

सत्यमेव जयते

COMPENDIUM OF INSTRUCTIONS FOR COVID-19 TESTING LABORATORY

Medical Education and Drugs Department Government of Maharashtra



Medical Education and Drugs Department

COMPENDIUM OF INSTRUCTIONS FOR COVID-19 TESTING LABORATORY

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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 6^{th} July, 2020. The Editorial Board shall be updating this on a regular basis.

We thank you all.

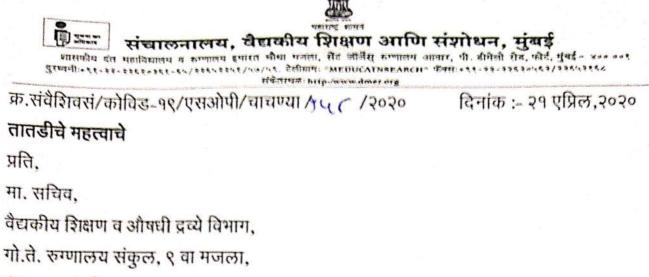
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मंत्रालय, मुंबई

विषय :- कोविड-१९ अंर्तगत करण्यांत येत असलेल्या चाचण्याबाबत Standard Operating Procedure for Laboratories

शासनाने कोविड-१९ च्या संदर्भात विविध उपाययोजना करण्याकरीता वेळोवेळी मार्गदर्शक सूचना प्रसिध्द केलेल्या आहेत. उक्त मार्गदर्शक सूचनाच्या अनुषंगाने राज्यामध्ये करण्यात येत असलेल्या कोविड-१९ चाचण्या करण्यास अधिक सुसुस्त्रा आणण्यासाठी तांत्रिक समितीने laboratories testing करीता standard operating procedure for laboratories तयार केल्या आहेत. सदरचे standard operating procedure शासनाच्या माहितीस्तव सादर

वैद्यकीय शिक्षण व संशोधन, मुंबई

Standard Operating Procedure for Laboratories testing COVID-19 samples in Maharashtra

Background

With the current scenario of COVID 19 global pandemic, where the cases all across the globe including India is rising rapidly day by day. Due to the fast spread of virus, it becomes critical to expedite setting up diagnostics for this new virus. Currently, there are many government and private labs which are functional in the country with all equipments and staff. With current availability of laboratory facilities in Maharashtra and considering the possibility of increase in the number of cases in future, it becomes important to increase the testing laboratories in the country. In addition, we also need to effectively utilize the available facilities by increasing their testing capacity with effective time and manpower management. All laboratories are required to follow guidelines published by ICMR. Diagnosis will help in early identification of the disease and containment of the disease.

Scope

This document proposes optimum time and manpower management with respect to efficient functioning of Laboratories involved in sampling and testing of COVID-19 patients in state of Maharashtra.

Sr. No	Different steps	Average time required
1	Sample decoding & Aliquoting (for 46 samples)	120 min
2	RNA Extraction (for 46 samples) using manual extraction method	120 min
3	Master Mix Preparation (for 46 samples)	60 min
4	PCR Amplification (for 46 samples:- I. Addition II. PCR III. Interpretation and Reporting	180 min

1. Optimum time for running one set of samples (one cycle):-

- Average time required for completing one cycle is **approx. 8 hours** for Screening. Final confirmation reports of initial positive samples will be available after 8 hr. This is as per *NIV protocol*.
- All initial Positives at the end of cycle to be kept aside. These samples will be run for confirmation in the next run.
- > Daily scheduling of cycles:-
 - 1. Cycle 1 : 8 AM to 4 PM
 - 2. Cycle 2 : 4 PM to 12
 - 3. Cycle 3 : 12 Midnight 8 AM

2. SOP for Effective running a RT PCR lab as per manpower and shift-wise for COVID testing:

Requirements: (Each shift 7 persons; 4 technically trained, 1 person authorised for reporting)

Team of 7 people (PER SHIFT) and 1 RT PCR Machine and manual RNA extraction and one Biosafety Cabinet

Each Batch of 48 reactions (46 samples and 2 controls)

Team 1 - 2 people: Technical person well familiar with molecular Biology techniques.

Team 2 - 2 people: Technical person well familiar with molecular Biology techniques.

Team 3 -1 person - Authorised for reporting

1 DEO (Data Entry Operator)

1 Lab attendant

PROCEDURE:

Sr.	Shift	RNA Extraction	PCR
No.			
1	8 AM to	Two batches of 46 samples	Two batches of 46 samples :
	4 PM	each.	1. Screening reaction for RNA
			extracted from Batch E.
		Batch : A and B	2. Screening reaction for RNA
			extracted from Batch A.
2	4 PM to	Two batches of 46 samples	Two batches of 46 samples :
	12	each.	1. Screening reaction for RNA
	Midnight		extracted from Batch B.
		Batch : C and D	2. Screening reaction for RNA
			extracted from Batch C.
3	12	Batch of 46 samples.	One Batch of 46 samples :
	Midnight		1. Screening reaction for RNA
	to - 8	Batch : E	extracted from Batch B.
	AM		2. Confirmation of all initial
			positive samples from Batch A to
			Batch E

- 1. In each shift, one team (Team 1) will do 2 batches of RNA extraction (maximum sample size 46)
- In each shift, one team (Team 2) will do 2 runs of MMX (maximum sample size 46). First run will be from RNAs extracted from previous batch.
- 3. Data entry for each shift will be completed in that shift

- 4. Reporting for that shift will be completed in that same shift for the respective batches whose screening is complete. Negative samples will immediately reported. Initial positive samples will be reported in the last shift. Two technicians will help for final reporting in the last shift.
- 5. In the third shift, one run will be of confirmatory
- 6. So total runs of screening will be 5 (230 samples screened)
- 7. One run will be confirmatory.
- If additional space, machine RT PCR & Biosafety cabinet, microcentrifuge and set of pipettes is available, with <u>4</u> additional technical manpower in each shift, 506 samples can be tested in a day. (will need additional Lab attendant and DEO)



Specimen Collection, Packaging and Transport Guidelines for 2019 novel Coronavirus (2019-nCoV)

Title: Specimen Collection, Packaging and Transport Guidelines for 2019 Novel Coronavirus (2019-nCoV)

SOP number: ICMR-NIV/2019-nCoV/Specimens_01Prepared by: Dr. Y.K. GuravDate: 19/01/2020Reviewed by: Dr. V. PotdarDate: 20/01/2020Approved by: Dr. P. AbrahamDate: 20/01/2020

Scope:

To be used by the Government health authorities/ hospitals/ clinicians/ laboratories planning to collect appropriate clinical samples as indicated for diagnosis of 2019-nCoV.

Purpose:

This document describes the information for collection, packaging and transport of clinical specimens to Influenza group at ICMR-National Institute of Virology (NIV), Pune, Maharashtra for diagnosis of 2019 Novel Coronavirus (2019nCoV)

Responsibilities:

- The clinician should decide necessity for collection of clinical specimens for laboratory testing of 2019-nCoV only after following the case definition as given by the health authorities, Government of India.
- Appropriate clinical sample need to be collected by laboratory personnel/ health care worker trained in specimen collection in presence of a clinician.
- By following all biosafety precautions and using personal protective equipment (PPEs), clinical samples need to be sent to the designated laboratory (ICMR-NIV, Pune) by following standard triple packaging.

Selection of patient:

Any person who presents with Severe Acute Respiratory Illness (SARI) AND any one of the following i.e. a history of travel from Wuhan, China in 14 days prior to symptoms onset; disease in healthcare worker working in an environment of SARI patients; unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment; should be urgently investigated. Updated case definition need to be followed as per MOHFW, Govt of India which is available on the website www.mohfw.gov.in

Specimen collection details:

(Adapted from the WHO guidelines on 2019-nCoV):

Specimen type	Collection materials	Transport to laboratory	Storage till testing	Comment
Nasopharyngeal and oropharyngeal swab	Dacron or polyester flocked swabs*	4 °C	≤5 days: 4 °C >5 days: -70 °C	The nasopharyngeal and oropharyngeal swabs should be placed in the same tube to increase the viral load.
Bronchoalveolar lavage	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	There may be some dilution of pathogen, but still a worthwhile specimen
Tracheal aspirate, nasopharyngeal aspirate or nasal wash	sterile container*	4 °C	≤48 hours: 4 °C >48 hours: −70 °C	Not applicable
Sputum	sterile container	4 °C	≤48 hours: 4 °C >48 hours: –70 °C	Ensure the material is from the lower respiratory tract
Tissue from biopsy or autopsy including from lung	sterile container with saline	4 °C	≤24 hours: 4 °C >24 hours: −70 °C	Autopsy sample collection preferably to be avoided
Serum (2 samples – acute and convalescent)	Serum separator tubes (adults: collect 3-5 ml whole blood)	4 °C	≤5 days: 4 °C >5 days: –70 °C	Collect paired samples: • acute – first week of illness • convalescent – 2 to 3 weeks later

*For transport of samples for viral detection, use VTM (viral transport medium) containing antifungal and antibiotic supplements. Avoid repeated freezing and thawing of specimens.

Specimen labelling and processing:

- Personal protective equipment (apron, hand gloves, face shield, N95 Masks etc.) need to be used and all biosafety precautions should be followed so as to protect individuals and the environment.
- Proper labelling (name/age/gender/specimen ID) need to be done on specimen container and other details of sender (name/address/phone number) on the outer container by mentioning "To be tested for 2019-nCoV"
- For any queries, the nodal officer from ICMR-NIV Pune (Dr Yogesh K. Gurav, Scientist E) may be contacted (Phone 020-26006290/ 26006390; Email: gurav.yk@gmail.com/gurav.yk@gov.in) and need to be informed in advance before sending specimens to ICMR-NIV, Pune.



Specimen Collection, Packaging and Transport Guidelines for 2019 novel Coronavirus (2019-nCoV)

Requirements	for Clinical Samples Colle	ction, Packaging and T	· · ·							
1. Sample vials and Virus Transport Medium (VTM)	2. Adsorbent material (cotton, tissue paper), paraffin, seizer, cello tape	3. A leak-proof seconda ziplock pouch, cryob tube, plastic containe	ox, 50 mL centrifuge							
4. Hard-frozen Gel Packs 5. A suitable outer container (e.g., thermocol box, ice-box, hard-board box (minimum dimensions: 10 x 10 x 10 cm) Frocedure for Specimen Packaging and Transport										
1. Use PPE while handling	2. Seal the neck of the	3. Cover the sample vials	4. Arrange primary							
specimen	sample vials using parafilm	using absorbent material	container (vial) in secondary container							
5. Placing the centrifuge tube inside a zip-lock pouch	6. Placing the zip-lock pouch inside a sturdy plastic container and seal the neck of the container	Note: Sample vials can also be placed inside a zip-lock pouch, covered in absorbent material and secured by heat- sealing or rubber bands. Then, the zip-lock pouch should be placed inside another plastic pouch and secured	7. Using a thermocol box as an outer container and placing the secondary container within it, surrounded by hard- frozen gel packs							
7. Using a hard card-board box as an outer container and placing the secondary container and the gel packs Documents to accompany:	8. Placing the completed Specimen Referral Form (available on www.niv.co.in) and request letter inside a leak-proof, zip-lock pouch	9. Securing the zip-lock pouch with the Specimen Referral Form on the outer container	 10. Attaching the labels: Senders' address, contact number; Consignee's address /contactnumber; Biological substance-Category B; 'UN 3373'; Orientation label, Handle with care 							
Documents to accompany: 1) Packaging list/proforma Invoid	ce 2) Air way bill (for air trans	port) (to be prepared by se	ender or shipper) 3) Value							

1) Packaging list/proforma Invoice 2) Air way bill (for air transport) (to be prepared by sender or shipper) 3) Value equivalence document (for road/rail/sea transport) [Note: 1. A vaccine-carrier/ice-box can also be used as an outer container 2. The minimum dimensions of the outer container should be 10 x 10 x 10 cm (length x width x height)]

Routing of samples:

- Clinical specimens, official documents and Specimen request forms for testing of 2019-nCoV need to be sent to the ICMR-NIV address (The Director, ICMR-National Institute of Virology, 20-A, Dr Ambedkar Road, Pune, Maharashtra, Pin: 4110001).
- For shipment-related queries/information, kindly contact Dr Sumit Bharadwaj (Scientist B, Influenza Group) on email: sumitduttbhardwaj@gmail.com, phone 020-26006290/26006390

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESAERCH

Advisory for sample collection sites:

ICMR has no objection on adoption of establishing convenient sample collection sites (drive through centers for sample collection etc.) by the respective State Governments.

