), Joka, Kolkata	
			763. #Burdwan Medical College, Burdwan	
			764. Calcutta National Medical College and Hospital, Kolkata	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				Sciences, Premises No 1489, (124) Mukundapur, EM Bypass, Kolkata 316. Jagannath Gupta Institute of Medical Sciences and Hospital, Kolkata, 24 Paraganas South
		TrueNAT	765. Raiganj Govt. Medical College and Hospital, Raiganj 766. Falakata SSH Hospital, District Alipurduar 767. Jhargram District Hospital, Jhargram District 768. Rampurhat Govt. Medical College and Hospital, Rampurhat, Birbhum 769. Diamond Harbour Govt. Medical College and Hospital, Diamond Harbour 770. Asansol District Hospital, Asansol 771. Balurghat District Hospital, Dakshin Dinajpur 772. Jangipur Sub-Divisional Hospital, Murshidabad 773. Uluberia Sub Divisional Hospital, Howrah	317. Anandaloke Sonoscan Centre Pvt. Ltd., 3/3 Hill Cart Road, Near Mahananda Bridge, Siliguri



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
			774. Serampore Walsh Sub-divisional Hospital, Hugli 775. Biswa Bangla Krirangan SARI/COVID Hospital, Jalpaiguri 776. Chanchal Sub-divisional Hospital (SDH), Malda 777. Purulia Government Medical College and Hospital, Purulia 778. M R Bangur District Hospital, Kolkata 779. Cooch Behar Government Medical College, Cooch Behar 780. Alipurduar District Hospital, Alipurduar 781. Basirhat District and Super-Speciality Hospital, Basirhat 782. Sub-divisional Hospital, Gangarampur , Dakshin Dinajpur District	
		CB-NAAT	783. College of Medicine and Sagore Dutta Hospital, Kolkata	318. AMRI Hospitals, Dept of Lab Medicine, JC 16-17, Sector III, Salt Lake City, Kolkata 319. The Calcutta Medical Research Institute (Dept of Pathology), 7/2 Diamond Harbour Raod, Kolkata 320. \$Dept of Lab Medicine, AMRI Hospital, 38/1A, Gariahat Road, Kolkata

S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
				321. SRL Limited, P S Srijan Tech Park, DN-52, Saltlake Sector V, Kolkata 322. \$Woodlands Multispeciality Hospital Limited (Department of Pathology), 8/5 Alipore Road, Kolkata
32.	Andaman & Nicobar Islands (3) Govt: 3	RT-PCR	784. ICMR-Regional Medical Research Centre, Port Blair	
		TrueNat	785. A&N Islands Institute of Medical Sciences, Port Blair	
		CB NAAT	786. GB Pant Hospital, Port Blair	
33.	Dadra & Nagar Haveli (1) Govt: 1	RT-PCR	787. Shri Vinoba Bhave Civil Hospital, Silvassa	
34.	Sikkim (2) Govt: 2	RT-PCR	788. Virus Research and Diagnostic Laboratory, STNM Hospital, Gangtok	
		TrueNAT	789. Intermediate Reference Laboratory, STNM Hospital, Gangtok	
35.	Leh-Ladakh (1) Govt: 1	RT-PCR	790. Sonam Nurboo Memorial Hospital, Leh	
36.	Lakshadweep (3)	TrueNat	791. Lakshadweep Medical Store, Kochi	



S. No.	Names of States	Test Category	Names of Government Institutes	Names of Private Institutes
	Govt: 3		792. Indira Gandhi Hospital, Kavaratti Island 793. Rajiv Gandhi Specialty Hospital, Agatti	



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार

कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 12/06/2020

Status of new COVID-19 Govt. & Private laboratories.

Government Medical College, Category 1

S. No.	State	Name of the Laboratory	Category	Update Status
1.	Chhattisgarh (1)	Chhattisgarh Institute of Medical Sciences, Bilaspur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
2.	Delhi (1)	IBHAS Delhi	1	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
3.	Maharashtra (2)	Topiwala National Medical College, Mumbai	1	Email sent to Dean/Mentor Ins/Municipal Commis/PS health on 15/04/2020. Telephonic discussion made with Dean
		HBT Medical College & Cooper Hospital Mumbai	1	Email sent to Dean/Mentor Ins/Municipal Commis. /PS, Health. on 15/04/2020.



Private Medical Colleges/ Private Laboratories:

S. No.	State	Name of the Medical College / Laboratory	Requirements	Status
1	Madhya Pradesh (2)	Index Medical College Hospital & Research Institute	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, NABL certificate expected in a week of time
		RKDF Medical College and Research centre, Bhopal	NABL certificate reqd	
2	Karnataka (1)	JN Medical College, KAHER Belagavi	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, No Update
3	Uttarakhand (2)	Mahantra Indresh Medical College, Dehradun	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, NABL certificate expected in a week of time
		Himalayan Institute of Medical Sciences, Dehradun	NABL certified but not for Realtime PCR based testing	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, NABL certificate pending.
4	Telangana (1)	RVM Institute of Medical Sciences And Resarech Center, Siddipet	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, NABL certificate expected in a two weeks time.
5	Uttar Pradesh (1)	Subharti Medical College, Meerut	NABL certified but not for Realtime PCR based testing	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, Undergoing laboratory assessment
6	Haryana (1)	M.M. Institute of Medical Sciences and Research, Ambala	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, NABL certificate expected in a week time
7	Maharashtra (16)	ORANGE CITY HOSPITAL & RESEARCH INSTITUTE, Nagpur	NABL certified Scope pending	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, Call not connected
		K.J Somaiya Medical College, Sion Mumbai	NABL certificate not received	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May. Call not answered
		Terna Medical College Talegaon Dabhade, Pune	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020.
		Annasaheb Chudaman Patil Memorial Medical College, Dhule	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May. Update pending
		Dr. VVPF's Medical College, Ahmednagar	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020 Follow-up call on 29 th May, NABL certification pending
		Smt. Kashibai Navale Medical	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS



S. No.	State	Name of the Medical College / Laboratory	Requirements	Status
		College, Pune		health on 15/04/2020 Follow-up call on 29 th May, RTPCR facility not available
		Dr. Ulhas Patil Medical College, Jalgaon	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, Call not answered
		BKL Walawalkar Rural Medical College, Ratanagiri	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
		Prakash Institute of Medical Sciences & Research, Sangli	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
		SMBT insitute of Medical Sciences & Research Centre, Nashik	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, Call not answered
		Vedanta Institute of Medical Sciences, Palghar	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
		NKP Salve Medical College, Nagpur	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
		MIMSR Medical College, Latur	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, Not applied for NABL certificate.
		Indian Institute of Medical Sciences & Research, Jalna	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, NABL certificate not received.
		Ashwini Rural Medical College, Hospital & Research Centre	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, Not applied for NABL, Facility not ready for COVID-19 testing
		Datta Meghe Medical College & Shalinitai Meghe Hospital and Research Centre, Nagpur	NABL certificate reqd	
8	Tamil Nadu (2)	Velammal Medical College Hospital & Research Institute, Madurai	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 16/04/2020, Follow-up call on 29 th May, NABL certificate pending.
		Dhanalakshmi Srinivasan Medical College & Hospital	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, Call not answered
9	Sikkim (1)	Sikkim Manipal College of Medical Sciences, Gangtok	NABL certificate reqd	Email sent to Dean/Mentor Ins/PS health on 15/04/2020, Follow-up call on 29 th May, NABL status is pending
10	Andhra Pradesh (2)	Alluri Sitarama Raju Academy of Medical Sciences, Eluru, West Godavari	NABL certificate reqd	
		Narayana Medical College, Nellore	NABL certificate reqd	

Protocol for approving a COVID-19 testing facility in view of National Emergency

ICMR is willing to facilitate establishment of a full-fledged COVID-19 testing facility in all Government Medical Colleges and Private Medical Colleges (for private MCs: NABL accreditation for real-time PCR of RNA viruses is required).

A laboratory will be considered fit for assessment by ICMR when the following basic requirements will be available:

1. Real Time RT-PCR machine which is calibrated and functional.
2. Biosafety Level 2 cabinet which is calibrated and functional.
3. Cold centrifuge
4. Pipettes, RNA extraction kits, plasticware and other basic consumables.
5. Autoclave for sterilizing the waste.
6. Staff is available and has some previous experience of work using real-time PCR machine.
7. Biomedical waste management policy in place and understanding on segregation of infectious waste.

Once the above requirements are met, only then ICMR may be approached for approval.

Steps of Approval from ICMR:

Categories	Nomenclature
Category 1: Any of the above-mentioned requirements 1-7 are not met.	Cannot be considered in the present form. State Govt. support is required for meeting the above criteria.
Category 2: All the above requirements 1-7 are fulfilled.	Under review
Category 3: Staff trained at nearest VRDL and the trainer recommends the lab.	Approved
Category 4: First test is run independently and successfully by the lab and results are shared with ICMR.	Functional Lab. Fit to start independent testing

**As and when the labs will move from category 1 to 2, ICMR will consider facilitating a COVID-19 testing facility.*

**INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI**

May 11, 2020

LIST OF MENTOR INSTITUTES ALONG WITH ALLOCATED STATES:

The following Mentor Institutes have been identified for various States (mentioned in table below). These Institutes are mandated to review the requests for approving any new laboratory for COVID testing

S.No.	Name of the Mentor Institute	States Allocated	Head of the Institute
1.	Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh	Jammu & Kashmir, Ladakh, Punjab, Haryana, Himachal Pradesh, Chandigarh, Uttarkhand	Prof. Jagat Ram Director, PGIMER, Chandigarh pgimer-chd@nic.in
2.	All India Institute of Medical Science (AIIMS), Delhi	Delhi & Bihar	Dr. Randeep Guleria Director, AIIMS, New Delhi director@aiims.edu
3.	All India Institute of Medical Science (AIIMS), Jodhpur	Rajasthan & Gujarat	Dr. Sanjeev Misra Director, AIIMS, Jodhpur director@aiimsjodhpur.edu.in
4.	Armed Force Medical College (AFMC), Pune	Mumbai & Pune	Lt Gen Nardeep Naithani Director & Commandant, Armed Forces Medical College, Pune coladm.afmc@nic.in
5.	All India Institute of Medical Science (AIIMS), Nagpur	Maharashtra (except Mumbai and Pune) & Goa, Dadra & Nagar Haveli, Daman & Diu	Maj Gen (Dr) Vibha Dutta, SM Director and CEO, AIIMS Nagpur directoraiimsnagpur@gmail.com
6.	National Institute of Mental Health & Neurosciences, Bengaluru	Karnataka	Dr. B. N. Gangadhar Director, NIMHANS, Bengaluru dirstaff@nimhans.ac.in
7.	Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram	Kerala, Andaman & Nicobar Islands, Lakshwadeep.	Dr. Asha Kishore Director, SCTIMST, Thiruvananthapuram Email: director@sctinst.ac.in
8.	Jawaharlal Institute of Postgraduate medical Education & Research (JIPMER), Puducherry	Tamil Nadu, Andhra Pradesh, Telangana, Puducherry	Dr. Rakesh Aggarwal, Director, JIPMER, Puducherry director@jipmer.edu.in

S.No.	Name of the Mentor Institute	States Allocated	Head of the Institute
9.	All India Institute of Medical Sciences (AIIMS), Bhubaneswar	Odisha & West Bengal	Dr. Gitanjali Batmanabane Director, AIIMS, Bhubaneswar director@aiimsbhubaneswar.edu.in
10.	King George Medical University (KGMU), Lucknow	Uttar Pradesh	Dr. M.L.Bhatt Vice Chancellor, KGMU, Lucknow vc@kgmcindia.edu
11.	All India Institute of Medical Sciences (AIIMS), Bhopal	Madhya Pradesh	Prof. Sarman Singh Director & CEO, AIIMS, Bhopal director@aiimsbhopal.edu.in
12.	All India Institute of Medical Sciences (AIIMS), Raipur	Chattisgarh & Jharkhand	Prof. (Dr.) Nitin M. Nagarkar Director, AIIMS, Raipur director@aiimsraipur.edu.in
13.	North- Eastern Indira Gandhi Regional Institute of Health & Medical Science (NEIGRIHMS), Shillong	Assam, Meghalaya, Sikkim, Tripura, Manipur, Mizoram, Arunachal Pradesh, Nagaland	Prof. (Dr.) D. M. Thappa Director, NEIGRIHMS, Shillong director-neigrihms@gov.in
14.	Nizam's Institute of Medical Science (NIMS), Hyderabad	Telangana	Dr. K. Manohar Director director@nims.edu.in, NIMS, Hyderabad



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Dated: 14.05.2020

INFORMATION FOR VALIDATION OF KITS FOR COVID-19

Request for validation of RT-PCR/RNA Extraction kits/VTM may be directly sent to ICMR Headquarters, New Delhi to the following email ID:

gstoteja@gmail.com

ICMR will respond to your request and will let you know where you will have to submit the kits for validation.

Additional Director General
ICMR, New Delhi

**INDIAN COUNCIL OF MEDICAL RESEARCH
NEW DELHI**

Date: 08/05/2020

Validation Centres for Diagnostics for COVID-19

SN	Name of the Institute	Head of the Institute	Nodal Person	Validation for
1	ICMR – National Institute of Virology (NIV), Pune	Dr. Priya Abraham Director director.niv@icmr.gov.in	Dr. Varsha Potdar , Scientist D & HOD potdarvarsha9@gmail.com 9890307757	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
2	CSIR – Centre of Cellular & Molecular Biology, Hyderabad	Dr. Rakesh K Mishra , Director mishra@ccmb.res.in	Dr. N. Madhusudana Rao Chief Scientist madhu@ccmb.res.in 9949973404	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
3	ICMR- National Institute of Malaria Research (NIMR), Dwarka , Delhi	Dr. Amit Sharma Director directornimr@gmail.com	Dr. Himmat Singh , Scientist D himmatpawar@gmail.com 9414242471	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
4	ICMR-National Institute of Epidemiology (NIE), Chennai	Dr. Manoj Murhekar Director directornie@icmr.org.in	Dr.C.P.Girish Kumar , Scientist –E girishmicro@gmail.com9840304596	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
5	ICMR-National Institute of Virology (NIV), field unit in Bengaluru	Dr. Ashok Office In-charge ashokmniv@gmail.com	Dr. Ashok , Office Incharge ashokmniv@gmail.com 9844250897	<ul style="list-style-type: none"> • RT-PCR • VTM
6	ICMR-Regional Medical Research Centre (RMRC), Bhubaneswar, Odisha	Dr. Sanghmitra Pati Director drsanghamitra12@gmail.com	Dr Jyotirnayee Turuk Scientist C, Microbiology drjyotirmayeeturuk@gmail.com 7653915589	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
7	ICMR-National Institute for Research in Reproductive Health (NIRRH) , Mumbai	Dr. Smita Mahale Director drsanghamitra12@gmail.com	Dr. Dhanashree Jagtap Scientist 'C' dhanashreedj@rediffmail.com 9321341919	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
8	Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh	Dr. Jagat Ram Director pgimer-chd@nic.in	Prof Mini P Singh Professor of Virology minipsingh@gmail.com; covidmentordrmini@gmail.com 09357784144	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
9	King George’s Medical University (KGMU), Lucknow	Dr. M.L.Bhatt Vice Chancellor vc@kgmcindia.edu	Prof. Amita Jain , HoD, Microbiology amita602002@yahoo.com 9415023928	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM
10	ICMR-Rajendra Memorial Research	Dr. Pradeep Das Director	Dr. Abhik Sen Scientist D abhiksen78@gmail.com	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits • VTM

SN	Name of the Institute	Head of the Institute	Nodal Person	Validation for
	Institute of Medical Science (RMRIMS), Patna	drpradeep.das@gmail.com		
11	ICMR-National Institute of Virology (NIV) field unit in Alapuzha, Kerala	Dr. A.P. Sugunan Scientist 'G' & Officer-in-Charge NIV Kerala Unit Govt. TD Medical College Hospital, Vandanam Alappuzha 688005 Kerala	Dr. A.P. Sugunan Scientist 'G' & apsugunan@gmail.com 9444389233	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits
12	ICMR - National AIDS Research Institute (NARI), Pune	Dr. Samiran Panda , Director	Dr. Vandana Saxena , Scientist - D vsaxena@nariindia.org 8554052508 Dr. Swarali Kurle , Scientist - C skurle@nariindia.org 9881155250	<ul style="list-style-type: none"> • RT-PCR
13	ICMR-National Institute of Pathology (NIP), New Delhi	Dr. Nasreen Z Ehtesham Director- in-Charge nzehtesham@gmail.com	Dr. Usha Agrawal Scientist F ushakaggarwal.nip@gov.in 8810439746	<ul style="list-style-type: none"> • RT-PCR
14	ICMR – National Institute of Cholera and Enteric Diseases (NICED), Kolkata	Dr. Shanta Dutta Director shanta.niced@icmr.gov.in	Dr. Mamta Chawla Sarkar Scientist-F chawlam70@gmail.com 9830660999	<ul style="list-style-type: none"> • RT-PCR • RNA Extraction Kits



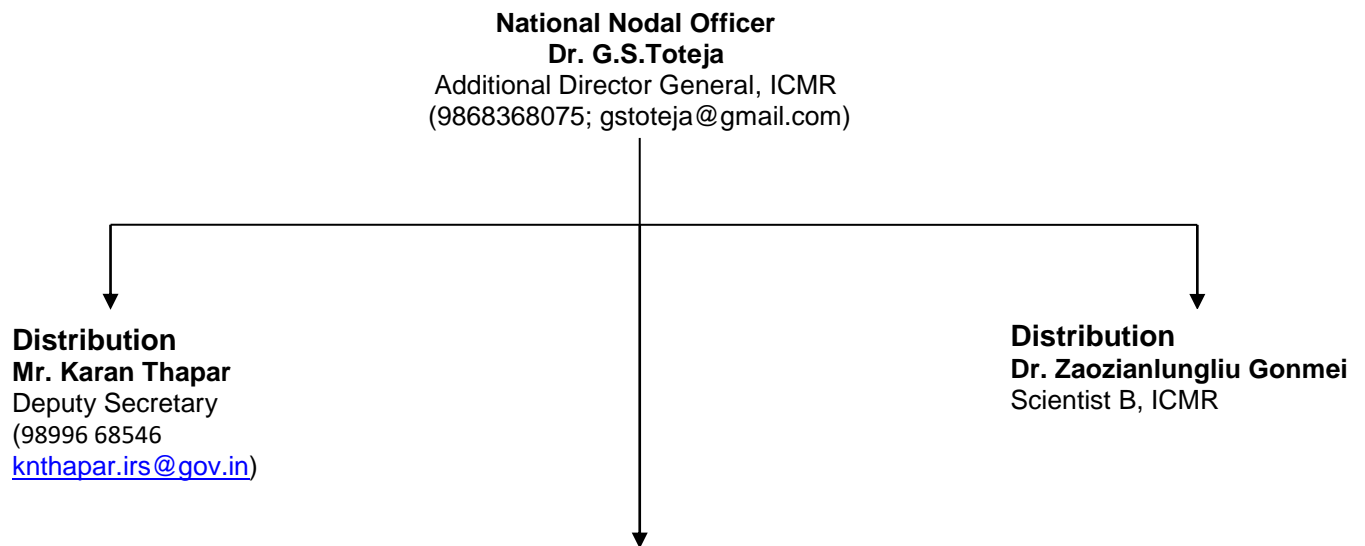
भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: July 6, 2020

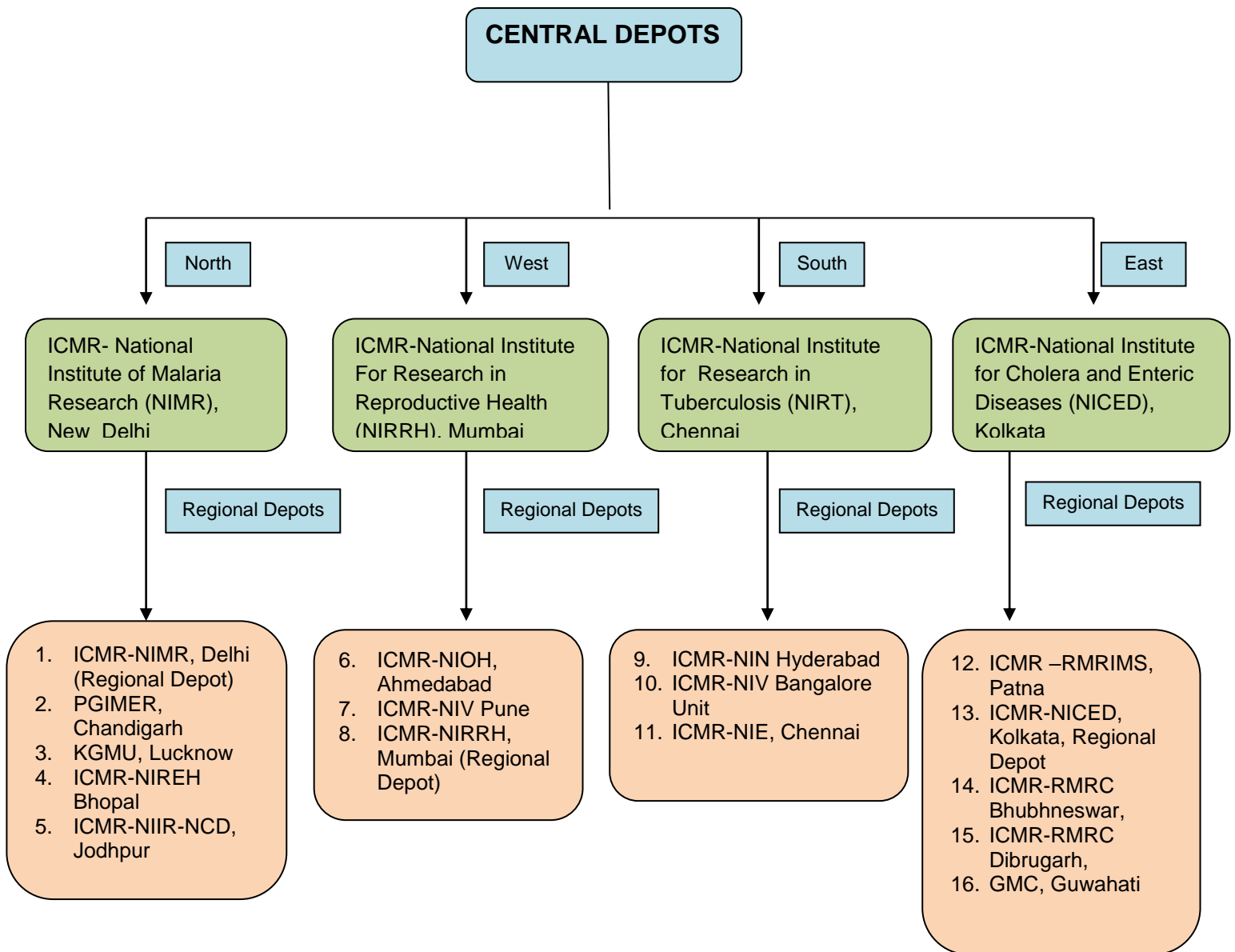
OFFICE ORDER

Subject: Details about ICMR depots; distribution; coordination and Validation teams



Central Depots, Regional depots and laboratories covered

Central Depots: 4 in number
Regional Depots: 16 in number



Note:* The laboratory should coordinate with their respective Depot team for any logistic issues. The Depot Team should coordinate with the Central Team at ICMR.
******Person identified for communication at ICMR with the Depot team

REGIONAL DEPOT 1: ICMR- National Institute of Malaria Research (NIMR), Sector 8 Dwarka,
Dwarka, New Delhi- 110077
Depot Head: Dr Amit Sharma, Director, ICMR-NIMR (directornimr@gmail.com)

States and Laboratories covered under ICMR-NIMR, New Delhi (39 Laboratories)

State	Name of laboratories	Contact Person
Delhi (15 labs)	<ol style="list-style-type: none"> 1. All India Institute Medical Sciences 2. Lady Hardinge Medical College 3. National Centre for Disease Control 4. Ram Manohar Lohia Hospital 5. Institute of Liver & Biliary Sciences 6. Army Hospital Research & Referral 7. Maulana Azad Medical College 8. Vardhman Mahavir Medical College & Safdarjung Hospital 9. University College of Medical Sciences 10. Army Base Hospital 11. IGIB-CSIR 12. Rajiv Gandhi Super Speciality Hospital, Taharpur 13. Vallabhbhai Patel Chest Institute (VPCI) 14. Defence Institute of Physiology & Allied Sciences (DIPAS), DRDO 15. Institute of Nuclear Medicine & Allied Sciences (INMAS-DRDO), New Delhi 	<p>Depot Team: *Dr. Ram Das, Scientist C (drrdas_3@yahoo.co.in; 9958883739)</p> <p>*Mr. Peeyush Mittal, NIMR (mittalpeeyush1991@gmail.com; 8395959484)</p> <p>*Mr. Anurag Gautam, PWC (9910014097)</p> <p>Central Team at ICMR: **Dr. Harmanmeet Kaur, Scientist C, ICMR (harmanmeet.kaur@gmail.com; 9999707557)</p>
Western U.P. (NCR only) (8 labs)	<ol style="list-style-type: none"> 16. Govt. Institute of Medical Sciences, Noida 17. National Institute of Biologicals, Noida (High throughput Laboratory) 18. Lala Lajpat Rai Memorial Medical College, Meerut 19. Jawaharlal Nehru Medical College, Aligarh 20. SN Medical College, Agra 21. ICMR-National JALMA Institute for Leprosy & Other Mycobacterial Diseases, Agra 22. Superspeciality Pediatrics Hospital and Postgraduate Teaching Institute (SSPHPGTI), Noida 23. College of Veterinary Sciences and Animal Husbandry, UP Pt. Deen Dayal Upadhyaya Pashu Chikitsa Vishwavidyalaya evam Go Anusandhan Sansthan, Mathura 	<p>Mr. Ashok Kumar, IPS, Director</p> <p>Mr. Harsh Nagpal, PWC</p>
Haryana (Other labs of Haryana covered by PGIMER Chandigarh depot) (9 labs)	<ol style="list-style-type: none"> 24. Pt. B.D. Sharma Post Graduate Inst. Of Med. Sciences, Rohtak 25. BPS Govt. Medical College, Sonapat 26. ESIC Hospital, Faridabad 27. Kalpana Chawla Govt. Medical College, Karnal 28. ICAR-National Research Centre on Equines, Hisar 29. Translational Health Science & Technology Institute, Faridabad 30. SHKM, Govt. Medical College, Mewat 31. Civil Hospital, Gurugram 32. Maharaj Agrasen Medical College, Agroha, Hisar 	
Uttarakhand (6 labs)	<ol style="list-style-type: none"> 33. Govt. Medical College, Haldwani 34. All India Institute of Medical Sciences, Rishikesh 35. Doon Medical College, Dehradun 36. Veer Chandra Singh Garhwali Govt. Institute of Medical Science & Research, Srinagar, Pauri, Garhwal 37. CSIR- Indian Institute of Petroleum, Dehradun 38. ICAR- Indian Veterinary Research Institute (IVRI), Mukteswar 	
Rajasthan (Other labs of Rajasthan covered by	<ol style="list-style-type: none"> 39. Government Medical College, Bharatpur 	

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.
The Depot Team should coordinate with the Central Team at ICMR.
**Person identified for communication at ICMR with the Depot team

NIIRNCD, Jodhpur depot) (1 lab)		
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REGIONAL DEPOT 2: Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh, Madhya Marg, Sector 12, Chandigarh, 160012
Depot Head: Dr. Jagat Ram, Director, PGIMER, Chandigarh

States and Laboratories covered under PGIMER, Chandigarh (23 Laboratories)

State	Name of laboratories	Contact Person
Punjab (3 Labs)	1. Govt. Medical College, Amritsar 2. Govt. Medical College, Patiala 3. Guru Gobind Singh Medical University, Faridkot	Depot Team: *Dr. Mini P Singh , Professor, Department of Virology, PGIMER minipsingh@gmail.com ; 9357784144) *Dr. Kapil Goyal , Assistant Professor, PGIMER kapilgoyalpgi@gmail.com ; 8872288864) *Mr. Somnath Mitra , PWC 7003252362 Central Team at ICMR: **Dr. Tanu Anand , Scientist D, ICMR drtanu.anand@gmail.com ; 98110 28964) Mr. Ashok Kumar , IPS, Director Mr. Harsh Nagpal , PWC
Haryana (3 Labs) Other labs covered by NIMR, New Delhi	4. Command Hospital, Chandimandir 5. Government Civil Hospital, Panchkula 6. District Civil Hospital, Ambala	
Jammu & Kashmir (6 Labs)	7. Govt. Medical College, Jammu 8. Command Hospital (NC) Udhampur 9. Sher-i-Kashmir Institute of Medical Sciences, Srinagar 10. Govt. Medical College, Srinagar 11. Sheri Kashmir Institute of Medical Science Medical College, Bemina, Srinagar 12. CSIR Indian Institute of Integrative Medicine, (IIIM), Srinagar	
Ladakh (1 Lab)	13. Sonam Norboo Memorial Hospital (SNMH), Leh	
Himachal Pradesh (7 Labs)	14. Indira Gandhi Medical College, Shimla 15. Dr. Rajendra Prasad Govt. Medical College, Tanda 16. Central Research Institute, Kasauli 17. Shri Lal Bahadur Shastri Govt. Medical College, Mandi 18. CSIR Institute of Himalayan Bioresource Technology, Palampur 19. Dr. Yashwant Singh Parmar Government Medical College, Nahan 20. Pt. JLN Government Medical College and Hospital, Chamba	
Chandigarh (3 Labs)	21. Postgraduate Institute of Medical Education & Research 22. Govt. Medical College 23. Institute of Microbial Technology	

REGIONAL DEPOT 3: King George's Medical University (KGMU), Shah Mina Road, Chowk, Lucknow, UP

Depot Head: Prof. M.L. Bhatt, Vice Chancellor (vc@kgmcindia.edu; drmlbhatt@yahoo.com)

States and Laboratories covered under KGMU, Lucknow (16 Laboratories)

State	Name of laboratories	Contact Person
Uttar Pradesh (other than Western UP) (16 Labs)	1. King George Medical University, Lucknow 2. Command Hospital, Lucknow 3. Sanjay Gandhi Post Graduate Institute, Lucknow 4. RML Hospital, Lucknow 5. Institute of Medical Sciences, Banaras Hindu University, Varanasi 6. MLN Medical College, Allahabad 7. BRD Medical College, Gorakhpur 8. MLB Medical College, Jhansi	Depot Team: *Prof. Amita Jain , HoD, Microbiology amita602002@yahoo.com ; 9415023928) *Prof. A.A. Mahdi , HoD, Biochemistry abbasalimahdi@gmail.com ;

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.

The Depot Team should coordinate with the Central Team at ICMR.

**Person identified for communication at ICMR with the Depot team

	9. ICMR-Regional Medical Research Centre, Gorakhpur 10. GSVM Medical College, Kanpur 11. Uttar Pradesh University of Medical Sciences , Saifai 12. ICAR- Indian Veterinary Research Institute (IVRI), Izatnagar 13. Central Drug Research Institute, Lucknow 14. Birbal Sahni Institute of Palaeosciences, Lucknow 15. Indian Institute of Toxicology Research, lucknow 16. *CSIR – National Botanical Research Institute, Lucknow	9889838100) Central Team at ICMR: **Dr. N C Jain , Scientist G, ICMR (drencejain@gmail.com; 9868807284) Mr. Ashok Kumar , IPS, Director Mr. Ankur Mishra , PWC
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REGIONAL DEPOT 4: ICMR- National Institute for Research in Environmental Health (**NIREH**), Bhopal
 Bypass Road, Bhauri Bhopal-462030, Madhya Pradesh, India
Depot Head: Dr. R. R. Tiwari, Director (tiwari.rr@gov.in)

State and Laboratories covered under ICMR-NIREH, Bhopal (26 Laboratories)

State	Name of laboratories	Contact Person
Madhya Pradesh (15 Labs)	1. All India Institute of Medical Sciences, Bhopal 2. ICMR-National Institute for Research on Tribal Health, Jabalpur 3. Mahatma Gandhi Memorial Medical College, Indore 4. Gandhi Medical College, Bhopal 5. ICMR-Bhopal Memorial Hospital & research Centre, Bhopal 6. Gajra Raja Medical College, Gwalior 7. Bundelkhand Medical College, Sagar 8. SS Medical College, Rewa 9. Defence Research and Development Organization, Gwalior. 10. ICAR-NIHSAD, Bhopal 11. Govt. Medical College, Ratlam 12. Netaji Subhash Chandra Bose Medical College, Jabalpur 13. Govt. Medical College, Khandwa 14. Atal Bihari Vajpayee Government Medical College (ABVGMC), Vidisha 15. *IISER, Bhopal	Depot Team: *Dr. Anil Prakash , Scientist- G (anilprakashin@yahoo.co.in; 9425403828) *Dr. Y. D. Sabde , Scientist- E (sabdevogesh@gmail.com; 9926329273) Central Team at ICMR: **Dr. N C Jain , Scientist G, ICMR (drencejain@gmail.com; 9868807284) Mr. Ashok Kumar , IPS, Director Mr. Ankur Mishra , PWC
Vidharbha Region (Maharashtra) (11 Labs)	16. Indira Gandhi Govt. Medical College, Nagpur 17. All India Institute of Medical Sciences, Nagpur 18. Govt. Medical College, Nagpur 19. Nagpur Veterinary College, MAFSU, Nagpur 20. Intermediate Reference Laboratory, Nagpur 21. Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha 22. Sant Gadge Baba Amravati University, Amravati 23. National Environmental Engineering Research Institute, Nagpur 24. Govt. Medical College, Chandrapur 25. Govt. Medical College, Yavatmal 26. Government Medical College, Gondia	

REGIONAL DEPOT 5: ICMR-National Institute for Implementation Research on Non-Communicable Diseases (**NIIR-NCD**), New Pali Road, Jodhpur
Depot Head: Dr. G.S.Toteja, Director (gstoteja2019@gmail.com)

State and Laboratories covered under ICMR-NIIR-NCD, Jodhpur (22 Laboratories)

State	Name of laboratories	Contact Person
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Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.
 The Depot Team should coordinate with the Central Team at ICMR.
****Person identified for communication at ICMR with the Depot team**

<p>Rajasthan (Bharatpur lab will be covered by NIMR, New Delhi depot) (22 Labs)</p>	<ol style="list-style-type: none"> 1. Sawai Man Singh Medical College, Jaipur 2. Rajasthan University of Health Sciences, Medical College, Jaipur 3. Dr. Sampurnan and Medical College, Jodhpur 4. Jhalawar Medical College, Jhalawar 5. RNT Medical College, Udaipur 6. SP Medical College, Bikaner 7. All India Institute of Medical Sciences, Jodhpur 8. JLN Medical College, Ajmer 9. Govt. Medical College, Kota 10. ICMR-National Institute for Implementation Research on Non-Communicable Diseases, Jodhpur 11. RVRS Govt. Medical College, Bhilwara 12. Government Medical College, Dungarpur 13. Pandit Deendayal Upadhyaya Medical College, Churu 14. Govt. Medical College, Sikar 15. Govt. Medical College, Barmer 16. Govt. Medical College, Pali 17. Govt. BDK District Hospital, Jhunjhunu 18. Military Hospital, Jaipur 19. District Hospital, Sirohi 20. District Hospital, Jalore 21. Advanced Molecular Laboratory, MG Hospital, Banswara 22. Govt. JLN District Hospital, Nagaur 	<p>Depot Team: *Dr. S.S.Mohanty, Scientist E (ssnimr@gmail.com; 8058642995) *Engineer Ramesh Hudda, Scientist B (ramesh.hudda@gmail.com; 9602755600) Central Team at ICMR: **Dr. Hemlata, Scientist C, ICMR (hemlata.jaint@gmail.com; 98187 43598) Mr. Prankur Gupta, IRSS Mr. Abhinav Sharma, PWC</p>
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REGIONAL DEPOT 6: ICMR- National Institute for Occupational Health (NIOH), near Raksha Shakti University, Meghaninagar, Ahmedabad, Gujarat 380016

Depot Head: Dr. Kamalesh Sarkar, Director (director-nioh@gov.in; kamalesh.sarkar@gmail.com)

State and Laboratories covered under ICMR-NIOH, Ahmedabad (22 Laboratories)

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues. The Depot Team should coordinate with the Central Team at ICMR.

****Person identified for communication at ICMR with the Depot team**

State	Name of laboratories	Contact Person
Gujarat (22 Labs)	<ol style="list-style-type: none"> 1. BJ Medical College, Ahmedabad 2. MP Shah Govt Medical College, Jamnagar 3. Govt. Medical College, Surat 4. Govt. Medical College, Bhavnagar 5. Govt. Medical College, Vadodara 6. Govt. Medical College, Rajkot 7. NHL Medical College, Ahmedabad 8. GMERS Medical College, Ahmedabad 9. GMERS Medical College, Gandhinagar 10. GMERS Medical College, Valsad 11. ICMR-National Institute of Occupational Health, Ahmedabad 12. Gujarat Cancer & Research Institute, Ahmedabad 13. Surat Municipal Institute of Medical Education & Research (SMIMER), Surat 14. GMERS Medical College and Hospital, Dharpur Patan 15. Gujarat Adani Institute of Medical Sciences, Bhuj 16. Gujarat Biotechnology Research Center, Gandhinagar 17. Gujarat Forensic Sciences University, Gandhinagar 18. GMERS Medical College, Gotri, Vadodara 19. GMERS Medical College, Himmatnagar 20. Dr. H.L. Trivedi Institute of Transplantation Services, Ahmedabad 21. GMERS Medical College, Junagadh 22. GMERS Medical College, Vadnagar 	<p>Depot Team:</p> <p>*Dr. P. Sivaperumal, Scientist D (sivaperumal.p@gov.in; sivaperum2003@yahoo.co.in; 9904721778)</p> <p>*Dr Kuldeep Upadhyay, Scientist B (drkuldeep_upadhyay@rediffmail.com; 8780829397)</p> <p>*Mr. Danish Syed, PWC (7977151805)</p> <p>Central Team at ICMR:</p> <p>**Dr. Hemlata, Scientist C, ICMR (hemlata.jaint@gmail.com; 9818743598)</p> <p>Mr. Prankur Gupta, IRSS</p> <p>Mr. Abhinav Sharma, PWC</p>

REGIONAL DEPOT 7: ICMR-National Institute of Virology (NIV), 20-A, Dr Ambedkar Road, Pune
Depot Head: Dr. Priya Abraham, Director (director.niv@icmr.gov.in)

State and Laboratories covered under ICMR-NIV, Pune (22 Laboratories)

State	Name of laboratories	Contact Person
Maharashtra (22 Labs)	<ol style="list-style-type: none"> 1. ICMR-National Institute of Virology, Pune 2. Armed Forces Medical College, Pune 3. BJ Medical College, Pune 4. Command Hospital (SC), Pune 5. Govt. Medical College, Aurangabad 6. V. M. Government Medical College, Solapur 7. Govt. Medical College, Miraj 8. Govt. Medical College, Akola 9. ICMR-National AIDS Research Institute, Pune 10. Swami Ramanand Teerth Marathwada, University, Nanded 11. Vilasrao Deshmukh Govt. Institute of Medical Sciences, Latur 12. RCSM Govt. Medical College, Kolhapur 13. National Center for Cell Sciences, Pune 14. Indian Institute of Science Education and Research (IISER), Pune 15. District General Hospital, Ahmednagar 16. Government Medical College, Baramati 17. Swami Ramanand Teerth Rural Government Medical College, Ambajogai 18. Agharkar Research Institute, Pune 19. District General Hospital, Ratnagiri 20. Dr. Shankarrao Chavan Govt. Medical College, Nanded 21. YCM Hospital, Pimpri 22. Babasaheb Ambedkar Marathwada University, 	<p>Depot Team:</p> <p>*Dr. Varsha Potdar, Scientist D & HOD (Potdarvarsha9@gmail.com; 9890307757)</p> <p>*Mrs Sheetal Jadhav Technical Assistant (sheetalk86@gmail.com; 9011529385)</p> <p>Central Team at ICMR:</p> <p>**Dr. Hemlata, Scientist C, ICMR (hemlata.jaint@gmail.com; 9818743598)</p> <p>Mr. Prankur Gupta, IRSS</p> <p>Mr. Abhinav Sharma, PWC</p>

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.
The Depot Team should coordinate with the Central Team at ICMR.
**Person identified for communication at ICMR with the Depot team

	Aurangabad	
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REGIONAL DEPOT 8: ICMR-National Institute For Research in Reproductive Health (NIRRH), J Merwanji St, Parel East, Parel, Mumbai, Maharashtra 400012

Depot Head: Dr. Vainav Patel, Scientist E (vainavp@gmail.com)

State and Laboratories covered under ICMR-NIRRH, Mumbai (15 Laboratories)

State	Name of laboratories	Contact Person
Maharashtra (other than Vidharbha) (13 Labs)	<ol style="list-style-type: none"> Seth GS Medical College & KEM Hospital, Mumbai Kasturba Hospital for Infectious Diseases, Mumbai National Institute of Virology Field Unit, Mumbai Grant Medical College & Sir JJ Hospital, Mumbai Shree Bhausaheb Hire Govt. Medical College, Dhule Haffkine Institute, Mumbai ICMR-National Institute for Research on Reproductive Health, Mumbai Rajiv Gandhi Medical College & CSM Hospital, Kalwa, Thane, Mumbai INHS Ashvini, Mumbai Tata Memorial Centre ACTREC, Mumbai Tata Memorial Hospital, Mumbai Model Rural Health Research Unit (MRHRU), Sub District Hospital, Agar, Dahanu, Palghar Govt. Medical College, Jalgaon 	<p>Depot Team:</p> <p>*Dr Rajendra Katkam, Sr Technical Officer III (katkamrajendra@gmail.com; +919967416155)</p> <p>*Dr Kiran Munne, Scientist B (dr.kiranmunne@gmail.com; +919923334435)</p> <p>Central Team at ICMR:</p> <p>**Dr. Hemlata, Scientist C, ICMR (hemlata.jaint@gmail.com; 9818743598)</p>
Goa (1 Lab)	14. Goa Medical College	Mr. Prankur Gupta , IRSS
Dadra & Nagar Haveli (1)	15. Shri Vinoba Bhave Civil Hospital, Silvassa	Mr. Abhinav Sharma , PWC

REGIONAL DEPOT 9: ICMR-National Institute of Nutrition (NIN), Beside Tarnaka Metro Station, Osmania University, PO, Hyderabad, Telangana 500007

Depot Head: Dr. Hemalatha, Director (rhemalathanin@gmail.com)

State and Laboratories covered under ICMR-NIN, Hyderabad (10 Laboratories)

State	Name of laboratories	Contact Person
Telangana (10 Labs)	<ol style="list-style-type: none"> Gandhi Medical College, Secunderabad Osmania Medical College, Hyderabad Sir Ronald Ross of Tropical & Communicable Diseases, Hyderabad Nizam's Institute of Medical Sciences, Hyderabad Institute of Preventive Medicine, Hyderabad ESIC Medical College, Hyderabad Kakatiya Medical College, Nizampura, Warangal Centre for Cellular & Molecular Biology, Hyderabad Centre for DNA Fingerprinting and Diagnostics, Hyderabad Railway Hospital, Lallaguda, Secunderabad 	<p>Depot Team:</p> <p>*Dr. B. Dinesh Kumar, Scientist G (nindineshpct@gmail.com; 9849082088)</p> <p>*Dr. P. Uday Kumar Scientist G (putchaadaykumar@yahoo.com; 9247339143)</p> <p>Dr. A Laxmaiah, Scientist G (laxmanavula09@gmail.com; 9395113419)</p> <p>Mr. Nikhil Abraham, PWC (9539804320)</p> <p>Central Team at ICMR:</p> <p>**Dr. Gitika Kharkwal, Scientist C, ICMR (gitikagk7@gmail.com; 7838912620)</p> <p>Mr. S. Rajesh, Director, NITI Aayog</p> <p>Mr. Haider, PWC</p>

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.

The Depot Team should coordinate with the Central Team at ICMR.

**Person identified for communication at ICMR with the Depot team

REGIONAL DEPOT 10: ICMR-National Institute of Virology Bangalore Unit (NIV-BU)

Depot Head: Dr. Ashok, Office Incharge (ashokmniv@gmail.com)

State and Laboratories covered under ICMR-NIV Bangalore Unit (33 Laboratories)

State	Name of laboratories	Contact Person
Karnataka (33 Labs)	<ol style="list-style-type: none"> 1. Hassan Inst. Of Med. Sciences, Hassan 2. Mysore Medical College & Research Institute, Mysore 3. Shivamogga Institute of Medical Sciences, Shivamogga 4. Command Hospital (Air Force), Bengaluru 5. Bangalore Medical College & Research Institute, Bengaluru 6. ICMR-National Institute of Virology, Bangalore Field Unit, Bengaluru 7. Gulbarga Institute of Medical Sciences, Gulbarga 8. Vijaynagar Institute of Medical Sciences, Bellary 9. National Institute of Mental Health and Neuro-Sciences, Bengaluru 10. Wenlock District Hospital, Mangalore 11. Karnataka Institute of Medical Sciences, Hubli 12. ICMR-National Institute of Traditional Medicine, Belagavi 13. Dharwad Institute of Mental Health & Neurosciences, Dharwad 14. Kidwai Memorial Institute of Oncology, Bengaluru 15. Mandya Institute of Medical Sciences (MIMS), Mandya 16. Instem, Bengaluru 17. Chamarajanagar Institute of Medical Sciences (CIMS), Chamarajanagar District 18. Indian Institute of Science, Bengaluru (Department of Biochemistry, Centre for Infectious Disease Research) 19. Gadag Institute of Medical Sciences, Gadag 20. Kodagu Institute of Medical Sciences, Kodagu District 21. Government Viral Diagnostic Laboratory, Shimoga District 22. Raichur Institute of Medical Sciences, Raichur 23. Bidar Institute of Medical Sciences, Bidar 24. Koppal Institute of Medical Sciences, Koppal 25. Karwar Institute of Medical Sciences, Karwar 26. Tumkur District Hospital, Tumkur 27. Bowring Lady Curzon Medical College and Research Institute (BLCMRI), Bangalore 28. SNR District Hospital, Kolar 29. Chigateri District Hospital, Davangere District 30. Yadgir Institute of Medical Sciences, District Hospital, Yadgir 31. District Hospital, Haveri 32. Belgaum Institute of Medical Sciences, Belgaum 33. District Public Health Laboratory, Ramanagara District 	<p>Depot Team:</p> <p>*Mr Srinivas Vilasagaram (Vilasagar.srinivas@gmail.com; 9581808969)</p> <p>*Mr Basavaraj HM (nivbng@gmail.com; 9739857549)</p> <p>Central Team at ICMR:</p> <p>**Dr. Gitika Kharkwal, Scientist C, ICMR (gitikagk7@gmail.com; 7838912620)</p> <p>Mr. S. Rajesh, Director, NITI Aayog</p> <p>Mr. Haider, PWC</p>

REGIONAL DEPOT 11: ICMR-National Institute of Epidemiology (NIE), R 127, 3rd Avenue, 2nd Main Rd, near Ambattur, Ayapakkam, Chennai, Tamil Nadu

Depot Head: Dr. Manoj Murhekar, Director (mmurhekar@nieicmr.org.in)

State and Laboratories covered under ICMR-NIE, Chennai (76 Laboratories)

State	Name of laboratories	Contact Person
Tamil Nadu (46 Labs)	<ol style="list-style-type: none"> 1. King Institute of Preventive Medicine & Research, Chennai 2. Madras Medical College, Chennai 3. Stanley Medical College, Chennai 4. Govt. Kilpauk Medical College, Chennai 5. ICMR-National Institute for Research in Tuberculosis, Chennai 	<p>Depot Team:</p> <p>*Dr.C.P.Girish Kumar, Scientist –E (girishmicro@gmail.com; 9840304596)</p> <p>*Dr.S.M.Jeyakumar, Scientist –</p>

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.

The Depot Team should coordinate with the Central Team at ICMR.

****Person identified for communication at ICMR with the Depot team**

	6. State Public Health Laboratory, Chennai 7. ICMR-National Institute of Epidemiology, Chennai 8. Dr. MGR Medical University, Chennai 9. Dr. ALM PG Institute of Basic Medical Sciences, Chennai 10. Govt. Medical College & Hospital, Omandurar Govt. Estate, Chennai 11. Govt. Theni Medical College, Theni 12. Tirunelveli Medical College, Tirunelveli 13. Govt. Medical College, Thiruvavur 14. Kumar Mangalam Govt. Medical College, Salem 15. Coimbatore Medical College, Coimbatore 16. Govt. Medical College & ESIC Hospital, Coimbatore 17. Government Medical College, Villipuram 18. Madurai Medical College, Madurai 19. K A P Viswanatham Govt. Medical College, Trichy 20. Perundurai Medical College, Perundurai 21. Govt. Dharmapuri Medical College, Dharmapuri 22. Govt. Medical College, Vellore 23. Thanjavur Medical College, Thanjavur 24. Kanyakumari Govt. Medical College, Nagercoil 25. Govt. Thoothukudi Medical College, Thoothukudi 26. Institute of Vector Control & Zoonoses, Hosur 27. Pasteur Institute of India, Coonoor 28. Rajah Muthiah Medical College, Chidambaram 29. Government Medical College, Karur 30. Govt. Tiruvannamalai Medical College & Hospital, Tiruvannamalai 31. Chengalpattu Government Medical College, Kancheepuram 32. Government Medical College and Hospital, Pudukkottai 33. Government Shivagangai Medical College, Shivagangai 34. Government District Headquarters Hospital, Virrudhu Nagar 35. Government District Headquarters Hospital, Ramanathapuram 36. Government District Headquarters Hospital, Ariyalur 37. Government District headquarter Hospital. Tiruppur 38. Government Kallakruichi Hospital, Kallakurichi 39. Government District Headquarters Hospital, Tiruvallur 40. Government District Headquarters, Namakkal 41. Centre Leather Research Institute, Adyar, Chennai 42. Government Headquarters Hospital, Dindigul 43. C.D Hospital, Greater Chennai Corporation, Chennai 44. Government District Head Quarters Hospital, Nagapattinam 45. Government Hospital, Tirupattur 46. Government Head Quarters Hospital, Krishnagiri	E (smijkumar@gmail.com ; 9440520475) *Mr. Muthu Raman, PWC (9940384010) Central Team at ICMR: **Dr. Gitika Kharkwal, Scientist C, ICMR (gitikagk7@gmail.com ; 7838912620) Mr. S. Rajesh, Director, NITI Aayog Mr. Haider, PWC
Puducherry (02 Labs)	47. Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry 48. Indira Gandhi Medical College, Puducherry	
Andhra Pradesh (11 labs)	49. Sri Venkateswara Institute of Medical Sciences, Tirupati 50. Rangaraya Medical College, Kakinada 51. Sidhartha Medical College, Vijaywada 52. Govt. Medical College, Ananthpur 53. Guntur Medical College, Guntur 54. Rajiv Gandhi Institute of Medical Sciences, Kadapa 55. Andhra Medical College, Visakhapatnam 56. Govt. Kurnool Medical College, Kurnool 57. Govt. Medical College, Srikakulam 58. Sri Venkateshwar Medical College, Tirupati 59. AIIMS, Manglapuri	
Kerala (16 Labs)	60. National Institute of Virology, Field Unit, Allapuzha 61. Govt. Medical College, Thiruvananthapuram 62. Govt. Medical College, Kozhikode 63. Govt. Medical College, Thrissur 64. Rajiv Gandhi Center for Biotechnology, Thiruvananthapuram	

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.

The Depot Team should coordinate with the Central Team at ICMR.

****Person identified for communication at ICMR with the Depot team**

	65. Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram 66. State Public Health Laboratory, Trivandrum 67. Inter University, Kottayam 68. Malabar Cancer Center, Thalassery 69. Central University of Kerala, Periyar, Kasaragod 70. Govt. Medical College, Ernakulum 71. Govt. Medical College, Manjeri 72. Govt. Medical College, Kottayam 73. Govt. Medical College, Kannur 74. Indian Institute of Science Education and Research (IISER), Thiruvananthapuram 75. Government Medical College, Palakkad	
Andaman and Nicobar (1 Lab)	76. ICMR- Regional Medical Research Centre, Port Blair	

REGIONAL DEPOT 12: ICMR-Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Agam Kuan, Sadikpur, Patna, Bihar
Depot Head: Dr. Pradeep Das, Director (drpradeep.das@gmail.com)

State and Laboratories covered under ICMR-RMRIMS, Patna (6 Laboratories)

State	Name of laboratories	Contact Person
Bihar (6 Labs)	1. ICMR-Rajendra Memorial Research Institute of Medical Sciences, Patna 2. Indira Gandhi Institute Medical Sciences, Patna 3. Patna Medical College, Patna 4. Darbhanga Medical College, Darbhanga 5. SKMCH, Muzaffarpur 6. All India Institute of Medical Sciences, Patna	Depot Team: *Dr. Ashish Kumar , Scientist C (ashish2k8@gmail.com ; 8210353361) *Dr. Manas R Dikhit , ICMR-PDF (manasranjandikhit@gmail.com ; 9304657119) Central Team at ICMR: **Dr. Harpreet Sandhu , Scientist F, ICMR (sandhuh.hq@icmr.gov.in ; 9810332718) Mr. H S Pahuja , IAS, Deputy Secretary Mr. Pranjal , PWC

REGIONAL DEPOT 13: ICMR-National Institute for Cholera and Enteric Diseases (**NICED**), P- C.I.T. Scheme XM, 33, CIT Rd, Subhas Sarobar Park, Phool Bagan, Belehata, **Kolkata**, West Bengal
Depot Head: Dr. Shanta Dutta, Director (drshantadutta@gmail.com)

State and Laboratories covered under ICMR-NICED, Kolkata (24 Laboratories)

State	Name of laboratories	Contact Person
West Bengal (18 Labs)	1. ICMR-National Institute of Cholera & Enteric Diseases, Kolkata 2. Institute of Post Graduate Medical Education & Research, Kolkata 3. Midnapore Medical College, Midnapore 4. North Bengal Medical College, Darjeeling 5. School of Tropical Medicine, Kolkata	Depot Team: *Dr. Mamta Chawla Sarkar , Scientist F (chawlam70@gmail.com ; 9830660999) *Dr. Provash Chandra

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues. The Depot Team should coordinate with the Central Team at ICMR.
****Person identified for communication at ICMR with the Depot team**

	6. Malda Medical College & Hospital, Malda 7. Command Hospital, Kolkata 8. Chittaranjan National Cancer Institute, Kolkata 9. R.G. Kar Medical College & Hospital, Kolkata 10. Murshidabad Medical College, Behrampur, Murshidabad 11. Nil Ratan Sircar Medical College, Kolkata 12. Bankura Medical College, Bankura 13. Suri Sadar Hospital, Birbhum 14. Medical College, Kolkata 15. College of Medicine and JNM Hospital, Kalyani, Nadia 16. ESI-Postgraduate Institute of Medical Science and Research (PGIMS), Joka, Kolkata 17. Burdwan Medical College, Burdwan 18. Calcutta National Medical College and Hospital, Kolkata	Sadhukhan, Scientist E (provash2000@gmail.com; 9830546338) *Mr. Pranavesh Kumar, PWC (9439732199) Central Team at ICMR: **Dr. Joy Kumar Chakma, Scientist E, ICMR (drjkna@yahoo.com; 7210660508) Mr. H S Pahuja, IAS, Deputy Secretary Mr. Pranjal, PWC
Tripura (1 Labs)	19. Govt. Medical College, Agartala	
Jharkhand (4 Labs)	20. MGM Medical College & Hospital, Jamshedpur 21. Rajendra Institute of Medical Sciences, Ranchi 22. Patliputra Medical College & Hospital, Dhanbad 23. Itki Aarogyashala, Ranchi	
Sikkim (1 Lab)	24. Virus Research and Diagnostic Laboratory, STNM Hospital, Gangtok	

REGIONAL DEPOT 14: ICMR-Regional Medical Research Centre (RMRC), NALCO Nagar, Chandrasekharpur, Bhubaneswar, Odisha 751023
Depot Head: Dr. Sanghamitra Pati, Director (drsanghamitra12@gmail.com)

State and Laboratories covered under ICMR-RMRC, Bhubaneswar (15 Laboratories)

State	Name of laboratories	Contact Person
Odisha (11 Labs)	1. ICMR-Regional Medical Research Centre, Bhubaneswar (High-throughput Laboratory) 2. All India Institute of Medical Sciences, Bhubaneswar 3. SCB Medical College and Hospital, Cuttack 4. MKCG Medical College, Berhampur 5. Ispat General Hospital, Rourkela 6. Veer Surendra Sai institute of Medical Science & Research, Sambalpur 7. Institute of Life Sciences, Bhubaneswar 8. ICAR- International Centre for Foot and Mouth Disease, Khordha, Odisha 9. Indian Institute of Science Education and Research (IISER), Berhampur 10. Bhima Bhoi Medical College and Hospital, Bolangir 11. Pandit Raghunath Murmu Medical College, Baripada	Depot Team: *Dr.G Bulliyya, Scientist-F (gbrmrcicmr@gmail.com; 9861321469) *Dr S K Palo, Scientist-D (drpalsubrat@gmail.com; 8763590449) Central Team at ICMR: **Dr. Harpreet Sandhu, Scientist F, ICMR (sandhuh.hq@icmr.gov.in; 9810332718)
Chhattisgarh (4 Labs)	12. All India Institute of Medical Sciences, Raipur 13. Late Baliram Kashyap M Govt. Medical College, Jagdalpur 14. JNM Medical College, Raipur 15. Late Shri Lakhi Ram Agrawal Memorial Govt. Medical College, Raigarh	Mr. H S Pahuja, IAS, Deputy Secretary Mr. Pranjal, PWC

REGIONAL DEPOT 15: ICMR-Regional Medical Research Centre (RMRC), Bokul, Lahowal, Dibrugarh, Assam
Depot Head: Dr. Kanwar Narain, Director (kanwar_narain@hotmail.com)

State and Laboratories covered under ICMR-RMRC, Dibrugarh (5 Laboratories)

State	Name of laboratories	Contact Person
Arunachal Pradesh	1. Tomo Riba Institute of Health & Medical	Depot Team:

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues. The Depot Team should coordinate with the Central Team at ICMR.
****Person identified for communication at ICMR with the Depot team**

(1 Lab)	Sciences, Naharlagun	<p>*Dr. Dipankar Biswas, Scientist F (dbiswas1967@gmail.com); +91-94351-31976)</p> <p>*Dr. S.K. Sharma, Scientist G (sksharma.rmcne@gov.in); +91-94351-31953)</p> <p>Central Team at ICMR:</p> <p>**Dr. Joy Kumar Chakma, Scientist E, ICMR (drjkna@yahoo.com); 7210660508)</p> <p>Mr. H S Pahuja, IAS, Deputy Secretary</p> <p>Mr. Pranjal, PWC</p>
Upper Assam (4 Labs)	<p>2. ICMR-Regional Medical Research Center, Dibrugarh</p> <p>3. Assam Medical College, Dibrugarh</p> <p>4. Jorhat Medical College, Jorhat</p> <p>5. CSIR North East Institute of Science and Technology (NEIST), Jorhat</p>	

REGIONAL DEPOT 16: Gauhati Medical College and Hospital (GMC), Narakasur Hilltop, Bhangagarh, Guwahati, Assam
Depot Head: Prof. Lahari Saikia, HOD, Microbiology (Lahari.saikia@yahoo.com)

State and Laboratories covered under GMC, Guwahati (12 Laboratories)

State	Name of laboratories	Contact Person
Lower Assam (6 Labs)	<p>1. Gauhati Medical College, Guwahati</p> <p>2. Silchar Medical College, Silchar</p> <p>3. Fakkhruddin Ali Ahmed Medical College, Barpeta</p> <p>4. Tezpur Medical College, Tezpur</p> <p>5. Defence Research Laboratory, Tezpur</p> <p>6. Diphu Medical College, Karbi Anglong</p>	<p>Depot Team:</p> <p>*Dr. Dina Raja, Associate Professor (dinaraja2016@gmail.com); 9864039629)</p> <p>*Dr. Shashank Sekhar, Assistant Professor (drshashank79@gmail.com); 9435033258)</p> <p>Central Team at ICMR:</p> <p>**Dr. Joy Kumar Chakma, Scientist E, ICMR (drjkna@yahoo.com); 7210660508)</p> <p>Mr. H S Pahuja, IAS, Deputy Secretary</p> <p>Mr. Pranjal, PWC</p>
Mizoram (1 Lab)	7. Zoram Medical College, Falkhawn, Aizawl	
Nagaland (1 Lab)	8. State Referral BSL-3 Laboratory, Naga Hospital, Kohima	
Meghalaya (2 Lab)	<p>9. North Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Shillong, Meghalaya</p> <p>10. Civil Hospital, Tura</p>	
Manipur (2 Labs)	<p>11. Jawaharlal Nehru Institute of Med. Sciences, Imphal East</p> <p>12. Regional Institute of Medical Sciences, Imphal</p>	

Note:* The laboratory should coordinate with their respective Depot team for any logistic issues.

The Depot Team should coordinate with the Central Team at ICMR.

**Person identified for communication at ICMR with the Depot team



ICMR-DCGI

GUIDELINES FOR VALIDATION AND BATCH TESTING OF COVID-19 DIAGNOSTIC KITS

4 JUNE 2020

DEPARTMENT OF HEALTH RESEARCH
MINISTRY OF HEALTH AND FAMILY WELFARE,
GOVERNMENT OF INDIA



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कल्याण मंत्रालय, भारत सरकार
Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

GUIDELINES FOR VALIDATION AND BATCH TESTING OF COVID-19 DIAGNOSTIC KITS

*(This is recommendatory and dynamic document without prejudice to
statutory provisions)*

1. VALIDATION

1.1 RT-PCR Kits

1.1.1 US-FDA approved kits will not require validation.

1.1.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: First batch of kits will require validation from any of ICMR identified validation centres (Annexure I) prior to DCGI approval; thereafter for post marketing; additional two batches should be tested as per medical device rule in four months time.

1.2 RNA Extraction and VTM Kits

1.2.1 US-FDA approved kits will not require validation.

1.2.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: One batch of kits will require validation from any of ICMR identified validation centres prior to DCGI approval.

1.3 Rapid Antibody Test; ELISA and CLIA Kits

1.3.1 US-FDA approved kits will not require validation.

1.3.2 CE-IVD approved/ Non US-FDA approved/ Indigenous Kits: The testing of three batches of kits will be required for validation from any of ICMR identified validation centres prior to DCGI approval.

2. BATCH TESTING FOR RT-PCR, RNA EXTRACTION KITS, VTM, RAPID ANTIBODY TEST, ELISA AND CLIA KITS

2.1 The firm will be required to provide batch testing certificate while delivering the consignment.

2.2 ICMR identified validation centre will undertake random samples testing of batches of kits for quality assurance



3. PROCEDURE FOR VALIDATION

3.1 The requests for validation of kits for RT-PCR; RNA Extraction, VTM, Rapid Antibody Test, ELISA and CLIA will be sent by the manufacturer/supplier through e-mail (**gstoteja@gmail.com**) to **Dr. G. S. Toteja, Additional Director General, ICMR and National Nodal Officer for validation**. The request from the manufacturer/supplier should mandatorily be accompanied with information as per Annexure II

3.2 The request after receipt and scrutiny will be :

3.2.1 Forwarded to any one of the ICMR identified validation centres depending upon the work load and other logistics issue if it is **first time validation**.

3.2.2 If the kit is for second time validation or subsequent validation or in case of any other issue; the manufacturer has to provide justification which will be reviewed at ICMR, New Delhi and decision will be communicated to manufacturer/supplier within a week. The request for re-validation will only be considered if there is any significant change in the composition or type of reagents in the kit.

3.3 Once the kit is delivered to the validation centre with adequate number of test reactions required, reagents, methodology etc; validation report will be sent to the manufacturer/supplier within 15 days.



ANNEXURE I

Centres for Validation and Batch Testing of COVID-19 Diagnostic Kits

S.No	Name of the Institute
ICMR INSTITUTES	
1.	ICMR – National Institute of Virology (NIV), Pune
2.	ICMR- Regional Medical Research Centre (RMRC), Bhubaneswar
3.	ICMR- National Institute for Research in Reproductive Health (NIRRH) , Mumbai
4.	ICMR- Rajendra Memorial Research Institute of Medical Science (RMRIMS), Patna
5.	ICMR- National Institute of Virology (NIV) field unit, Alappuzha
6.	ICMR- National AIDS Research Institute (NARI), Pune
7.	ICMR- National Institute of Pathology (NIP), New Delhi
8.	ICMR - National Institute of Cholera and Enteric Diseases (NICED), Kolkata
9.	ICMR- National Institute for Implementation Research on Non-Communicable Diseases (NIIRNCD), Jodhpur
DBT INSTITUTES	
10.	DBT- Translational Health Science and Technology Institute (THSTI), Faridabad
11.	DBT- International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi
12.	DBT- Rajiv Gandhi Centre for Biotechnology (RGCB), Thiruvananthapuram
13.	DBT- Institute of Life Sciences (ILS), Bhubaneswar
14.	DBT- Institute for Stem Cell Science and Regenerative Medicine (InSTEM), Bengaluru
CSIR INSTITUTES	
15.	CSIR- Institute of Genomics and Integrative Biology (IGIB), New Delhi
16.	CSIR- Institute of Microbial Technology (IMTECH), Chandigarh
17.	CSIR- Centre for Cellular & Molecular Biology (CCMB), Hyderabad
OTHERS	
18.	Kasturba Hospital for Infectious Diseases, Mumbai
19.	Institute of Liver and Biliary Sciences, New Delhi
20.	Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh
21.	King George's Medical University (KGMU), Lucknow
22.	National Institute of Biologicals (NIB), Noida
23.	The King Institute of Preventive Medicine and Research, Chennai
24.	Sawai Man Singh Medical College, Jaipur



ANNEXURE II

FORMAT FOR INFORMATION FOR VALIDATION OF RT-PCR/RNA EXTRACTION KITS/VTM AND RAPID ANTIBODY TEST, ELISA AND CLIA

A. RT-PCR KITS

Name of the Company (manufacturer)	Name of the supplier	Name of the Kit & Batch No.	Multiplex or *Singleplex with no. of genes	First Time Validation by ICMR (Yes/No)	If it is not first time validation	
					Details of last validation along with validation report	Difference in Kit composition as compared to first validation

* Only kit with minimum two gene targets will be considered

B. RNA EXTRACTION KITS

Name of the Company (manufacturer)	Name of the supplier	Name of the Kit & Batch No.	Magnetic or Column Based	First Time Validation by ICMR (Yes/No)	If it is not first time validation	
					Details of last validation along with validation report	Difference in Kit composition as compared to first validation

C. VTM, RAPID ANTIBODY TEST, ELISA AND CLIA

Name of the Company (manufacturer)	Name of the supplier	Name of the KIT & Batch No.	First Time Validation by ICMR (Yes/No)	If it is not first time validation	
				Details of last validation along with validation report	Difference in product as compared to first validation



INDIAN COUNCIL OF MEDICAL RESEARCH
Department of Health Research
(Ministry of Health & Family Welfare)
V Ramalingaswami Bhawan, Post Box 4911,
Ansari Nagar-AIIMS, New Delhi – 110029 Delhi, India
Website: <http://www.icmr.gov.in>



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 01.07.2020

LIST OF IgG ELISA/CLIA KITS FOR COVID 19 VALIDATED BY ICMR IDENTIFIED VALIDATION CENTRES

Sl. No	Name of Company	Name of the Kit	*Batch Number
1.	Zydus Cadila Healthcare Ltd., Ahmedabad (Gujarat), India	COVID Kavach IgG ELISA	CoV2HI GG96-001 CoV2HI GG96-002 CoV2HI GG96-003
2.	Euroimmun US Inc., USA	Euroimmun Anti- SARS-COV-2 IgG ELISA	E200420AW
3.	Calbiotech Inc., USA	Erbalisa COVID-19 IgG ELISA	CVG6087
4.	YHLO iFlash, China	SARS-CoV-2 IgG CLIA	C86095G-20200206 C86095G-20200210
5.	Karwa Enterprises Pvt. Ltd, Delhi, India	KAVACH Karwa SARS-COV 2 IgG ELISA	A06201 A06202 A06203

The **IgG ELISA** and **CLIA** tests are recommended only for the following purpose:

- Serosurveys to understand the proportion of population exposed to infection including asymptomatic individuals. Depending upon the level of seroprevalence of infection, matching public health interventions can be implemented for prevention and control of the disease.
- Survey in high risk or vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc) to know who has been infected in the past and has now recovered.