However, the following advice is provided by ICMR:

- The sample collection should be done using the recommended Personal Protective Equipment (PPE).
- These sites should be disinfected regularly as per recommended procedures.
- All recommended biosafety and biosecurity precautions should be implemented.
- Sample transport to the nearest COVID-19 testing laboratory should be ensured under proper cold-chain conditions and with triple layered packing.

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

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 									
*A1 PERSON DETAILS	/ILL NOT BE ACCEPTED IN CASE OF ANY BLANK)								
"A.I PERSON DETAILS									
*Patient Name:	*Age:YearsMonth , Gender: * Male Female Others								
*Present Patient Village or Town:	*Mobile Number:								
	*Mobile Number belongs to: Self 🗌 Family 🗌 Other 🗌								
*District of present residence:	*Nationality:								
*State of present residence:									
(These fields to be filled for all patients including foreigners)									
*A.2 SPECIMEN INFORMATION FROM REFERRING AG	ENCY								
*Specimen type BAL/ETA TS/NPS/NS	Blood in EDTA Acute sera Covalescent sera Other								
*Collection date									
*Label									
*Is it a repeated sample? Yes No									
*Sample collection facility name:	*Collection facility pin-code								
*A.3 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									
Cat 4: Hospitalized SARI (Severe Acute Respiratory Illness)	patient								
Cat 5a: Asymptomatic direct and high risk contact of confirm	med case – family member								
Cat 5b: Asymptomatic healthcare worker in contact with co	nfirmed case without adequate protection								
Section B- OTHER FIELDS TO BE UPDATED									
B.1 PERSON DETAILS									
Present patient address:	Pin code:								
	Date of Birth: ////////////////////////////////////								
	Patient Passport No. (for Foreign national only)								
Email id:									
Patient Aadhar No. (For Indians)									
B.2 EXPOSURE HISTORY(2 WEEKS BEFO	RE THE ONSET OF SYMPTOMS)								
	Yes No								
If yes, place(s) of travel:, Stay/trave	el duration:// to/ (dd/mm/yy)								
2. Have you been in contact with lab confirmed COVID-	19 patient: Yes 🗌 No 📃								
If yes, name of confirmed patient:									
3. Were you Quarantined?: Yes No	If yes, where were you quarantined: Home 🗌 Facility 🗌								
4. Are you a health care worker working in hospital invo	olved in managing patients: Yes No								

B.3 CLINICAL SYMPTOMS AND SIGNS
Date of onset of symptoms / / (dd/mm/yy) First Symptom:
Symptoms Yes Symptoms Yes Symptoms Yes From (dd/mm) To (dd/mm) Cough Diarrhoea Vomiting Fever at evaluation if yes, Image: Cough if yes, Image: C
Breathlessness Nausea Haemoptysis Body ache if yes,/ Sore throat Chest pain Nasal discharge
Sputum Abdominal pain (HISTORY)
Respiratory infection at sample collection: Severe Acute Respiratory Illness (SARI): Yes 🗌 No 🗌 ARI: Yes 🗌 No 🗌
B.4 UNDERLYING MEDICAL CONDITIONS
Condition Yes Condition Yes Condition Yes
COPD Bronchitis Diabetes Hypertension
Chronic renal disease 🖂 Malignancy 🖾 Heart disease 🖾 Asthma
IMMUNOCOMPROMISED CONDITION: YES/ NO Other underlying conditions:
B.5 HOSPITALIZATION, TREATMENT AND INVESTIGATION
Hospitalization date: / / / (dd/mm/yy) DIAGNOSIS:
DIFFERENTIAL DIAGNOSIS: ETIOLOGY IDENTIFIED:
ATYPICAL PRESENTATION: YES/NO UNUSUAL/UNEXPECTED COURSE: YES/NO
OUTCOME: Discharge/Death/ OUTCOME date: / / / / / / / / / / / / / / / / / / /
Phone mobile number: Hospital Name/address:
Name of Doctor:

DETAILS OF HEALTH AUTHORITY (FOR SENDING THE REPORT)

Name of Doctor Hospital Name /address

EMAIL ID

Phone /mobile number Signature and Date

For Official Use – To be filled by COVID-19 testing lab facility

Date of sample receipt(dd/mm/yy)	Sample accepted/ Rejected	Date of testing	Test result	Repeat Sample required	Sign of Authority (Lab in charge)

	INDIAN COUNCIL OF MEDICAL RESEARCH															
	DEPARTMENT OF HEALTH RESEARCH															
	Requisite information to be submitted by private laboratories interested in COVID 19 testing															
S.No	Name of lab	Head Office	Total No of collection sites	Location of Collection sites	Influenza testing by RT- PCR Y/N	No of RT-PCR Machine available	No of Biosafety cabinets	Dedicated area for molecular diagnostics	COVID 19 testing reagents available Y/N	List of reagents available	Quantity of Reagent available	If not available please mention timeline for procurement	NABL/CAP/ILAC Accreditation & Scope of Accreditation	Participation in EQAS Programme (If any)	Modality of Sample Collection	No cost /chargeable
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																

Interested private laboratories may kindly send the filled in performa to Dr. Neeraj Aggarwal at: aggarwal.n@icmr.gov.in

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH Strategy of COVID19 testing in India (17/03/2020):

Background:

WHO declared an outbreak of febrile respiratory illness of unknown etiology in December 2019 from Wuhan, Hubei province of China. Since its emergence, the disease has rapidly spread to neighboring provinces of China as well 151 other countries mainly through International travel. Infection is spread through droplets of an infected patient generated by coughing and sneezing or through prolonged contact with infected patients.

Currently, India has witnessed only imported cases of COVID19 and limited local transmission from imported cases to their immediate contacts. Community transmission of the disease has not been documented till now. If community transmission is documented, the above testing strategy will undergo changes to evolve into stage appropriate testing strategy.

Objectives:

- To contain the spread of infection / community transmission of COVID19 by improving access.
- To provide free of cost and reliable diagnosis to all individuals meeting the inclusion criteria of COVID19 testing.
- To avoid indiscriminate testing and reducing panic and optimally utilize the resources of the country and scale up facilities for testing.

Current scenario:

- All individuals requiring to be tested are being offered at no cost.
- Accessibility and availability of the test is being increased every day by adding optimum numbers of testing laboratories every week.
- Currently, the cost of the first step screening assay is INR 1500 and additional confirmatory assays is INR 3000.
- As a part of the laboratory expansion process, ICMR has engaged with non-ICMR / MOHFW Govt. laboratories to initiate testing facilities. This includes CSIR, DBT, DRDO, Govt. Medical Colleges etc.
- ICMR is also engaging with high-quality private laboratories that includes NABL accredited labs to understand the modalities of increasing access to the test while ensuring appropriate safeguards.
- ICMR is operationalizing already existing high throughput diagnostic systems (upto 1400 samples per day) to exponentially augment the testing capacity in heavily overloaded states. It is proposed to install high throughput systems in atleast 5 locations (with possibility of scale-up to 10 locations) on an urgent basis.

- ICMR-NIV, Pune has already placed orders to augment the existing stockpile of reagents to 1 million tests which would be available soon. WHO has also been requested to provide additional 1 million probes for testing.
- Advisory for testing are being reviewed and updated periodically (09/03/2020 and 16/03/2020). The testing strategy is reviewed by a high-level Expert Committee constituted by Secretary DHR & DG, ICMR and Chaired by Prof, Randeep Guleria, Director, All India Institute of Medical Sciences, Delhi.

Current testing strategy:

i. All asymptomatic people who have undertaken International travel:

- They should stay in home quarantine for 14 days.
- They should be tested only if they become symptomatic (fever, cough, difficulty in breathing etc.).
- If test result is positive, then they should be isolated and treated as per the standard protocol.

ii. All contacts of laboratory confirmed positive cases:

- They should stay in home quarantine for 14 days.
- They should be tested only if they become symptomatic (fever, cough, difficulty in breathing etc.).
- If test result is positive, then they should be isolated and treated as per the standard protocol.
- iii. Health care workers managing respiratory distress / Severe Acute Respiratory Illness should be tested when they are symptomatic.

Guidelines for private sector laboratories intending to initiate COVID19 testing:

- Laboratory test should be only offered when prescribed by a qualified physician as per ICMR guidance for testing. Since the guidance evolves periodically, the latest revised version should be followed.
- ICMR will share the SOPs for laboratory testing and provide positive controls for establishing the test as soon as the concerned private laboratory has procured the primers, probes and reagents as per SOPs. Adoption of commercial kits for testing should be based on validations conducted by ICMR-National Institute of Virology (NIV), Pune.
- Appropriate biosafety and biosecurity precautions should be ensured while collecting samples from a suspect patient. Alternatively, a disease specific separate collection site may be created.
- All the private testing laboratories ensure immediate/ real-time reporting to the State officials of IDSP (Integrated Disease Surveillance Program of Govt. of India)and ICMR Hq. for timely initiation of contact tracing and research activities.

- ICMR strongly appeals that private laboratories should offer COVID19 diagnosis at no cost.

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Revised Strategy of COVID19 testing in India (Version 3, dated 20/03/2020)

Background:

WHO declared an outbreak of febrile respiratory illness of unknown etiology in December 2019 from Wuhan, Hubei province of China. Since its emergence, the disease rapidly spread to neighboring provinces of China as well as to 182 other countries. Infection is spread through droplets of an infected patient generated by coughing and sneezing or through prolonged contact with infected patients.

Currently, India has witnessed cases of COVID19 mostly related to travel and local transmission from imported cases to their immediate contacts. Community transmission of the disease has not been documented till now. Once community transmission is documented, the above testing strategy will undergo changes to evolve into stage appropriate testing strategy.

Advisory for testing are being reviewed and updated periodically (09/03/2020, 16/03/2020 and 20/03/2020). The testing strategy is reviewed by the National Task Force constituted by Secretary DHR & DG, ICMR and Chaired by Prof. V. K. Paul, Member, NITI Aayog.

Objectives:

- To contain the spread of infection of COVID19.
- To provide reliable diagnosis to all individuals meeting the inclusion criteria of COVID19 testing.

Current testing strategy:

- i. All symptomatic individuals who have undertaken international travel in the last 14 days:
- ii. All symptomatic contacts of laboratory confirmed cases.
- iii. All symptomatic health care workers.
- iv. All hospitalized patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath).
- v. 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.

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Strategy for COVID19 testing in India (Version 4, dated 09/04/2020)

- All symptomatic individuals who have undertaken international travel in the last 14 days
- 2. All symptomatic contacts of laboratory confirmed cases
- 3. All symptomatic health care workers
- 4. All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)
- 5. 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

In hotspots/cluster (as per MoHFW) and in large migration gatherings/ evacuees centres

- 6. All symptomatic ILI (fever, cough, sore throat, runny nose)
 - a. Within 7 days of illness rRT-PCR
 - b. After 7 days of illness Antibody test (If negative, confirmed by rRT-PCR)

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Applications invited from Government & Private Medical Colleges for setting up COVID-19 testing facility:

ICMR invites applications from all Government and Private Medical Colleges for establishing a COVID-19 testing facility. All Medical Colleges with following infrastructure and expertise may apply:

- i. 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.
- ii. Availability of cold centrifuge/microfuge for RNA extraction
- iii. Availability of a functioning and calibrated real-time PCR machine.
- iv. Staff Requirements:
 - A. Availability of following minimum staff:
 - Medical Microbiologists 1 or more with experience of work in Molecular Virology.
 - Technicians At least 4-6 (2-3/shift) with relevant experience of work in Molecular Virology.
 - Multi-Task Staff 1 or more for washing / cleaning
 - B. Desired expertise of the staff:
 - Good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis, RNA extraction and real-time PCR.
 - Experience of work in virology and handling clinical specimens, especially respiratory samples.
- v. A robust Institutional policy on biomedical waste management of human origin.
- vi. Well defined arrangement for segregation and discarding of biomedical waste.

Additionally, for all applicants from Private Medical Colleges, it is essential to submit a copy of the NABL accreditation certificate and scope of accreditation for real-time PCR for RNA viruses.

Separate information should be provided on each of the above component (i to vii).

Detailed guidance on requirements for infrastructure and consumables for real-time RT-PCR Laboratory are placed at Annexure 2.

Interested Medical Colleges may apply to:

Dr. Nivedita Gupta Scientist F Division of Epidemiology & Communicable Diseases Indian Council of Medical Research, Ansari Nagar, New Delhi

Applications should be accompanied with pictures of the laboratory infrastructure covering points i to iii and vi separately.

All applications should be submitted by email at: <u>arvind.nccs@gmail.com</u> and <u>jitunarayan@gmail.com</u>

1

EQUIPMENT AND CONSUMABLE REQUIREMENTS FOR SETTING UP A REAL TIME PCR TESTING FACILITY

On-site requirements of existing functional equipment

- Biosafety cabinet (BSC) class 2A (calibrated)
- -20 °C deep freezer with UPS, for storage of reagents (primers/ probes/ positive controls)
- -80°C deep freezer with UPS, for storage of aliquoted samples/ viral RNA in cryovials
- 4°C refrigerator (for storage of viral transport medium, and for short term storage of samples and extracted RNA)
- UPS (2 nos., 2KVA each, with 2 hours back-up, for real time PCR instrument and nucleic acid extraction systems – if not available, then to be carried); and confirm about power backup for the two deep freezers (check about duration of power outages, if any)
- Real-time PCR machine
- Microcentrifuge / Refrigerated Centrifuge

Required equipment and consumables

- I. For sample collection:
 - a. Personal protective equipment (PPE)
 - b. Viral Transport Medium (VTM)
 - c. Flocked Dacron swabs (2 swabs/ sample collection from 1 patient)

II. During processing

- a. Biosafety cabinet class IIA/ IIB
- b. Personal protective equipment: N95 masks, coveralls (protective against blood and body fluids), nitrile gloves, shoe cover, head cover
- c. Vortex mixer
- d. Microcentrifuge (Cold centrifuge)
- e. Cryovials (2 ml)
- f. Cryobox
- g. Pipette aid
- h. Disposable plastic pipettes
- i. Sprit lamp
- j. Forceps (if no spirit lamp, then disposable forceps for each sample)
- k. 70 % ethanol (also required for next stage, i.e., extraction)
- I. 1% sodium hypochlorite (4% stock, to be freshly reconstituted daily to 1% with water)
- m. Discarding jars
- n. Biomedical waste disposal (BMW) bags (with ties for sealing; preferably autoclavable, if discarding autoclave is available/ used locally) and bins
- o. Iceboxes with gel packs or regular ice supply in laboratory (from icemaker)
- p. Tube rack (15 ml tubes)

q. For tube / cryovial labelling - Marker pens, cellotape, or label printouts (printer with label maker)

III. Nucleic acid extraction

- Manual extraction using kits for Viral RNA extraction: Viral RNA mini kits (Qiagen) or other viral RNA extraction kits for manual extraction
- 1.7 ml Eppendorf tubes (separate ones also required for next step)
- Cryovial/ Eppendorf tube rack (separate ones also required for next step)
- Microcentrifuge (small equipment)
- Micropipettes- 100-1000ul, 20-200ul (additional separate micropipettes of required volumes also listed for next stage, i.e. real time PCR)
- Filter barrier tips: 1000ul, 200ul
- Tissue rolls
- Hand sanitizers
- Biohazard labels

IV. Real time PCR

- Real time PCR machine (open system) calibrated for the fluorophore dyes which are present on the probes
- Reagents for setting up Real-time
 - PCR primers and probes specific for SARS-CoV2 targets
 - PCR master mix reagents (e.g., Thermo Fisher/ Invitrogen AgPath/ Superscript III Platinum real time PCR reagents) with buffer and enzyme

• PCR reagents

- Primers for E gene screening and
- Probes for E gene screening and RDRP/ ORF 1b targets
- PCR Buffer and enzyme mix
- \circ Positive control
- PCR workstations 1 for mastermix preparation; 1 for RNA addition
- Cryovial racks
- PCR tubes/ PCR plates
- PCR plate adhesive seals and plate sealer
- Micropipettes- 0.5-10ul (2 nos., 1 for PCR master mix and 1 for RNA addition), 2-20ul, 20-200ul
- Filter barrier tips 10ul, 20ul, 200ul
- Microspin (small equipment)
- Plate centrifuge (small equipment)
- Electronic micropipette (optional small equipment, but convenient and reduces time duration of testing)
- Nuclease free water for PCR
- RNaseP

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Advisory for initiation of additional COVID-19 testing laboratories

Currently, the Indian Council of Medical Research (ICMR) has approved the COVID-19 testing in more than 200 laboratories across the country. Based on the new requests from several districts of India for initiation of COVID-19 testing, ICMR has formulated the following guidelines for establishment of a new testing laboratory for COVID-19 testing in any district.

In areas with no operational COVID-19 testing facility, a new facility will be considered subject to fulfillment of the following criteria (applicable from 5th April, 2020):

- i) The number of suspected cases in that particular district should be more than 100 per day.
- ii) The nearest testing laboratory for COVID-19 is more than:
 - a. Plain areas- 250 kms (4-5 hrs @ 60 Km/hr)
 - b. Hilly areas- 150 kms (5 hrs @ 30Km/hr)
- iii) In case there are testing laboratories within the above mentioned distance, each of the existing testing laboratories should be testing at least 100 samples per day.
- iv) If the nearest testing laboratory is within the above mentioned distance, and not testing 100 samples per day, and does not agree to test the samples from the affected district, then the existing laboratory will be closed down, and permission will be given to the new laboratory.
- v) The district should have a government laboratory with the following:
 - 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.

(Proofs of the above mentioned requirements need to be submitted to ICMR while applying for a new testing laboratory, which will include documents and photographs of the laboratory) vi) If the district has no government laboratory, but has a private laboratory which can apply for COVID-19 testing, the laboratory should have NABL accreditation, and the scope of accreditation must include real-time PCR for respiratory viruses.

(All the required documentations which needs to be provided by the private laboratory to ICMR is available in the official website of ICMR)

Indian Council of Medical Research

New-Delhi

Date: 03/04/2020

Advisory for ICMR approved private labs that are doing COVID 19 testing by Real time RT-PCR

Kindly store all positive samples at appropriate temperature (-20C/-80C) till shipped to National Institute of Virology, Pune as mentioned in earlier issued guidelines. Labs can send samples either fortnightly or monthly depending on their convenience. All positive samples must be sent to Dr. Varsha Potdar at NIV Pune. 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.

F. No. Z.28015/23/2020-EMR Government of India Ministry of Health and Family Welfare

Nirman Bhawan, New Delhi Dated the 21st March, 2020

ORDER

The guidelines laid down by Indian Council of Medical Research for COVID-19 testing in private laboratories in India (as annexed) is notified vide Clause (i) and (l) of sub-section 2 of Section 10 of DM Act, 2005, under the power delegated vide order F. NO. 40-2/2020-DM1 (A); dated 11th March, 2020 for strict follow up and compliance.

Preet

Secretary, Ministry of Health & Family Welfare Government of India Guidelines for COVID-19 testing in private laboratories in India

The test to be conducted by a laboratory which has NABL accreditation for real-time PCR assay for RNA virus.

Whom to test:

Laboratory test should only be offered when prescribed by a qualified physician as per the ICMR guidleines for COVID-19 testing. Since the guidance evolves periodically, the latest revised version should be followed (link below).

(https://icmr.nic.in/sites/default/files/upload_documents/2020-03-20_covid19_test_v3.pdf)/ www. mohfw.gov.in.

Sample collection and Testing guidelines:

- Appropriate biosafety and biosecurity precautions should be ensured while collecting respiratory samples (oropharnygeal and nasal swab) from a suspect patient. Alternatively, a COVID-19 specific separate sample collection site may be created.
- Preferably, home collection of samples may be done by all the private laboratories. This will help avoid the contact of people with the suspect case during local travel to reach the laboratory.
- Only real time PCR based assays are recommended. Conventional PCR, in-house real time PCR and antibody/antigen tests are not recommended for COVID19 testing.
- Commercial kits for real time PCR based diagnosis of COVID-19 should be US FDA approved or European CE Certified or both for *in vitro* diagnosis of COVID-19 under emergency use, under intimation to DCGI, MoH&FW. Nucleic acid extraction kits and other reagents should be of standard quality.
- All the laboratory staff involved in COVID-19 testing should be appropriately trained in Good Laboratory Practices and performing real-time PCR.
- All the biomedical waste should be disposed off in accordance with National guidelines (https://dhr.gov.in/sites/default/files/Bio-medical_Waste_Management_Rules_2016.pdf).
- The sample should be opened only in Biosafety Cabinet Class II A2. At the time of sample disposal, the Viral Transport Medium (VTM) with swabs should be discarded in a biohazard bag containing 2% Lyzol or 5% freshly prepared hypochlorite solution.

Bag should then be sealed using plastic tag and disposed of in accordance with the National guidelines.

 Government ID to support the current address and contact number of the suspect patient should be collected at the time of sample collection.

Reporting protocols:

- Before any laboratory (private or public) start their activities, they must ensure immediate/real time reporting of the test results along with the contact details to the ICMR HQ database accessible at https://cvstatus.icmr.org.in. Login credentials to each lab for uploading the data will be given by ICMR.
- Each laboratory will be given a registration number by ICMR. The registration number given by ICMR should be prominently exhibited in case any advertisement is made and also in the report.
- The access to specified data and analysis to stakeholders like IDSP, MoHFW will be provided through API for timely initiation of contact tracing and appropriate control measures.
- The request should be send at aggarwal.n@icmr.gov.in indicating name, contact details and mobile number of nodal contact for the lab.

Policy for sample storage and destruction:

- All COVID19 positive samples will need to be transported to ICMR-NIV, Pune under suitable biosafety and biosecurity precautions as laid down by ICMR. The negative samples will be destroyed within one week of collection.
- No sample should be shared with any other organisation for any purpose.

Cost of the test:

The National Task Force recommends that the maximum cost for testing sample should not exceed Rs 4,500/-. This may include Rs 1,500 as a screening test for suspect cases, and an additional Rs 3,000/- for confirmation test. However, ICMR encourages free or subsidized testing in this hour of National public health emergency.

These guidelines may be amended from time to time.

Failure to comply with any of the above guidelines will result in legal action.



ICMR-National Institute of Virology (ICMR-NIV), Pune

Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



Purpose: This protocol is designed to detect 2019-nCoV in human clinical specimens

Introduction: The purpose of this document is to provide interim guidance to laboratories and stakeholders involved in laboratory testing of patients who meet the definition of suspected case of pneumonia associated with a novel coronavirus identified in Wuhan, China.

(https://www.who.int/health-topics/coronavirus/laboratorydiagnostics-for-novelcoronavirus)

Principle: The real time assay uses the TaqMan fluorogenic probe based chemistry that uses the 5' nuclease activity of Taq DNA polymerase and enables the detection of a specific PCR product as it accumulates during PCR cycles.