Please Note:

- The ELISA tests have been validated in the laboratory. However, the performance of the test may be subject to variation under field conditions.
- *Above listed ELISA tests are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.
- IgG ELISA / CLIA tests which are US-FDA approved** can be used directly after due marketing approval from DCGI.
- Names and contact details of the manufacturers of COVID Kavach IgG ELISA is enclosed for reference.



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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

ICMR has transferred COVID Kavach IgG ELISA technology to below mentioned pharma companies:

S.No.	Name of Company	Contact Details
1	Zydus Cadila Healthcare Ltd	Vivek Kant Tripathi Zydus Corporate Park, 4th Floor, B Wing, Scheme No. 63, Survey No. 536, Near Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat Mobile: +919717273066 Email:vivekkant.tripathi@zyduscadila.com
2	Meril Diagnostics Pvt. Ltd	Paparaidu Sanapala Dy. General Manager(Technical Head) Vapi-Gujarat Mobile: +9195741 44456 Email:paparaidu.sanapala@merillife.com
3	Voxtur Bio Ltd.	Dr Veeraal Gandhi, Chairman Plot No. A-1, Royal Compound, Tamanman Kaman Bhivandi Road, Vasai, Palghar, Mumbai-401208 Mobile: +91-9819720123 Email: veeraal@voxturbio.com
4	Trivitron Healthcare Pvt. Ltd	Nitin Sawant, President D -134, MIDC, Industrial Area, Shirvane, Opposite Dr. D YPatil University, Nerul, Navi Mumbai – 400706 Mobile: +91 8291282827 Email: santosh.jagtap@trivitron.com
5	J. Mitra & Co. Pvt Ltd	Sangeeta Gupta, Head Technical A-180, Okhla Industrial Area, Phase-1, New Delhi - 110020 Mobile:+918800192205; Email : tcmgr@jmitra.co.in
6	Karwa Enterprises Pvt Ltd	Dr. Vivek Varma, Head – Operations Rapid Diagnostic Group of Companies B-82, Industrial Area, G.T. Karnal Road, New Delhi – 110033 Mobile: +91 9535998155; Email: drjindal@rdgc.in
7	Avecon Healthcare Pvt Ltd	Rajesh Aggarwal Plot No. 338, Industrial Growth Centre Saha, Haryana- 133104 Mobile: + 91 9315445391; Email : exportzone@aveconhealthcare.com

Rapid / CLIA/ ELISA Kits approved for testing of Covid-19 with the conditions.

Date: 06.07.2020

S. No.	Name of the Firm	Type of Kit	Country
1	M/s CPC Diag. Pvt. Ltd, Chennai	Chemiluminescent Immuno Assay IgG & IgM (CLIA) CE Approved and in Australia	M/s Shenzhen YHLO Biotech Co. Ltd. China
2	M/s Eris LifeSciences, Ahmedabad	Florescent, IgG & IgM	M/s Maccure Biotechnology .Ltd. China CE Approved and in China
3	M/s Cadila Healthcare Ltd, Ahmedabad	Antibody rapid test IgG/IgM	M/s. Hangzhou Clongene Biotech Co.Ltd. China CE Approved
4	M/S Vishat Diagnostics Pvt Ltd Mumbai	Antibody rapid test IgG/IgM	M/S Hangzhou All Test Biotech co Ltd China CE approved
5	S.D. Biosensor Delhi	Fluorescent Rapid ANTIGEN Test	M/s S.D. Biosensor, korea CE Approved
6	M/S Trivitron Healthcare Pvt Ltd, Chennai	Antibody test IgG/IgM CE approved	M/s Autobio Diag Co Ltd, China
7	M/S Trivitron Healthcare Pvt Ltd, Chennai	Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China
8	M/S SNIBE Diagnostics (India), Gurgaon	Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China

9	M/S Vishat Diagnostics Pvt Ltd Mumbai	ELISA CE approved	M/S Zhengzhou Human well Biocel Technology Ltd China
10	M/s Sowar Private Ltd Delhi	Rapid Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc China
11	M/S Immunoshop India Pvt Ltd Thane	Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China
12	M/S Athenese Dx Pvt Ltd Chennai	Rapid Antibody test IgG/IgM CE approved	M/s Beijing Genese Biotech Inc , China
13	M/S Bioline Diagnostics , Delhi	Antibody test IgG/IgM CE approved	M/S Hangzhou All Test Biotech co Ltd China CE approved
14	M/S Immunoshop India Pvt Ltd Thane	Antibody test IgG/IgM CE approved	M/s Goldsite Diagnostics Inc, China
15	Accurex Biomedical Pvt Ltd, Thane	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
16	Indelox Global Distribution, Pvt Ltd, Bangalore	Antibody test IgG/IgM CE approved	M/S Dongguan Bosh Biotechnology China
17	M/S POCT Services Pvt Ltd Delhi	Antibody test IgG/IgM CE approved	M/S Zybo Inc China
18	M/S Krishgen Biosystems Mumbai	Antibody test IgG/IgM CE approved	M/sWuhan UNScience Biotechnology co Ltd, China
19	M/s Rapid Diagnostics Pvt Ltd Delhi	Antibody test IgG/IgM CE approved	M/s Hangzhou Biotech Co Ltd China
20	M/s PTS Diagnostics India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Changsha Sinocare Inc China
21	M/s Gland Pharma	Antibody test IgG/IgM CE approved	M/S Shanghai Fosun Long March, China
22	M/s Accrediated Consultant Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Hangzhou All Test Biotech co Ltd China
23	M/s Accrediated Consultant Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Humasis Co Ltd Korea
24	M/s Cosmic Scientific Chennai	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
25	M/S Agappe Diagnostics Ltd	Antibody test IgG/IgM CE approved	M/s Hangzhou Biotech Co Ltd China

26	M/S Trivitron Healthcare Ltd	Antibody test IgG/IgM CE approved	M/S Beijing Lepu Medical Technology Co Ltd China
27	M/S Rafael Diagnostics, Pune	Antibody test IgG/IgM CE approved	M/S BMT Diagnostics Israel
28	M/S Matrix Lab Chennai	CLIA CE Approved	Auto-biodiagnostics Co Ltd China
29	M/S Providence International Labs	Antibody test IgG/IgM CE approved	M/S Hangzhou Reality Tech Co Ltd
30	M/S Voxtur Bio Ltd	Antibody test IgG/IgM	Indigenous
31	M/S Vanguard Diag Pvt Ltd	Antibody test IgG/IgM	Indigenous
32	M/S S.D.Biosensor, Pvt Ltd	Antibody test IgG/IgM Duo(Standard Q)	M/s S.D . Biosensor, Inc South Korea
33	M/S Weldon Biotech(I) Pvt.Ltd.	iChrome FIA(Fluoracence ImmunoAssay) Covid-19 Ab	M/s Boditech Med Inc. Korea
34	M/s HLL	Antibody test IgG/IgM	Indigenous
35	M/s Raymed Trading Group Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/S Beijing Lepu Medical Technology Co Ltd China
36	Hemogenomics Pvt. Ltd. Bangalore	Antibody test IgG/IgM CE approved	M/S PCL Inc. South Korea
37	M/s Aracion Technology Pvt. Ltd	Antibody test IgG/IgM CE approved	M/S Hecin Scientific Inc. China
38	M/s CPC Diagnostics Pvt. Ltd.	Anti SAR- COV-2 ELISA IgA/ IgG	M/s Euroimmune AG Germany
39	M/s Bilcare Ltd. Pune	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
40	M/s Bravo Pharmaceuticals Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Biosynex S.A France
41	M/s Harmony LifeSciences Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
42	M/s Inbios India, New Delhi	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
43	M/s Imperial LifeSciences Pvt. Ltd	Antibody test IgG/IgM CE approved	M/s NewScen Coast Biopharmaceutical Co. Ltd. China

44	M/s POCT Services Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Gen Body Inc. South Korea
45	M/s Trivitron Healthcare Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Innovita(Tang Shen) Biological Technology Co. Ltd. China
46	M/s Concept HealthCare	Antibody test IgG/IgM CE approved	M/s Celtex Biotech(Suzhou) Co. Ltd. China
47	M/s Bio Innovations Thane	Antibody test IgG/IgM CE approved	M/s Primer Design Ltd. U.K
48	M/s AR KAY Medicos Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
49	M/s Kin Diagnostics West Bengal	FIA iChroma IgG/IgM CE approved	M/s Boditech Med Inc. South Korea
50	M/S Aracion Technology Pvt LTd	Antibody test IgG/IgM CE approved	M/s Innovita(Tang Shen) Biological Technology Co. Ltd.China
51	M/S Meridian Medicare LTD	Antibody test IgG/IgM CE approved	M/s Gen Body Inc. South Korea
52	M/S SD Bio Sensor Healthcare Pvt Ltd	Standard Q COVID-19 IgG/IgM Duo	Indigenous
53	M/S Tara Medicos Pvt Ltd Jaipur	Antibody test IgG/IgM CE approved	M/S CELLEX INC,CHINA
54	M/s Med Source Ozone Biomedicals Pvt Ltd	COVID-19 IgG/IgM Rapid Test	Indigenous
55	Immunoscience India Pvt Ltd	COVID-19 IgG/IgM Rapid Test	Indigenous

56	M/s S.D Biosensor Healthcare Pvt. Ltd.	Standard Q Covid-19 IgG/IgM Combo	M/s S.D Biosensor Inc. Korea
57	M/s BioHouse Solutions Pvt. Ltd. Delhi	COVID-19 IgG/IgM Rapid Test	M/s Bio Medomics Inc. USA
58	M/s True Healthcare India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
59	M/s Immunoshop India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/S Shenzhen Cifotronic Technology Ltd. China
60	M/s Clini Experts Services Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Biocan Diagnostics Inc. Canada
61	M/s Inbios India, Delhi	Antibody test IgG/IgM CE approved	M/S CELLEX Biotech (Suzhou) Co. Ltd ,CHINA
62	M/S Synergy Scientific Services Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Schenzhen Reagent Technology Co Ltd China
63	M/S Bioscience Sales Corp. Delhi	Antibody test IgG/IgM CE approved	M/S Shenzhan Watmind Medical Co. Ltd , China
64	M/s Gastro Lab India Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Sche Bo Biotech AG, Germany
65	M/S Doctor Analytical Laboratories Pvt Ltd	Antibody test IgG/IgM CE approved	M/s Biocan Diagnostics Inc. Canada

66	M/S MDAAC International Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Atlab Link(Beijing) Technology Co Ltd , China
67	M/S Kin Diagnostics	Antibody test IgG/IgM CE approved	M/S Sugentech Inc South Korea
68	M/s Alere Medical Pvt. Ltd.	PanBio Antibody test IgG/IgM CE approved	M/s Abbott Rapid Diagnostics Germany Having Mfg. Site at Abon Biopharma(Hangzhou) Co. Ltd. China
69	M/s Incarp Instruments Pvt. Ltd. Hyderabad	FIA IgG/IgM AntiBody Test CE approved	M/s Boditech Med Inc. South Korea

70	M/s Nucleus 18 Turnkey Projects Pvt. Ltd. Telangana	Antibody test IgG/IgM Australian EUA	M/s Innovita (Tangshan) Biological Technology Co. Ltd. China
71	M/S Elder Projects Ltd Mumbai	Antibody test IgG/IgM CE approved	M/S Shanghai Outdo Biotech Co Ltd China
72	M/S KDH Biomedicals Pvt Ltd Mumbai	Antibody test IgG/IgM CE approved	M/s Dynamiker Biotechnology (Tianjin) Co Ltd China
73	M/S KDH Biomedicals Pvt Ltd Mumbai	ELISA IgG and ELISA IgM/IgA CE approved	M/s Dynamiker Biotechnology (Tianjin) Co Ltd China
74	Bio Dx Healthcare New Delhi	Antibody test IgG/IgM CE approved	M/S Zybio Inc, China
75	M/s Trivitron Healthcare Pvt LTD	Antibody test IgG/IgM CE approved	M/s Shenzhen Lifotronic Technology Co. Ltd. China
76	M/s Saffron Naturele Product Pvt. Ltd. U.P	Antibody test IgG/IgM CE approved	M/s Hangzhou Clongene Biotech Co. Ltd. China
77	M/s Bioplus Healthcare Pvt Ltd Bangalore	Antibody test IgG/IgM CE approved	M/s Cellex BioTech (Suzhou) Co. Ltd. China
78	M/s N.W Overseas, Haryana	Antibody test IgG/IgM CE approved	M/s Beijing Lepu Medical Technology Co. Ltd. China
79	M/s Premier Nutraceuticals Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Shanghai Outdo Bio Tech Co. Ltd. China
80	M/s Genetix BioTech Asia Ltd..	Antibody test IgG/IgM	M/s Sugentech Inc. South Korea
81	M/S Alpine Biomedicals Pvt Ltd Haryana	Rapid Antibody test IgG/IgM	Indigenous
82	S A Diagnostics Pvt Ltd Mumbai	Antibody test IgG/IgM	M/S Genrui Biotech Inc China
83.	M/s Abbott Healthcare Pvt Ltd	Chemiluminescent Microparticle Immunoassay With Architect System	M/S Abbott Ireland Diag Div. Ireland
84	M/s Lab Care Diag, India Pvt Ltd	Antibody test IgG/IgM	Indigenous

85	M/S Nulife, Noida	Antibody test IgG/IgM	Indigenous
86	M/s Tulip Diagnostics Pvt Ltd Goa	Coviscreen-Rapid Double Antigen test for detection of IgG/IgM/IgA	Indigenous
87	M/s Roche Diagnostics India Pvt. Ltd. Delhi	ECLIA Elecys Anti SARS COV2	M/s Roche Diagnostics GmbH, Germany
88	M/s Sidak LifeCare Pvt. Ltd.	Antibody test IgG/IgM	Indigenous
89	M/s S.D Biosensor HealthCare Pvt. Ltd.	Standard Q COVID-19 IgG/IgM Combo	Indigenous
90	M/s Diasorin Healthcare India Pvt. Ltd.	CLIA	M/s Diasorin S.P.A, Italy
91	M/s Iris Hightech Pvt. Ltd. Delhi	Antibody test IgG/IgM	M/s Pharmact GmbH, Germany
92	M/s Mindray Medical India Pvt. Ltd. Mumbai	CLIA	M/s Shenzhen Mindray, China
93	M/s Ortho Clinical Diagnostics India Pvt. Ltd.	Vitros Immunodiagnostic Total Reagent Pack	M/s Ortho Clinical Diagnostics, USA
94	M/S DiaSys Diagnostics India Pvt Ltd	Antibody test IgG/IgM	M/S Beijing Lepu Medical Technology Co Ltd China
95	M/S Jetta Labs	Antibody test IgG/IgM	M/s Hangzhou Test Sea Biotechnology China
96	M/s V.S Yarns Pvt. Ltd. Ludhiana	Antibody test IgG/IgM	M/s Accobiotech, Malaysia
97	M/s CliniExperts Services Pvt. Ltd	Antibody test IgG/IgM	M/s Europlaz Technologies, U.K
98	M/s Cadila Healthcare Ltd.	ELISA	Indigenous

99	M/s Deep Meditech Pvt. Ltd. Delhi	Antibody test IgG/IgM	M/s Autobio Diag Co Ltd, China
100	M/S McW Healthcare Pvt Ltd	Antibody test IgG/IgM	M/s Technogenetics S.r.l Italy
101	M/S Omega Dx (Asia) Pvt Ltd	ELISA	M/S Genesis Diagnostics Ltd , UK
102	M/S Abbott Healthcare Pvt Ltd	CMIA	M/S Abbott Ireland
103	M/S Ortho Clinical Diag. India Pvt. Ltd	CLIA, IgG qualitative immunodiagnostic assay kit	M/S Ortho clinical Diag. UK
104	M/S Ortho Clinical Diag. India Pvt. Ltd	VITROS (Immunodiagnosics Assay Kit) including IgG,IgA and IgM	M/S Ortho clinical Diag. UK
105	M/S Athenese-Dx Pvt. Ltd	Antibody test IgG/IgM	M/S CTK Biotech Inc, USA
106	M/S Tosoh India Pvt Ltd	ELISA IgA, ELISA IgG, ELISA IgM	M/S NovaTec GmbH, Germany
107	M/S Biorad Laboratories (India) Pvt Ltd	Platellia SARS-COV2 Total Ab	M/S Biorad , France
108	M/S Novomed Inc Pvt Ltd	ELISA IgG/IgM	M/S Ga Generic Assay GmbH Germany
109	M/S Ortho Clinical Diag. India Pvt. Ltd	CLIA , Vitros IgG	M/S Ortho clinical Diag. UK
110	M/S S D Biosensor Healthcare Pvt Ltd	Standard Q COVID-19Ag	Indigenous
111	M/S J. Mitra	COVID IgM+IgG+IgA Microlisa	Indigenous

112	m/s Laj Exports Ltd	Rapid IgG/IgM	Biohit Healthcare (Hefei) Co Ltd China
113	M/S Siemens Healthcare Pvt Ltd	.ADVIA Centaur SARS-COV-2 (IgG/IgM) .Atellica IM SARS-COV-2(IgG/IgM) Dimension EXL SARS-COV-2(IgG/IgM)	M/S Siemens Healthcare Diag. Inc USA
114	M/S Inbios India	Detect IgG ELISA	M/S Inbios International Inc, USA
115	M/S Sirius Biocare Pvt Ltd	SCO-2IgG ELISA	M/S Inbios International Inc, USA
116	M/S Beckman Coulter India PVt Ltd	Access SARS-COV-2 IgG CLIA	M/S Beckman Coulter Ireland



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 01.07.2020

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

Till date, 146 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 &	SARS-CoV-2/SARS-CoV Multiplex	F2005S-2M



Sl. No	Name of Company	Name of the Kit	*Batch Number
	Production, LLC, Russia (365 Medical India)	Rteal-Time PCR detection kit	
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.	JN Medsys Pte Ltd, Singapore	Protect COVID-19 RT-qPCR Kit	RD 202004-001
33.	KILPEST (3B BlackBio Biotech India Ltd., Bhopal, India)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	CoV-19/V2/2020/01
34.	Kogene Biotech, Seoul, Korea	Power Check 2019 nCoV Real Time PCR Kit	R6900TD200423
35.	Indian Institute of Technology, Delhi, India	Covid 19 Probe-free Real Time PCR Diagnostic Kit	09042020
36.	InnoDx Solutions Pvt. Ltd	InnoDetect COVID-19 RT-PCR kit Version 1	COV-21-JU-20



Sl. No	Name of Company	Name of the Kit	*Batch Number
37.	Intron Biotechnology, Korea (Loften India Pvt Ltd)	LiliF COVID-19 Real Time RT-PCR kit	H215051153
38.	Lab Care Diagnostics (India) Pvt. Ltd., Mumbai, India	Accucare COVID-19 One-step RT-pCR kit	RPCR200401 RPCR200402
39.	LabGenomics , South Korea	LabGun Real Time PCR Kit	COV20D001 COV20D002 COV20D004 COV20D006
40.	Lab Genomics Co Ltd, Republic of Korea (Siemens Healthcare Private Limited)	LabGun COVID-19 Assay plus	CVA 20E001
41.	Lifespan Biotech Pvt Ltd	LS COVID-19 RT-qPCR kit	VLC20002
42.	Lipomic Healthcare Pvt. Ltd., New Delhi	Lipomic COVID-19 multiplex Realtime RT-PCR Kit	LIPO-001
43.	LLC Art Biotech	Art Test COVID-19 kit	C19300320
44.	Maccura Biotechnology Co Ltd China (Eris Lifesciences Ltd)	SARS-CoV-2 Nucleic Acid Detection Kit (Flourescent PCR)	0420131
45.	Med Achievers Private Limited, Noida, Uttar Pradesh, India	Genome Analyst SARS-CoV-2 detection kit	Lot No. GA0306-20-A, Batch No. MGA202003006
46.	Medsorce Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
47.	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091 MRD097 MRD098 M1052007
48.	Mylab Discovery Solutions, Pune, India	Patho Detect	PP00005-C-0320001 PP00005-C-0420001 PP00005-C-0320002 PP00005-C-0420002
49.	Mylab Discovery solutions, Pune, India	Pathodetect (Two tube assay)	PP00005-C-0520003
50.	OSANG Health Care, South Korea	Gene Finder COVID-19	2003-R45-22
51.	Pishtaz Teb Zaman Diagnostics, Iran (Corevyan Private limited)	COVID-19 One-step RT-PCR kit	99001
52.	POCT Services Pvt. Limited, Lucknow, India	Q-line Molecular Coronavirus (COVID-19) RT-PCR kit	P200401
53.	Primer Design, UK	Z-Path Covid-19C (Genesig)	JN-02780-0011
54.	Progenie Molecular , Spain (CliniExperts Services Private Limited, New Delhi)	RealCycler Coronavirus SARS-CoV-2 (ORF8+ E gene)	RC1405



Sl. No	Name of Company	Name of the Kit	*Batch Number
55.	Roche Diagnostics , Switzerland	Light Mix Modular SARS-CoV-2 (COVID19) RdRp	48492015
56.	Sansure Biotech Inc., Changsha, China	Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-Fluorescence Probing)	2020029/S3102E
57.	Seegene, South Korea	Allplex 2019-nCoV assay	RP4520A01 RP4520D34 RP4520D47 RP4520D50 RP4520D51 RP4529D70
58.	Sentinel Diagnostics, Italy	STAT-NAT COVID-19 B Realtime RT-PCR Kit	00310 00324 00365
59.	SD Biosensor, South Korea	nCoV Real-Time Detection kit	MNCO 0120004 MNCO0120009
60.	SNP Biotechnology R&D Ltd, Turkey (Wockhardt Ltd)	COVID-19 Real Time PCR kit v1	2006R2
61.	Triviron healthcare Pvt Ltd	Covidsure Pro Multiplex RT-PCR kit	COVID-M-001
62.	Triviron healthcare Pvt Ltd	COVIDsure Multiplex Realtime RT-PCR kit	COVID-C-T-004
63.	Oscar Medicare Pvt. Ltd., New Delhi, India	COVID-19 RT-PCR Kit	OSCOV-003 Catalog No. OSCOV-96
64.	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
65.	YOUSEQ, UK	COVID19 E,N,RdRp & S gene Multiplex qPCR kit	YSM1641
66.	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 DCGL. The complete list of US-FDA SARS-CoV-2 real time PCR kits is available at (<https://www.finddx.org/covid-19/pipeline/>).

PCR Kits approved for testing of Covid-19 as on 06.07.2020

S. No.	Name of the Firm	Type of Kit	Country
1	Roche Diagnostic, Mumbai	PCR	USA
2	S.D Biosensor, Delhi	PCR	M/s. SD Biosensor Korea, CE Approved
3	Matrix, Chennai	PCR	M/s Ghangzhou Wandfo Biotech Co.Ltd. China, CE Approved
4	Siemens Healthcare Pvt. Ltd.	PCR	M/s. Lab Genomics Co. Ltd., South Korea, CE Approved
5	Mylab, Pune	PCR	Indigenous approved by NIV Pune
6	Med Source Ozone Biomedical Pvt. Ltd.	PCR	M/s. Hangzhon Biotechnology Co. Ltd., China, CE Approved
7	Invitrogen Bioservices (Thermofisher)	PCR	M/s. Life Technologies, USA, US Approved

8	M/s Athenese Dx Pvt. Ltd. Chennai	PCR	M/S Certest Biotec, Spain CE approved
9	M/s Altona Diag.Pvt Ltd, Delhi	PCR	M/S Altona Diag. GmbH Germany CE approved
10	M/s Apollo Hospital Enterprise Ltd, Chennai	PCR	M/S Sanscure Biotech Inc China CE approved
11	M/S Gastro Lab Pune	PCR	M/S Immunodiagnostic Inc Germany CE approved
12	Soution One Delhi	PCR	M/S Seegene Inc South Korea CE approved
13	M/S Cepheid, Delhi	PCR	M/S Cepheid , USA Approved by USFDA FOR EMERGENCY USE
14	M/S Trivitron Healthcare Pvt Ltd, Chennai	PCR	M/S Shandong Yingsheng Biotechnology Co Ltd , China CE approved
15	M/S Genetix Biotech Asia Pvt Ltd, Delhi	PCR	M/S Primer Design Ltd , UK CE approved
16	M/s Gland Pharma Ltd , Telangana	PCR	M/S Shanghai Fosum co Ltd China CE approved
17	M/S Perkin Elmer India Pvt Ltd	PCR	M/S Suzhou Sym-Bio China CEapproved
18	M/S Fisher Bio Pharma Services Ahmedabad	PCR	M/S Life Technologies, USA Approved by USFDA and CE for Emergency use
19	M/S Abbott Healthcare Pvt	PCR	M/S Abbott Molecular

	Ltd		Inc USA Approved by USFDA and CE for Emergency use
20	M/S POCT Services Pvt Ltd , Delhi	PCR	M/S Zybo Inc, China
21	M/S 3i Molecular Solutions, Banglore	PCR	M/s Seegene Inc, Korea
22	M/S Cosmic Scientific , Chennai	PCR	M/S Getein Biotech China
23	M/S Inbios India Delhi	PCR	M/S Sanscure Biotech Inc China CE approved
24	M/S Molbio Diag. Pvt Ltd Goa	Truenat Beta PCR	Approved as screening test and not for confirmatory test Indigenous
25	M/S Kilpest India Ltd , Bhopal	TruPCR	Indigenous
26	M/S Imperial Life Sciences Pvt Ltd	PCR	M/S BGI Biotechnology (Wuhan) co. Ltd China
27	M/S Krishgen Biosystems Mumbai	PCR	M/S Kreative Technolab USA
28	M/s Cosara Diagnostics Pvt. Ltd.	PCR	M/s Co-Diagnostics Inc. USA
29	M/s POCT Services Pvt. Ltd	PCR	M/s Micobiomed Co.Ltd. South Korea
30	M/s POCT Services Pvt. Ltd.	PCR	M/s YD Diagnostics Corp. South Korea
31	M/s Hemogenomics Pvt. Ltd. Bangalore	PCR	M/s PCL Inc. South Korea
32	M/s Medsource Ozone Biomedicals Pvt.Ltd.	PCR	Indigenous
33	M/s Medsmart Logistics Pvt. Ltd.	PCR	M/s Sansure Biotech Inc. China
34	M/s ADT India Pvt. Ltd. Delhi	PCR	M/s ADT Biotech Sdn Malaysiap

35	M/s Triviron Healthcare Pvt. Ltd.	PCR	M/s Shanghai ZJ Bio Tech. Co. Ltd. China
36	M/s Qiagen India Pvt. Ltd.	SARS COV-2 Panel	M/s Qiagen GmbH Germany
37	M/S Life Cell International PVT LTD	PCR	M/S Osang Healthcare Ltd , South Korea
38	M/s Humole Diagnostics Pvt Ltd	PCR	M/s Seegene Inc, South Korea
39	M/S Krypton Biomedicals Pvt Ltd	PCR	M/s Seegene Inc, South Korea
40	M/S Aadivighnesh Chem Pvt Ltd	PCR	M/S Dia Carta Inc USA
41	M/S KDH Biomedical Pvt Ltd	PCR	M/s Vircell Spain
42	M/s Advy Chemical Pvt Ltd Mumbai	PCR	M/S Shanghai ZJ Biotech Co. Ltd, China
43	M/S Becton Dickinson India Pvt Ltd	PCR	M/S Gene Ohm Sciences Canada Inc , Canada
44	M/S Biomeriux India Pvt Ltd	PCR	M/S Biomeriux S.A France
45	M/S Elder Projects Ltd Thane	PCR	M/S Sanscure Biotech Inc China CE approved
46	Vinclan Technologies Pvt Ltd	PCR	M/S Shanghai Fosun Long March Medical Science Co. Ltd, China CE Approved and USFDA(EUA)
47	M/S MDAAC International Pvt Ltd	PCR	M/S Coyote Biosciences Co. Ltd, China
48	M/s Agappe Diagnostics Ltd	Fluorescent PCR	M/S Maccuara Biotechnology Ltd China

49	M/s Parekh Integrated Services Pvt. Ltd. Mumbai	PCR	M/s Quidel Corporation, USA, USFDA(EUA)
50	M/S KDH Biomedicals Pvt Ltd Mumbai	PCR	M/s Dynamiker Biotechnology (Tianjin) Co Ltd China
51	M/S BIODX Healthcare New Delhi	PCR Flourescent Probe method	M/S Zybio Inc, China
52	M/S Bharat Parenterals Ltd Vadodara	PCR	M/S Well Bios Inc South Korea
53	M/s Namoha Bio Pvt. Ltd. New Delhi	PCR	M/S Well Bios Inc South Korea
54	M/s Cosara Diagnostics Pvt. Ltd. Ahmedabad	PCR	Indigenous
55	M/s Rihim Pharma International LLP, Delhi	PCR	M/s AIT Biotech PTE Ltd. Singapore
56	M/s Sirius Biocare Pvt. Ltd. Kolkata	PCR	M/s Inbios International Inc. USA
57	M/S Horiba India Pvt Ltd	PCR	M/s Boditech Med Inc South Korea
58	M/S Huwel Lifesciences Pvt Ltd, Telangana	PCR	Indigenous
59	M/S Cronies Pharma & Biosciences Pvt Ltd Telangana	PCR	M/S DowGene Co Ltd South Korea
60	M/s Health ARX Technology Pvt. Ltd. Delhi	PCR	M/s SolGent Co. Ltd. South Korea
61	M/s Invitrogen BioServices India Pvt. Ltd.	PCR	M/s Life Technologies USA
62	M/S Inbios India Delhi	PCR	M/S Inbios INTERNATIONAL ,USA
63	M/s Diagnostics Biosystems (India) Delhi	PCR	M/s Advanced Molecular Diag. UK
64	M/S Helini Biomolecules	PCR	Indigenous
65	M/S Meril Diagnostics Pvt Ltd	PCR	Indigenous

66	M/S Prosper Channel Life Sciences India Pvt Ltd	PCR	M/S Shanghai Fosun Long March China
67	M/S 365 Medical	PCR	M/S DNA Technology Research and Production Russia
68	M/S Allied Biotechnology India Pvt Ltd	PCR	M/S In-bios International USA
69	M/S Biotron Healthcare India Pvt Ltd	PCR	M/S Atila Biosystems ,USA
70	M/s Jetta Labs	PCR	M/S Sansure Biotech Inc China
71	M/s Siemens Healthcare Pvt. Ltd.	PCR	M/s Lab Genomics Co, Ltd. South Korea
72	M/s Siemens Healthcare Pvt. Ltd.	PCR	M/s FastTrack Diagnostics Luxembourg
73	M/S KHC Healthcare India Pvt Ltd N. Delhi	PCR	M/S Bioneer Corporation , South Korea
74	M/S BYUNGMAN Electric Pvt Ltd Haryana	PCR	M/S Paxgen Bio Co. Ltd, South Korea
75	M/S Deep Meditech Pvt Ltd Delhi	PCR	M/S Zybio Inc, China
76	M/S Perkin Elmer India Pvt Ltd	PCR	M/S Wallace Oy, Finland
77	M/S Inbios India , N.Delhi	PCR	M/S Sentinel S.p.a Italy
78	M/S Alpha Agencies , Karnataka	PCR	M/S Intron Biotechnology Inc, South Korea

79	M/s Godolo & Godolo Exports Pvt. Ltd.	PCR	M/s RTA, Turkey
80	M/s Holly Drugs Pvt. Ltd.	PCR	M/s Wuhan Easydiagnosis, China
81	M/s Lab care Diagnostics, India Pvt. Ltd.	PCR	Indigenous
82	M/s Biohouse Solutions Pvt. Ltd	PCR	M/s Sentinel S.P.A, Italy
83	M/S BioGenomics Ltd	PCR	Indigenous
84	M/s Jaya Surgical & Pharma Pvt. Ltd. Hyderabad	PCR	M/s Sansure Biotech Inc. China
85	M/s Lab X, Kerala	PCR	M/s Y.D Diagnostics Corp. South Korea
86	M/s Invitrogen Bioservices India Pvt. Ltd.	PCR	M/s Life Technologies Corp. USA
87	M/s Cygen Consultancy Pvt. Ltd., Imphal	PCR	M/s Seegene Inc. South Korea
88	M/s Bharat Parenterals Ltd., Vadodara	PCR	M/s K.H Medical Co. Ltd. South Korea
89	M/s CPC Diagnostics Pvt. Ltd.	PCR	M/s Euroimmune AG Germany
90	M/s Stag Global Pvt. Ltd,	PCR	M/s Osang Healthcare Co. Ltd. South Korea
91.	M/S Innvolution Healthcare	PCR	M/S General Biologicals Corp, Taiwan

92	M/S Healthcare Pvt Ltd	PCR	M/S RTA, TURKEY
93	M/s Imperial Life Sciences Pvt Ltd	PCR	M/S PCL Inc, Korea
94	M/S Shiva Scientific Company	PCR	M/s BAG Diag. GmbH, Germany
95	M/S Bilcare Ltd	PCR	M/S BioSewoom Inc South Korea
96	M/S Brinton Pharmaceutical Ltd	PCR	M/S BGI EuropeA/S Denmark
97	M/S CliniExperts Services Pvt Ltd	PCR	M/S Progenie Molecular Spain
98	M/S Molbio Diagnostics Pvt Ltd	Truenat	Indigenous
99	M/S ADT India Pvt Ltd	PCR	M/S Gene Proof Czech Republic
100	M/S Kin Diagnostics, Kolkata	PCR	M/s Kogenebiotech Co Ltd, South Korea
101	M/S Loftin India Pvt Ltd	PCR	M/S INtRON Biotechnology Inc, South Korea
102	M/s Gravity Global Hospitality Pvt Ltd	PCR	M/S 1drop Inc South Korea
103	M/S POCT Services Pvt Ltd	PCR	Indigenous
104	M/S Meridian Biotech	PCR	M/S Seegene Inc South Korea

105	M/S Angstrom Biotech Pvt Ltd	PCR	Indigenous
106	M/S Kilpest India Ltd	PCR TRUPCR(V-3.2)	Indigenous
107	M/S Artec Diagnostic System	PCR	M/S Season Biomaterials Inc South Korea
108	M/S Hemogenomics Pvt Ltd	PCR	M/S Hologic Inc, USA
109	M/S Asvins Lifetechnologies Pvt Ltd	PCR	M/S Season Biomaterials South Korea
110	M/S Topaim Properties Pvt Ltd	PCR	M/S Shanghai Fosun Long March Medical Science Co Ltd China
111	M/S GCC Biotech India Pvt Ltd	PCR	Indigenous
112	M/S Siemens Healthcare Pvt Ltd	PCR	M/S Lab Genomics Co. Ltd, South Korea
113	M/S Avantor Performance Materials India Ltd	PCR	M/S Altona Diagnostics GmbH Germany
114	M/s Parekh Integrated Services Pvt Ltd	PCR	M/S Quidal Corp USA
115	M/S Wockhardt Ltd	PCR	M/S SNP Biotechnology Turkey
116	M/S Mili Healthcare Pvt Ltd	PCR	M/S Sansure Biotech Inc China
117	M/S Oscar Medicare Pvt Ltd	PCR	Indigenous

118	M/S Innvolution Healthcare Pvt Ltd	PCR	M/S General Biologicals Corp, Taiwan
119	M/S Gene Store India Pvt Ltd	Expert SARS-COV-2) PCR	Indigenous
120	M/S Triviron Healthcare Pvt Ltd	COVID Sure Multiplex RT-PCR	Indigenous
121	M/S Genes2Me Pvt Ltd	Multiplex RT-PCR	Indigenous
122	M/S Nandan Exports & Imports Pvt Ltd	1 copy COVID –qPCR	1drop Inc, South Korea



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स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर नई दिल्ली-110029

Indian Council of Medical Research

Department of Health Research
Ministry of Health & Family Welfare, Govt. of India
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029

डॉ. जी. एस. टोटेजा
अपर महानिदेशक
Dr. G. S. Toteja
Additional Director General

D.O.No.ECD/COVID19/Misc./2020

Dated: 22nd April 2020

To

Chief Secretaries
(all States)

Subject: Protocol for using Rapid antibody test – regarding

I am writing to you, with respect to issues raised by a few states about rapid antibody tests. In its advisory dated 17th April 2020, ICMR had clearly laid down the scope, purpose and usage of the rapid antibody tests.