Coronaviruses under the subgenus Sarbecovirus that includes 2019-nCoV, SARS-CoV and bat SARS-like coronaviruses were used to generate a non-redundant alignment. Three assays based on their matching to the Wuhan virus as per inspection of the sequence alignment were designed

First line screening assay: E gene assay

Pl note along with novel corona real time PCR protocol, sample should be tested for Influenza detection

Reference:

https://www.who.int/health-topics/coronavirus/laboratory-diagnostics-for-novelcoronavirus

Requirements:

- a. Instruments:
 - 1. Real Time PCR machines (Make : ABI, Rm. Real time PCR room)
 - Model:7500 Fast:

Model:7500 Fast Dx:

- Serial no: 275012996 Serial no: 275030301
- Model:7500:
- Serial no: 275006294 Serial no: 275005234
- Model: 7500 Fast Dx:
- Serial no: 27300325 Serial no: 27200433
- Model:7500 Step one Plus: Serial no: 27

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ICMR-National Institute of Virology (ICMR-NIV), Pune

Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



	2	•	v cabinet (Make: Micro ent preparation room)	FITT, Model:	MFI BIO4X2, Seria	l no: 14476, Rm
	1. R 2.R	For reagent 0.5-10 µl 20-200 µl 100-1000 µ For master 0.5-10 µl 2-20µl 20-200 µl 100-1000 µ Rm. RNA add 5-100 µl mu 2-20 µl	(Make: BIOHiT, Ser (Make: Thermo, Ser 1 (Make: Thermo, Ser mix preparation(Make: (Serial no:V4 (Serial no: V4 (Serial no: U7)	ial no: CH175 ial no: CH286 Thermo) 4877) 42740) 5613) 01229) HiT, Serial no.	05) 11) 6545582) V17267)	
	c. S d.	preparation Minispin: (1 Hood: (Mak Miniplate sp Plastic war 96 Thin wal Consumab	plus: (Make: BIOSA	N, Serial no no: 1775, Loca Rm: Real time Serial no. V-15 tion tubes (8 t ml Eppendorf Free gloves, La	15975, Location: tion: Rm no: Reagent PCR room) 5725, Rm: Real Time ubes/strip), 96 Thin tubes, stand, micro ti b coats, aerosol barrie	preparation room, PCR room) wall PCR plates, ips, 96 well cooler
	f.	Reagents: 1. 2. 3. 4.	Invitrogen SuperScript No.11732088) AgPath-ID [™] One-St QIAamp Viral RNA M extraction Kit Nuclease Free Water	ep RT-PCR		,
Document No	.: SP.01	Document Na	ame: Standard Operating Proc by rRT-PCR : First Line Scree		ion of 2019 novel coronavi	irus (2019-nCoV) in suspe
Issue No.: 01		Issue Date:		Group Nam	e.: Human Influenza	Page No.: Page 2 of 6



ICMR-National Institute of Virology (ICMR-NIV), Pune

Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



5. Ethanol (96–100%)

Primers and Probes

Assay/	Oligonucleotide	Sequence (5'-3')	
Use	ID		
E gene	E_Sarbeco_F1	ACAGGTACGTTAATAGTTAATAGCGT	
	E_Sarbeco_R2	ATATTGCAGCAGTACGCACACA	
	E_Sarbeco_P1	FAM-	
		ACACTAGCCATCCTTACTGCGCTTCG	
		-BHQ	
RNaseP gene (Internal Control)	RNaseP Forward	AGATTTGGACCTGCGAGCG	
	RNaseP Reverse	GAGCGGCTGTCTCCACAAGT	
	RNaseP Probe	FAM-	
		TTCTGACCTGAAGGCTCTGCGCG-	
1		BHQ	

R is G/A; FAM, 6-carboxyfluorescein; BHQ, Black Hole Quencher

Documentation:

- Clinical sample register
- RNA extraction Laboratory book
- Real time PCR Laboratory book
- Result record book

Procedure/Protocol:

- 1. Perform RNA extraction of clinical samples according to "RNA extraction- QIAmp viral RNA Mini Kit" protocol in RNA extraction area.
- 2. Perform real time PCR reactions as shown in table for E gene assays and RNasP housekeeping gene.
- 3. Determine the number of reactions (N) to set up per assay. In addition, include Negative control, Positive control and MOCK (human source cell line) in the test.
- 4. Prepare excess reaction cocktail to account for pipetting error.

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



If number of samples (n) including controls = 1 to 10, then N = n + 1

5. In the **clean reagent preparation room** prepare the Master Mix:

Calculate the amount of each reagent to be added for each Primer /probe set reaction master mix.

The calculations are as follows:

Component	Volume for E gene	Volume for RNasP
H ₂ O (RNAse free)	5µl	5 µl
2x Reaction mix	12.5 µl	12.5 µl
PP mix	1.5 µl	1.5 µl
AgPath One-Step RT-	1 µl	1 µl
PCR *		
Template RNA	5 µl	5 µl
Total	25 μl	25 μl

* Invitrogen SuperScrip III Platinum One-Step Quantitative Kit, use 0.5ul and adjust the water volume to 5.5µl

- 6. Mix reaction mixtures by pipetting up and down. Do not vortex.
- 7. Centrifuge for 5-10 sec to collect contents at bottom of the tube, and then place the tube in cold rack.
- 8. Set up reaction strip tubes or plates in 96-well cooler rack.
- 9. Dispense 20µl of each master mix into each well as per the plate set up.
- 10. Before moving the plate to the nucleic acid handling area. Pipette 5ul of the nuclease free water into NTC wells. Cap NTC wells.
- In the nucleic acid extraction room, add 5ul of each sample and 5ul of Mock extraction control into respective wells as per the set up.
- 12. Cap the column or cover the plate with tissue paper to which the samples and mock control has been added.

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



- 13. Finally, pipette 5 µl of positive viral template control (E gene invitro transcribed RNA and for RNasP add pooled influenza control) into all VTC wells in **positive control** addition area. Cap VTC wells/ or seal the plate with optical sealer. Centrifuge the plate for 10 seconds. Make sure that bubbles are eliminated from the bottom of the reaction tubes.
- 14. For real time PCR set up follow the instructions given by the Real-time PCR system manual for plate set up. **Save your plate setup!**

Reverse Transcription*	55°C for 30 min
Taq inhibitor inactivation	95°C for 3 min
PCR amplification (45 Cycles)	95°C for 15 Sec 58°C for 30 sec* (data collection)

15. The reaction volume is 25 $\mu l.$ Program the run method as follows:

Fluorescence data should be collected during the 58° C incubation step.

16. After completion of the run, save the run and analyze the collected data.

Interpretation/examination:

- The NTC reactions for primer / probe sets should not exhibit fluorescence growth curves that cross the threshold line. If a false positive occurs with one or more of the primer and probe NTC reactions, sample contamination may have occurred. Invalidate the run and repeat the assay with stricter adherence to the procedure guidelines.
- All clinical samples should exhibit RNase P reaction curves that cross the threshold line at or before 35 cycles, thus indicating the presence of sufficient RNA from human RNase P gene indicating the specimen is of acceptable quality.

Document No.: SP.01	Document Name: Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in susp human cases by rRT-PCR : First Line Screening assay		rus (2019-nCoV) in suspected	
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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



	However, it is possible that some samples may fail to give positive reactions due to	
	low cell numbers in the original clinical sample.	
	Failure to detect RNase P in any of the clinical samples may indicate:	
a.	Improper extraction of nucleic acid from clinical materials resulting in loss of	
b.	RNA or carry-over of RT-PCR inhibitors from clinical specimens	
c.	Absence of sufficient human cellular material in sample to enable detection	
d.	Improper assay set up and execution	
e.	Reagent or equipment malfunction	
3.	The MOCK should NOT exhibit fluorescence growth curves for primer/probe sets	
	for 2019-nCoV E gene. Only in RP target, MOCK should show fluorescence growt	
	curve. If any 2019-nCoV E gene specific primer/probes exhibit a growth curve that	
	crosses the threshold line, interpret as follows:	
	a. Contamination of RNA extraction reagents may have occurred. Invalidate	
	the run and confirm reagent integrity of RNA extraction reagents prior to	
	further testing.	
	b. Cross contamination of samples occurred during RNA extraction	
	procedures or assay setup. Invalidate the run and repeat the assay with	
	stricter adherence to procedure guidelines.	
4.	PTC reactions should produce a positive result with the 2019-nCoV E gene and	
	RNaseP reactions between 20 and 30 cycles. If expected positive reactivity is not	
	achieved, invalidate the run and repeat the assay with stricter adherence to	
	procedure guidelines. Do not use PTC reagents that do not generate expected result	
5.	When all controls meet stated requirements, a specimen is considered presumptive	
	positive for 2019-nCoV reaction growth curves cross the threshold line within 35	
	cycles.	
6.	Immediately send the sample to Reference laboratory i.e NIV Pune	

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : First Line Screening assay



.					
Limitation 1.	s Analysts should be trained and familiar with testing procedures and interpreta results prior to performing the assay.	ation of			
2.	A false negative result may occur if inadequate numbers of organisms are pre	sent in			
3.	 the specimen due to improper collection, transport or handling. 3. A false negative result may occur if an excess of DNA/RNA template is present in the reaction. If inhibition of the RP control reaction is noted for a particular sample, extracted RNA can be tested at 2 or more dilutions (e.g., 1:10 and 1:100) to verify result. 				
laborato	If the sample is positive, immediately send the sample to Reference laboratory i.e. ICMR –NIV Pune for Confirmatory testing. It is only after confirmatory test becomes positive, then the sample can be				
declared	positive				
Co	onfirmatory assay Available at ICMR NIV • ORF 1b				
	• RdRp gene assay				
	• E gene assay				
	• N gene assay				

Report: Communicate the result on daily basis to ICMR NIV Pune

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	human cases by rRT-F Issue Date:	human cases by rRT-PCR : First Line Screening Issue Date:	human cases by rRT-PCR : First Line Screening assay Issue Date: Group Name.: Human Influenza



Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



Purpose: This protocol is designed to detect 2019-nCoV in human clinical specimens

Introduction: The purpose of this document is to provide interim guidance to laboratories and stakeholders involved in laboratory testing of patients who meet the definition of suspected case of pneumonia associated with a novel coronavirus identified in Wuhan, China. (https://www.who.int/health-topics/coronavirus/laboratorydiagnostics-for-novel-coronavirus)

Principle: The real time assay uses the TaqMan fluorogenic probe based chemistry that uses the 5' nuclease activity of Taq DNA polymerase and enables the detection of a specific PCR product as it accumulates during PCR cycles.

Coronaviruses under the subgenus Sarbecovirus that includes 2019-nCoV, SARS-CoV and bat SARS-like coronaviruses were used to generate a non-redundant alignment. Confirmatory assays designed based on their matching to the Wuhan virus as per inspection of the sequence alignment. Suspected human sample should be first tested for E gene assay and then confirmatory assay by RdRp and N gene assay.

Confirmatory assay: RdRp, ORF gene assay

Reference:

https://www.who.int/health-topics/coronavirus/laboratory-diagnostics-for-novelcoronavirus

Requirements:

- a. Instruments:
 - 1. Real Time PCR machines (Make : ABI, Rm. Real time PCR room)
 - Model:7500 Fast: Serial no: 275012996
 - Model:7500 Fast Dx: Serial no: 275030301
 - Model:7500:
- Serial no: 275006294 Dx: Serial no: 275005234
- Model: 7500 Fast Dx: Serial no: 2
 - Model:7500 Step one Plus: Serial no: 27200433
- 2. Biosafety cabinet (Make: Micro FITT, Model: MFI BIO4X2, Serial no: 14476, Rm no: Reagent preparation room)

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



b. Pipettes

1. Rm. Reagent preparation room For reagent dilutions 0.5-10 µl (Make: BIOHiT, Serial no: 6519410) 20-200 µl (Make: Thermo, Serial no: CH17505) 100-1000 µl (Make: Thermo, Serial no: CH28611) For master mix preparation(Make: Thermo) (Serial no:V44877) 0.5-10 µl 2-20µl (Serial no: V42740) 20-200 µl (Serial no: U75613) 100-1000 µl (Serial no: CH01229)

2.Rm. RNA addition room:

5-100 µl multichannel (Make: BIOHiT, Serial no. 65455	82)
2-20 μl (Make: Thermo, Serial no. V1726	7)
3. Rm. Real Time PCR room (Positive control addition)	
2-20 μl (Make: Thermo, Serial no.V90525)

c. Small equipments

Vortex V1 plus: (Make: BIOSAN, Serial no: 15975, Location: Rm no: Reagent preparation room),

Minispin : (Make: TAESON, Serial no: 1775, Location: Rm no: Reagent preparation room, Hood: (Make: Serial no. V-14971, Rm: Real time PCR room)

Miniplate spinner: (Make: Labnet, Serial no. V-15725, Rm: Real Time PCR room)

- **d. Plastic ware:** MicroAmp Fast reaction tubes (8 tubes/strip), 96 Thin wall PCR plates, 96 Thin wall PCR plates 0.1 ml, 1.7ml Eppendorf tubes, stand, micro tips, 96 well cooler
- e. Consumables: Disposable powder free gloves, Lab coats, aerosol barrier tips (20ul, 200ul and 1000ul), Laboratory marking pen, tissue paper rolls

f. Reagents:

- 1. Invitrogen SuperScript[™]III Platinum[®] One-Step Quantitative Kit (Cat. No.11732088)
- 2. AgPath-ID[™] One-Step RT-PCR
- 3. QIAamp Viral RNA Mini Kit (QIAGEN, Cat#52906) or equivalent RNA extraction Kit
- 4. Nuclease Free Water
- 5. Ethanol (96–100%)

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



Primers and Probes

Assay/ Use	Oligonucleotide ID	Sequence (5'-3')
RdRp	RdRP_SARSr-F2	GTGARATGGTCATGTGTGGCGG
	RdRP_SARSr-R1	CARATGTTAAASACACTATTAGCATA
	RdRP_SARSr-P2 Specific for Wuhan-CoV	FAM-CAGGTGGAACCTCATCAGGAGATGC- QSY
HKU ORF	HKU-ORF1b-nsp14F	TGGGGYTTTACRGGTAACCT'
gene	HKU-ORF1b-nsp14 R	AACRCGCTTAACAAAGCACTC
	HKU-ORF1b-nsp14 P	FAM-TAGTTGTGATGCWATCATGACTAG- QSY

FAM, 6-carboxyfluorescein; QSY Quencher (select quencher none in plate set up)

Documentation:

- Clinical sample register
- RNA extraction Laboratory book
- Real time PCR Laboratory book
- Result record book

Procedure/Protocol:

- 1. Perform RNA extraction of clinical samples according to "RNA extraction- QIAmp viral RNA Mini Kit" protocol in RNA extraction area.
- 2. Perform real time PCR reactions as shown in table for RdRp, ORF and N gene assays Determine the number of reactions (N) to set up per assay. In addition, include Negative control, Positive control and MOCK (human source cell line) in the test.
- 3. Prepare excess reaction cocktail to account for pipetting error.

If number of samples (n) including controls = 1 to 10, then N = n + 1

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



4. In the **clean reagent preparation room** prepare the Master Mix:

Calculate the amount of each reagent to be added for each Primer /probe set reaction master mix. The calculations are as follows:

Component	Volume for RdRp gene	Volume for ORF
H ₂ O (RNAse free)	5 µl	5 µl
2x Reaction mix	12.5 µl	12.5 µl
PP Mix	1.5 µl	1.5 µl
AgPath One-Step RT-	1 µl	1 µl
PCR *		
Template RNA	5 µl	5 µl
Total	25 μl	25 μl

* Invitrogen SuperScrip III Platinum One-Step Quantitative Kit, use 0.5ul and adjust the water volume to 5.5µl

- 5. Mix reaction mixtures by pipetting up and down. Do not vortex.
- 6. Centrifuge for 5-10 sec to collect contents at bottom of the tube, and then place the tube in cold rack.
- 7. Set up reaction strip tubes or plates in 96-well cooler rack.
- 8. Dispense 20μ l of each master mix into each well as per the plate set up.
- 9. Before moving the plate to the nucleic acid handling area. Pipette 5ul of the nuclease free water into NTC wells. Cap NTC wells.
- 10. **In the nucleic acid extraction room**, add 5ul of each sample and 5ul of Mock extraction control into respective wells as per the set up.
- 11. Cap the column or cover the plate with tissue paper to which the samples and mock control has been added.

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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



- 12. Finally, pipette 5ul of positive viral template control into all VTC wells in **positive control** addition area. Cap VTC wells/ or seal the plate with optical sealer. Centrifuge the plate for 10 seconds. Make sure that bubbles are eliminated from the bottom of the reaction tubes.
- 13. For real time PCR set up follow the instructions given by the Real-time PCR system manual for plate set up. **Save your plate setup!**
- 14. The reaction volume is 25ul.Program the run method as follows:

Reverse Transcription	55°C for 30 min
Taq inhibitor inactivation	95°C for 3 min
PCR amplification	95°C for 15 Sec
(45 Cycles)	58°C for 30 sec* (data collection)

Fluorescence data should be collected during the 58°C incubation step.

15. After completion of the run, save the run and analyze the collected data.

Interpretation/examination:

- The NTC reactions for primer / probe sets should not exhibit fluorescence growth curves that cross the threshold line. If a false positive occurs with one or more of the primer and probe NTC reactions, sample contamination may have occurred. Invalidate the run and repeat the assay with stricter adherence to the procedure guidelines.
- 2. The MOCK should NOT exhibit fluorescence growth curves for primer/probe sets for 2019nCoV RdRp, ORF and N gene. Only in RP target, MOCK should show fluorescence growth curve. If any 2019-nCoV RdRp, ORF and N gene specific primer/probes exhibit a growth curve that crosses the threshold line, interpret as follows:
 - a. Contamination of RNA extraction reagents may have occurred. Invalidate the run and confirm reagent integrity of RNA extraction reagents prior to further testing.

	Document Name: Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in human cases by rRT-PCR : confirmation assay			irus (2019-nCoV) in suspected
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Standard Operating Procedure For Detection of 2019 novel coronavirus (2019-nCoV) in suspected human cases by rRT-PCR : confirmation assay



- b. Cross contamination of samples occurred during RNA extraction procedures or assay setup. Invalidate the run and repeat the assay with stricter adherence to procedure guidelines.
- 3. PTC reactions should produce a positive result with the 2019-nCoV RdRp, and ORF and N gene reactions between 20 and 30 cycles. If expected positive reactivity is not achieved, invalidate the run and repeat the assay with stricter adherence to procedure guidelines. Do not use PTC reagents that do not generate expected result.
- 4. When all controls meet stated requirements, a specimen is considered confirmed positive for 2019-nCoV reaction growth curves cross the threshold line within 35 cycles for E gene, and both RdRp, ORF Or either RdRp or ORF

Limitations

- **1.** Analysts should be trained and familiar with testing procedures and interpretation of results prior to performing the assay.
- 2. A false negative result may occur if inadequate numbers of organisms are present in the specimen due to improper collection, transport or handling.
- 3. A false negative result may occur if an excess of DNA/RNA template is present in the reaction.

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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: 20/04/2020

Total Operational (initiated independent testing) Government Laboratories reporting to ICMR 201 + 03 collection sites:

S. No.	Names of States		Names of Medical Colleges
1.	Andhra Pradesh	1.	Sri Venkateswara Institute of Medical Sciences,
	(7)		Tirupati
		2.	Rangaraya Medical College, Kakinada
		3.	Sidhartha Medical College, Vijaywada
		4.	Govt. Medical College, Ananthpur
		5.	Guntur Medical College, Guntur
		6.	Rajiv Gandhi Institute of Medical Sciences,
			Kadapa
		7.	Andhra Medical College, Visakhapatnam
2.	Assam (6)	8.	Gauhati Medical College, Guwahati
		9.	Regional Medical Research Center, Dibrugarh
		10.	Jorhat Medical College, Jorhat
		11.	Silchar Medical College, Silchar
		12.	Fakkhruddin Ali Ahmed Medical College,
			Barpeta
		13.	Tezpur Medical College, Tezpur
3.	Bihar (6)	14.	Rajendra Memorial Research Institute of Medical
			Sciences, Patna
		15.	Indira Gandhi Institute Medical Sciences, Patna
		16.	Patna Medical College, Patna
		17.	Darbhanga Medical College, Darbhanga
		18.	SKMCH, Muzaffarpur
		19.	All India Institute of Medical Sciences, Patna
4.	Chandigarh (3)	20.	Post Graduate Institute of Medical Education &
			Research
		21.	Govt. Medical College
		22.	*Institute of Microbial Technology
5.	Chhattisgarh (3)	23.	All India Institute of Medical Sciences, Raipur
		24.	Late Baliram Kashyap M Govt. Medical College,
			Jagdalpur
		25.	JNM Medical College, Raipur
6.	Delhi (8)	26.	All India Institute Medical Sciences
		27.	Lady Hardinge Medical College
		28.	National Centre for Disease Control
		29.	Ram Manohar Lohia Hospital
		30.	Institute of Liver & Biliary Sciences
		31.	Army Hospital Research & Referral
		32.	Maulana Azad Medical College

S. No.	Names of States		Names of Medical Colleges
		33.	Vardhman Mahavir Medical College &
			Safdarjung Hospital
7.	Gujarat (10)	34.	BJ Medical College, Ahmedabad
		35.	MP Shah Govt Medical College, Jamnagar
		36.	Govt. Medical College, Surat
		37.	Govt. Medical College, Bhavnagar
		38.	Govt. Medical College, Vadodara
		39.	Govt. Medical College, Rajkot
		40.	NHL Medical College, Ahmedabad
		41.	GMERS, Ahmedabad
		42.	National Institute of Occupational Health,
			Ahmedabad
		43.	Surat Municipal Institute of Medical Education
			& Research (SMIMER), Surat
8.	Goa (1)	44.	Goa Medical College, Goa
9.	Haryana (6)	45.	Pt. B.D. Sharma Post Graduate Inst. Of Med.
		10	Sciences, Rohtak, Haryana
		46.	BPS Govt. Medical College, Sonipat
		47.	ESIC Hospital, Faridabad
		48.	Kalpana Chawla Govt. Medical College, Karnal
		49.	*ICAR-National Research Centre on Equines, Hisar
		50.	*Translational Health Science & Technology
		50.	Institute, Faridabad
10.	Himachal	51.	Indira Gandhi Medical College, Shimla
10.	Pradesh (3)	52.	Dr. Rajendra Prasad Govt. Medical College,
		02.	Tanda
		53.	Central Research Institute, Kasauli
11.	Jammu &	54.	Govt. Medical College, Jammu
	Kashmir (4)	55.	Command Hospital (NC) Udhampur
		56.	Sher-i-Kashmir Institute of Medical Sciences,
			Srinagar
		57.	Govt. Medical College, Srinagar
12.	Jharkhand (4)	58.	MGM Medical College & Hospital, Jamshedpur
		59.	Rajendra Institute of Medical Sciences, Ranchi
		60.	Patliputra Medical College & Hospital, Dhanbad
		61.	Itki Aarogyashala, Ranchi
13.	Karnataka (13)	62.	Hassan Inst. Of Med. Sciences, Hassan
		63.	Mysore Medical College & Research Institute,
			Mysore
		64.	Shivamogga Institute of Medical Sciences,
			Shivamogga
		65.	Command Hospital (Air Force), Bengaluru
		66.	Bangalore Medical College & Research Institute,
			Bengaluru
		67.	National Institute of Virology, Bangalore Field
		6.0	Unit, Bengaluru
		68.	Gulbarga Institute of Medical Sciences, Gulbarga
		69.	Vijaynagar Institute of Medical Sciences, Bellary
		70.	National Institute of Mental Health and Neuro-
			Sciences, Bangalore

S. No.	Names of States		Names of Medical Colleges
		71.	Wenlock District Hospital, Mangalore
		72.	Karnataka Institute of Medical Sciences, Hubli
		73.	National Institute of Traditional Medicine,
			Belagavi
		74.	Dharwad Institute of Mental Health &
			Neurosciences, Dharwad
14.	Kerala (13)	75.	National Institute of Virology, Field Unit,
			Allapuzzha
		76.	Govt. Medical College, Thiruvanathapuram
		77.	Govt. Medical College, Kozhikode
		78.	Govt. Medical College, Thrissur
		79.	Rajiv Gandhi Center for Biotechnology,
			Thiruvanathapuram
		80.	Sree Chitra Tirunal Institute of Medical Sciences,
			Thiruvanathapuram
		81.	State Public Health Laboratory, Trivandrum
		82.	Inter University, Kottayam
		83.	Malabar Cancer Center, Thalassery
		84.	Central University of Kerala, Periye, Kasaragod
		85.	Govt. Medical College, Ernakulum
		86.	Govt. Medical College, Manjeri
		87.	Govt. Medical College, Kottayam
15.	Maharashtra (22)	88.	National Institute of Virology, Pune
		89.	Seth GS Medical College & KEM Hospital,
			Mumbai
		90.	Kasturba Hospital for Infectious Diseases, Mumbai
		91.	National Institute of Virology Field Unit, Mumbai
		91. 92.	Armed Forces Medical College, Pune
		93.	BJ Medical College, Pune
		94.	Indira Gandhi Govt. Medical College, Nagpur
		95.	Grant Medical College & Sir JJ Hospital, Mumbai
		96.	Govt. Medical College, Aurangabad
		97.	V. M. Government Medical College, Solapur
		98.	Haffkine Institute, Mumbai
		99.	Shree Bhausaheb Hire Govt. Medical College,
			Dhule
		100.	Government Medical College, Miraj
			All India Institute of Medical Sciences, Nagpur
			Nagpur Veterinary College, MAFSU, Nagpur
			Govt. Medical College, Akola
			National Institute for Research on Reproductive
			Health, Mumbai
		105.	Rajiv Gandhi Medical College & CSM Hospital,
			Kalwa, Thane, Mumbai
		106.	National AIDS Research Institute, Pune
		107.	*Tata Memorial Centre ACTREC, Mumbai
		108.	*National Centre for Cell Sciences, Pune
		109.	*National Environmental Engineering Research
			Institute, Nagpur