ICMR has always emphasized that the confirmatory test for diagnosis of COVID-19 infection is RT – PCR test of throat and/ or nasal swab, which detects virus at early stage.

I would again reiterate that antibody rapid tests are largely to be used as a tool for surveillance with respect to formation of antibody in persons exposed to the virus. Globally also, the utility of this test is evolving and it is currently being used for detecting the formation of antibodies in individuals. These test results are also dependent on field conditions.

We have been given to understand that many States have procured such kits and on State's request, ICMR has also arranged and made available rapid antibody test kits with the clear understanding that these tests cannot replace the RT-PCR tests to diagnose the COVID-19 cases.

However, to further assist the States, ICMR will continue to collect data from various States to assess the scope and extent of utility of these rapid antibody tests in fields conditions of our country and will keep advising the States on regular basis.

In view of this, States are advised to follow the prescribed protocol for these tests and use it for the purposes for which these are meant. It is reiterated that to contain Corona Virus infection, RT-PCR tests must be continued vigorously as the principal diagnostic tests.

With kind regards,

Yours sincerely,

(G.S. Toteja)



Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

Till date, 56 antibody based rapid tests have been validated, and the following were found to be satisfactory. 11 of these kits are manufactured in India.

S.No.	Name of Company	Name of Kit	Lot no./Batch no.
1.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
2.	Voxtur Bio Ltd, Surat (Gujarat), India	Coronavirus (COVID-19) IgG/IgM Rapid Test	PCCV200301S
3.	VANGUARD Diagnostics, Delhi, India	COVID-19 IgM/IgG Antibody Detection Card Test	RCOVID200301T
4.	HLL Lifecare Limited, Gurugram (Haryana) India	Makesure COVID-19 Rapid test	CVCT030420 CVCT0204203 CVCT0104202
5.	Lab Care Diagnostics India Pvt. Ltd, Mumbai (Maharashtra), India	ACCUCARE IgM/IgG Lateral Flow Assay kit	CVC 200401
6.	NuLifecare, Noida (Uttar Pradesh), India	Abchek COVID-19 IgM/IgG Antibody Rapid Test	NUL/COV-19/R&D/001
7.	Alpine Biomedicals, Ambala (Haryana), India	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test	A10420 A20420
8.	Medsorce Ozone Biomedicals, Haryana, India	COVID 19 IgM/IgG Rapid Test Kit (ver 2.0)	COV-002
9.	Immuno Science India Pvt. Ltd, Pune (Maharashtra), India	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies	E142001
10.	SD Biosensors, Healthcare Pvt. Ltd., Gugugram (Haryana), India	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test	E054002 E054004
11.	BMT Diagnostics (Rafael Diagnostic), Israel	BMT COVID-19 IgG/IgM Rapid Test Kit	COV20030059 COV20030059-1
12.	SIDAK Life Care Pvt. Ltd., New Delhi, India	One Step COVID-19 IgM/IgG Antibody	COVID19S004A COVID19S004B COVID19S004C
13.	Diagnocure, Solan (Himachal Pradesh), India	Xamin COVID-19 Rapid Test Device	DI/COV19/R&D/001 DI/COV19/R&D/002

Rapid antibody tests are not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
 - Test result is available within 30 minutes
 - Test may come positive after 7-10 days of infection
 - The test may remain positive for several weeks after infection
 - Positive test indicates exposure to SARS-CoV-2
 - Negative test does not rule out COVID-19 infection
- These rapid antibody test kits have been validated in the laboratory. However, the performance of the kits may be subject to variation under field conditions.
- Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.



Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

S. No.	Kit Detail	Lot no./Batch no.
14.	SARS-CoV-2 Antibody test (Lateral flow method): Guangzhou Wondfo Biotech Mylan Laboratories Limited (CE-IVD) M R Roofs Private Ltd Abbott Laboratories Zydus Cadilla	# W19500309 W19500302 W19500351 W19500338
15.	COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD)	# CK2003010410

The marketing licenses to the distributors of these 2 companies have been **cancelled** by the Central Drugs Standard Control Organization (CDSCO).

Antibody based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Advisory on Use of Rapid Antigen Detection Test for COVID-19

Dated: 14th June 2020

Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.
2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.
3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or standalone antigen detection assay: **Standard Q COVID-19 Ag detection kit**, was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.

4. Brief description of the Standard Q COVID-19 Ag detection:

- i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.
- ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
- iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.
- iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and



biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

- v) Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.
- vi) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.
- vii) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes. After that the test strip should be discarded.
- viii) The test kit should be stored between 2° to 30° C.
- ix) Detailed instructions for use can be accessed through the video link: <https://youtu.be/mBdaOHJWxI4>

5. Validation of the Test:

I. Sites:

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

- i) Indian Council of Medical Research, Delhi; and
- ii) All India Institute of Medical Sciences, Delhi

II. Results:

- i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.
- ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

6. Conclusions and Recommendations:

- i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.
- ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.



iii) **In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing in the following settings in combination with the gold standard RT-PCR test:**

A. Containment zones or hotspots *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C.):*

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts with co-morbidities (*lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders*) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. Healthcare settings *(to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):*

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:
 - Patients undergoing chemotherapy
 - Immunosuppressed patients including those who are HIV+;
 - Patients diagnosed with malignant disease;
 - Transplant patients;
 - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
 - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures;
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

****ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- i) **Suspected individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.**
- ii) *Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.*
- iii) *The test should be conducted **onsite** under strict medical supervision and within one hour of sample collection in extraction buffer.*



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 03/07/2020

Invitation for Expression of Interest for Validation of Rapid Antigen Detection Assays for COVID-19:

Context:

As India is lifting lockdowns in various parts of the country in a phased manner, it is expected to see an upsurge in cases of COVID-19 due to increased transmission of SARS-CoV-2 virus. In view of this, it is important to scale up testing capacity to the maximum possible levels.

The gold standard RT-PCR diagnostic test for COVID-19 has limitations in terms of widespread availability. In view of this, there is urgent requirement of reliable and convenient rapid point of care antigen detection assays with high sensitivity and specificity. Such assays could be used as potential diagnostic tests in all possible public and private healthcare settings and made available for mass testing.

So far, ICMR has validated and approved only one rapid antigen detection assay from SD Biosensor.

ICMR invites applications for validation of rapid antigen detection tests for COVID-19 from all manufacturers who have developed such test.

ICMR has identified the following sites for validation of the rapid point-of-care antigen detection tests for COVID-19:

1. All India Institute of Medical Sciences, Delhi
2. SMS Medical College, Jaipur
3. King George Medical University, Lucknow
4. Kasturba Hospital for Infectious Diseases, Mumbai
5. Post Graduate Institute of Medical Education & Research, Chandigarh
6. Jawaharlal Institute of Postgraduate Medical Education & Research, Puducherry
7. National Institute of Virology, Kerala Unit, Alappuzha
8. Bangalore Medical College & Research Institute, Bengaluru
9. National Institute of Mental Health and Neurosciences, Bengaluru

Essential criteria for validation:

1. A minimum of 300 rapid antigen tests would be required for each validation.
2. A minimum of 3-4 instruments (if the test results are to be interpreted using a specialized equipment such as fluorescence immunoassay readers etc.) will be required.
3. Ability to provide training to technical staff involved in validation of the test.



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4. If the kit is approved after validation, the manufacturers should be committed to make adequate supplies of the product available to India with immediate effect.
5. Import / test license from CDSCO/DCGI wherever applicable.

All interested manufacturers fulfilling the above essential criteria are requested to send their applications to the following email id:

guptanivedita.hq@icmr.gov.in



Subject-line of the email should read as: REQUEST FOR VALIDATION OF COVID-19 RAPID ANTIGEN TEST.



Date: 06/07/2020

List of Companies / Vendors of Rapid Antigen Test Kits for COVID-19 who have approached ICMR for validation

S. No	Name of the kit	Name of company	India/ Other countries	Name of the supplier	Current status at validation centre
1	STANDARD Q COVID-19 Ag	SD Biosensor	South Korea / India	SD Biosensor	Validated, Approved
2	Camtech COVID-19 rapid Antigen Test	Camtech Diagnostics	Singapore	Mittal Commercial	Kits in transit
3	COVID-19 N- Antigen rapid test	Agappe Diagnostics, Kochi	India	Agappe Diagnostics, Kochi	Kits in transit
4	COVID-19 Antigen Rapid Card Test	Bhat Bio-Tech India, Bangalore	India	Invex, India	Kits received on 03/07/2020
5	COVID-19 Ag Respi Strip	CorisBioconcept, Belgium	Belgium	Vishat Diagnostics Pvt. Ltd, Mumbai	Kits in transit
6	Biocredit COVID-19 Ag	Rapigen Inc	South Korea	Imperial Life Sciences, Gurgaon	Kits in transit
7	COVID-19 Ag FIA Card	J. Mitra & Co. Ltd	India	J. Mitra & Co. Ltd	Kits yet to be dispatched
8	COVID-19 Antigen Rapid Test	M/s Medsource Ozone Biomedicals Pvt. Ltd	India	M/s Medsource Ozone Biomedicals Pvt. Ltd	Kits in transit
9	Q-Line Rapid COVID-19 Rapid Antigen Test	POCT Services Pvt Ltd	India	POCT Services Pvt Ltd	Kits received on 04/07/2020
10	MAKESURE COVID- 19 ANTIGEN RAPID CARD	HLL Lifecare Ltd	India	HLL Lifecare Ltd	Kits received on 05/07/2020
11	V Strip COVID-19 Antigen rapid Test	Panion& BF Biotech, Taiwan	Taiwan	Tricell Biologics, Chennai	Kits yet to be dispatched
12	Formosa One Sure SARS-CoV-2 Ag Rapid Test Kit	Formosa Biomedical Technology Corp.	Taiwan	Intai Lifesciences LLP, India	Kits yet to be dispatched
13	ASPEN COVID Antigen Rapid Test	Aspen Laboratories	India	Aspen Laboratories, Delhi	Kits in transit
14	COVID FIA Antigen Test	SD Biosensor	South Korea / India	SD Biosensor	Kits received on 01/07/2020
15	COVSCAN Ag Rapid Test	NextGen Invitro Diagnostics Pvt Ltd	India	NextGen Invitro Diagnostics Pvt Ltd	Kits yet to be dispatched
16	GB QUIK Covid-19 Rapid Antigen test Kit	Genuine Biosystem Private Limited	India	Genuine Biosystem Private Limited	Response awaited
17	COVID-19 ANTIGEN Lateral Test Device	Lab-Care Diagnostics (India) Pvt. Ltd.	India	Lab-Care Diagnostics (India) Pvt. Ltd.	Response awaited

	GOVERNMENT OF MAHARASHTRA DIRECTORATE OF HEALTH SERVICES, Pune office, Pune		
Office	26124299	New Central Building, 1 st Floor, Pune 411 001.	
Personal	26125792 26122256	Website: arogya.maharashtra.gov.in E-mail Address: dhspune1@gmail.com jdsh@rediffmail.com	
<u>Health Services</u>	O/W No. COVID- 19 private lab Permission/ IgG and Rapid Ag / Date: 30.06.2020 28478-519		

To,

All the laboratories applying for conducting of Rapid Antigen Tests & IgG Antibody Tests.

Sub – Regarding Permission to private lab for COVID-19 testing by Rapid antigen Test. (Point of care test Poc) and IgG Antibody test (IgG test only for surveillance and not for diagnosis)

Ref – 1. ICMR Advisory for newer Additional Strategies for COVID-19 testing dated on 23.06.2020.
2. Medical Education & Drugs Department circular, dated 23-06-2020.

As per above reference and subject private labs in Maharashtra are applying for COVID-19 testing by Rapid antigen testing and IgG Antibody test to this office. Following guidelines need to be followed by all laboratories.

(I) For Standard Q Covid 19 Antigen Detection Test.

ICMR recommends deployment of the rapid antigen test in all private labs accredited by National Accreditation Board for Laboratories (NABL) and approved by ICMR as COVID-19 testing labs. For Rapid antigen all hospitals and labs need to register with ICMR to obtain the login credentials for data entry.

Interested Institutes may send their request on the following email id's

ag-pvthosp-nabh@icmr.gov.in

All laboratories should inform & report to the concerned District Civil Surgeons & for MCGM concerned EHO.

All data of testing needs to be entered into the ICMR portal on a real time basis. The ICMR portal has been modified to include a component on antigen testing. Detailed video is available on ICMR website at <http://www.icmr.gov.in/vedio/dataentry Antigen v4.mp4> and all labs/hospitals initiating testing through the rapid antigen test need to ensure that all

symptomatic negative patients should be essentially referred to a real time RT-PCR test for COVID-19.

(II) For IgG Antibody Test for Covid 19

IgG based ELISA and CILIA assays are recommended only for conducting sero-surveys ICMR is mandated to review and conduct research on the evolving trends of the disease and accordingly advice to share the comprehensive report of antibody testing with ICMR at the given email id mmurhekar@gmail.com. In addition to this, report should be sent on ssumaharashtra@gmail.com & also to the concerned District Civil Surgeons & EHO in MCGM.

All private labs need to refer & follow the guidelines given by ICMR along with Medical Education & Drugs Department circular which are attached here with.

Reporting format for Hospital / Lab Sero-surveillance of Antibody testing is attached herewith



Dr. Archana Patil
Director of health Services, Pune

Copy to-

1. United Diagnostics, Pimpale Gurav Pune.
2. Shraddha Pathology, Nigadi, Pune.
3. Saxena Lab, Shivajinagar, Pune.
4. Rohan Lab, Pandharpur, Dist Solapur.
5. Dr. Lal Pathlabs, Pune.
6. Doshi pathology Lab, Akluj, Solapur.
7. Mangal Lab, Baramati.

Copy for information-

1. Principal secretary, Health, Mumbai.
2. MD & Commissioner, NHM, Mumbai.

Copy for necessary action-

1. All District Civil Surgeons.
2. EHO, MCGM.

**Covid 19 Hospital / Laboratory Sero-surveillance Report
(IgG Antibody Test Report)**

Name of Hospital / Laboratory:

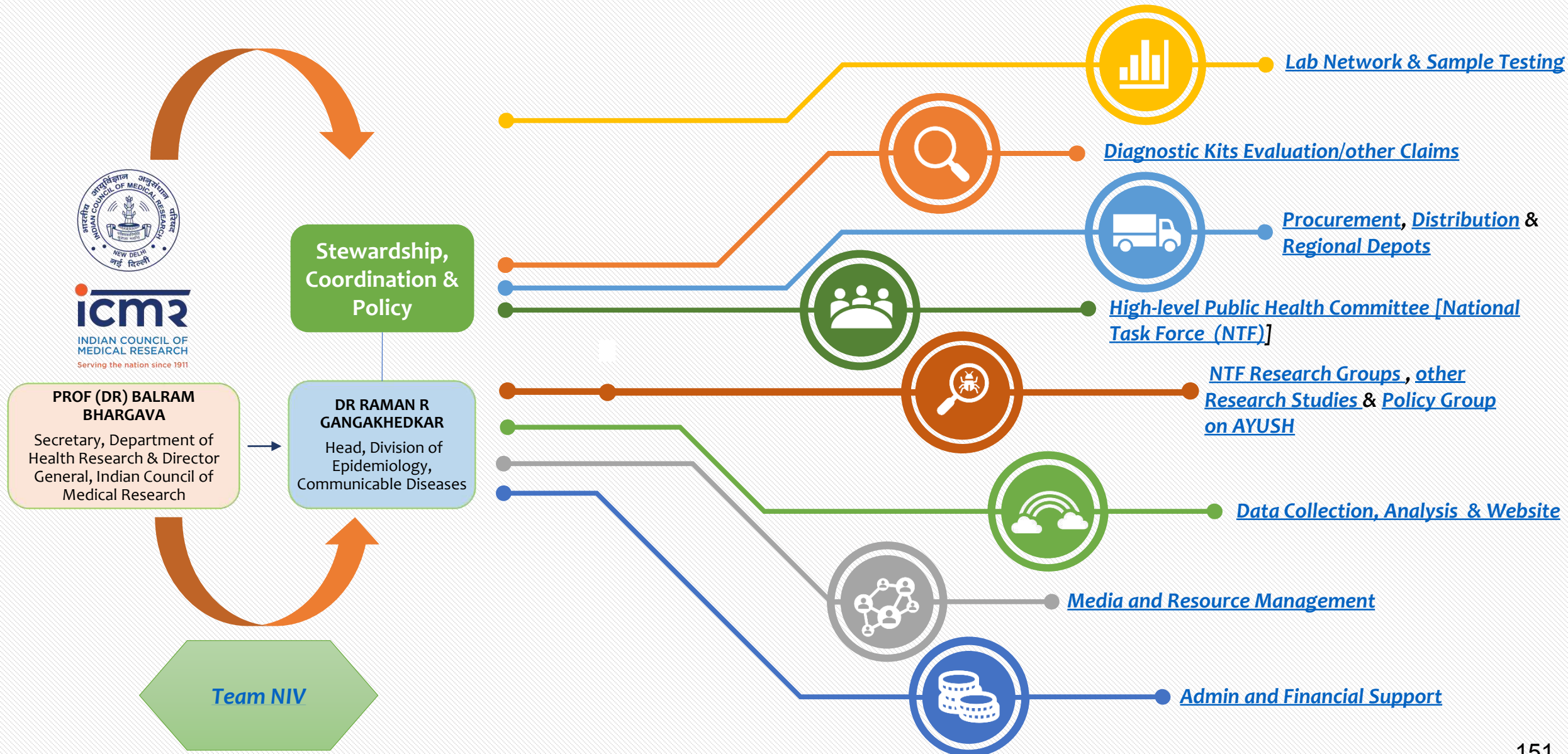
Address:

Phone no:

Date of Reporting:

SN	Name	Age	Sex	Address	Phone no	Occupation	In the last 30 days, did you have				Antibody testing		
							fever/cough/sore throat/breathlessness?	Fever	Shortness of Breath	Cough	Sore throat	Date	Result

ICMR Rapid Response Team for COVID-19



Lab Network & Sample Testing



Lab Network & Sample Testing

Dr. Nivedita Gupta
guptanivedita.hq@icmr.gov.in

Government Labs

Dr. Ira Praharaj
praharaj.ira@icmr.gov.in

Dr. Sidhartha Giri
sidhartha.g@icmr.gov.in

Dr. Jitendra Narayan
Scientist C, DHR-ICMR
jitendra.narayan@gov.in

Private Labs

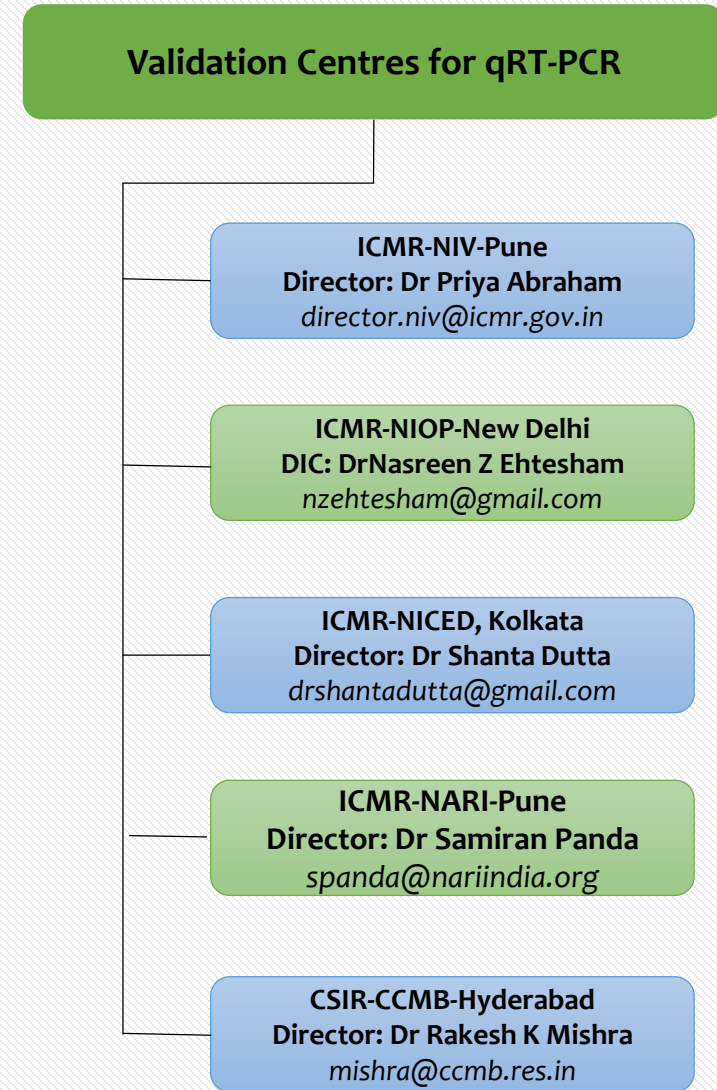
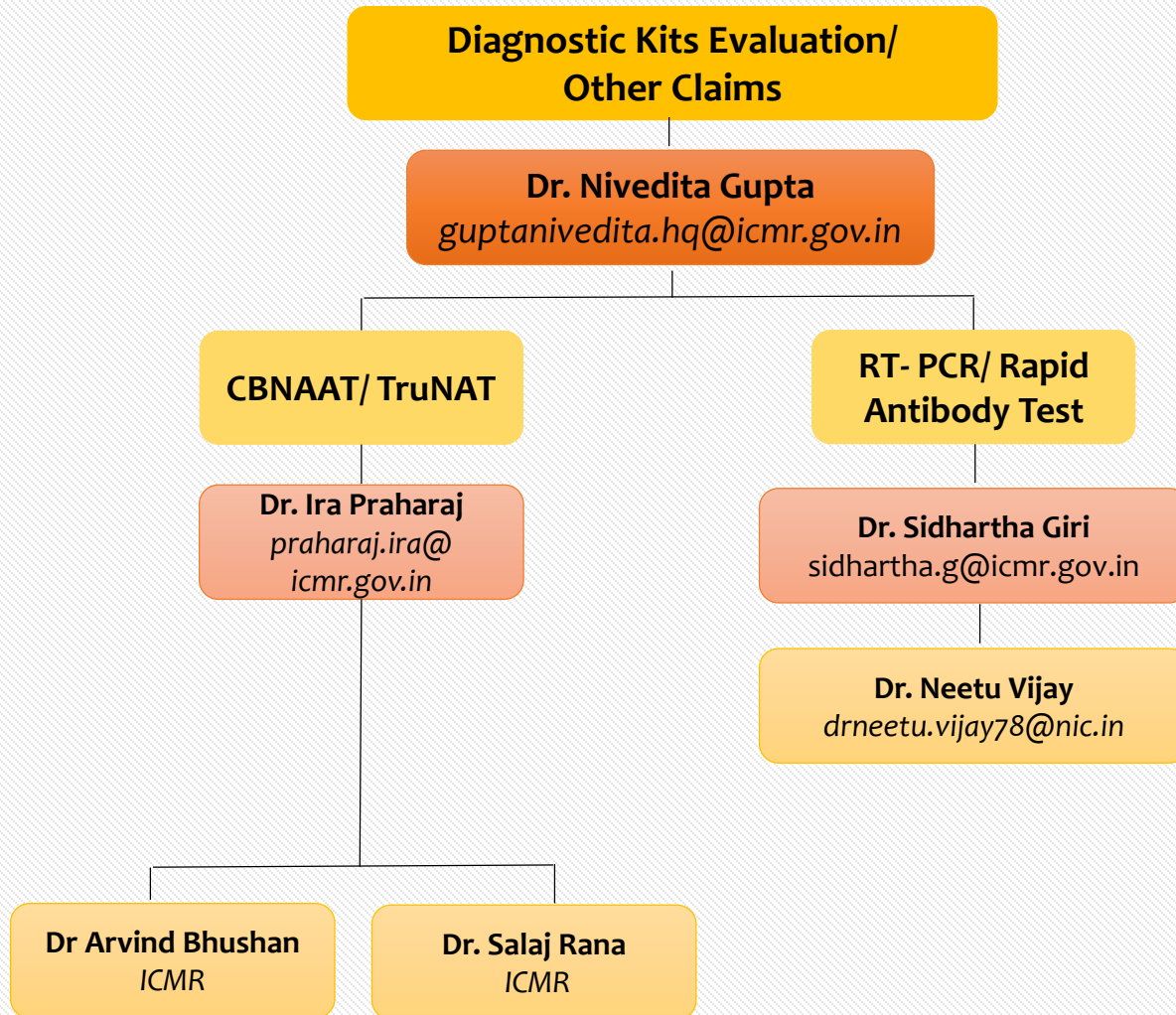
Dr. Neeraj Aggarwal
aggarwal.n@icmr.gov.in

Dr. Ginu Khan
Scientist C, ICMR

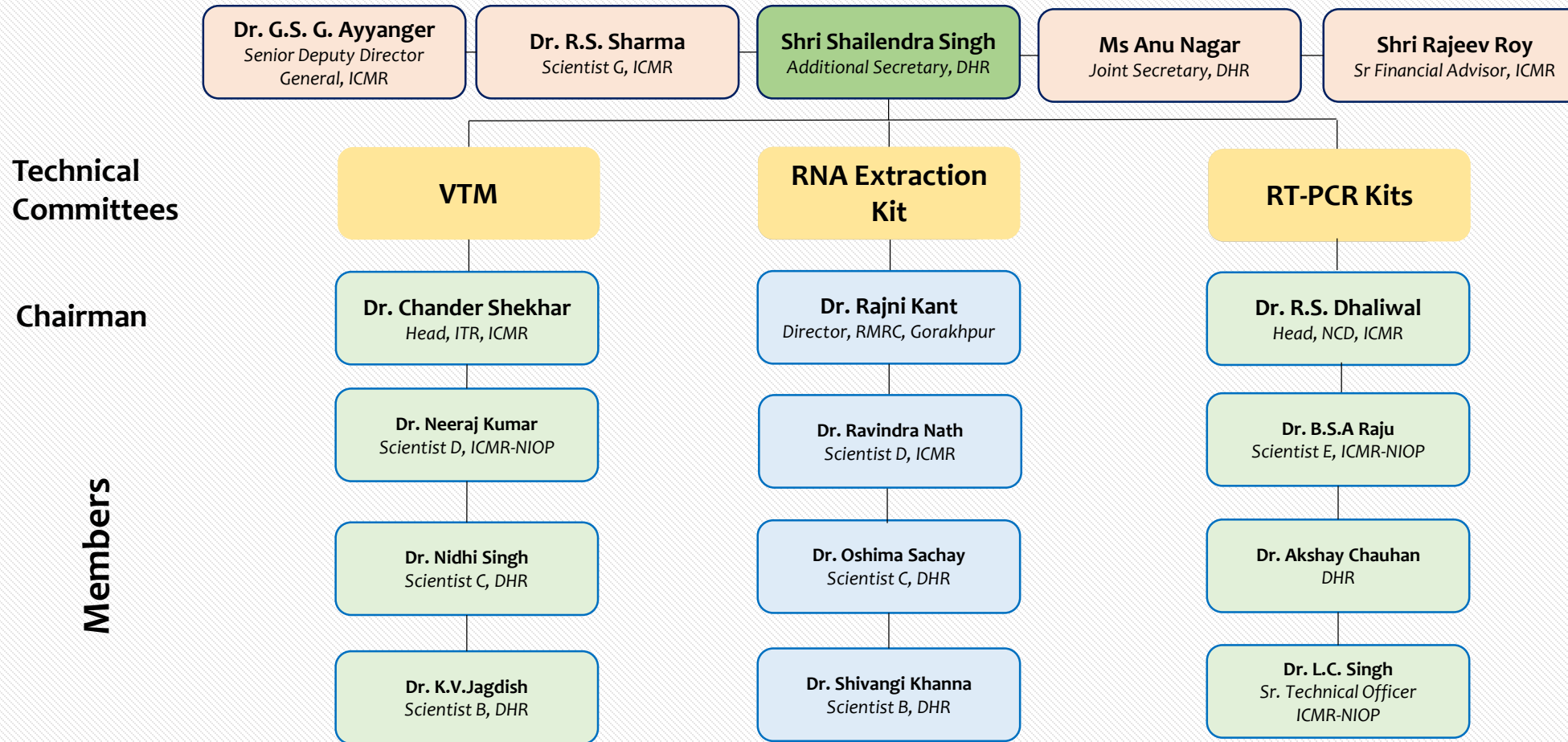
Dr. Deepak Mallick
Scientist B, ICMR



Diagnostic Kits Validation



Procurement



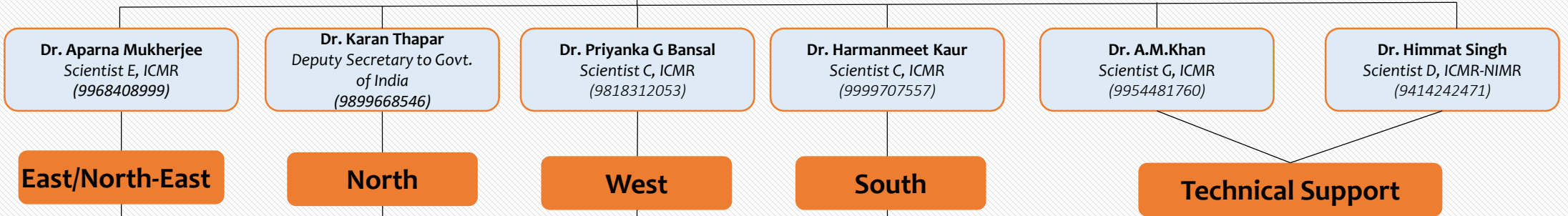
Distribution



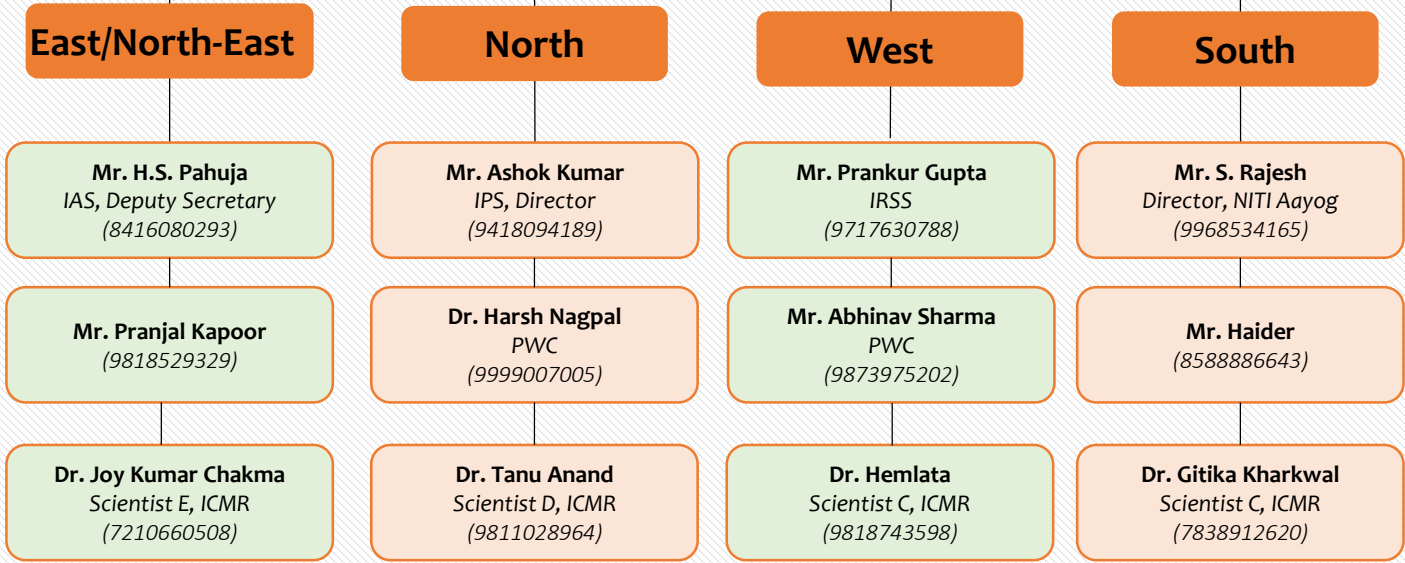
Dr. G.S. Toteja
Additional Director General,
ICMR
(9868388075)