S. No.	Names of States	Names of Medical Colleges
16.	Madhya Pradesh	110. All India Institute of Medical Sciences, Bhopal
	(10)	111. National Institute for Research on Tribal Health,
	()	Jabalpur
		112. Mahatma Gandhi Memorial Medical College,
		Indore
		113. Gandhi Medical College, Bhopal
		114. Bhopal Memorial Hospital & research Centre,
		Bhopal
		115. Gajra Raja Medical College, Gwalior
		116. Bundelkhand Medical College, Sagar
		117. SS Medical College, Rewa
		118. *Defence Research & Development Organization,
		Gwalior
		119. *ICAR-NIHSAD, Bhopal
17.	Manipur (2)	120. Jawaharlal Nehru Institute of Med. Sciences,
		Imphal-East, Manipur
		121. Regional Institute of Medical Sciences, Imphal
18.	Meghalaya (1)	122. North Eastern Indira Gandhi Regional Institute
- 01		of Health & Medical Sciences, Shillong,
		Meghalaya
19.	Mizoram (1)	123. Zoram Medical College
20.	Odisha (6)	124. Regional Medical Research Centre,
-0.		Bhubaneshwar (<i>High-throughput Laboratory</i>)
		125. All India Institute of Medical Sciences,
		Bhubaneshwar
		126. SCB Medical College and Hospital, Cuttack
		127. MKCG Medical College, Berhampur
		128. Ispat General Hospital, Rourkela
		129. *Institute of Life Sciences, Bhubaneshwar
21.	Puducherry (1)	130. Jawaharlal Institute of Postgraduate Medical
		Education & Research, Puducherry
22.	Punjab (3)	131. Govt. Medical College, Amritsar
		132. Govt. Medical College, Patiala
		133. Guru Gobind Singh Medical University, Faridkot
23.	Rajasthan (9)	134. Sawai Man Singh Medical College, Jaipur
		135. Dr. Sampurnan and Medical College, Jodhpur
		136. Jhalawar Medical College, Jhalawar
		137. RNT Medical College, Udaipur
		138. SP Medical College, Bikaner
		139. All India Institute of Medical Sciences, Jodhpur
		140. JLN Medical College, Ajmer
		141. Govt. Medical College, Kota
		142. National Institute for Implementation Research
		on Non-Communicable Diseases (Formerly
		DMRC), Jodhpur
24.	Tamil Nadu (22)	143. King Institute of Preventive Medicine & Research,
		Chennai
		144. Madras Medical College, Chennai
		145. Govt. Theni Medical College, Theni
		146. Tirunelveli Medical College, Tirunelveli
		147. Govt. Medical College, Thiruvarur

S. No.	Names of States	Names of Medical Colleges
		148. Kumar Mangalam Govt. Medical College, Salem
		149. Coimbatore Medical College, Coimbatore
		150. Govt. Medical College, Villupuram
		151. Madurai Medical College, Madurai
		152. K A P Viswanatham Govt. Medical College, Trichy
		153. Perundurai Medical College, Perundurai
		154. Govt. Dharmapuri Medical College, Dharmapuri
		155. Govt. Medical College, Vellore
		156. Thanjavur Medical College, Thanjavur
		157. State Public Health Laboratory, Chennai
		158. National Institute of Epidemiology, Chennai
		159. Kanyakumari Govt. Medical College, Nagercoil
		160. Govt. Thoothukudi Medical College,
		Thoothukudi
		161. Institute of Vector Control & Zoonoses, Hosur
		162. Pasteur Institute of India, Coonoor
		163. Govt. Kilpauk Medical College, Chennai
		164. Govt. Medical College & ESIC Hospital,
		Coimbatore
25.	Telangana (8)	165. Gandhi Medical College, Secunderabad
		166. Osmania Medical College, Hyderabad
		167. Sir Ronald Ross of Tropical & Communicable
		Diseases, Hyderabad.
		168. Nizam's Institute of Medical Sciences, Hyderabad
		169. Institute of Preventive Medicine, Hyderabad
		170. ESIC Medical College, Hyderabad
		171. *Centre for Cellular & Molecular Biology,
		Hyderabad
		172. *Centre for DNA Fingerprinting & Diagnostics,
		Hyderabad
26.	Tripura (1)	173. Government Medical College, Agartala
27.	Uttar Pradesh	174. King George Medical University, Lucknow
	(15)	175. Institute of Medical Sciences, Banaras Hindu
		University, Varanasi
		176. Jawaharlal Nehru Medical College, Aligarh
		177. Command Hospital, Lucknow
		178. Lala Lajpat Rai Memorial Medical College,
		Meerut
		179. Sanjay Gandhi Post Graduate Institute, Lucknow
		180. MLN Medical College, Allahabad
		181. Uttar Pradesh University of Medical Sciences
		(Formerly Uttar Pradesh RIMS), Saifai
		182. MLB Medical College, Jhansi
		183. Regional Medical Research Centre, Gorakhpur
		184. SN Medical College, Agra
		185. RML Hospital, Lucknow
		186. Govt. Institute of Medical Sciences, Noida
		187. GSVM Medical College, Kanpur
		188. National Institute of Biologicals, Noida (High-
		throughput Laboratory)
28.	Uttarakhand (2)	189. Govt. Medical College, Haldwani

S. No.	Names of States	Names of Medical Colleges	
		190. All India Institute of Medical Sciences, Rishikesh	
29.	West Bengal (9)	191. National Institute of Cholera & Enteric Diseases,	
		Kolkata	
		192. Institute of Post Graduate Medical Education &	
		Research, Kolkata	
		193. Midnapore Medical College, Midnapore	
		194. North Bengal Medical College, Darjeeling	
		195. School of Tropical Medicine, Kolkata	
		196. Malda Medical College & Hospital, Malda	
		197. Command Hospital, Kolkata	
		198. Chittaranjan National Cancer Institute, Kolkata	
		199. R.G. Kar Medical College & Hospital, Kolkata	
30.	Andaman &	200. Regional Medical Research Centre, Port Blair	
	Nicobar Islands		
	(1)		
31.	Dadra & Nagar	201. Shri Vinoba Bhave Civil Hospital, Silvassa	
	Haveli (1)		
	Collection sites only		
31.	Sikkim (1)	202. Sir Thutob Namgyal Memorial (STNM), Gangtok	
32.	Ladakh (1)	203. Sonam Norboo Memorial Hospital (SNMH), Leh	
33.	Arunachal	204. Tomo Riba Institute of Health & Medical Sciences	
	Pradesh (1)	(TRIHMS), Naharlagun	

*CSIR/DBT/DST/DAE/ICAR/DRDO Labs. No support is sought from ICMR/ State Govt.



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: 20/04/2020

List of Private Laboratories to test COVID-19

S. No.	Names of States	Names of Laboratory and Address	
1.	Delhi (11)	 Lal Path Labs, Block -E, Sector 18, Rohini, Delhi Dr Dangs Lab, C-2/1, Safadarjung Development Area, New-Delhi 	
		 Laboratory Services, Indraprastha Apollo Hospitals, Sarita Vihar, New Delhi Max Lab, Max Super Spciality Hospital, Saket, 	
		New-Delhi	
		5. Sir Ganga Ram Hospital Clinical Lab Services, Sir Ganga Ram Hospital, Delhi	
		 Oncquest Labs Ltd, 3-Factory Road, New-Delhi Prognosis Laboratories, 515-16, Sector 19, Dwarka City X-Ray & Scan Clinic Pvt Ltd, 4B/18, Tilak Nagar, New-Delhi Lifeline Laboratory, H-11, Green Park Extension, New-Delhi Dept of Lab Services, Dr. B.L. Kapur Memorial Hospital, 5, Pusa Road, New-Delhi 	
		11.Dept of Laboratory Services, Action Cancer	
		Hospital, A-4, Paschim Vihar (East), New-Delhi	
2.	Gujarat (4)	12. Unipath Specialty laboratory limited, 102, Sanoma Plaza, Opposite Parimal Garden, Besides JMC House, Ellisbridge, Ahmedabad	
		13. Supratech Micropath Laboratory & Research Institute Pvt Ltd, Kedar, Ahmedabad	
		14. SN GeneLab Pvt Ltd, President Plaza –A, Near Mahavir Hospital, Nanpura, Surat	
		15. Pangenomics International Pvt Ltd, Ellis Bridge, Ahmedabad	
3.	Haryana (6)	16. Strand Life Sciences, A-17, Sector 34, Gurugram 17. SRL Limited, GP26, Sector 18, Gurugram	
		18. Modern Diagnostic & Research Centre-Lab, 363-364/4, JAwahar Nagar. Gurgaon	
		19. Core Diagnostics Pvt Ltd, Udyog Vihar Phase-3, Gurgaon	
		20. MolQ Laboratory, Plot 28,29; Sector 18(P), Electronic city, Udyog Vihar, Phase IV, Gurgaon	
		21. Pathkind Diagnostics Pvt Ltd, Plot 55-56, Phase 4, Udyog Vihar, Sec 18, Gurgaon	

4. Karnataka (5) 22. Neuberg Anand Reference Laboratory, Anand Towe #54, Bowring Hospital Road, Bengaluru 23. Cancyte Technologies Pvt Ltd, Sri Shankara Researd Centre, Bengaluru 24. Sakra World Hospital Lab Services, Devarabeesanaha VArthur Hobli, Bengaluru 24. Sakra World Hospital Lab Services, Devarabeesanaha VArthur Hobli, Bengaluru 25. Central Diagnostic Lab, Vydehi Institute of Medic Sciences and Research Centre, #82, E.P.I.P. Are Whitefield, Bengaluru 5. Kerala (2) 27. DDRC SRL Diagnostics Pvt Ltd, Panampilly Nage Ernakulam 6. Madhya Pradesh (2) 29. Chirayu Medical College & Hospital, Bhopal Indo Highway, Bhaisakhedi, Bhopal 30. Sampurna Sodani Diagnostic Clinic, LG-1, Mor Centre, 16/1 Race Course Road, Indore 31. Thyrocare Technologies Limited, D37/1, TTC MID Turbhe, Navi Mumbai 32. Suburban Diagnostics (India) Pvt. Ltd., 306, 307/T, 3 Floor, Sunshine Bld., Andheri (W), Mumbai 33. Metropolis Healthcare Ltd, Unit No. 409-416, 4th Floo Commercial Building-1, Kohinoor Mall, Mumbai 34. Sir H.N. Reliance Foundation Hospital And Researd Centre, Molecular Medicine, Reliance Life Sciences P Ltd., R-282, TTC Industrial Area, Rabale, Navi Mumbai 35. SRL Limited, Prime Square Building, Plot No 1, Gaiwa Industrial Estate, SV Road, Goregaon, Mumbai 36. A.G. Diagnostics Pvt Ltd, Nayantara Building, Pune 37. Kokilaben Dhirubhai Ambani Hospital Laboratory, Fo	search nahalli Iedical Area, ghatta Nagar,	#54, Bowring Hospital Road, Bengaluru 23. Cancyte Technologies Pvt Ltd, Sri Shankara Resea	Karnataka (5)	Λ
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39. iGenetic Diagnostics Pvt Ltd, Krislon House, Andhe	ndheri			
East, Mumbai		-		
40. Tata Memorial Centre Diagnostic Services-Ta	s-Tata			
Memorial Hospital, Parel, Mumbai				
41. Sahyadri Speciality Labs, Plot No 54, S.No. 89-9	89-90,	41. Sahyadri Speciality Labs, Plot No 54, S.No. 89		
Lokmanya Colony, Kothrud, Pune		Lokmanya Colony, Kothrud, Pune		
42. Dr. Jariwala Lab & Diagnostics LLP, 1st Floor, Rasr				
Heights, Rokadia Lane, Off Mandpeshwar Road, Bori	Borivli			
(W), Mumbai				
43. Ruby Hall Clinic, Dept of Laboratory, Grant Medic	ledical			
Foundation, 40, Sassoon Road, Pune	-			
44. Metropolis Healthcare Limited, Construction Hous	iouse,			
796/189-B, Bhandarkar Institute Road, Pune	511/1			
45. Qualilife Diagnostics, Balaji Arcade, 1st Floor, 544/ Netaji Subhash Road, Mulund (W), Mumbai	,++/A,			
46. SRL Diagnostics – Dr. Avinash Phadke (SRL Diagnosti				
	netice	10.000 DIATIONICO – DI. AVIIIAOII I HAUNE IONE DIATION		
-	r, L.J.	Pvt Ltd), Mahalaxmi Engineering Estate, 2nd Floor,		
	r, L.J.	Pvt Ltd), Mahalaxmi Engineering Estate, 2 nd Floor, Cross Road No 1, KJ Khilnani High School, Ma		
Marve Road, Malad West, Mumbai	r, L.J. Mahim	Pvt Ltd), Mahalaxmi Engineering Estate, 2 nd Floor, Cross Road No 1, KJ Khilnani High School, Ma (West), Mumbai		
48. Department of Laboratory Medicine – P.D. Hindu	r, L.J. Mahim	 Pvt Ltd), Mahalaxmi Engineering Estate, 2nd Floor, Cross Road No 1, KJ Khilnani High School, Ma (West), Mumbai 47.Sunflower Lab & Diagnostic Center, Keshav K 		