National Nodal Officer

Central Team

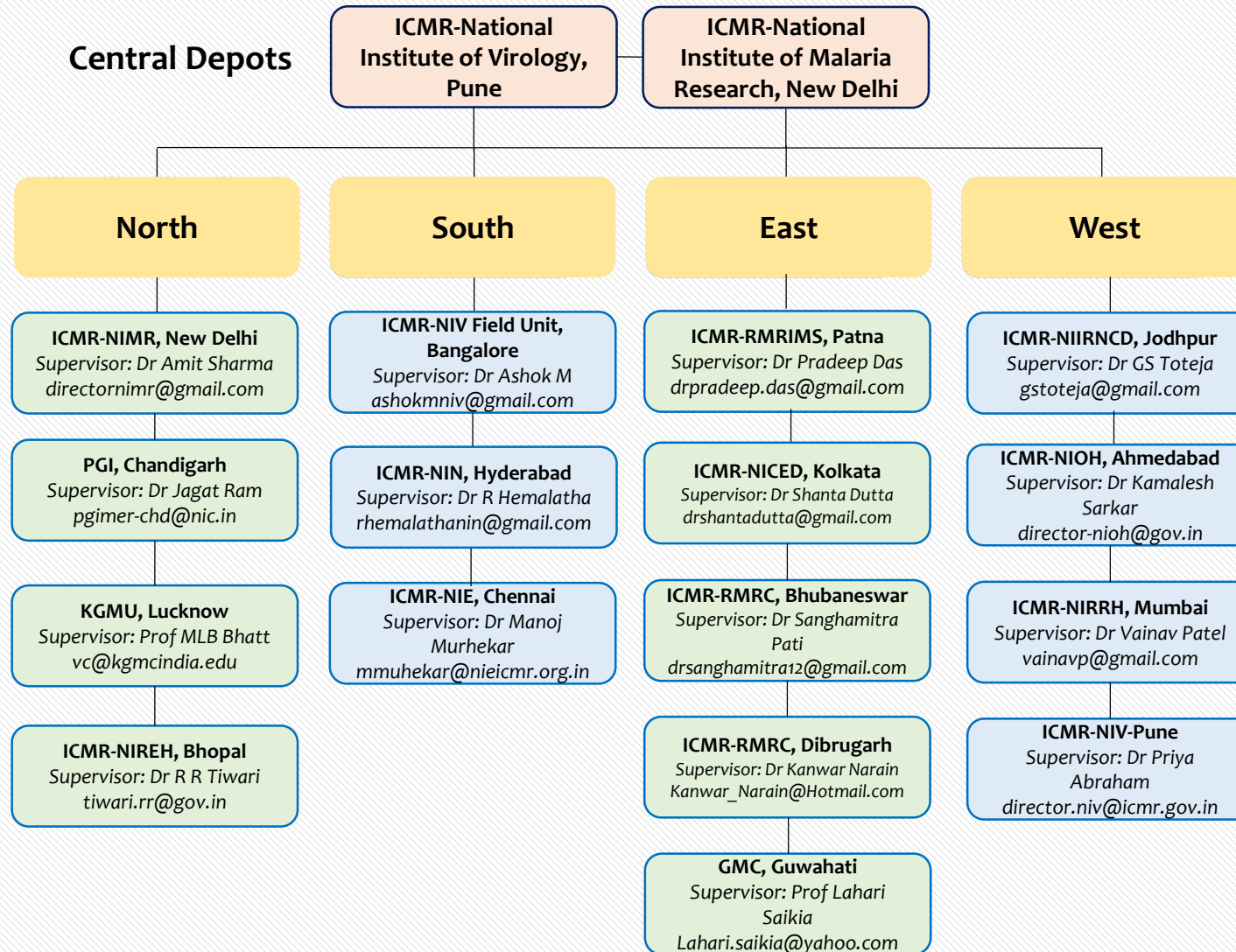


Regional Teams

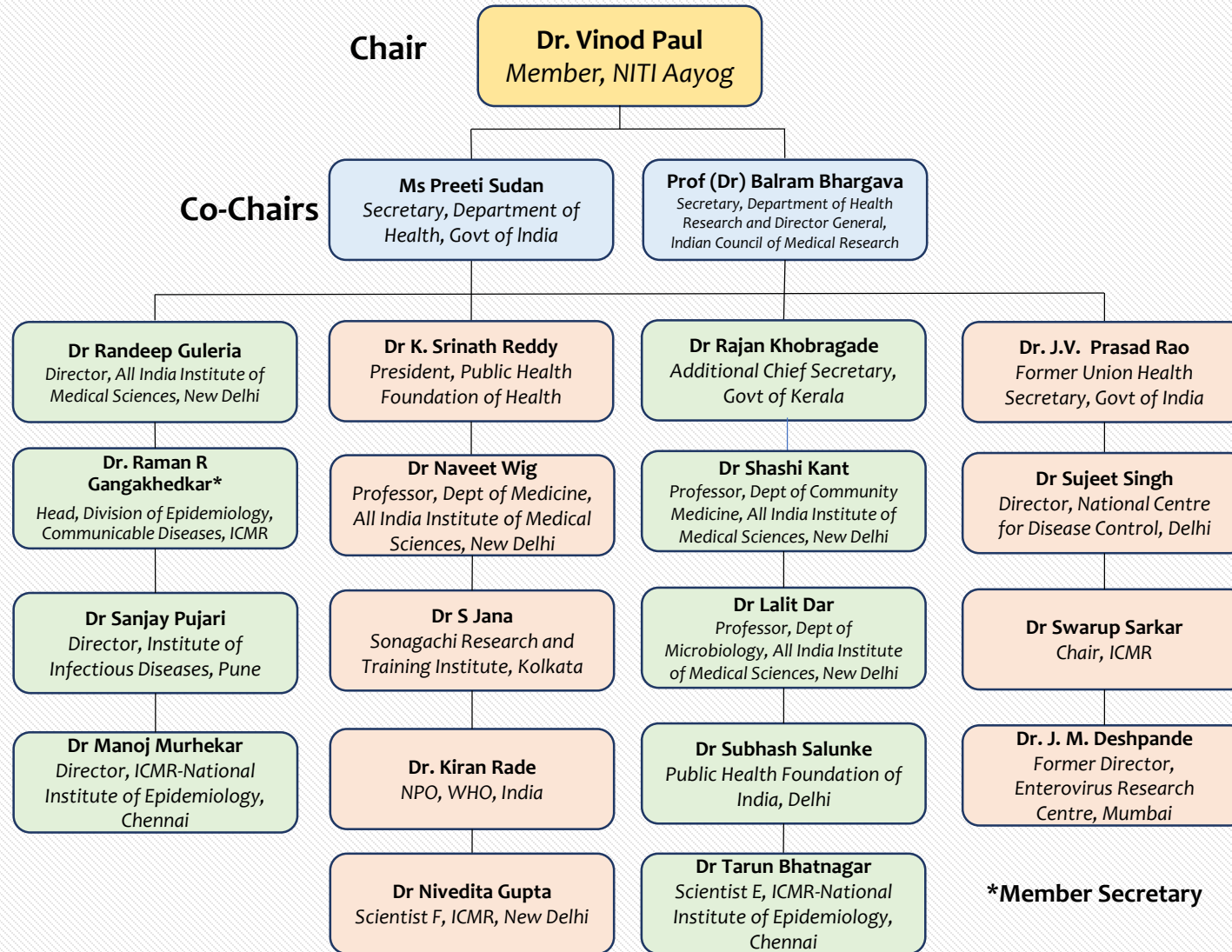


Distribution: Regional Depots

Regional Depots



High-level Technical Committee of Public Health Experts (National Task Force)



National Task Forces – Research Groups

Clinical Research

Dr Randeep Guleria*
AIIMS, New Delhi

Dr Naveet Wig
AIIMS, New Delhi

Dr RR Gangakhedkar
ICMR

Dr Sanjay Pujari
Institute of Infectious
Diseases, Pune

Dr OC Abraham
CMC Vellore

Dr Anup Aggarwal
ICMR

Dr Rajeev Soman
Hinduja

Dr Atul Patel
Infectious Diseases Clinic,
Ahmedabad

Dr N Kumarasamy
YRG

Dr DK Behra
PGIMER

Dr Padma Priyadarshini
ICMR-NIRT

Dr Pranab Chatterjee
ICMR

Diagnostics & biomarkers

Dr DA Gadkari*
NARI

Dr Jagdeesh Deshpande
ICMR

Dr Lalit Dar
AIIMS

Dr Priya Abraham
ICMR-NIV

Dr Pragya Yadav
ICMR-NIV

Dr Madhuri Thakar
ICMR-NARI

Dr Ira Praharaj
ICMR

Dr Amita Jain
KGMU

Dr Nivedita Gupta
ICMR

Dr Sandhya Kabra
NCDC

Dr Dinakar M Salunke
ICGEB

Dr Naveen Khanna
ICGEB

Dr Neeraj Aggarwal
ICMR

Epidemiology & Surveillance

Dr DCS Reddy*
BHU

Dr JP Muliylil
CMC

Dr Swarup Sarkar
ICMR

Dr Naman Shah
JSS

Dr Giridhara Babu
PHFI

Dr Manoj Murhekar
ICMR-NIE

Dr. Sidhartha Giri
ICMR

Dr Sujeet Singh
NCDC

Dr Shashi Kant
AIIMS

Dr RM Pandey
AIIMS

Dr Sanjay Zodpey
PHFI

Dr Kiran Rade
WHO India

Dr Tarun Bhatnagar
ICMR-NIE

Operations Research

Dr NK Arora*
INCLN

Dr Kiran Rade
WHO India

Dr Rajan Khobragade
Govt of Kerala

Dr Subhash Salunke
PHFI

Dr Shankar Prinja
PGIMER

Dr Ravi Varma
ICWA

Dr Beena Thomas
ICMR-NIRT

Dr Sanjay Chauhan
ICMR-NIRRH

Dr Sandip Mandal
ICMR

Dr Sanket Kulkarni
IDSP

Dr Arvind Pandey
ICMR

Dr Rakhal Gaitonde
SCTIMST

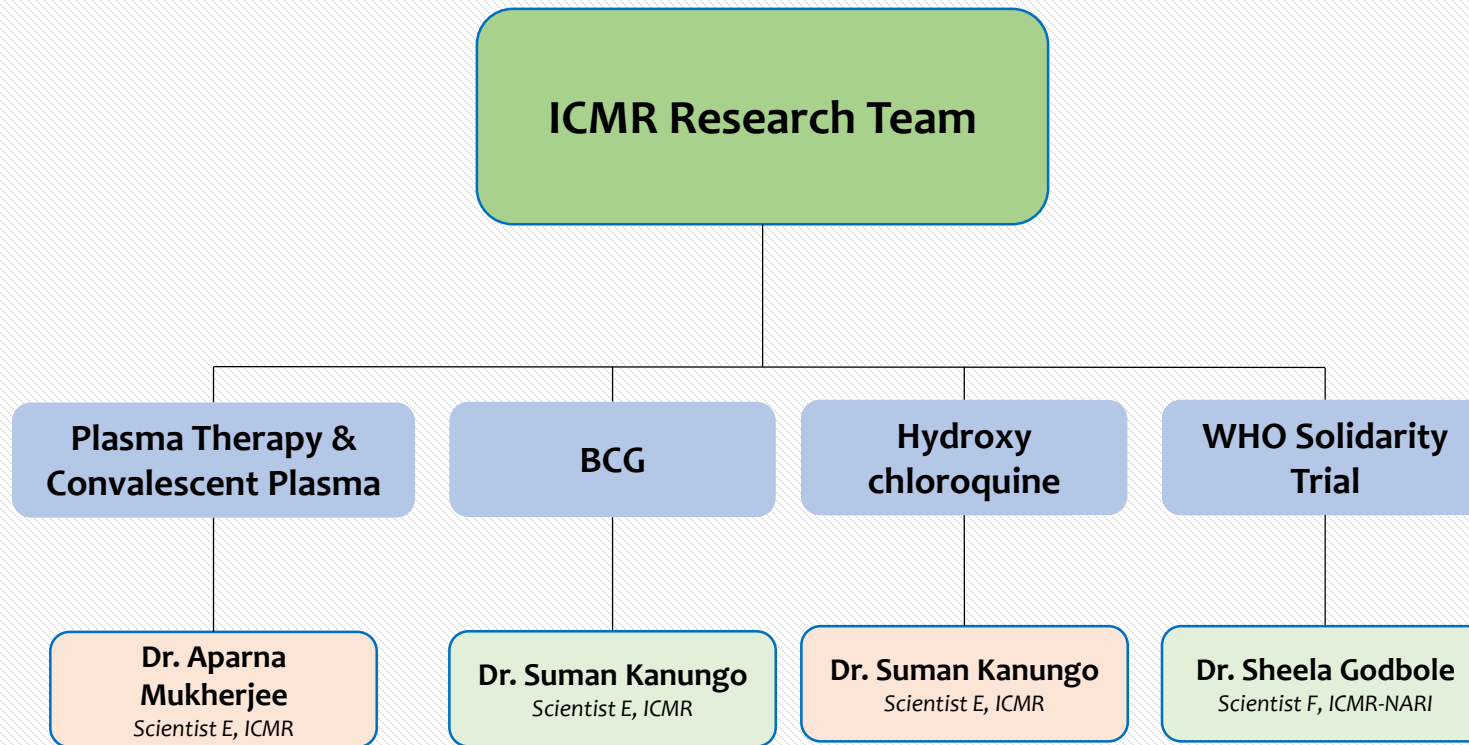
Dr Shalini Bharat
TISS

Dr JP Narayan
WHO

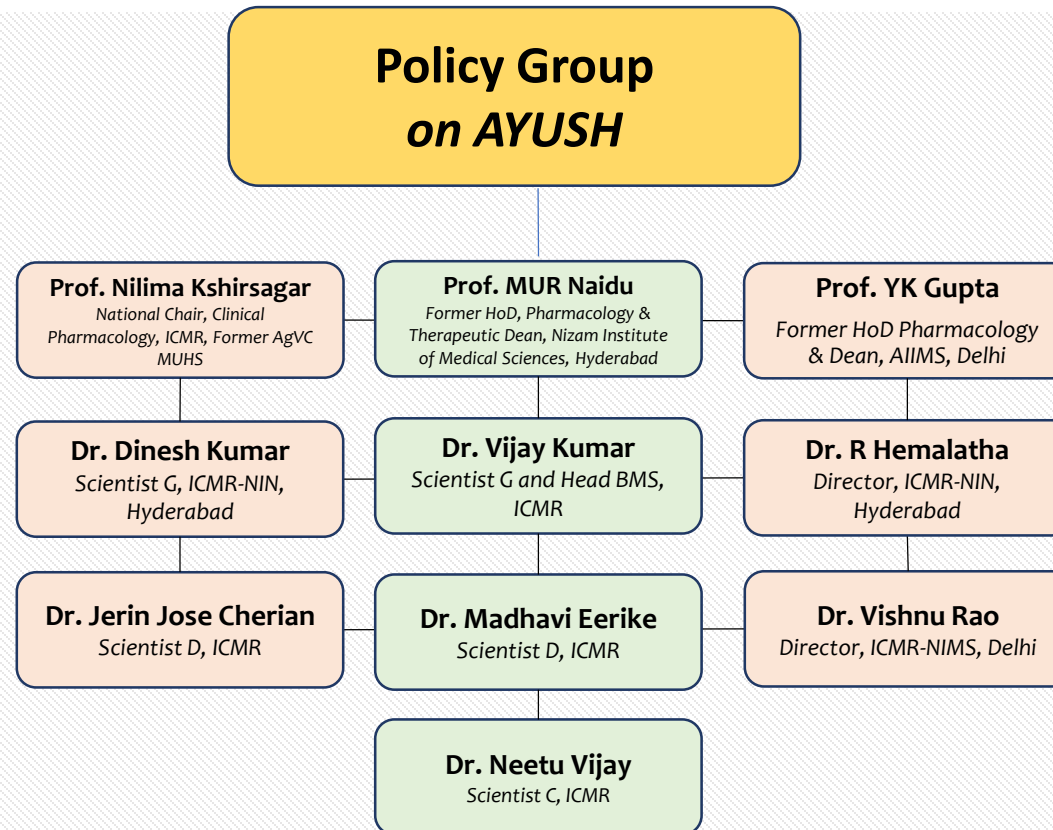
Dr Sumit Aggarwal
ICMR

*Chair

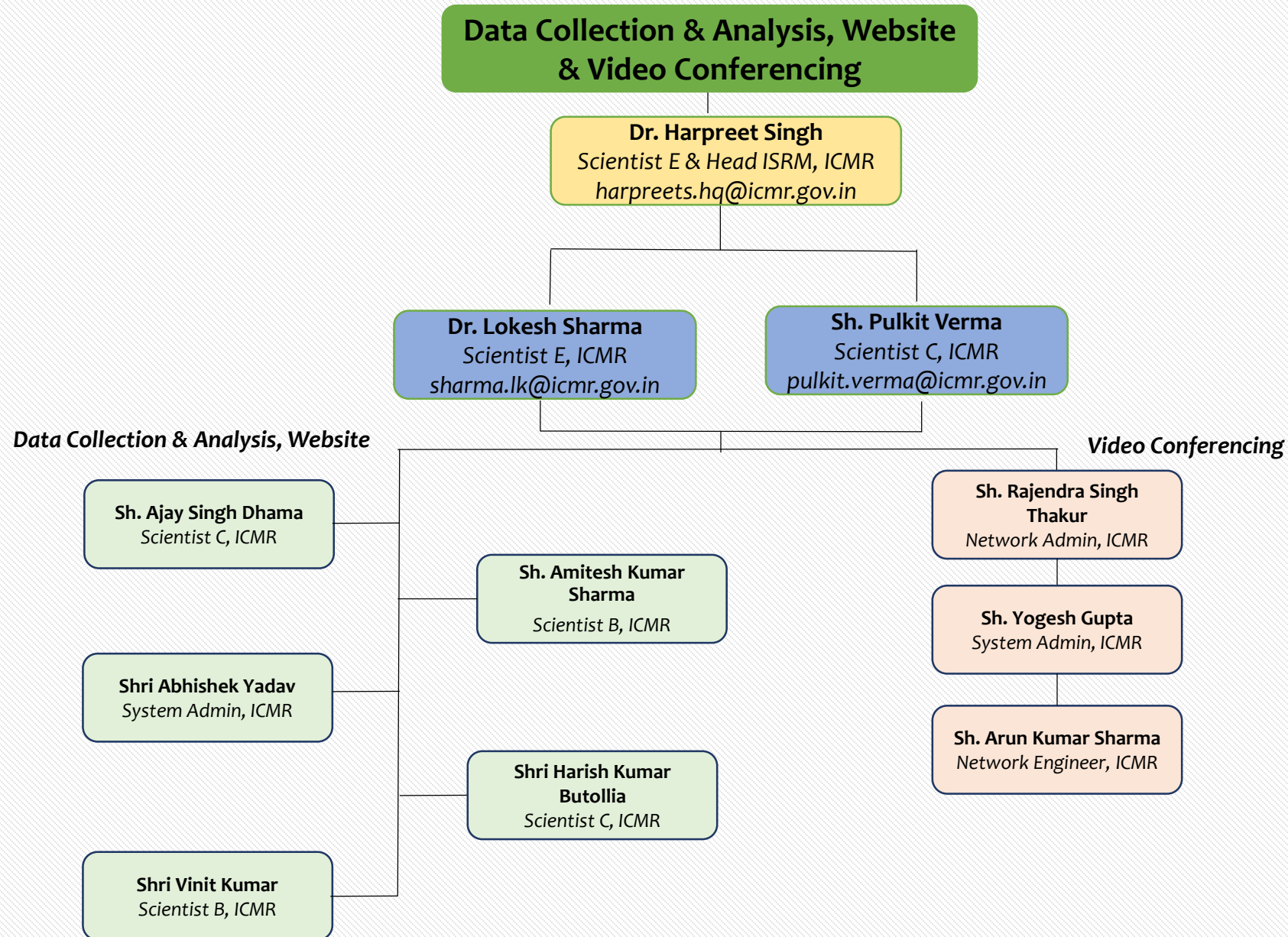
Multi-centric Therapeutic Research Studies



Policy Group on Ayurveda, Unani, Homeopathy, Siddha and Other Systems



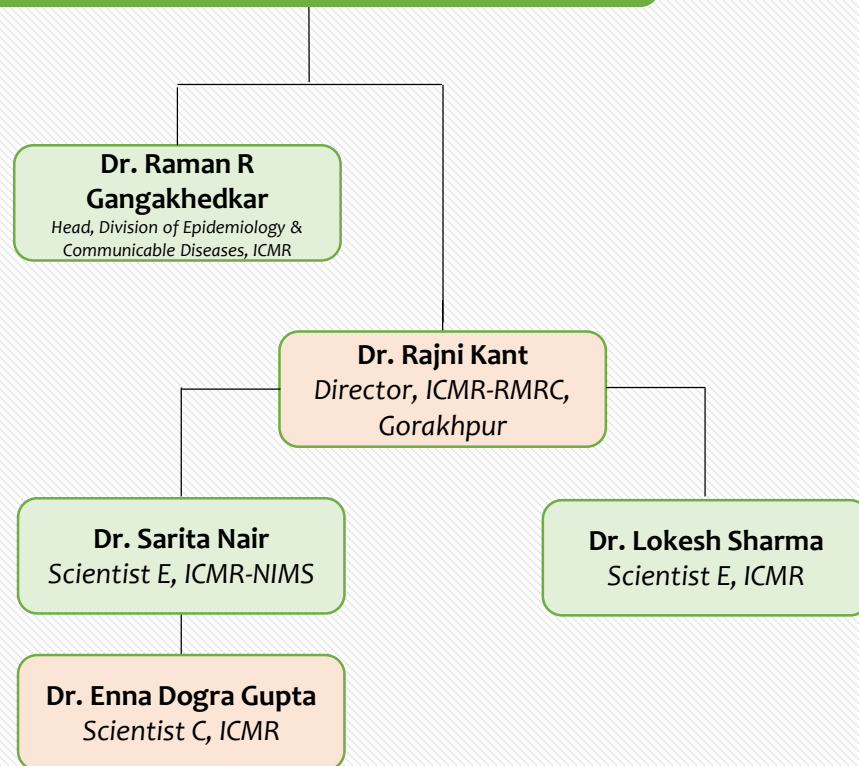
Data Collection & Analysis, Website & Video Conferencing



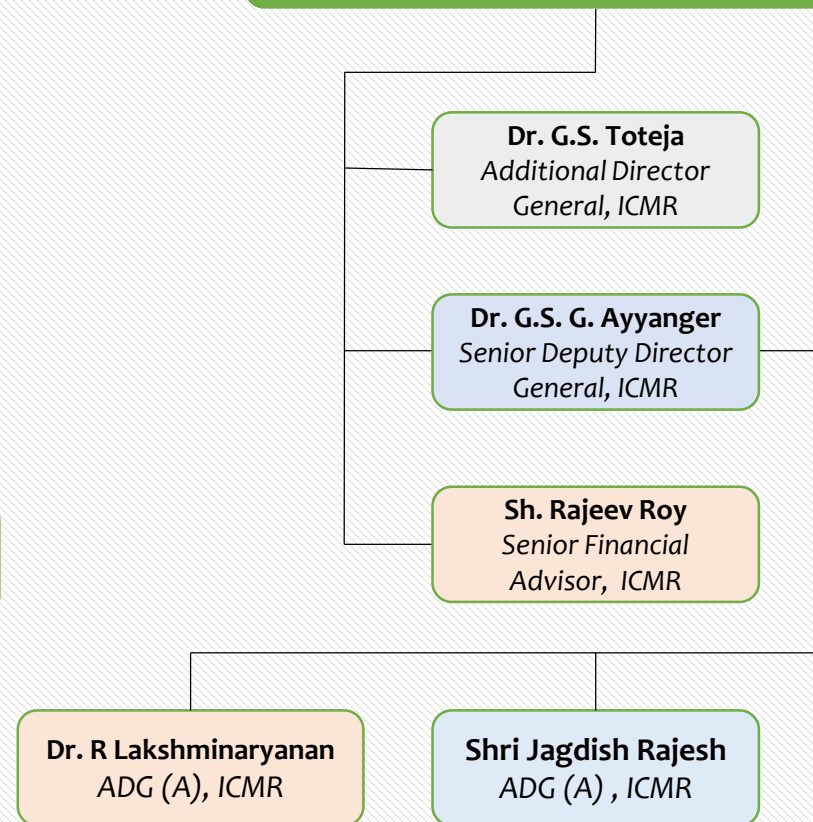
Media, Resource Management, Admin and Financial Support



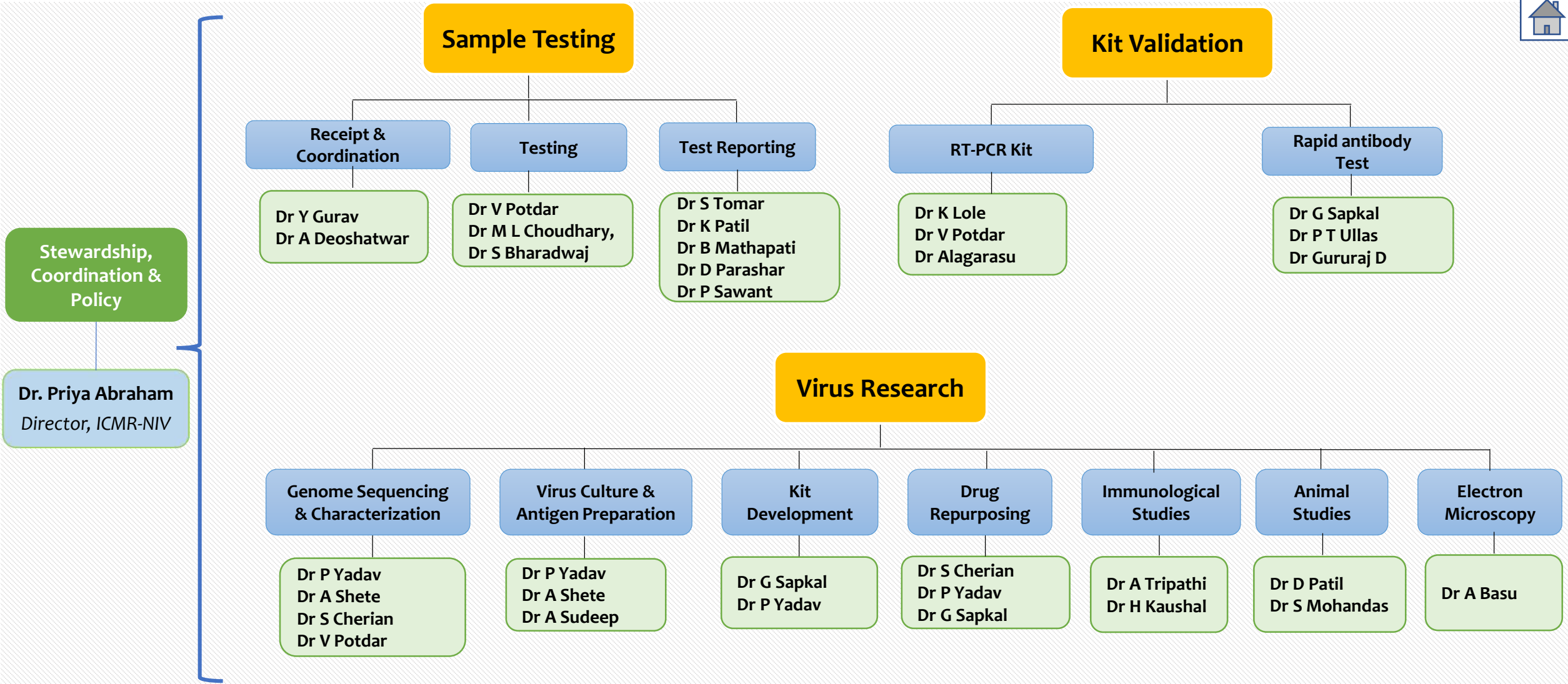
Media and Resource Management



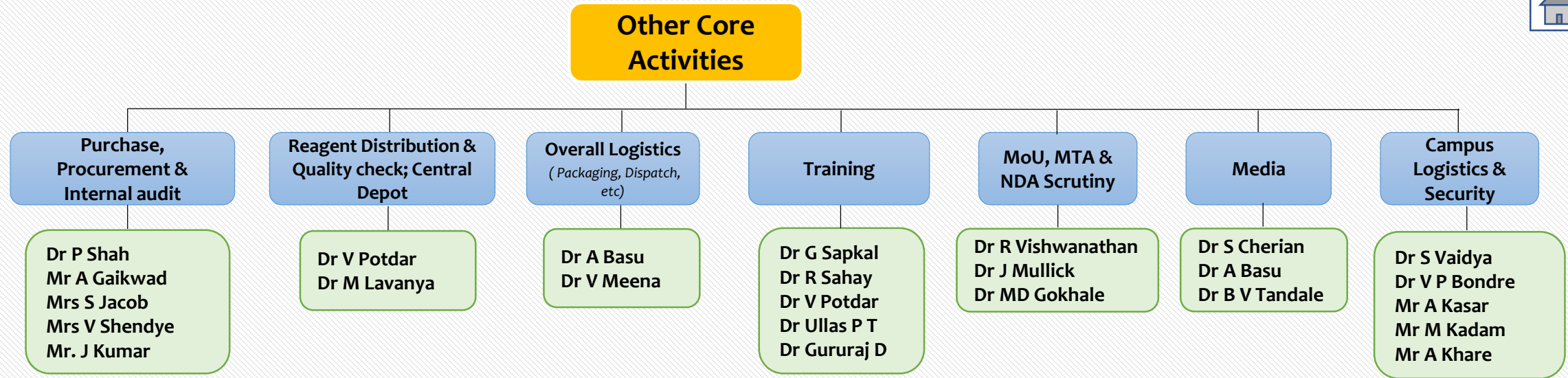
Admin and Financial Support



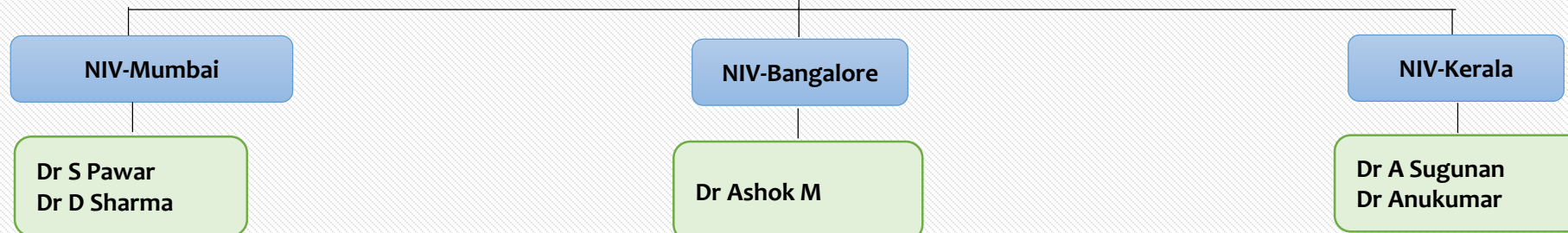
ICMR-NIV COVID-19 Response Teams



ICMR-NIV COVID-19 Response Teams (continued)



Testing at ICMR-NIV field units





सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNASc, FASc, FNA, DSc

Secretary to the Government of India

Department of Health Research

Ministry of Health & Family Welfare &

Director-General, ICMR

Subject: **National COVID-19 sero-survey**

Dear **Dr. Vyas**,

I thank you and officials from your administration for extending the support for completing the sero-survey to estimate the sero-prevalence SARS-CoV-2 infection in your state. We have completed the testing of sera samples collected from different districts. The result of IgG positivity by district is given below:

District	Number of samples tested	Number positive	Unweighted prevalence (%)
Bid	396	4	1.01
Parbhani	396	6	1.51
Nanded	393	5	1.27
Sangli	400	5	1.25
Ahmadnagar	404	5	1.23
Jalgaon	396	2	0.5

Testing of hotspot cities is still ongoing and we will share the results once testing is complete.

Thank you once again to you and officials from your administration for the support in the conduct of the sero-survey. We look forward to your continued support in the next round of sero-survey.

With regards,

Yours sincerely,

Balram Bhargava

(Balram Bhargava)

Dr. Pradeep Kumar Vyas

Principal Secretary,

Department of Health & Family Welfare,

Government of Maharashtra,

Mumbai – 400001, Maharashtra.

Copy to :

1. The Director, ICMR-National Institute of Virology, Pune
2. The Director, ICMR - National AIDS Research Institute, 73 'G' Block, MIDC, Bhosari, Pune 411026
3. The Director, ICMR-National Institute of Immunohaematology, Mumbai, Maharashtra
4. Dr SampadaBangar, Scientist D, National AIDS Research Institute
5. Dr AvinashDeoshatwar, ICMR-National Institute of Virology, Pune
6. Dr.Reetika Malik Yadav, Scientist B, ICMR National Institute of Immunohaematology (NIIH), Mumbai



सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएस, एफएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

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Secretary to the Government of India

Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR



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भारतीय आयुर्विज्ञान अनुसंधान परिषद

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

भारत सरकार

वी. रामलिंगस्वामी भवन, अंसारी नगर

नई दिल्ली - 110 029

Indian Council of Medical Research

Department of Health Research

Ministry of Health & Family Welfare

Government of India

V. Ramalingaswami Bhawan, Ansari Nagar

New Delhi - 110 029

DO.No.ECD/COVID19/Misc./2020

Dated 19th June 2020

Subject: Ramping up testing for COVID-19 in containment zones and hospitals.

Dear (Chief Secretaries of all states)

1. Real Time RT-PCR is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. However, in view of the specialized laboratory requirements, this test cannot be performed at every district level labs which do not have molecular virology facilities.
2. The TrueNat and CBNAAT systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges for COVID-19 diagnosis. These platforms have widespread availability even at district and PHC as these platforms are widely used for diagnosis of Tuberculosis as well as other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.
3. In an effort to ramp up the testing capacity, ICMR has approved a total of 960 labs in public and private sector. However, inspite of these developments in testing, there is an urgent need to introduce rapid point of care diagnostic tests to make testing widely available in all parts of the country.
4. Rapid antigen-based detection assays have been used successfully for early diagnosis of diseases like Malaria, Leishmania, viral and bacterial respiratory infections etc. Such tests can be used as point of care diagnostics in field settings and have minimal biosafety and biosecurity requirements. In view of this, ICMR had been exploring alternate quick and reliable options for diagnosis of COVID-19.

5. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay for quick diagnosis of SARS-CoV-2 developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. The assay is known as **Standard Q COVID-19 Ag kit**. On validation, the test has been found to have a very high specificity with moderate sensitivity. ICMR now also recommends use of Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020. In this regard, which may be accessed at: https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test_14062020.pdf. The advisory clearly delineates the recommended groups of individuals who should be tested using the antigen detection assay. Key points in the advisory are enclosed as Annexure 1 for your perusal.

6. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor. Contact details are as follows:

Dr. CS Bedi

Mobile No: +919810426069

Email: drbedi@icloud.com

ICMR has negotiated the price of the kit. The upper price cap negotiated by the Committee is Rs. 450/-.

For any technical assistance /clarifications, details of the ICMR contact point are given below:

Dr. Sidhartha Giri, Scientist E, ICMR

Mobile No: +918754617892

Email: sidhartha.g@icmr.gov.in


7. **Kindly note that in addition to the details of all the tests conducted by the RT-PCR, TrueNat, CBNAAT, results of Antigen detection assay also need to be entered into the existing ICMR data entry portal where a separate field has been incorporated to accommodate all testing data emerging through the rapid antigen test.**
8. In addition, vide earlier letter No. dated from Secy DHR & DG to all states, ICMR has advised states on use of IgG antibody assays for conducting serosurveys in asymptomatic frontline workers like healthcare workers, sanitation workers, security staff etc. for assessing their serostatus for COVID-19. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf. As the apex research organization of the country, ICMR is mandated to review and conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, I advise you to share all the antibody testing results with ICMR at the email id given below: mmurhekar@gmail.com.
9. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened. Therefore, it is advised that all the patients who are being tested by any of the above methods, may be requested to share one personal Identity, issued by Govt. of India to establish the authenticity of the individual. Also, it has been noted that the phone numbers shared by individuals at the time of testing are often

incorrect. Therefore, it is advisable that at the time of testing, a missed call should be given on the shared phone number to verify its correctness,

10. In view of this, I request you all to kindly take required steps to scale up the testing capacity in your respective state by adopting various available testing options, making testing available to all symptomatic individuals in your state. This will enable early detection and containment of infection which in turn would save several lives.

With regards,

Yours sincerely,


(Balram Bhargava)

Copy to:

1. Smt. Preeti Sudan, Secretary (HFW), MOHFW, New Delhi
2. Shri Rajesh Bhushan, OSD, MOHFW, New Delhi
3. All Health Secys of States / UTs

Key points to remember for use of COVID-19 quick antigen detection assay:

- Minimum time taken for RT-PCR test is 2-5 hours.
- Antigen detection test is a rapid point of care test and has no specialized laboratory requirements.
- One nasopharyngeal swab is to be collected and tested **onsite within one hour of sample collection.**
- Sample collection and testing is to be performed by a trained health care worker with proper PPE.
- Can be interpreted between 15 to 30 minutes with a naked eye.
- Kit needs to be stored between 2° to 30° C.

Rapid antigen detection test for COVID 19 can be used to test individuals in the following categories:

A. Containment zones or hotspots:

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. Healthcare settings:

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

Interpretation of the test:

Symptomatic Individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

Preeti Sudan

Secretary

Department of Health & Family Welfare
Ministry of Health & Family Welfare



Government Of India

Prof. (Dr.) Balram Bhargava

Secretary

Department of Health Research &
Director General ICMR
Ministry of Health & Family Welfare

Dated: July 01, 2020

**Empowering citizens for testing of SARS-CoV-2 virus
to save precious lives and contain the virus**

**Dear Chief Secretary/ Administrator
Adviser to Governor/Advisor to Lt. Governor**

1. At the outset, I would like to compliment you and your team for the immense efforts being made to contain the SARS-CoV-2 virus and save the lives of people during this pandemic. While morbidity and mortality have been relatively low in most parts of the country, as compared to many other countries in the world, the virus has been spreading to newer areas. In this backdrop, it is important to maintain strict vigil and continue to make all possible efforts to minimize the damage that can be caused by this pandemic. With the start of Unlock-2, focus will continue to be on saving lives and also protecting livelihood as more and more economic activities are expected to pick up gradually.
2. Since 'test-track-treat' is the key strategy for early detection and containment of the pandemic, it is important to augment testing for SARS-CoV-2 in all parts of the country. This is the only way to detect the infection early and prevent its spread. To ramp up testing in the country, ICMR has so far approved a total of 1,049 public and private laboratories for COVID-19 testing. Of this, 761 labs are in public sector and 288 are in private sector. Further, ICMR has also recommended use of a rapid point-of-care antigen test kit for diagnosis and more such kits are being validated to increase the available options to the citizens.
3. However, it has been observed that in some States/ UTs, the capacity utilization of the testing labs particularly the ones in private sector, is grossly sub-optimal. It is strongly advised that you should take all possible steps to ensure full capacity utilization of all COVID-19 testing laboratories in the State/ UT.
4. It has also been observed that some States/ UTs have mandated the need of a prescription from a Government doctor for making an individual eligible to undergo COVID-19 test. In view of the increased load on government healthcare facilities, this mandatory requirement may at times pose an impediment for an individual to get tested and lead to unnecessary delays. At this juncture, it is absolutely necessary to facilitate testing at the earliest by enabling all qualified medical practitioners including private practitioners to prescribe COVID test to any individual fulfilling the criteria for testing as per ICMR guidelines. In fact, ICMR strongly recommends that laboratories should be free to test any individual in accordance to the ICMR guidelines and State authorities must not restrict an individual from getting tested, as early testing will help in containing the virus and saving lives.

5. I would like to draw your attention towards the available modalities for testing. While RT-PCR is the gold standard for diagnosis of COVID-19, ICMR has recently approved the use of a point-of-care rapid antigen test for early detection of COVID-19. The test is quick, simple, safe and can be used as a point-of-care test in containment zones as well as hospitals, as per criteria specified by ICMR for testing. Detailed information can be accessed at:

i) https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf

ii) https://www.icmr.gov.in/pdf/covid/strategy/New_additional_Advisory_23062020_2.pdf

6. In view of the above, it is requested that impediments, which restrict testing may be removed forthwith. Further, to facilitate testing:

i.) Efforts should be made in 'campaign mode' by setting up camps/ using mobiles vans in high incidence areas to collect samples of all symptomatic individuals as well as their contacts, and get those samples tested by using rapid antigen tests. The positive individuals should be treated according to the treatment protocol and the negative ones should be tested for RT-PCR;

ii.) The rate for RT-PCR test by private labs should be finalized.

iii.) It should be mandatory for all labs to upload the testing data on the ICMR database as well as report to State/ District/ City authorities for surveillance and contact tracing.

7. I am sure while you will take immediate steps to facilitate and ramp up testing in your state, it is expected that equal attention will be paid to 'contact tracing' as it holds the key to containing the virus. It has been observed that in some states, delineation of containment zones and contact tracing has not been undertaken with the rigour and meticulousness that is required. You may like to review this aspect at the earliest and take necessary corrective measures.

With regards

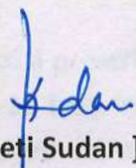
Yours sincerely



[Dr. Balram Bhargava]

Secretary

D/o Health Research and DG, ICMR



[Preeti Sudan]

Secretary

D/o Health and Family Welfare



डॉ. जी. एस. टोटेजा
अपर महानिदेशक
Dr. G. S. Toteja
Additional Director General

भारतीय आयुर्विज्ञान अनुसंधान परिषद्
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर नई दिल्ली-110029

Indian Council of Medical Research
Department of Health Research
Ministry of Health & Family Welfare, Govt. of India
V. Ramalingaswami Bhawan, Ansari Nagar, New Delhi - 110029

D.O.No.ECD/COVID19/Misc./2020
3rd July, 2020

Sub: Regarding expedited approval of TrueNat / CBNAAT for COVID-19 testing in private labs /hospitals

Dear Sir/Madam,

This is in continuation to the earlier letter dated 1st July 2020, requesting you all to ramp up testing for COVID-19 in your state.

1. So far, ICMR has included a mandatory criterion for obtaining NABL accreditation for all COVID-19 testing private laboratories including those with TrueNat/CBNAAT platform. This is primarily to ensure high quality testing and ensure correct interpretation of test results. Many of the labs are doing this test for the first time. In view of this, it is prudent to comply with NABL norms and obtain accreditation of private labs. This will also help in improving the overall quality of private labs in your state.

2. I also wish to emphasize that in the backdrop of the COVID crisis, NABL has established expedited approval mechanisms with fast-track approvals being granted within 7 days. However, the need to augment testing for COVID-19 in the current situation is well understood. ICMR is committed to support all states in ramping up testing. In view of this, **all private laboratories in your state who intend to initiate TrueNat/CBNAAT based testing for COVID-19 should be encouraged to immediately apply for NABL accreditation. All the labs who have applied can reach out to ICMR (at aggarwal.n@icmr.gov.in) with a copy of their NABL application**, ICMR will provide expedited approval for TrueNat/CBNAAT subject to NABL approval, which can be submitted within a maximum time span of four weeks from the date of approval.

3. I request you direct the concerned private labs / hospitals in your state who intend to initiate COVID testing using TrueNat/CBNAAT, to adopt the above mechanism for obtaining approval for COVID testing from ICMR. This will further enable you to ramp up testing in your state with immediate effect.

With regards,

Yours sincerely,


(Dr.G.S.Toteja)

All Chief Secretaries (States)/Addl.Chief Secretaries/Secretaries/Commissioners/Principal Secretaries (Health & Family Welfare)

CC:

1. Ms. Preeti Sudan, Secretary, Health & F.W., Nirman Bhawan, New Delhi.
2. Shri Rajesh Bhushan, OSD, Ministry of Health & F.W., Nirman Bhawan, New Delhi.

**Fixation of rate for conducting
RtPCR Covid-19 test in NABL &
ICMR approved private laboratories**

GOVERNMENT OF MAHARASHTRA

Public Health Department,
G.T. Hospital Compound, 10th Floor,
Mantralaya, Mumbai-400 001

No. Corona-2020/C.R.123/Arogya-5, Date: 13 June, 2020.

- Ref: 1) ICMR's D.O letter No. ECD/COVID-19/MISC/2020, dated 25.05.2020
2) Public Health Department, GOM, Government Resolution No. Corona-2020/C.R.123/Arogya-5, dated 02.06.2020

ORDER

The Covid-19 pandemic not only presents a public health Crisis but also imposes a great financial hardship on most of the vulnerable population. Presently in Maharashtra there are 53 Government laboratories which are mostly in the Medical colleges, State Government Hospitals and institutions and 43 private laboratories which are NABL accredited and approved by ICMR for testing the samples for Covid-19. As per ICMR circular issued on 17th March, 2020, RtPCR testing for Covid-19 was made available through private laboratories and upper limit of single test charge was capped at Rs 4500/-. Meanwhile RtPCR testing kits are now being manufactured in India and are readily available and hence ICMR vide letter dated 25th May, 2020 has communicated to States to negotiate and fix mutually agreeable price for RtPCR tests for Covid-19.

2. Hence vide Government resolution dated 2nd June, 2020 a committee was constituted to fix the rate for RtPCR test in the State of Maharashtra for Covid-19 to be done in the private laboratories. The committee discussed the issue with private laboratories and submitted its report to the Government. Based on the report State Government exercising the powers bestowed under the Epidemic Act, 1897 directs that no private laboratory should charge any amount more than indicated below for RtPCR test for Covid-19 in the State of Maharashtra.

Sr No.	Particulars	Rates per test (in Rs.)
1	Pickup of sample from collection site, Transportation and Reporting (including all charges)	2200/-
2	Collection of sample from patient's residence / Health care facility, Transportation & Reporting (including all charges)	2800/-

- i. All the testing protocols as laid down by ICMR and the Government of India from Time to Time shall be followed by the Private laboratories.
- ii. The Private Laboratories shall share the data pertaining to the results of these tests for Covid-19 with state Government and ICMR on a real time basis through ICMR portal (cvanalytics). Any violation of the same shall lead to suspension or cancellation of permission to carryout RtPCR Tests.
- iii. All the private NABL & ICMR approved Labs are instructed that, information of the patients should be maintained with utmost confidentiality. All the private Covid-19 testing labs must preserve the RtPCR machine generated data and graphs for future verification by the State Government. The labs are also instructed to display the rates in visible manner.
- iv. The management of approved private lab should appoint a Nodal Officer from their side and submit their details to the concerned Municipal Commissioner and/or district Collectors.
- v. Municipal Commissioner & District Collectors should develop mechanism to collect the samples of the eligible person as per the prevalent testing criteria and also should appoint a Nodal Officer for smooth operation
- vi. Concerned authorities (if applicable in case of certain Municipal Corporation/ Districts) shall expedite processing of the pending bills of private laboratories.
- vii. All the private NABL & ICMR approved labs, in the state are directed to follow the above guidelines scrupulously.
- viii. All the District collectors and Municipal commissioners in the state shall monitor the above labs closely, enforce the rates strictly by giving wide publicity on the issue of Covid-19 tests by the Private NABL & ICMR approved labs in the state.
- ix. The new revised rates would be effective from 14th June, 2020.

By Order and in the Name of the Governor of Maharashtra


Dr. Pradeep Vyas
Principal Secretary

Copy to:

Chief Secretary, Government of Maharashtra.
Additional Chief Secretary to Chief Minister, Government of Maharashtra.
Secretary to Dy. Chief Minister, Government of Maharashtra
Private Secretary to Health Minister, Government of Maharashtra
Secretary, Department of Medical Education and Drugs, Ministry, Mumbai
Commissioner, Health Services and Director, National Health Mission, Mumbai
District Collector (All)
Municipal Commissioner (All)
Chief Executive Officer, Zilla Parishad (All)
Director, Health Services, Mumbai and Pune

SARS-COV-2 चे अँन्टीजेन निदानासाठी
Standard Q Covid-19 Ag detection
kit वापराबाबत.

महाराष्ट्र शासन
सार्वजनिक आरोग्य विभाग
गो. ते. रुग्णालय संकुल इमारत,
१० वा मजला, मंत्रालय, मुंबई ४०० ००१.
शासन निर्णय क्र. कोरोना-२०२०/प्र.क्र.१७३/आरोग्य- ५
दिनांक: २२ जून, २०२०

संदर्भ :-

- १) उपरोक्त विषयाच्या अनुषंगाने आयसीएमआरच्या दिनांक १४.०६.२०२० व दिनांक १९.०६.२०२०च्या मार्गदर्शक सूचना.

प्रस्तावना :-

कोविड-१९ बाधेसाठी सद्यःस्थितीत आर.टी.पी.सी.आर. ही एकमेव निदान चाचणी आहे. या चाचणीसाठी आर.टी.पी.सी.आर. मशीनरी/ट्रुनॅट/सी.बी.नॅट यांच्याद्वारे चाचण्या केल्या जातात. आर.टी.पी.सी.आर. चाचणीसाठी लागणारा वेळ तसेच सी.बी.नॅटद्वारे तपासणीसाठी एका वेळी केवळ एक ते चार मर्यादेत होणाऱ्या तपासण्या तसेच कार्टीज ची अनुपलब्धता व जास्तीची किंमत ही या चाचण्यांबाबतची उणे बाजू आहेत. कोविड बाधेची निश्चिती लवकरात लवकर होण्यासाठी अनेक प्रयोगशाळांमध्ये संशोधन सुरु आहे. आता आय.सी.एम.आर. ने तपासणीअंती Standard Q Covid-19 Ag detection kit द्वारे SARS-COV-2 चे अँन्टीजेन निदान होत असल्याचे खातरजमा केलेली आहे. या टेस्टमुळे निगेटिव्ह निदान करण्याचे प्रमाण ९९.३ ते १०० टक्के आहे. तर पॉझिटिव्ह निदान चे प्रमाण ५०.६ ते ८४ टक्के (रुग्णाच्या शरीरातील व्हायरल लोड नुसार) आहे. त्यामुळे अत्यंत तातडीच्या प्रसंगी ही किट वापरून निदान करता येणे शक्य असल्याने कोविड-१९ साठी रॅपिड अँन्टीजेन टेस्ट करण्यास आय.सी.एम.आर सह ऑल इंडीया इन्स्टीटयुट ऑफ मेडीकल सायन्सनेही तपासणीअंती SD Biosensor या एकमेव कंपनीच्या Standard Q Covid-19 Ag detection kit किटला मान्यता दिलेली आहे.

या टेस्टचा वापर कॅन्टॅमेंट झोन/हॉटस्पॉटमध्ये वैद्यकीय अधिकाऱ्यांच्या मार्गदर्शनाखाली करता येणे शक्य आहे.

फ्ल्यू सदृश्य लक्षणे असलेल्या तसेच अतिजोखमीच्या व्यक्तीच्या संपर्कातील लक्षणे नसलेल्या व इतर हृदय विकार/फुफ्फुस/यकृत/मुत्रपिंड विकार/मधुमेह तसेच रक्तदाब इ. विकार असलेल्या त्याचप्रमाणे केमो थेरेपी, एचआयव्ही पॉजीटिव्ह, अवयव प्रत्यारोपण केलेले

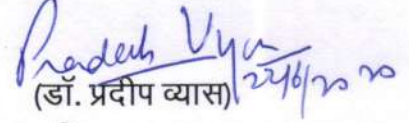
किंवा वयोवृद्ध व्यक्तींवर तसेच गरोदर महिलांवर तातडीने उपचारासाठी/रुग्णालयामध्ये आंतररुग्ण भरतीसाठी तातडीची चाचणी म्हणून या रॅपीड अँटीजेन टेस्ट चा उपयोग करणे शक्य आहे. ही चाचणी रुग्ण असलेल्या जागेवर, निदानासाठी स्त्राव घेतल्यानंतर एक तासाच्या आत व वैद्यकीय अधिकाऱ्याच्या निरीक्षणाखालीच करणे शक्य असल्याचे आसीएमआर ने त्यांच्या मार्गदर्शिकेमध्ये नमूद केलेले आहे. या चाचणीचे निदान केवळ १५ व जास्तीत जास्त ३० मिनिटात होत असल्याने कोणत्याही बाह्य उपकरणांशिवाय नुसत्या डोळ्याने करता येणे शक्य आहे. या बाबी लक्षात घेता राज्यात कॅन्टॅमेंट झोन/हॉटस्पॉट/शासकीय रुग्णालये/शासकीय वैद्यकीय महाविद्यालय संलग्न रुग्णालयांमध्ये तातडीच्या उपचारांची आवश्यकता असलेल्या रुग्णांसाठी रॅपीड अँटीजेन टेस्ट चा उपयोग करण्याची बाब शासनाच्या विचाराधीन होती. यास्तव खालीलप्रमाणे निर्णय घेण्यात येत आहे.

शासन निर्णय :-

- १) फ्ल्यू सदृश्य लक्षणे असलेल्या तसेच अतिजोखमीच्या व्यक्तीच्या संपर्कातील लक्षणे नसलेल्या व इतर हृदय विकार/फुफ्फुस/यकृत/मुत्रपिंड विकार/मधुमेह तसेच रक्तदाब इ. विकार असलेल्या त्याचप्रमाणे केमो थेरपी, एचआयव्ही पॉजीटीव्ह, अवयव प्रत्यारोपण केलेले किंवा वयोवृद्ध व्यक्तींवर तसेच गरोदर महिलांवर तातडीने उपचारासाठी/रुग्णालयामध्ये आंतररुग्ण भरतीसाठी तातडीची चाचणी करण्यासाठी SD Biosensor या कंपनीच्या Standard Q Covid-19 Ag detection kit द्वारे तपासणी करण्यास मान्यता देण्यात येत आहे.
- २) आय.सी.एम.आर. ने SD Biosensor या कंपनी सोबत वाटाघाटी करून Standard Q Covid-19 Ag detection kit मधील एका टेस्टची किंमत प्रति टेस्ट ₹ ४५० या दराने निश्चित केलेली आहे.
- ३) महानगरपालिका क्षेत्रात कॅन्टॅमेंट झोन/हॉटस्पॉटमध्ये उपरोक्त नुसार मोठ्या प्रमाणावर तपासणी करण्याची आवश्यकता भासल्यास संबंधित आयुक्त, महानगरपालिका त्यांच्या महानगरपालिका क्षेत्रासाठी/महानगरपालिका रुग्णालयांसाठी Standard Q Covid-19 Ag detection kit खरेदी करू शकतील.
- ४) राज्य शासनाच्या सार्वजनिक आरोग्य विभाग/शासकीय वैद्यकीय महाविद्यालय संलग्न रुग्णालयांसाठी SD Biosensor या कंपनीचे Standard Q Covid-19 Ag detection kit १ लाख टेस्ट (प्रति किट २५ टेस्ट या प्रमाणे एकूण ४०,००० किट) प्रति टेस्ट ₹ ४५० + GST/- या दराने खरेदी करण्यास मान्यता देण्यात येत आहे.
- ५) यासाठी लागणारे ₹ ४.५० कोटी + GST इतका निधी हा राष्ट्रीय/राज्य आपत्ती निवारण निधीतून करण्यास मान्यता देण्यात येत आहे.
- ६) सदर खरेदी आयुक्त, आरोग्य सेवा तथा अभियान संचालक, राष्ट्रीय आरोग्य अभियान यांचे स्तरावर करण्यात येईल.

- ७) खाजगी वैद्यकीय महाविद्यालय संलग्न रुग्णालये/खाजगी आरोग्य संस्था उपरोक्त दराने Standard Q Covid-19 Ag detection kit खरेदी करू शकतील.
- ८) आय.सी.एम.आर. ची संदर्भाधीन पत्रे या शासन निर्णयाच्या सोबत प्रपत्र -अ व ब म्हणून सुलभ संदर्भास्तव जोडण्यात येत आहे.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने,


(डॉ. प्रदीप व्यास) 22/6/2020

प्रधान सचिव, महाराष्ट्र शासन

प्रत,

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- २) मा. मुख्यमंत्री यांचे अपर मुख्य सचिव, मंत्रालय, मुंबई.
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- ४) मा. आरोग्य मंत्री यांचे खाजगी सचिव, मंत्रालय, मुंबई.
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- ६) सचिव, मदत व पुर्नवसन, महसुल विभाग, मंत्रालय, मुंबई.
- ७) आयुक्त, आरोग्य सेवा तथा अभियान संचालक, राष्ट्रीय आरोग्य अभियान, मुंबई.
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- १३) संचालक, वैद्यकीय शिक्षण व संशोधन, मुंबई.
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- १६) अध्यक्ष, इंडियन मेडीकल असोशिएशन (सर्व)
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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Advisory on Use of Rapid Antigen Detection Test for COVID-19

Dated: 14th June 2020

Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in-terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.
2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.
3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or standalone antigen detection assay: **Standard Q COVID-19 Ag detection kit**, was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.
4. **Brief description of the Standard Q COVID-19 Ag detection:**
 - i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.
 - ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
 - iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.
 - iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and



biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

- v) Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.
- vi) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.
- vii) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes. After that the test strip should be discarded.
- viii) The test kit should be stored between 2° to 30° C.
- ix) Detailed instructions for use can be accessed through the video link: <https://youtu.be/mBdaOHJWxI4>

5. Validation of the Test:

I. Sites:

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

- i) Indian Council of Medical Research, Delhi; and
- ii) All India Institute of Medical Sciences, Delhi

II. Results:

- i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.
- ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

6. Conclusions and Recommendations:

- i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.
- ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.



iii) **In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing in the following settings in combination with the gold standard RT-PCR test:**

A. Containment zones or hotspots (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C.):

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. Healthcare settings (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:
 - Patients undergoing chemotherapy
 - Immunosuppressed patients including those who are HIV+;
 - Patients diagnosed with malignant disease;
 - Transplant patients;
 - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
 - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures;
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

****ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- i) **Suspected individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.**
- ii) Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.
- iii) The test should be conducted **onsite** under strict medical supervision and within one hour of sample collection in extraction buffer.



सत्यमेव जयते

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एफएएचए, एफएएमएस, एफएनएएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

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स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक, आई सी एम आर

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Secretary to the Government of India

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Indian Council of Medical Research

Department of Health Research

Ministry of Health & Family Welfare

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DO.No.ECD/COVID19/Misc./2020

Dated 19th June 2020

Subject: Ramping up testing for COVID-19 in containment zones and hospitals.

Dear (Chief Secretaries of all states)

1. Real Time RT-PCR is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. However, in view of the specialized laboratory requirements, this test cannot be performed at every district level labs which do not have molecular virology facilities.
2. The TrueNat and CBNAAT systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges for COVID-19 diagnosis. These platforms have widespread availability even at district and PHC as these platforms are widely used for diagnosis of Tuberculosis as well as other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.
3. In an effort to ramp up the testing capacity, ICMR has approved a total of 960 labs in public and private sector. However, inspite of these developments in testing, there is an urgent need to introduce rapid point of care diagnostic tests to make testing widely available in all parts of the country.
4. Rapid antigen-based detection assays have been used successfully for early diagnosis of diseases like Malaria, Leishmania, viral and bacterial respiratory infections etc. Such tests can be used as point of care diagnostics in field settings and have minimal biosafety and biosecurity requirements. In view of this, ICMR had been exploring alternate quick and reliable options for diagnosis of COVID-19.

5. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay for quick diagnosis of SARS-CoV-2 developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. The assay is known as **Standard Q COVID-19 Ag kit**. On validation, the test has been found to have a very high specificity with moderate sensitivity. ICMR now also recommends use of Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020. In this regard, which may be accessed at: [https://www.icmr.gov.in/pdf/covid/strategy/Advisory for rapid antigen test 14062020.pdf](https://www.icmr.gov.in/pdf/covid/strategy/Advisory%20for%20rapid%20antigen%20test%2014062020.pdf). The advisory clearly delineates the recommended groups of individuals who should be tested using the antigen detection assay. Key points in the advisory are enclosed as Annexure 1 for your perusal.

6. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor. Contact details are as follows:

Dr. CS Bedi

Mobile No: +919810426069

Email: drbedi@icloud.com

ICMR has negotiated the price of the kit. The upper price cap negotiated by the Committee is Rs. 450/-.

For any technical assistance /clarifications, details of the ICMR contact point are given below:

Dr. Sidhartha Giri, Scientist E, ICMR

Mobile No: +918754617892

Email: sidhartha.g@icmr.gov.in

7. **Kindly note that in addition to the details of all the tests conducted by the RT-PCR, TrueNat, CBNAAT, results of Antigen detection assay also need to be entered into the existing ICMR data entry portal where a separate field has been incorporated to accommodate all testing data emerging through the rapid antigen test.**
8. In addition, vide earlier letter No. dated from Secy DHR & DG to all states, ICMR has advised states on use of IgG antibody assays for conducting serosurveys in asymptomatic frontline workers like healthcare workers, sanitation workers, security staff etc. for assessing their serostatus for COVID-19. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at [https://www.icmr.gov.in/pdf/covid/kits/ELISA CLIA Kits List 03062020.pdf](https://www.icmr.gov.in/pdf/covid/kits/ELISA%20CLIA%20Kits%20List%2003062020.pdf). As the apex research organization of the country, ICMR is mandated to review and conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, I advise you to share all the antibody testing results with ICMR at the email id given below: mmurhekar@gmail.com.
9. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened. Therefore, it is advised that all the patients who are being tested by any of the above methods, may be requested to share one personal Identity, issued by Govt. of India to establish the authenticity of the individual. Also, it has been noted that the phone numbers shared by individuals at the time of testing are often

incorrect. Therefore, it is advisable that at the time of testing, a missed call should be given on the shared phone number to verify its correctness,

10. In view of this, I request you all to kindly take required steps to scale up the testing capacity in your respective state by adopting various available testing options, making testing available to all symptomatic individuals in your state. This will enable early detection and containment of infection which in turn would save several lives.

With regards,

Yours sincerely,

Balram Bhargava
(Balram Bhargava)

Copy to:

1. Smt. Preeti Sudan, Secretary (HFW), MOHFW, New Delhi
2. Shri Rajesh Bhushan, OSD, MOHFW, New Delhi
3. All Health Secys of States / UTs

Key points to remember for use of COVID-19 quick antigen detection assay:

- Minimum time taken for RT-PCR test is 2-5 hours.
- Antigen detection test is a rapid point of care test and has no specialized laboratory requirements.
- One nasopharyngeal swab is to be collected and tested **onsite within one hour of sample collection.**
- Sample collection and testing is to be performed by a trained health care worker with proper PPE.
- Can be interpreted between 15 to 30 minutes with a naked eye.
- Kit needs to be stored between 2° to 30° C.

Rapid antigen detection test for COVID 19 can be used to test individuals in the following categories:

A. Containment zones or hotspots:

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. Healthcare settings:

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

Interpretation of the test:

Symptomatic Individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.

राज्यामध्ये कोविड -१९ उपाययोजनेतर्गत कोविड
- १९ चाचण्यांचे बळकटीकरण करणेबाबत

महाराष्ट्र शासन

वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग,

शासन परिपत्रक क्रमांक :संकीर्ण-२०२०/प्र.क्र. २७ / औषधे-२
गोकुळदास तेजपाल रुग्णालय आवार, नविन इमारत, ९ वा मजला,
लोकमान्य टिळक मार्ग, मुंबई - ४०० ००९.

दिनांक : २३ जून , २०२०.