S. No.	Names of States	Names of Laboratory and Address
		 National Hospital and Medical Research Centre, Veer Savarkar Marg, Mahim, Mumbai 49. Aditya Birla Memorial Hospital – Laboratory, Aditya Birla Marg, Chinchwad, Pune 50. Vaidya Lab Thane, Unit of Millenium Special Lab Pvt Ltd, Odyssey Park, 2nd Floor, 201, Raghunath Nagar, Wagle Estate, Thane
8.	Orissa (1)	51. Dept of Lab Services, Apollo Hospitals, Bhubaneswar
9.	Punjab (2)	 52. Department of Microbiology, Dayanand Medical College & Hospital, Tagore Nagar, Civil Lines, Ludhiana 53. Tuli Diagnostic Centre, Majitha Road, Amritsar
10.	Rajasthan (2)	 54. Central Lab, The Mahatma Gandhi University of Medical Sciences and Technology, RIICO Institution Area, Sitapura, Tonk Road, Jaipur 55. Dr. B Lal Clinical Lab Pvt Ltd, 6-E, Malviya Industrial Area, Malviya Nagar, Jaipur
11.	Tamil Nadu (10)	 56. Dept. of Clinical Virology, CMC, Vellore 57. Department of Laboratory Services, Apollo Hospitals Enterprise Ltd, Chennai 58. Neuberg Ehrlich Lab Pvt Ltd, 46-48 Masilamani Road, Balaji Nagar, Chennai 59. Sri Ramachandra Medical College & Research Institute, Porur, Chennai 60. Microbiology Lab, Veerakeralam Road, Coimbatore 61. YRG CARE, Taramani, Chennai 62. Hitech Diagnostic Centre- A Unit of Dr. Ganesan's Hitech Diagnostic Centre PVt Ltd, Poonamallee High Road, Chennai 63. MIOT Hospitals – Dept of Lab Medicine, 4/112, Mount Poonamallee Road, Manapakkam, Chennai 64. Madras Medical Mission Clinical Lab Services, 4-A, Dr. J. Jayalalitha Nagar, Mogappair East, Chennai 65. PSG Hospitals Diagnostic Centre, Avinashi Road, Peelamedu, Coimbatore
12.	Telangana (12)	 66. Laboratory Services, Apollo Hospitals, 6th Floor, Health Street Building, Jubilee Hills, Hyderabad 67. Vijaya Diagnostic Centre Pvt Ltd, Street No 19, Himayath Nagar, Hyderabad 68. Vimta Labs Ltd, Plot No 142, Phase 2, IDA Cherlapally, Hyderabad 69. Apollo Health and Lifestyle Limited, Diagnostic Labortory, Bowenpally, Secunderabad 70. Dr. Remedies Labs Private Ltd, A3, Titus Plaza, Sharma Commercial Complex, Punjagutta, Hyderabad 71. Pathcare Labs Pvt Ltd, Medchal, Hyderabad 72. American Institute of Pathology And Lab Sciences Pvt Ltd, Citizens Hospital, Serilingampally, Hyderabad 73. Medcis Pathlabs India Pvt Ltd, Plot No 16 & 17, Swathi Plaza, Anand Nagar, New Bowenpally, Secunderabad 74. Department of Lab Medicine, Yashoda Hospital, 9th Floor, 1-1-156 & 157, Alexander Road, Secunderabad 75. Biognosys Technologies (India) Pvt Ltd, #8-148/174/11, NRI Colony, Near Aleap Industrial Area, Medchal, Malkajgiri 76. Dept of Lab Medicine, Star Hospitals, A Unit of Unimed

S. No.	Names of States	Names of Laboratory and Address
		Health Care Pvt Ltd, 8-2-594/B, Road No 10, Banjara Hills, Hyderabad
		77. Tenet Diagnostics, Plot No 51, Kineta Towers, Journalist Colony, Road No 3, Banjara Hills, Hyderabad
13.	U.P. (2)	 78. RML Mehrotra Pathology Pvt Ltd, Nirala Nagar, Lucknow 79. Dept of Lab Medicine, Jaypee Hospital, Sector 128, Noida
14.	Uttarakhand (1)	80. Dr. Ahuja's Pathology and Imaging Centre, 7-B, Astley Hall, Dehradun
15.	West Bengal (6)	 81. Apollo Gleneagles Hospitals, 58 Canal Circular Road, Kolkata 82. Tata Medical Center, Rajarhat, Kolkata 83. Laboratory Services, Peerless Hospitex Hospital & Research Centre, 360, Panchasayar, Kolkata 84. AMRI Hospitals, Dept of Lab Medicine, JC 16-17, Sector III, Salt Lake City, Kolkata 85. Suraksha Diagnostic Pvt Ltd (Dept of Lab Services), 12/1, Premises No 02/0327, DG Block (Newtown), Action Area 1D, Newtown, Kolkata 86. Dr. Lal Pathlabs Ltd – Kolkata Reference lab, Plot No CB-31/1, Premises No 031-0199, Street No 199, Action Area 1C, Newtown, Kolkata

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Date: 20/04/2020

Status of new COVID-19 Govt. & Private testing laboratories as per request of the State Govt.

CATEGORYWISE LIST OF GOVERNMENT LABORATORIES:

S. No.	State	Name of the Laboratory	Category
1	Chhattisgarh (1)	LSLRAM Govt. Medical College, Raigarh	2
2	Gujarat (1)	Gujarat Cancer & Research Institute, Ahmedabad	2
		RMMC, Government Medical College	2
3	Tamil Nadu (2)	Chidambaram, Cuddalore District	
		Dr ALM Institute of Medical Sciences, Taramani	2
4	Uttarakhand (1)	Doon Medical College, Dehradun	2
5	Puduchery(1)	IGMC, Puduchery	2

Proposals of Category 1 labs received by ICMR and referred back to State/ Mentor Institute

S. No.	State	Name of the Laboratory	Category	Update Status
1.	Andhra Pradesh (3)	Govt. Medical College, Kurnool	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Govt. Medical College, Srikakulam	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		ACSR Govt. Medical College, Nellore	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
2.	Bihar (2)	ANMMCH, Gaya	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		JNMC, Bhagalpur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
3.	Chattishgarh (1)	Chhattisgarh Institute of Medical Sciences, Bilaspur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
4.	Delhi (2)	Rajiv Gandhi Super speciality Hospital, Delhi	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		IBHAS Delhi	1	Email sent to Dean/Mentor Ins/PS health on 15/04/2020
5.	Gujarat (1)	GMERS, Gandhinagar	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
6.	Haryana (4)	Shaheed Hasan Khan Mewati, Govt. Medical College, Nalhar, Nuh	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Maharaja Agrasen Medical College, Agroha, Hisar	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		SHKM, Govt. Medical College, Nalhar, Nuh	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Command Hospital, Chandimandir	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
8.	Kerala (3)	Govt. Medical College, Ernakulum	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Govt. Medical College, Kottayam	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Govt. Medical College, Kannur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
9.	Madhya Pradesh (1)	S.S. Medical College, Rewa	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
10.	Maharashtra (12)	Govt. Medical College, Latur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Swami Ramanand Theerth Rural Govt. Medical College, Ambajogai	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Rajashri Chhatrapati Shahu Maharaj Govt. Medical College, Kolhapur	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		Mahatam Gandhi Insitute of Medcal Sciences, Sevagaram, Wardha	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		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
		Lokmanya Tilka Medical College, Sion Mumbai	1	Email sent to Dean/Mentor Ins/Municipal Commis on 15/04/2020. Telephonic discussion made with Dean and Micro HoD
		HBT Medical College & Cooper Hospital Mumbai	1	Email sent to Dean/Mentor Ins/Municipal Commis./PS,Health. on 15/04/2020.
		Govt. Medical College, Baramati,	1	Email sent to Dean/Mentor Ins/PS,Health. on 15/04/2020

		Shri Vasantrao Naik Govt. Medical College, Yavatmal	1	Email sent to Dean/Mentor Ins/ PS,Health. on 15/04/2020
		Govt. Medical College, Chandrapur	1	Email sent to Dean/Mentor InsPS,Health. on 15/04/2020
		Dr. Shankrrao Chavan Govt. Medical College, Nanded,	1	Email sent to Dean/Mentor Ins/ PS,Health. on 15/04/2020
		Government Medical College,Gondia	1	Email sent to Dean/Mentor Ins/ PS,Health. on 15/04/2020
11.	Meghalaya (1)	Govt. Civil Hospital, Tura, Meghalaya	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
12	Odisha (1)	VIMSAR, Burla	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
13.	Rajasthan (1)	RVRS Medical College, Bhilwara	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
14.	Tamil Nadu (1)	Kanyakumari Govt. Medical College, Nagercoil	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
15.	West Bengal (2)	Murshidabad Medical College & Hospital	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020
		NRS Medical College and Hospital, West Bengal	1	Email sent to Nodal officer16/04/2020
16	Uttarakhand (1)	Srinagar Medical College, Pauri Garwal	1	Email sent to Dean/Mentor Ins/PS health on 14/04/2020

Private Medical Colleges/ Private Laboratories:

S. No.	State	Name of the Medical College / Laboratory	Requirements
1	Madhya Pradesh (5)	RD Gardi Medical College, Ujjain	NABL certificate reqd
		Sri Aurobindo Institute of Medical Sciences, Indore	NABL certificate reqd
		Central Lab, Indore	NABL certificate reqd
		Index Medical College Hospital & Research Institute	NABL certificate reqd
		RKDF Medical College and Research centre, Bhopal	NABL certificate reqd
2	Karnataka (3)	JN Medical College, KAHER Belagavi	NABL certificate reqd
		S. S Institute of Medical Sciences and Research	NABL certificate reqd
		Centre	
		K.S.Hegde Medical Academy, Mangalore	NABL certificate reqd
3	Gujarat (1)	Apollo Hospital, Gandhinagar	NABL certificate reqd
4	Uttarakhand (2)	Mahantra Indresh Medical College, Dehradun	NABL certificate reqd
		sh (5) RD Gardi Medical College, Ujjain N Sri Aurobindo Institute of Medical Sciences, Indore N Central Lab, Indore N Index Medical College Hospital & Research Institute N RKDF Medical College Hospital & Research Institute N RKDF Medical College and Research centre, Bhopal N JN Medical College, KAHER Belagavi N S. S Institute of Medical Sciences and Research N Centre K.S.Hegde Medical Academy, Mangalore N Apollo Hospital, Gandhinagar N Mahantra Indresh Medical College, Dehradun N Himalayan Institute of Medical Sciences, Dehradun N Himalayan Institute Of Medical Sciences And Resarech N Center, Siddipet N Subharti Medical College, Meerut N Subharti Medical College, Meerut N Subharti Medical College, Meerut N M.M. Institute of Medical Sciences and Research, Ambala N O ORANGE CITY HOSPITAL & RESEARCH N MGM Medical College and Hospital, Aurangabad N K.J Somaiya Medical College, Sion Mumbai N Terna Medical College Talegaon Dabhade, P	NABL certified but not for
			Realtime PCR based testing
5	Telangana (2)	LEPRA Society, Hyderabad	NABL certificate reqd
		RVM Institute Of Medical Sciences And Resarech	NABL certificate reqd
6	Uttar Pardesh (2)		NABL certificate reqd
		Subharti Medical College,Meerut	NABL certified but not for
			Realtime PCR based testing
7	Haryana (2)	Imperial Life Sciences, Gurgaon	NABL certificate reqd
		M.M. Institute of Medical Sciences and Research,	NABL certificate reqd
8	Maharastra (19)	ORANGE CITY HOSPITAL & RESEARCH	NABL certified Scope pending
		INSTITUTE, Nagpur	
		MGM Medical College and Hospital, Aurangabad	NABL certificate not received
		K.J Somaiya Medical College, Sion Mumbai	NABL certificate not received
		Terna Medical College Talegaon Dabhade, Pune	NABL certificate reqd
			NABL certificate reqd
		Annasaheb Chudaman Patil Memorial Medical	NABL certificate reqd
		College, Dhule	