वाचा :-

१. आयसीएमआर संस्थेद्वारे Advisory to start rapid antibody based blood test for COVID-19बाबत दिनांक ०४ एप्रिल २०२० रोजी दिलेल्या मार्गदर्शक सूचना
२. सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय, भारत सरकार, नवी दिल्ली याचे पत्र क्रमांक VIP /4/2020/ECD-1 (Vol-J),dated 17.04.2020
३. सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय,भारत सरकार ,नवी दिल्ली यांचे अर्ध शासकीय पत्र क्रमांक ECD/COVID -19/Misc/2020,dated 19.06.2020

सध्या सर्वत्र पसरलेल्या कोविड -१९ संसर्गजन्य आजाराच्या अनुषंगाने विविध उपयायोजना केल्या जात आहेत. कोविड रुग्णांच्या चाचणी करिता अचूकता व एकाचवेळी चार ते पाच तासांच्या कालावधीत ९० नमूने (Sample)तपासणीची क्षमता असणारी Real Time RTPCR या चाचणी प्रणालीस सुवर्ण मानांकित दर्जा प्राप्त आहे.सदर चाचणीसाठी वैशिष्टपूर्ण व सुसज्जता व जैवीक सुरक्षा व सुविधांची आवश्यकता असते.

TrueNat आणि CBNAATया चाचणी प्रणालीचा क्षयरोग व अन्य संसर्गजन्य आजारांचे निदान करण्यासाठी जिल्हा तसेच प्राथमिक आरोग्य केंद्र स्तरावर यशस्वीपणे वापर सदर चाचणी प्रणालीचा विशिष्ट (Customized) स्वरूपाचे कार्टेज वापरून कोविड -१९ चाचण्या केल्या जातात. राज्यामध्ये आजमितीसभारतीय आयुर्विज्ञान अनुसंधान परिषद (आयसीएमआर) संस्थेने मान्यता प्रदान केलेल्या सुमारे १०४, Real Time RTPCR, TrueNat आणि CBNAAT शासकीय व खाजगी कोविड चाचणी प्रयोगशाळा कार्यरत आहेत. तथापी असे असूनही कोविड चाचण्याची क्षमता व त्याचे बळकटीकरण करण्याची नितांत आवश्यकता आहे.याबाबत मलेरिया, लिशमिनीया, तसेच अन्य विषाणू व जिवाणूजन्य श्वसन आजारांच्या शीघ्र निदानामध्ये (early diagnosis)Rapid Antigen based तत्वावर आधारित चाचणी प्रणालीचा वापर करण्यात येतो. सदर धर्तीवर आयसीएमआर संस्था कोविड -१९ तपासणी त्वरीत ,पर्यायी व विश्वसनीय पर्यायाच्या शोधात होती.

त्यानुषंगाने याबाबत उपरोक्त दिनांक १९.०६.२०२० च्या पत्रान्वयेभारतीय आयुर्विज्ञान अनुसंधान परिषद(आयसीएमआर) संस्थेने खालीलप्रमाणे सूचना दिलेल्या आहेत.

१. एसडी बायोसेन्सर या उत्पादकांनी त्यांच्या मनेसर गुरुग्राम येथील उत्पादन युनिटमध्ये SARS - COV-२ या साथरोगाच्या जलद निदान चाचणीकरता Antigen based प्रणालीवर आधारित चाचणीकरीता उत्पादित केलेल्या Standard Q COVID-19 Ag Kitचे आयसीएमआर व एम्स,नवी दिल्ली या संस्थांनी स्वतंत्रपणे मुल्यमापन केले आहे. त्यामध्ये सदर निदान प्रणाली Very high specificity with moderate sensitivity असल्याचे आढळून आले आहे. आयसीएमआर संस्थेने सदर कीटचा प्रतिबंधित क्षेत्र (कन्टेनमेंट झोन) व रुग्णालयांमध्ये कोविड निदानाकरिता सुवर्ण मानांकन प्राप्त आरटीपीसीआर प्रणालीसह सदर कीटचा वापर करण्याची शिफारस केलेली आहे. याबाबत आयसीएम संस्थेने दिनांक १४.०६.२०२० अन्वये मार्गदर्शक सूचना निर्गमित केल्याआहेत. सदर पत्र सोबत जोडले आहे. (परिशिष्ट -१) म्हणून जोडले आहे. सदर मार्गदर्शक सूचना खालील संकेतस्थळावर उपलब्ध आहे.
https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf सदर प्रणाली कोणत्या घटकांकरिता वापरण्यात यावी याबाबतच्या स्पष्ट शिफारशी आयसीएमआर संस्थेद्वारे तयार करण्यात आले आहे. (परिशिष्ट -२)
२. आयसीएमआर संस्थेने प्रमाणित केलेल्या Standard Q COVID-19 Ag Kit उपलब्धतेबाबतची माहिती आयसीएमआर संस्थेच्या उपरोक्त दिनांक १९.०६.२०२० (परिशिष्ट -३) च्या पत्रात नमूद आहे.
३. आयसीएमआर संस्थेने उपरोक्त कीट संबधी तांत्रिक सहाय्य करिता खालील प्रमाणे अधिकाऱ्याची नियुक्ती केली आहे.

डॉ.सिध्दार्थ गिरी, वैज्ञानिक ई आयसीएमआर

भ्रमणध्वनी क्रमांक - +९१८७५४६१७८९२

ईमेल - Email: sidhartha.g@icmr.gov.in

४. RTPCR, TrueNat आणि CBNAATया चाचण्यांच्या माहिती बरोबर अँटीजन डिटेक्शन तत्त्वारिल चाचण्यांची माहितीसुध्दा प्रचलित आयसीएमआर डेटा एन्ट्री पोर्टलवरील स्वतंत्र रकान्यात भरण्यात यावी याची कृपया सर्वसंबंधितांनी नोंद घ्यावी.

५. सचिव, आरोग्य संशोधन विभाग व महासंचालक यांच्या दिनांक ०३.०६.२०२० (परिशिष्ट -४) पत्राच्या अनुषंगाने आयसीएमआर संस्थेने राज्यास कोविड शोध मोहिमेत आघाडीवर कार्यरत असलेल्या लक्षणेविरहित (asymptomatic) आरोग्य सेवक, स्वच्छता सेवक, सुरक्षासेवक इत्यादींमध्ये कोविडची लक्षणे आहेत किंवा कसे यांची तपासणी करण्यासाठी IgG antibody assays चा वापराबाबत मागदर्शक सूचना दिलेल्या आहेत. आरसीएमआर संस्थेने ELISA आणि CLIA kits च्या वापराबाबतच्या मागदर्शक सूचनांची यादी https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf या संकेतस्थळावर उपलब्ध आहे. आयसीएमआर संस्थेच्या उपरोक्त दिनांक १९.०६.२०२० च्या पत्रान्वये Antibody चाचणीच्या सर्व निकालाची माहिती mmurhekar@gmail.com या ई मेलवर पाठविणेबाबतचे सूचित केलेले आहे.
६. चाचणी, पाठपुरावा व उपचार (Test, Track and Treat) या कार्यपध्दतीद्वारेच कोविड -१९ संसर्गजन्य आजाराचा प्रतिबंध करणे व मानवी जीव वाचविणे हा एकमेव पर्याय आहे. यास्तव राज्यातील प्रत्येक भागातील कोविड -१९ आजाराची लक्षणे असणाऱ्या प्रत्येक व्यक्तीस कोविड -१९ चाचणी करण्यासाठी व्यापक प्रमाणात सुविधा उपलब्ध करून देणे गरजेचे आहे. तसेच संसर्गाचा प्रतिबंध करण्यासाठी संपर्क शोध यंत्रणांचे अधिक बळकटीकरण करणे आवश्यक आहे. सदर बाबीच्या अनुषंगाने कोणत्याही चाचणी प्रणालीद्वारे कोविड चाचणी करण्याच्या प्रत्येक व्यक्तीची त्यास भारत सरकारने उपलब्ध करून दिलेल्या कोणत्याही ओळखपत्राद्वारे पडताळणी करणे आवश्यक आहे. याबाबत कोविड चाचणी करण्यात येणाऱ्या व्यक्तींनी दिलेले भ्रमणध्वनी क्रमांक चुकीचे असल्याचे निदर्शनास आलेले आहे. सबब सदर चाचणी करण्यास येणाऱ्या व्यक्तीने उपलब्ध करून दिलेल्या भ्रमणध्वनी क्रमांकाची पडताळणी सदर क्रमांकावर Miss Call देवून करणे शक्य आहे. त्याप्रमाणे आवश्यकतेनुसार पडताळणीची कार्यवाही करावी.
७. उपरोक्त वाचा येथे नमूद दिनांक ०४.०४.२०२० (परिशिष्ट - ५)च्या मागदर्शक सूचनानुसार तसेच आरोग्य आणि कुटुंब कल्याण मंत्रालय, नवी दिल्ली यांच्या दिनांक १७.०४.२०२० (परिशिष्ट - ६) नुसार Rapid Antibody चाचणी करणेबाबतच्या मार्गदर्शक सूचना देण्यात आलेल्या आहेत. त्याचप्रमाणे आयसीएमआर संस्थेने प्रमाणित केलेल्या Antibody Test Kitची यादी दिनांक ०३.०६.२०२० आणि १९.०६.२०२० (परिशिष्ट -७) अन्वये प्रसिध्द केलेली आहे. सदर बाबी आयसीएमआर संस्थेच्या खालील संकेतस्थळावर उपलब्ध आहेत

१. https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_03062020.pdf

२. https://www.icmr.gov.in/pdf/covid/kits/Antibody_based_tests_19062020.pdf


८. महाराष्ट्र राज्यातील सर्व शासकीय / निमशासकीय / खाजगी / महानगरपालिका / नगर परिषद / धर्मदाय / खाजगी रुग्णालये तसेच प्रयोगशाळा यांना आयसीएमआर संस्थेने कोविड -१९ चाचणीकरिता Antigen TEST आणि Antibody Test याबाबत निर्देशित केलेल्या मार्गदर्शक सूचनेनुसार सदर Antigen Test आणि Antibody Test चा व्यापक प्रमाणावर वापर करण्यास प्रोत्साहित करण्यात येत आहे. यानुसार त्यांनी त्यांच्याकडे दाखल होणाऱ्या रुग्णांवर आवश्यकतेनुसार सदर चाचण्या कराव्यात आणि या चाचण्यांची माहिती आयसीएमआर संस्थेच्या संकेतस्थळावरील विहित प्रपत्रात नियमित भरावी. सदर चाचण्यांची माहिती सार्वजनिक आरोग्य विभाग (परिशिष्ट-८) (ssumaharashtra@gmail.com) जिल्हाधिकारी / महानगरपालिका / नगर परिषद व इतर संबंधित अधिकृत संस्थांना वेळोवेळी निर्देशित केल्यानुसार नियमितपणे सादर करण्याबाबत कार्यवाही करावी.

९. सेट्रल ड्रग्स स्टॅंडर्ड कंट्रोल ऑर्गनायझेशन (CDSCO) यांनी दिनांक १७.०६.२०२० अन्वये कोविड -१९ च्या "Rapid/CLIA/ELISA kits approved for testing of COVID -१९ with the condition" त्यांच्या संकेतस्थळावर प्रसिध्द केलेली आहे. (परिशिष्ट -९)

भारतीय आयुर्विज्ञान अनुसंधान परिषद (आयसीएमआर) व सेट्रल ड्रग्स स्टॅंडर्ड कंट्रोल ऑर्गनायझेशन (CDSCO) या संस्थांनी दिलेल्या वरील सूचना तसेच याबाबत वेळोवेळी देण्यात येणाऱ्या अद्यावत सूचना / निर्देश इत्यादीच्या अनुषंगाने राज्यातील सर्व शासकीय / खाजगी रुग्णालये आणि शासकीय व खाजगी प्रयोगशाळा यांनी व्यापक प्रमाण प्रमाण कोविड -१९ चाचण्या करण्याबाबत कार्यवाही करावी.

महाराष्ट्राचे राज्यपाल यांच्या आदेशानुसार व नावाने.

सहपत्र : परिशिष्ट १ ते ९.


(डॉ. संजय मुखर्जी)
सचिव, महाराष्ट्र शासन

प्रति,

१. मा. मुख्यमंत्री महोदयांचे प्रधान सचिव, मुख्यमंत्री सचिवालय, मुंबई
२. मा. उपमुख्यमंत्री महोदयांचे सचिव, मंत्रालय, मुंबई
३. मा.मंत्री (वैद्यकीय शिक्षण) यांचे खाजगी सचिव
४. मा. मंत्री (आरोग्य) यांचे खाजगी सचिव, मंत्रालय, मुंबई
५. मा. राज्यमंत्री (वैद्यकीय शिक्षण) यांचे खाजगी सचिव, मंत्रालय मुंबई
६. मा. राज्यमंत्री (आरोग्य) मंत्रालय, मुंबई
७. मा. मुख्य सचिव, महाराष्ट्र राज्य, मुंबई
८. प्रधान सचिव , सार्वजनिक आरोग्य विभाग, मंत्रालय, मुंबई
९. प्रधान सचिव , नगर विकास विभाग, मंत्रालय, मुंबई
१०. प्रधान सचिव , कोरोना नियंत्रण कक्ष , मंत्रालय , मुंबई
११. आयुक्त, मुंबई महानगरपालिका, मुंबई

१२. आयुक्त , अन्न व औषधे प्रशासन, मुंबई
१३. धर्मदाय आयुक्त, महाराष्ट्र राज्य, मुंबई
१४. सर्व विभागीय आयुक्त
१५. सर्व जिल्हाधिकारी
१६. सर्व आयुक्त महानगरपालिका
१७. व्यवस्थापकीय संचालक, हाफकीन जीव औषध निर्माण महामंडळ, मुंबई
१८. संचालक, वैद्यकीय शिक्षण आणि संशोधन, मुंबई
१९. संचालक आरोग्य सेवा संचालनालय, मुंबई
२०. सर्व अधिष्ठाता, शासकीय वैद्यकीय महाविद्यालय व रुग्णालय, मुंबई
२१. सर्व मुख्याधिकारी, नगर परिषद,
२२. सर्व जिल्हा शल्य चिकीत्सक
२३. निवडनस्ती (औषधे-२)

परिपत्रका सोबतच्या परिशिष्टांची सविस्तर माहिती.

परिशिष्ट क्र.	विषय	वेब लिंक
परिशिष्ट-१	ICMR Advisory on Use of Rapid Antigen Detection Test for COVID-१९ दिनांक १४.०६.२०२०.	https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test१४०६२०२०.pdf
परिशिष्ट - २	ICMR यांचे दिनांक १९.०६.२०२० च्या पत्रामधील प्रपत्र-१ Key points to remember for use of COVID-१९ quick antigen detection assay	----
परिशिष्ट - ३	सचिव, आरोग्य व कुटुंब कल्याण मंत्रालय, भारत सरकार, नवी दिल्ली यांचे अर्ध शासकीय पत्र क्रमांक ECD/COVID -१९/Misc/२०२०, dated १९.०६.२०२०	----
परिशिष्ट - ४	सचिव, आरोग्य संशोधन विभाग व महासंचालक यांचे दिनांक ०३.०६.२०२० चे पत्र.	https://www.icmr.gov.in/pdf/covid/kits/ELISA_CLIA_Kits_List_०३०६२०२०.pdf
परिशिष्ट - ५	आयसीएमआर संस्थेद्वारे Advisory to start rapid antibody based blood test for COVID-१९ बाबत दिनांक ०४.०४.२०२० रोजी दिलेल्या मार्गदर्शक सूचना	https://www.icmr.gov.in/pdf/covid/strategy/Advisory_Antibody_Testing_०४०४२०२०.pdf
परिशिष्ट - ६	आरोग्य आणि कुटुंब कल्याण मंत्रालय, नवी दिल्ली यांच्या दिनांक १७.०४.२०२० नुसार Rapid Antibody चाचणी करणेबाबतच्या मार्गदर्शक सूचना	https://www.icmr.gov.in/pdf/covid/strategy/Rapid_Antibody_test_Protocol.pdf
परिशिष्ट - ७	Guidance on rapid antibody kits for COVID-१९ दिनांक १९.०६.२०२०	https://www.icmr.gov.in/pdf/covid/kits/Antibody_based_tests_१९०६२०२०.pdf
परिशिष्ट - ८	सार्वजनिक आरोग्य विभाग यांचे माहिती भरावयाचा नमूना.	----
परिशिष्ट -९	Central Drugs Standard Control Organization : Rapid/CLIA/ELISA kits approved for testing of COVID -१९ with the condition दिनांक १७.०६.२०२०.	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk५Mw==



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स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Advisory on Use of Rapid Antigen Detection Test for COVID-19

Dated: 14th June 2020

Background:

1. Real time RT-PCR is the gold standard frontline test for diagnosis of COVID19. Various open and closed RT-PCR platforms (Open systems RT-PCR machines, TrueNat and CBNAAT) are currently being used for COVID19 diagnosis in India. All these platforms require specialized laboratory facilities in terms of equipment, biosafety & biosecurity. Minimum time taken for the test varies between different systems with a minimum of 2-5 hours including the time taken for sample transportation. These specifications limit the widespread use of the RT-PCR test and also impedes quick augmentation of testing capacity in various containment zones and hospital settings.
2. In view of this, there is urgent need of a reliable point-of-care rapid antigen detection test with good sensitivity and specificity for early detection of the disease.
3. There are no reliable antigen detection tests available worldwide, which could be used as rapid point of care tests for quick detection of COVID-19 positive patients. Such tests would help in proper implementation of the Govt. strategy to test, track and treat. Such tests will also help in allaying the anxiety and fear of healthcare workers and aid in better clinical management of the patients. In view of this, an independent two site evaluation of the only available or stand-alone antigen detection assay available in India, **Standard Q COVID-19 Ag detection kit**, was conducted with an aim to evaluate its sensitivity, specificity and feasibility of use as a point-of-care test for early detection of SARS-CoV-2.
4. **Brief description of the Standard Q COVID-19 Ag detection:**
 - i) **Standard Q COVID-19 Ag detection kit** is a rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. has been developed by SD Biosensor, a South Korea based company, having its manufacturing unit in Manesar, Gurugram, India.
 - ii) Each test kit comes with an inbuilt COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection.
 - iii) One Nasopharyngeal swab needs to be collected using the customized sample collection swab provided with the kit. No other sample (throat swab, bronchoalveolar lavage or sputum) should be used.
 - iv) After sample collection, the swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and



biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs.

- v) Once the sample is collected in the extraction buffer, it is stable only for one hour. Therefore, the antigen test needs to be conducted at the site of sample collection in the healthcare setting. Transportation to the lab is not recommended.
- vi) Once the sample goes into the buffer and is mixed properly, the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are put into the well of the test strip.
- vii) The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. **Maximum duration for interpreting a positive or negative test is 30 minutes.** After that the test strip should be discarded.
- viii) The test kit should be stored between 2° to 30° C.
- ix) Detailed instructions for use can be accessed through the video link: <https://youtu.be/mBdaOHJWxI4>

5. Validation of the Test:

I. Sites:

Standard Q COVID-19 Ag detection assay by SD Biosensor was evaluated independently by the following agencies:

- i) Indian Council of Medical Research, Delhi; and
- ii) All India Institute of Medical Sciences, Delhi

II. Results:

- i) Standard Q COVID-19 Ag rapid antigen detection test has a very high specificity (i.e. ability to detect true negatives). Specificity ranged from 99.3 to 100% at the two sites.
- ii) Sensitivity of the test (i.e. ability to detect true positives) ranged from 50.6% to 84% in two independent evaluations, depending upon the viral load of the patient. Higher viral load correlated with higher sensitivity.

6. Conclusions and Recommendations:

- i) Standard Q COVID-19 Ag detection assay by SD Biosensor is the standalone antigen detection test which is available in India and has been validated.
- ii) ICMR encourages other manufacturers / developers who have antigen detection assays to come forward for validation.
- iii) **In view of its high specificity while relatively low sensitivity, ICMR recommends the use of Standard Q COVID-19 Ag detection assay as a point of care diagnostic assay for testing in the following settings in combination with the gold standard RT-PCR test:**



A. Containment zones or hotspots (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C.):

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts with co-morbidities (*lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders*) of a confirmed case to be tested once between day 5 and day 10 of coming into contact.

B. Healthcare settings (to be performed onsite under strict medical supervision and maintaining kit temperature between 2° to 30° C):

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients who are hospitalized or seeking hospitalization, in the following high-risk groups:
 - Patients undergoing chemotherapy
 - Immunosuppressed patients including those who are HIV+;
 - Patients diagnosed with malignant disease;
 - Transplant patients;
 - Elderly patients (>65 yrs of age) with co-morbidities (lung disease, heart disease, liver disease, kidney disease, diabetes, neurological disorders, blood disorders)
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions:
 - Elective/emergency surgical procedures like neurosurgery, ENT surgery, dental procedures;
 - Non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

****ILI case is defined as one with acute respiratory infection with fever $\geq 38^{\circ}\text{C}$ AND cough.***

Use of the rapid antigen test is recommended in A & B categories above subject to the following conditions:

- i) **Suspected individuals who test negative for COVID-19 by rapid antigen test should be definitely tested sequentially by RT-PCR to rule out infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.**
- ii) **Samples (only nasopharyngeal swabs) to be collected by a trained healthcare worker following full infection control practices including use of proper PPE.**
- iii) **The test should be conducted *on-site* under strict medical supervision and within one hour of sample collection in extraction buffer.**
- iv) **ALL TESTING RESULTS USING THE STANDARD Q COVID-19 AG DETECTION ASSAY MUST ESSENTIALLY BE ENTERED ON THE ICMR COVID-19 PORTAL AND ALSO COMMUNICATED TO THE STATE AUTHORITIES AND OFFICIALS OF THE INTEGRATED DISEASE SURVEILLANCE PROGRAMME (IDSP) ON A REAL-TIME BASIS.**

Annexure 1:

Key points to remember for use of COVID-19 quick antigen detection assay:

- Minimum time taken for RT-PCR test is 2-5 hours.
- Antigen detection test is a rapid point of care test and has no specialized laboratory requirements.
- One nasopharyngeal swab is to be collected and tested **onsite within one hour of sample collection.**
- Sample collection and testing is to be performed by a trained health care worker with proper PPE.
- Can be interpreted between 15 to 30 minutes with a naked eye.
- Kit needs to be stored between 2° to 30° C.

Rapid antigen detection test for COVID 19 can be used to test individuals in the following categories:

A. Containment zones or hotspots:

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. Healthcare settings:

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

Interpretation of the test:

Symptomatic individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.



सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

एमडी, डीएम, एफआरसीपी (जी.), एफआरसीपी (ई.), एफएसीसी,
एफएएचए, एफएएमएस, एफएनएस, एफएएससी, एफ.एन.ए., डी.एस.सी.

सचिव, भारत सरकार

स्वास्थ्य अनुसंधान विभाग

स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं

महानिदेशक, आई सी एम आर

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MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNAsc, FASc, FNA, DSc

Secretary to the Government of India

Department of Health Research

Ministry of Health & Family Welfare &

Director-General, ICMR



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भारत सरकार

वी. रामलिंगस्वामी भवन, अंसारी नगर

नई दिल्ली - 110 029

Indian Council of Medical Research

Department of Health Research

Ministry of Health & Family Welfare

Government of India

V. Ramalingaswami Bhawan, Ansari Nagar

New Delhi - 110 029

DO.No.ECD/COVID19/Misc./2020

Dated 19th June 2020

Subject: Ramping up testing for COVID-19 in containment zones and hospitals.

Dear (Chief Secretaries of all states)

1. Real Time RT-PCR is the gold standard test for detecting cases of COVID-19. The test requires specialized laboratory setup with specific biosafety and biosecurity precautions to be followed. Average time taken is around 4-5 hours from receipt of sample to getting the result. The advantage of this platform lies in its accuracy of detection as well as ability to run upto 90 samples in a single run. However, in view of the specialized laboratory requirements, this test cannot be performed at every district level labs which do not have molecular virology facilities.
2. The TrueNat and CBNAAT systems have also been deployed for diagnosis of COVID-19 in view of availability of customized cartridges for COVID-19 diagnosis. These platforms have widespread availability even at district and PHC as these platforms are widely used for diagnosis of Tuberculosis as well as other infectious diseases. These platforms have a quick turnaround time (30 -60 minutes) but only 1-4 samples can be tested in one run, limiting the maximum numbers that can be tested to 24-48 samples / day. The viral lysis buffer that comes with the COVID-19 cartridges inactivates the virus and poses minimum biosafety hazard. Safety is further augmented by the closed nature of these platforms and minimum sample handling. These features have facilitated use of these platforms at grass root level thereby increasing access to testing.
3. In an effort to ramp up the testing capacity, ICMR has approved a total of 960 labs in public and private sector. However, inspite of these developments in testing, there is an urgent need to introduce rapid point of care diagnostic tests to make testing widely available in all parts of the country.
4. Rapid antigen-based detection assays have been used successfully for early diagnosis of diseases like Malaria, Leishmania, viral and bacterial respiratory infections etc. Such tests can be used as point of care diagnostics in field settings and have minimal biosafety and biosecurity requirements. In view of this, ICMR had been exploring alternate quick and reliable options for diagnosis of COVID-19.

5. ICMR and AIIMS, Delhi independently evaluated the stand-alone rapid point of care antigen detection assay for quick diagnosis of SARS-CoV-2 developed by SD Biosensor with manufacturing unit at Manesar, Gurugram. The assay is known as **Standard Q COVID-19 Ag kit**. On validation, the test has been found to have a very high specificity with moderate sensitivity. ICMR now also recommends use of Standard Q COVID-19 Ag detection test as a point of care diagnostic assay for testing in the containment zones as well as hospitals in combination with the gold standard RT-PCR test. ICMR has issued an advisory dated 14th June 2020. In this regard, which may be accessed at: [https://www.icmr.gov.in/pdf/covid/strategy/Advisory for rapid antigen test 14062020.pdf](https://www.icmr.gov.in/pdf/covid/strategy/Advisory%20for%20rapid%20antigen%20test%2014062020.pdf). The advisory clearly delineates the recommended groups of individuals who should be tested using the antigen detection assay. Key points in the advisory are enclosed as Annexure 1 for your perusal.

6. **Standard Q COVID-19 Ag kit** is available with the local vendor of SD Biosensor. Contact details are as follows:

Dr. CS Bedi

Mobile No: +919810426069

Email: drbedi@icloud.com

ICMR has negotiated the price of the kit. The upper price cap negotiated by the Committee is Rs. 450/-.

For any technical assistance /clarifications, details of the ICMR contact point are given below:

Dr. Sidhartha Giri, Scientist E, ICMR

Mobile No: +918754617892

Email: sidhartha.g@icmr.gov.in

7. **Kindly note that in addition to the details of all the tests conducted by the RT-PCR, TrueNat, CBNAAT, results of Antigen detection assay also need to be entered into the existing ICMR data entry portal where a separate field has been incorporated to accommodate all testing data emerging through the rapid antigen test.**

8. In addition, vide earlier letter No. dated from Secy DHR & DG to all states, ICMR has advised states on use of IgG antibody assays for conducting serosurveys in asymptomatic frontline workers like healthcare workers, sanitation workers, security staff etc. for assessing their serostatus for COVID-19. Guidance of ICMR on the list of available ELISA and CLIA kits can be accessed at [https://www.icmr.gov.in/pdf/covid/kits/ELISA CLIA Kits List 03062020.pdf](https://www.icmr.gov.in/pdf/covid/kits/ELISA%20CLIA%20Kits%20List%2003062020.pdf). As the apex research organization of the country, ICMR is mandated to review and conduct research on the evolving trends of the disease and accordingly advise the states / country on the public health policies. In view of this, I advise you to share all the antibody testing results with ICMR at the email id given below: mmurhekar@gmail.com.

9. Since test, track and treat is the only way to prevent spread of infection and save lives, it is imperative that testing should be made widely available to all symptomatic individuals in every part of the country and contact tracing mechanisms for containment of infection are further strengthened. Therefore, it is advised that all the patients who are being tested by any of the above methods, may be requested to share one personal Identity, issued by Govt. of India to establish the authenticity of the individual. Also, it has been noted that the phone numbers shared by individuals at the time of testing are often

incorrect. Therefore, it is advisable that at the time of testing, a missed call should be given on the shared phone number to verify its correctness,

10. In view of this, I request you all to kindly take required steps to scale up the testing capacity in your respective state by adopting various available testing options, making testing available to all symptomatic individuals in your state. This will enable early detection and containment of infection which in turn would save several lives.

With regards,

Yours sincerely,

Balram Bhargava
(Balram Bhargava)

Copy to:

1. Smt. Preeti Sudan, Secretary (HFW), MOHFW, New Delhi
2. Shri Rajesh Bhushan, OSD, MOHFW, New Delhi
3. All Health Secys of States / UTs

Key points to remember for use of COVID-19 quick antigen detection assay:

- Minimum time taken for RT-PCR test is 2-5 hours.
- Antigen detection test is a rapid point of care test and has no specialized laboratory requirements.
- One nasopharyngeal swab is to be collected and tested **onsite within one hour of sample collection.**
- Sample collection and testing is to be performed by a trained health care worker with proper PPE.
- Can be interpreted between 15 to 30 minutes with a naked eye.
- Kit needs to be stored between 2° to 30° C.

Rapid antigen detection test for COVID 19 can be used to test individuals in the following categories:

A. Containment zones or hotspots:

- i) All symptomatic Influenza Like Illness (ILI).
- ii) Asymptomatic direct and high-risk contacts (with co-morbidities) of a lab confirmed case.

B. Healthcare settings:

- i) All symptomatic ILI patients presenting in a healthcare setting and are suspected of having COVID19 infection.
- ii) Asymptomatic patients in high risk groups: undergoing chemotherapy; immunosuppressed patients; patients suffering with malignant disease; transplant patients; elderly patients (>65 yrs of age) with co-morbidities
- iii) Asymptomatic patients undergoing aerosol generating surgical / non-surgical interventions like elective/emergency surgical procedures: Neurosurgery, ENT surgery, dental procedures; and non-surgical interventions like bronchoscopy, upper GI endoscopy and dialysis;

Interpretation of the test:

Symptomatic individuals who test negative by the antigen test should be definitely tested sequentially by RT-PCR to rule out COVID19 infection, whereas a positive test should be considered as a true positive and does not need reconfirmation by RT-PCR test.



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 03.06.2020

**LIST OF IgG ELISA KITS FOR COVID 19 VALIDATED BY ICMR IDENTIFIED
VALIDATION CENTRES**

Sl. No	Name of Company	Name of the Kit	*Batch Number
1.	Zydus Cadila Healthcare Ltd., Ahmedabad, Gujarat, India	COVID Kavach ELISA IgG	CoV2HI GG96-001 CoV2HI GG96-002 CoV2HI GG96-003
2.	Euroimmun US Inc., USA	Euroimmun Anti- SARS-COV-2 ELISA IgG	E200420AW
3.	Calbiotech Inc., USA	Erbalisa COVID-19 IgG ELISA	CVG6087

The **IgG ELISA** and **CLIA** tests are recommended only for the following purpose:

- Serosurveys to understand the proportion of population exposed to infection including asymptomatic individuals. Depending upon the level of seroprevalence of infection, matching public health interventions can be implemented for prevention and control of the disease.
- Survey in high risk or vulnerable populations (health care workers, frontline workers, immunocompromised individuals, individuals in containment zones etc) to know who has been infected in the past and has now recovered.

Please Note:

- The ELISA tests have been validated in the laboratory. However, the performance of the test may be subject to variation under field conditions.
- *Above listed ELISA tests are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.
- IgG ELISA / CLIA tests which are US-FDA approved** can be used directly after due marketing approval from DCGI.
- Names and contact details of the manufacturers of COVID Kavach IgG ELISA is enclosed for reference.



ICMR has transferred COVID Kavach ELISA IgG technology to below mentioned pharma companies:

S.No.	Name of Company	Contact Details
1	Zydus Cadila Healthcare Ltd	Mr Vivek Kant Tripathi Zydus Corporate Park, 4th Floor, B Wing, Scheme No. 63, Survey No. 536, Near Vaishnodevi Circle, Sarkhej-Gandhinagar Highway, Ahmedabad-382481, Gujarat, India Mobile: +919717273066 Email:vivekkant.tripathi@zyduscadila.com
2	Meril Diagnostics Pvt. Ltd	Mr Paparaidu Sanapala Dy. General Manager(Technical Head) Vapi, Gujarat, India Mobile: +919574144456 Email: paparaidu.sanapala@merillife.com
3	Voxtur Bio Ltd.	Dr Veeraal Gandhi Chairman Plot No. A-1, Royal Compound, Tamanman Kaman Bhivandi Road, Vasai, Palghar, Mumbai-401208, India Mobile: +91-9819720123 Email: veeraal@voxturbio.com
4	Trivitron Healthcare Pvt. Ltd	Mr Nitin Sawant, President D -134, MIDC, Industrial Area, Shirvane, Opposite Dr. D YPatil University, Nerul, Navi Mumbai – 400706, India Mobile: +91 8291282827 Email: santosh.jagtap@trivitron.com
5	J. Mitra & Co. Pvt Ltd	Ms Sangeeta Gupta Head Technical A-180, Okhla Industrial Area, Phase-1, New Delhi - 110020, India Mobile:+918800192205 Email : tcmgr@jmitra.co.in
6	Karwa Enterprises Pvt Ltd	Dr. Vivek Varma, Head – Operations Rapid Diagnostic Group of Companies B-82, Industrial Area, G.T. Karnal Road, New Delhi – 110033, India Mobile: +91 9535998155 Email: drjindal@rdgc.in
7	Avecon Healthcare Pvt Ltd	Mr Rajesh Aggarwal Plot No. 338, Industrial Growth Centre Saha, Haryana- 133104, India Mobile: + 91 9315445391 Email : exportzone@aveconhealthcare.com

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DEPARTMENT OF HEALTH RESEARCH

Advisory to start rapid antibody based blood test for COVID-19 (4 April 2020)

Strategy for areas reporting clusters (containment zone) and in large migration gatherings/evacuees centres

Cases of Influenza Like Illness (ILI) to be monitored in health facilities. Any surge in cases to be monitored and brought to the notice of Surveillance Officer/CMO for additional investigation.

As a matter of abundant precautions, all symptomatic ILI persons should be advised home quarantine for 14 days.

At facility level, symptomatic ILI individuals to be tested using rapid antibody tests.

- **Antibody test negative:**
 - If warranted, confirm by real-time RT-PCR using throat/nasal swab.
 - RT-PCR negative: Likely non-COVID-19 ILI
 - RT-PCR positive: **Confirmed COVID-19 Case** and action as per protocol to be initiated for isolation, treatment and contact tracing.

OR

- If real-time RT-PCR not done, home quarantine and repeat antibody testing after 10 days of the last rapid antibody test.
 - Antibody test negative: Likely non-COVID-19 ILI.
 - Antibody test positive: there is possibility of recent infection, quarantine for another 10 days.
- **Antibody test positive:** After clinical assessment, treatment in hospital or isolation as per protocol. Action as per protocol to be initiated for contact tracing.

If symptoms worsen, refer to designated COVID-19 hospitals.

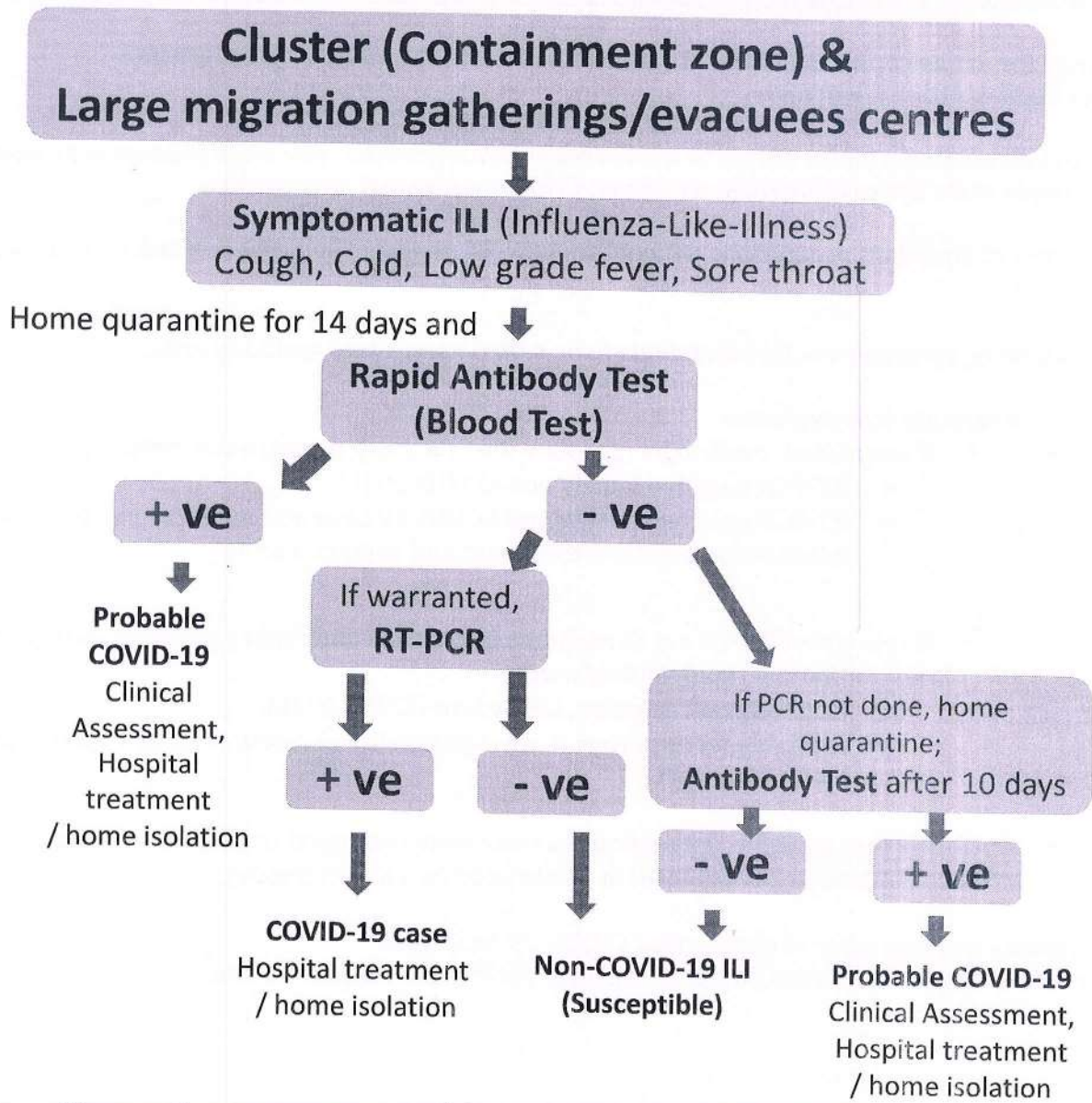
When home quarantine is not feasible, consider facility-based quarantine.

General Guidelines:

- Healthcare workers doing the rapid antibody test to use gloves, mask, and head covers.
- Healthcare workers collecting throat/nasal swab to follow standard national infection control guidelines.
- The rapid antibody tests approved by US-FDA/CE-IVD or non-CE-IVD validated by ICMR-NIV with marketing approval by DCGI be used.
- In order to ensure that all such cases are monitored and necessary action is initiated with respect to infectious disease management, details of all test results shall be uploaded in ICMR portal.
- All such organizations are duty bound to register themselves to ICMR portal and upload the data in real-time.
- Failure to do so, they will be held liable to action under Disaster Management Act, 2005.

STRATEGY FOR USE OF RAPID ANTIBODY BASED BLOOD TEST

(4 April, 2020)



If symptoms worsen, refer to designated COVID-19 hospitals



सत्यमेव जयते

प्रोफेसर (डा.) बलराम भार्गव, पदम श्री
एम.डी., डी.एम., एफ.आर.सी.पी. (जी.), एफ.आर.सी.पी. (ई.), एफ.ए.सी.सी.,
एफ.ए.ए.ए.ए., एफ.ए.एम.एस., एफ.ए.न.ए.एस., एफ.ए.एस.सी., एफ.ए.न.ए., डी.एस.सी.
सचिव, भारत सरकार
स्वास्थ्य अनुसंधान विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय एवं
महानिदेशक, आई सी एम आर

Prof. (Dr.) Balram Bhargava, Padma Shri

MD, DM, FRCP (Glasg.), FRCP (Edin.),
FACC, FAHA, FAMS, FNAsc, FASc, FNA, DSc

Secretary to the Government of India

Department of Health Research
Ministry of Health & Family Welfare &
Director-General, ICMR



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भारत सरकार
वी. रामलिंगस्वामी भवन, अंसारी नगर
नई दिल्ली - 110 029

Indian Council of Medical Research

Department of Health Research
Ministry of Health & Family Welfare
Government of India
V. Ramalingaswami Bhawan, Ansari Nagar
New Delhi - 110 029

D.O.No. VIR/4/2020/ECD-I (Vol.I)

Dated: 17th April 2020

Addl.Chief Secretaery/Secretary/Principal Secretary Health (All States)

Sub: Protocol for using 'Rapid antibody test' in Hot area – epidemiological studies and surveillance

I am writing to you with reference to the rapid antibody test kits for COVID-19 testing. It is understood that many States intend to use these kits in affected areas.

2. The National Task Force at ICMR has carefully reviewed the data evolving from various countries on use of such kits. Based on available evidence, the testing strategy for COVID-19 has been revised further. The revised document is enclosed for your reference.

3. It is critical to understand the following key facts while using the rapid antibody tests:

- Gold standard frontline test for COVID-19 diagnosis is **real time PCR based molecular test**, which is aimed at early virus detection.
- The rapid antibody test cannot replace the frontline test.
- The rapid Antibody test is a **supplementary tool** to assess the prevalence of the diseases within a specific area / perimeter.
- The rapid antibody test will **only be of utility after a minimum of 7 days of onset of symptoms**.
- Data about these rapid tests is emerging and understanding of their utility for diagnosis is still evolving.
- The rapid tests are useful for **epidemiological studies and surveillance purposes**.
- **THE TEST HAS TO BE DONE UNDER STRICT MEDICAL SUPERVISION.**

4. The enclosed ICMR advisory is for Hot spots. In case your state does not have a Hot spot, these tests may be used for:-

- a) Any hotspot which may emerge in future
OR
- b) As a surveillance tool for epidemiological purposes in such areas where cases have not emerged so far.

5. Before starting the rapid test, it should be registered on covid19cc.nic.in/ICMR and data related to the test should be reported on the same.

With best regards

Yours sincerely

Balram Bhargava
(Balram Bhargava)

Enclosed: As above

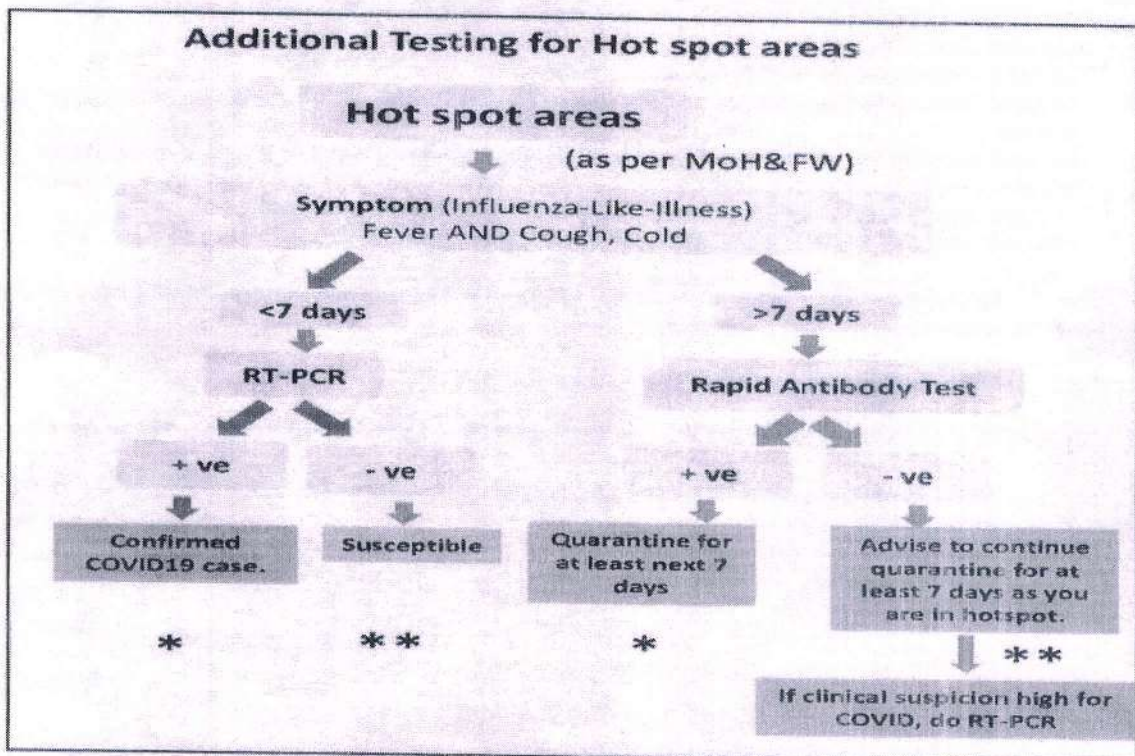
CC: Chief Secretary/Administrators

A. COVID-19 Testing Strategy for India (Recommended for the entire country)

Real-Time PCR (RT-PCR) test and Point-of-Care molecular diagnostic assays are recommended for diagnosis of COVID-19 among individuals belonging to the following categories:

- All symptomatic individuals who have undertaken international travel in the last 14 days
- All symptomatic contacts of laboratory confirmed cases
- All symptomatic health care workers
- All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)
- Asymptomatic direct and high-risk contacts of a confirmed case should be tested once between day 5 and day 14 of coming in his/her contact

B. Additional (in addition to A) Testing recommended in hot spots



- * Refer to Hospital if symptoms appear / worsen
- ** Follow precautions, social distancing, use masks, frequent hand washing, avoid unnecessary travel)

Balwan Dhalgum



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

Till date, 56 antibody based rapid tests have been validated, and the following were found to be satisfactory. 11 of these kits are manufactured in India.

S.No.	Name of Company	Name of Kit	Lot no./Batch no.
1.	BioMedomics (CE-IVD), China	Biomedomics COVID-19 IgM IgG Rapid Test	20200226
2.	Voxtur Bio Ltd, Surat (Gujarat), India	Coronavirus (COVID-19) IgG/IgM Rapid Test	PCCV200301S
3.	VANGUARD Diagnostics, Delhi, India	COVID-19 IgM/IgG Antibody Detection Card Test	RCOVID200301T
4.	HLL Lifecare Limited, Gurugram (Haryana) India	Makesure COVID-19 Rapid test	CVCT030420 CVCT0204203 CVCT0104202
5.	Lab Care Diagnostics India Pvt. Ltd, Mumbai (Maharashtra), India	ACCUCARE IgM/IgG Lateral Flow Assay kit	CVC 200401
6.	NuLifecare, Noida (Uttar Pradesh), India	Abchek COVID-19 IgM/IgG Antibody Rapid Test	NUL/COV-19/R&D/001
7.	Alpine Biomedicals, Ambala (Haryana), India	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test	A10420 A20420
8.	Medsorce Ozone Biomedicals, Haryana, India	COVID 19 IgM/IgG Rapid Test Kit (ver 2.0)	COV-002
9.	Immuno Science India Pvt. Ltd, Pune (Maharashtra), India	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies	E142001
10.	SD Biosensors, Healthcare Pvt. Ltd., Gugugram (Haryana), India	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test	E054002 E054004
11.	BMT Diagnostics (Rafael Diagnostic), Israel	BMT COVID-19 IgG/IgM Rapid Test Kit	COV20030059 COV20030059-1
12.	SIDAK Life Care Pvt. Ltd., New Delhi, India	One Step COVID-19 IgM/IgG Antibody	COVID19S004A COVID19S004B COVID19S004C
13.	Diagnocure, Solan (Himachal Pradesh), India	Xamin COVID-19 Rapid Test Device	DI/COV19/R&D/001 DI/COV19/R&D/002

Rapid antibody tests are not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
 - Test result is available within 30 minutes
 - Test may come positive after 7-10 days of infection
 - The test may remain positive for several weeks after infection
 - Positive test indicates exposure to SARS-CoV-2
 - Negative test does not rule out COVID-19 infection
- These rapid antibody test kits have been validated in the laboratory. However, the performance of the kits may be subject to variation under field conditions.
 - Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.



Date: 19/06/2020

Guidance on rapid antibody kits for COVID-19

S. No.	Kit Detail	Lot no./Batch no.
14.	SARS-CoV-2 Antibody test (Lateral flow method): Guangzhou Wondfo Biotech	#
	Mylan Laboratories Limited (CE-IVD)	W19500309
	M R Roofs Private Ltd	W19500302
	Abbott Laboratories	W19500351
	Zydus Cadilla	W19500338
15.	COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD)	# CK2003010410

The marketing licenses to the distributors of these 2 companies have been cancelled by the Central Drugs Standard Control Organization (CDSCO).

Antibody based rapid tests which are US-FDA approved can be used directly after due marketing approval from DCGI.

4/2/2020 - 2

8 A LABWISE REPORT

DATE:

GOVERNMENT

SR. NO.	GOVERNMENT LABS	TESTS CAPACITY	NUMBER OF KITS AVAILABLE	TOTAL SAMPLES COLLECTED		TOTAL NUMBER OF POSITIVES		TOTAL NUMBER OF NEGATIVES		TOTAL NUMBER OF RESULTS AWAITED	REMARKS
				TODAY	PROGRESSIVE	TODAY	PROGRESSIVE	TODAY	PROGRESSIVE		

8 A LABWISE REPORT

PRIVATE

SR. NO.	PRIVATE LABS	TESTS CAPACITY	NUMBER OF KITS AVAILABLE	TOTAL SAMPLES COLLECTED		TOTAL NUMBER OF POSITIVES		TOTAL NUMBER OF NEGATIVES		TOTAL NUMBER OF RESULTS AWAITED	REMARKS
				TODAY	PROGRESSIVE	TODAY	PROGRESSIVE	TODAY	PROGRESSIVE		

Rapid / CLIA/ ELISA Kits approved for testing of Covid-19 with the conditions.

Date: 17.06.2020

S. No.	Name of the Firm	Type of Kit	Country
1	M/s CPC Diag. Pvt. Ltd, Chennai	Chemiluminescent Immuno Assay IgG & IgM (CLIA) CE Approved and in Australia	M/s Shenzhen YHLO Biotech Co. Ltd. China
2	M/s LifeSciences, Ahmedabad	Eris Florescent, IgG & IgM	M/s Maccure Biotechnology .Ltd. China CE Approved and in China
3	M/s Healthcare Ahmedabad	Cadila Ltd, Antibody rapid test IgG/IgM	M/s. Hangzhou Clongene Biotech Co.Ltd. China CE Approved
4	M/S Diagnostics Pvt Ltd Mumbai	Vishat Antibody rapid test IgG/IgM	M/S Hangzhou All Test Biotech co Ltd China CE approved
5	S.D. Biosensor Delhi	Fluorescent ANTIGEN Test Rapid	M/s S.D. Biosensor, korea CE Approved
6	M/S Healthcare ,Chennai	Trivitron Pvt Ltd Antibody test IgG/IgM CE approved	M/s Autobio Diag Co Ltd, China
7	M/S Healthcare ,Chennai	Trivitron Pvt Ltd Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China
8	M/S Diagnostics Gurgaon	SNIBE (India), Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China

9	M/S Vishat Diagnostics Pvt Ltd Mumbai	ELISA CE approved	M/S Zhengzhou Human well Biocel Technology Ltd China
10	M/s Sowar Private Ltd Delhi	Rapid Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc China
11	M/S Immunoshop India Pvt Ltd Thane	Chemiluminescence Immuno Assay CLIA CE approved	M/s Shenzhen New Industries Biomedical Engineering (SNIBE), China
12	M/S Athenese Dx Pvt Ltd Chennai	Rapid Antibody test IgG/IgM CE approved	M/s Beijing Genese Biotech Inc , China
13	M/S Bioline Diagnostics , Delhi	Antibody test IgG/IgM CE approved	M/S Hangzhou All Test Biotech co Ltd China CE approved
14	M/S Immunoshop India Pvt Ltd Thane	Antibody test IgG/IgM CE approved	M/s Goldsite Diagnostics Inc, China
15	Accurex Biomedical Pvt Ltd, Thane	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
16	Indelox Global Distribution, Pvt Ltd, Bangalore	Antibody test IgG/IgM CE approved	M/S Dongguan Bosh Biotechnology China
17	M/S POCT Services Pvt Ltd Delhi	Antibody test IgG/IgM CE approved	M/S Zybo Inc China
18	M/S Krishgen Biosystems Mumbai	Antibody test IgG/IgM CE approved	M/sWuhan UNScience Biotechnology co Ltd, China
19	M/s Rapid Diagnostics Pvt Ltd Delhi	Antibody test IgG/IgM CE approved	M/s Hangzhou Biotech Co Ltd China
20	M/s PTS Diagnostics India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Changsha Sinocare Inc China
21	M/s Gland Pharma	Antibody test IgG/IgM CE approved	M/S Shanghai Fosun Long March, China
22	M/s Accredited Consultant Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Hangzhou All Test Biotech co Ltd China
23	M/s Accredited Consultant Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Humasis Co Ltd Korea
24	M/s Cosmic Scientific Chennai	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
25	M/S Agappe Diagnostics Ltd	Antibody test IgG/IgM CE approved	M/s Hangzhou Biotech Co Ltd China

26	M/S Triviron Healthcare Ltd	Antibody test IgG/IgM CE approved	M/S Beijing Lepu Medical Technology Co Ltd China
27	M/S Rafael Diagnostics, Pune	Antibody test IgG/IgM CE approved	M/S BMT Diagnostics Israel
28	M/S Matrix Lab Chennai	CLIA CE Approved	Auto-biodiagnostics Co Ltd China
29	M/S Providence International Labs	Antibody test IgG/IgM CE approved	M/S Hangzhou Reality Tech Co Ltd
30	M/S Voxtur Bio Ltd	Antibody test IgG/IgM	Indigenous
31	M/S Vanguard Diag Pvt Ltd	Antibody test IgG/IgM	Indigenous
32	M/S S.D.Biosensor, Pvt Ltd	Antibody test IgG/IgM Duo(Standard Q)	M/s S.D . Biosensor, Inc South Korea
33	M/S Weldon Biotech(I) Pvt.Ltd.	iChrome FIA(Fluoracence ImmunoAssay) Covid-19 Ab	M/s Boditech Med Inc. Korea
34	M/s HLL	Antibody test IgG/IgM	Indigenous
35	M/s Raymed Trading Group Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/S Beijing Lepu Medical Technology Co Ltd China
36	Hemogenomics Pvt. Ltd. Bangalore	Antibody test IgG/IgM CE approved	M/S PCL Inc. South Korea
37	M/s Aracion Technology Pvt. Ltd	Antibody test IgG/IgM CE approved	M/S Hecin Scientific Inc. China
38	M/s CPC Diagnostics Pvt. Ltd.	Anti SAR- COV-2 ELISA IgA/ IgG	M/s Euroimmune AG Germany
39	M/s Bilcare Ltd. Pune	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
40	M/s Bravo Pharmaceuticals Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Biosynex S.A France
41	M/s Harmony LifeSciences Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
42	M/s Inbios India, New Delhi	Antibody test IgG/IgM CE approved	M/S Getein Biotech Inc, China
43	M/s Imperial LifeSciences Pvt. Ltd	Antibody test IgG/IgM CE approved	M/s NewScen Coast Biopharmaceutical Co. Ltd. China

44	M/s POCT Services Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Gen Body Inc. South Korea
45	M/s Trivitron Healthcare Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Innovita(Tang Shen) Biological Technology Co. Ltd. China
46	M/s Concept HealthCare	Antibody test IgG/IgM CE approved	M/s Celtex Biotech(Suzhou) Co. Ltd. China
47	M/s Bio Innovations Thane	Antibody test IgG/IgM CE approved	M/s Primer Design Ltd. U.K
48	M/s AR KAY Medicos Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
49	M/s Kin Diagnostics West Bengal	FIA iChroma IgG/IgM CE approved	M/s Boditech Med Inc. South Korea
50	M/S Aracion Technology Pvt LTd	Antibody test IgG/IgM CE approved	M/s Innovita(Tang Shen) Biological Technology Co. Ltd.China
51	M/S Meridian Medicare LTD	Antibody test IgG/IgM CE approved	M/s Gen Body Inc. South Korea
52	M/S SD Bio Sensor Healthcare Pvt Ltd	Standard Q COVID-19 IgG/IgM Duo	Indigenous
53	M/S Tara Medicos Pvt Ltd Jaipur	Antibody test IgG/IgM CE approved	M/S CELLEX INC,CHINA
54	M/s Med Source Ozone Biomedicals Pvt Ltd	COVID-19 IgG/IgM Rapid Test	Indigenous
55	Immunoscience India Pvt Ltd	COVID-19 IgG/IgM Rapid Test	Indigenous

56	M/s S.D Biosensor Healthcare Pvt. Ltd.	Standard Q Covid-19 IgG/IgM Combo	M/s S.D Biosensor Inc. Korea
57	M/s BioHouse Solutions Pvt. Ltd. Delhi	COVID-19 IgG/IgM Rapid Test	M/s Bio Medomics Inc. USA
58	M/s True Healthcare India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Humasis Co. Ltd. South Korea
59	M/s Immunoshop India Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/S Shenzhen Cifotronic Technology Ltd. China
60	M/s Clini Experts Services Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Biocan Diagnostics Inc. Canada
61	M/s Inbios India, Delhi	Antibody test IgG/IgM CE approved	M/S CELLEX Biotech (Suzhou) Co. Ltd ,CHINA
62	M/S Synergy Scientific Services Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Schenzhen Reagent Technology Co Ltd China
63	M/S Bioscience Sales Corp. Delhi	Antibody test IgG/IgM CE approved	M/S Shenzhan Watmind Medical Co. Ltd , China
64	M/s Gastro Lab India Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Sche Bo Biotech AG, Germany
65	M/S Doctor Analytical Laboratories Pvt Ltd	Antibody test IgG/IgM CE approved	M/s Biocan Diagnostics Inc. Canada

66	M/S MDAAC International Pvt Ltd	Antibody test IgG/IgM CE approved	M/S Atlab Link(Beijing) Technology Co Ltd , China
67	M/S Kin Diagnostics	Antibody test IgG/IgM CE approved	M/S Sugentech Inc South Korea
68	M/s Alere Medical Pvt. Ltd.	PanBio Antibody test IgG/IgM CE approved	M/s Abbott Rapid Diagnostics Germany Having Mfg. Site at Abon Biopharma(Hangzhou) Co. Ltd. China
69	M/s Incarp Instruments Pvt. Ltd. Hyderabad	FIA IgG/IgM AntiBody Test CE approved	M/s Boditech Med Inc. South Korea

70	M/s Nucleus 18 Turnkey Projects Pvt. Ltd. Telangana	Antibody test IgG/IgM Australian EUA	M/s Innovita (Tangshan) Biological Technology Co. Ltd. China
71	M/S Elder Projects Ltd Mumbai	Antibody test IgG/IgM CE approved	M/S Shanghai Outdo Biotech Co Ltd China
72	M/S KDH Biomedicals Pvt Ltd Mumbai	Antibody test IgG/IgM CE approved	M/s Dynamiker Biotechnology (Tianjin) Co Ltd China
73	M/S KDH Biomedicals Pvt Ltd Mumbai	ELISA IgG and ELISA IgM/IgA CE approved	M/s Dynamiker Biotechnology (Tianjin) Co Ltd China
74	Bio Dx Healthcare New Delhi	Antibody test IgG/IgM CE approved	M/S Zybio Inc, China
75	M/s Triviron Healthcare Pvt LTD	Antibody test IgG/IgM CE approved	M/s Shenzhen Lifotronic Technology Co. Ltd. China
76	M/s Saffron Naturele Product Pvt. Ltd. U.P	Antibody test IgG/IgM CE approved	M/s Hangzhou Clongene Biotech Co. Ltd. China
77	M/s Bioplus Healthcare Pvt Ltd Bangalore	Antibody test IgG/IgM CE approved	M/s Cellex BioTech (Suzhou) Co. Ltd. China
78	M/s N.W Overseas, Haryana	Antibody test IgG/IgM CE approved	M/s Beijing Lepu Medical Technology Co. Ltd. China
79	M/s Premier Nutraceuticals Pvt. Ltd.	Antibody test IgG/IgM CE approved	M/s Shanghai Outdo Bio Tech Co. Ltd. China
80	M/s Genetix BioTech Asia Ltd..	Antibody test IgG/IgM	M/s Sugentech Inc. South Korea
81	M/S Alpine Biomedicals Pvt Ltd Haryana	Rapid Antibody test IgG/IgM	Indigenous
82	S A Diagnostics Pvt Ltd Mumbai	Antibody test IgG/IgM	M/S Genrui Biotech Inc China
83.	M/s Abbott Healthcare Pvt Ltd	Chemiluminescent Microparticle Immunoassay With Architect System	M/S Abbott Ireland Diag Div. Ireland
84	M/s Lab Care Diag, India Pvt Ltd	Antibody test IgG/IgM	Indigenous

85	M/S Nulife, Noida	Antibody test IgG/IgM	Indigenous
86	M/s Tulip Diagnostics Pvt Ltd Goa	Coviscreen-Rapid Double Antigen test for detection of IgG/IgM/IgA	Indigenous
87	M/s Roche Diagnostics India Pvt. Ltd. Delhi	ECLIA Elecys Anti SARS COV2	M/s Roche Diagnostics GmbH, Germany
88	M/s Sidak LifeCare Pvt. Ltd.	Antibody test IgG/IgM	Indigenous
89	M/s S.D Biosensor HealthCare Pvt. Ltd.	Standard Q COVID-19 IgG/IgM Combo	Indigenous
90	M/s Diasorin Healthcare India Pvt. Ltd.	CLIA	M/s Diasorin S.P.A, Italy
91	M/s Iris Hightech Pvt. Ltd. Delhi	Antibody test IgG/IgM	M/s Pharmact GmbH, Germany
92	M/s Mindray Medical India Pvt. Ltd. Mumbai	CLIA	M/s Shenzhen Mindray, China
93	M/s Ortho Clinical Diagnostics India Pvt. Ltd.	Vitros Immunodiagnostic Total Reagent Pack	M/s Ortho Clinical Diagnostics, USA
94	M/S DiaSys Diagnostics India Pvt Ltd	Antibody test IgG/IgM	M/S Beijing Lepu Medical Technology Co Ltd China
95	M/S Jetta Labs	Antibody test IgG/IgM	M/s Hangzhou Test Sea Biotechnology China
96	M/s V.S Yarns Pvt. Ltd. Ludhiana	Antibody test IgG/IgM	M/s Accobiotech, Malaysia
97	M/s CliniExperts Services Pvt. Ltd	Antibody test IgG/IgM	M/s Europlaz Technologies, U.K
98	M/s Cadila Healthcare Ltd.	ELISA	Indigenous

99	M/s Deep Meditech Pvt. Ltd. Delhi	Antibody test IgG/IgM	M/s Autobio Diag Co Ltd, China
100	M/S McW Healthcare Pvt Ltd	Antibody test IgG/IgM	M/s Technogenetics S.r.l Italy
101	M/S Omega Dx (Asia) Pvt Ltd	ELISA	M/S Genesis Diagnostics Ltd , UK
102	M/S Abbott Healthcare Pvt Ltd	CMIA	M/S Abbott Ireland
103	M/S Ortho Clinical Diag. India Pvt. Ltd	CLIA, IgG qualitative immunodiagnostic assay kit	M/S Ortho clinical Diag. UK
104	M/S Ortho Clinical Diag. India Pvt. Ltd	VITROS (Immunodiagnostic Assay Kit) including IgG,IgA and IgM	M/S Ortho clinical Diag. UK
105	M/S Athenese-Dx Pvt. Ltd	Antibody test IgG/IgM	M/S CTK Biotech Inc, USA
106	M/S Tosoh India Pvt Ltd	ELISA IgA, ELISA IgG, ELISA IgM	M/S NovaTec GmbH, Germany
107	M/S Biorad Laboratories (India) Pvt Ltd	Platellia SARS-COV2 Total Ab	M/S Biorad , France
108	M/S Novomed Inc Pvt Ltd	ELISA IgG/IgM	M/S Ga Generic Assay GmbH Germany
109	M/S Ortho Clinical Diag. India Pvt. Ltd	CLIA , Vitros IgG	M/S Ortho clinical Diag. UK
110	M/S S D Biosensor Healthcare Pvt Ltd	Standard Q COVID-19Ag	Indigenous
111	M/S J. Mitra	COVID IgM+IgG+IgA Microlisa	Indigenous

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इमेल द्वारे

जा. क्र. कोविड उ.यो./कोविड किट/१४६४-२०/११

दि. १६जून, २०२०

प्रति,

मा. सचिव
वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग
मंत्रालय, मुंबई-०१

विषय :- COVID-१९ च्या नैदानिक चाचणी करिता वापरण्यात येणाऱ्या Rapid टेस्ट किट बाबत.

महोदय

विषयांकित प्रकरणी शासनास सादर करण्यात येते कि, औषध नियंत्रक (भारत) यांचेद्वारा कोविड १९ च्या चाचणी करिता मान्यता देण्यात आलेल्या Rapid Antigen Test Kit आणि Antibody Rapid Test kit चे उत्पादन व विक्री करणाऱ्या संस्थांची यादी त्यांचे संकेतस्थळ cdsco.gov.in वर प्रसिद्ध केली आहे. सदर यादी ची प्रत यासोबत जोडली आहे.

भारतीय आयुर्विज्ञान अनुसंधान परिषदेने दि. १४/०६/२०२० रोजी त्यांचे संकेतस्थळावर Rapid Antigen detection test for COVID-१९ च्या वापराबाबत मार्गदर्शक सूचना प्रसिद्ध केल्या आहेत.

वरील सर्व बाबी विचारात घेता, औषध नियंत्रक (भारत) यांनी मान्यता दिलेल्या Rapid antigen kit and Rapid antibody किट चा वापर शासनाच्या अखत्यारीतील सर्व यंत्रणा जसे वैद्यकीय शिक्षण विभाग व सार्वजनिक आरोग्य विभाग यांचे अखत्यारीतील रुग्णालये, प्रयोगशाळा, केंद्र शासनाची रुग्णालये, खाजगी रुग्णालये व प्रयोगशाळा इ, भारतीय आयुर्विज्ञान अनुसंधान परिषद (ICMR) ने वेळोवेळी निर्गमित केलेल्या मार्गदर्शिकेनुसार(Advisory Notice) कोविड १९ च्या चाचणी करिता करू शकतात.

तरि आपल्या माहितीस्तव सविनय सादर.

आपला

अरुण उन्हाळे, भा.क्र.स.

आयुक्त

अन्न व औषध प्रशासन, महा. राज्य

मुंबई-५१