		1	1
		Dr. VVPF's Medical College, Ahmednagar	NABL certificate reqd
		Smt. Kashibai Navale Medical College, Pune	NABL certificate reqd
		Dr. Ulhas Patil Medical College, Jalgaon	NABL certificate reqd
		BKL Walawalkar Rural Medical College, Ratanagiri	NABL certificate reqd
		Prakash Institute of Medical Sciences & Research,	NABL certificate reqd
		Sangli	
		SMBT insitute of Medical Sciences & Research	NABL certificate reqd
		Centre, Nashik	
		Vedanta Institute of Medical Sciences, Palghar	NABL certificate reqd
		NKP Salve Medical College, Nagpur	NABL certificate reqd
		MIMSR Medical College, Latur	NABL certificate reqd
		Indian Institute of Medical Sciences & Research,	NABL certificate reqd
		Jalna	
		Panjabrao Deshmukh Medical College, Amravati	NABL certificate reqd
		Ashwini Rural Medical College,	NABL certificate reqd
		Hospital & Research Centre	
		Datta Meghe Medical College &	NABL certificate reqd
		Shalinitai Meghe Hospital and Research Centre,	1
		Nagpur	
9	Tamil nadu (4)	Velammal Medical College Hospital & Research	NABL certificate reqd
		Institute, Madhurai	
		Sundaram Medical Foundation	NABL certificate reqd
		Dr. Rangarajan Memorial Hospital, Chennai	
		Dhanalakshmi Srinivasan Medical College &	NABL certificate reqd
		Hospital	
		Karpagam Faculty of Medical Sciences &	NABL certificate reqd
		Research, Coimbatore	
10	Sikkim (1)	Sikkim Manipal College of Medical Sciences,	NABL certificate reqd
		Gangtok	
11	Andhra Pradesh (2)	Alluri Sitarama Raju Academy of Medical Sciences,	NABL certificate reqd
		Eluru, West Godavari	
		Narayana Medical College, Nellore	NABL certificate reqd

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

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

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

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.

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

Steps of Approval from ICMR:

*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 DEPARTMENT OF HEALTH RESEARCH

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.

<u>Caution:</u> 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 will not provide diagnostic kits / reagents to these laboratories. ICMR advisory on use of commercial kits may also be accessed at <u>www.icmr.nic.in</u>. 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 <u>www.icmr.nic.in</u>) 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:
 - Dr. Harpreet Singh: hsingh@bmi.icmr.org.in
 - Dr. Ira Praharaj: praharaj.ira@icmr.gov.in

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



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

Date: 12/04/2020

Validation Centres for qRT-PCR Diagnostics for COVID-19

ICMR has identified the following 05 Centres of Excellence for validation of non-US FDA and non-EUA/CE-IVD approved kits for COVID-19 testing.

S. No.	Name of Institute	Officer's Name, Designation and Contact Details	
1.	ICMR – National Institute of Virology (NIV), Pune	Dr Priya Abraham Director Email:director.niv@icmr.gov.in Mob: +91-8940843532	
2.	ICMR - National AIDS Research Institute (NARI), Pune	Dr Samiran Panda, Director Email: spanda@nariindia.org Mob. +91-9830908475	
3.	ICMR-National Institute of Pathology (NIP), New Delhi	Dr Nasreen Z Ehtesham Director- in-Charge Email: nzehtesham@gmail.com Mob: +91-8826377433	
4.	ICMR – National Institute of Cholera and Enteric Diseases (NICED), Kolkata	Dr Shanta Dutta Director Email: shanta.niced@icmr.gov.in Mob: +91-9830152971	
5.	CSIR – Centre of Cellular & Molecular Biology, Hyderabad	Dr. Rakesh K Mishra, Director Email: mishra@ccmb.res.in Phone No.040-27160789	

• All the above centres are advised to share validation report of the test kit with the concerned company.

• Validation of US-FDA and European CE/IVD approved kits is not to be undertaken.

20.04.2020

Performance evaluation of commercial kits for detection of SARS-CoV-2 RNA by Real Time PCR

Validation by ICMR institutes

Till date, 33 real-time PCR kits have been validated by ICMR validation centres, and the following were found to be satisfactory.

S. No	Name of Company	Name of the Kit	*Batch number
1	Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
2	MY LAB	Patho Detect	PP00005-C-032001
3	Seegene	Allplex 2019-nCoV assay	RP4520A01
4	SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004
5	KILPEST (BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	COV-19/V2/2020/01
6	Huwel Lifesciences	Quantiplus CoV detection kit ver 2.0	QLCNV0620
7	BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
8	ABI (Applied bio systems)	TaqMan 2019-nCoV Control Kit v1	47532-020720
9	Medsource Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
10	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID 19] Real-time PCR kit	01/2020 MFD: 04/2020
11	ADT Biotech Sdn Bhd, Malaysi2	LyteStar 2019 nCoV RT-PCR kit 1.0	nCoV-2003-06; nCoV-2004-02; nCoV-2004-03
12	OSANG Health Care	Gene Finder COVID-19	2003-R45-22
13	Cepheid	Xpert Xpress SARS-CoV-2	1000191996, 1000191998, 1000191999
14	Biogenomics (India)	BIO COVID ID/ COVID-19 qualitative PCR detection kit v. 2	BGL/IVD/COV/0420 /004
15	Meril Diagnostics	Meril COVID-19 One-step RT-PCR Kit	MRD091

*Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.

Real-time PCR kits which are US-FDA and/or CE-approved

The complete list of US-FDA and/or CE-approved SARS-CoV-2 real-time PCR kits is available at (<u>https://www.finddx.org/covid-19/pipeline/</u>). US-FDA and/or CE-IVD approved kits can be used directly after due marketing approval from DCGI.

17.04.2020

Performance evaluation of commercial kits for detection of SARS-CoV-2 RNA by Real Time PCR

Validation by ICMR institutes

Till date, 31 real-time PCR kits have been validated by ICMR validation centres, and the following were found to be satisfactory.

S. No	Name of Company	Name of the Kit	*Batch number
1	Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
2	MY LAB	Patho Detect	PP00005-C-032001
3	Seegene	Allplex 2019-nCoV assay	RP4520A01
4	SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004
5	KILPEST (BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	COV-19/V2/2020/01
6	Huwel Lifesciences	Quantiplus CoV detection kit ver 2.0	QLCNV0620
7	BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019-nCoV	6020200107
8	ABI (Applied bio systems)	TaqMan 2019-nCoV Control Kit v1	47532-020720
9	Medsource Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
10	Helini Biomolecules, Chennai, India	Helini Coronavirus [COVID 19] Real-time PCR kit	01/2020 MFD: 04/2020
11	ADT Biotech Sdn Bhd, Malaysi2	LyteStar 2019 nCoV RT-PCR kit 1.0	nCoV-2003-06; nCoV-2004-02; nCoV-2004-03
12	Medsource Ozone Biomedicals	COVID-19 RT-PCR kit	20200433
13	OSANG Health Care	Gene Finder COVID-19	2003-R45-22
14	Cepheid	Xpert Xpress SARS-CoV-2	1000191996, 1000191998, 1000191999
15	Biogenomics (India)	BIO COVID ID/ COVID-19 qualitative PCR detection kit v. 2	BGL/IVD/COV/0420 /004

*Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.

Real-time PCR kits which are US-FDA and/or CE-approved

The complete list of US-FDA and/or CE-approved SARS-CoV-2 real-time PCR kits is available at (<u>https://www.finddx.org/covid-19/pipeline/</u>). US-FDA and/or CE-IVD approved kits can be used directly after due marketing approval from DCGI.

Guidelines for use of commercial kits for nasal/throat swab based diagnosis of COVID-19 in India, 10 April, 2020

• A total of 24 non- US FDA EUA/CE IVD real-time RT-PCR kits have been validated by ICMR validation Centres. Following kits are found suitable for use:

Name of Company	Name of the Kit	*Batch No.
1. Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	023005
2. MY LAB	Patho Detect	PP00005-C-032001
3. KILPEST (BLACKBIO)	TRUPCR version 2	COV-19/V2/2020/01
4. Seegene	Allplex 2019-nCoV assay	RP4520A01
5. SD Biosensor	nCoV Real-Time Detection kit	MNCO 0120004
6. Huwel Lifesciences	Quantiplus CoV detection kit ver2.0	QLCNV0620

*Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.

- Central Drugs Standard Control Organization (CDSCO) has been intimated for above listed kits.
- USFDA /EU CE-IVD certified kits can be used directly after due marketing approval from DCGI.

Guidelines for use of commercial kits for nasal/throat swab based diagnosis of COVID-19 in India, 2 April, 2020

- Currently, RT-PCR probes for diagnosis of COVID-19 are procured from USA by ICMR-NIV and are distributed to the testing laboratories across the country
- ICMR welcomes use of commercial kits for diagnosis of COVID-19
- US FDA EUA/CE IVD approved kits can be used directly after due approval from DCGI and intimation to ICMR
- ICMR has established a fast-track mechanism for validation of non US FDA EUA/CE IVD approved kits at ICMR NIV. Test kits with 100% concordance among true positive and true negative samples will be approved for commercial use in India
- ICMR NIV has completed evaluation of **20** non- US FDA EUA/CE IVD kits. The results of the validation are summarized in the following table

Name of Company	Name of the Kit	Concordance among true negative (%)	Concordance among true positive (%)
1. Altona Diagnostics	RealStar SARS-CoV-2 RT-PCR kit 1.0	100%	100%
2. MY LAB	Patho Detect	100%	100%
3. BGI	Real Time Fluorescent RT-PCR Kit for detecting 2019- nCoV	100%	90%
4. Krishgen Bio System	SARS-CoV-2 Coronavirus Real Time RT-PCR (RT- qPCR) Detection Kit v1	100%	80%
5. ABI	TaqMan 2019-nCoV Control Kit v1	100%	90%
6. HIMEDIA	Hi –PCR Corona Virus (CoViD-19) Probe PCR Kit	100%	5%
7. HUWEL	Quantiplus Coronavirus (2019nCoV) detection kit	100%	40%
8. IIT-Delhi	SYBR Green based one step QRT-PCR	98%	10%
9. KILPEST (BLACKBIO)	TRUPCR	100%	75%
10. Genesig	Coronavirus (COVID19) genesig Real Time PCR Assay	100%	84%
11. Roche	LightMix Modular SARS and Wuhan CoV E gene	91%	100%
12. Roche	LightMix Modular SARS and Wuhan CoV N gene	93%	67%
13. Roche	LightMix Modular Wuhan RdRp gene	100%	60%
14. Seegene	Allplex 2019-nCoV assay	100%	100%
15. SD Biosensor	nCoV Real-Time Detection kit	100%	100%
16. AmpliGene India Biotech	AmpEZ Covid -19 using real-time PCR machine	Inconclusive resu product develop	ults. Needs further ment
17. AmpliGene India Biotech	AmpEZ Covid -19 using Ampligene device	Inconclusive resu product develop	ults. Needs further ment
18. Biogenomics	COVID -19 detection kit	82%	100%
19. COSARA Diagnostics	SARAGENE Corona Virus (2019 NCV) test kit	88%	100%
20. KILPEST (3B BLACKBIO)	TRUPCR SARS-CoV-2RT-qPCR kit version 2	100%	100%

(Sensitivity and specificity of the kits could not be calculated since there were no false positive and false negative samples)

• ICMR recommends these results and the Central Drugs Standard Control Organization (CDSCO) has been intimated.

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 14.04.2020

Guidance on the use of Truenat[™] beta CoV

- 1. ICMR has validated Truenat[™] beta CoV test on Truelab[™] workstation and has recommended it as a screening test.
- 2. All positive samples need to be reconfirmed by a separate confirmatory assay for SARS-CoV-2.
- 3. Throat/nasal swabs will be collected in the viral transport medium (VTM) with virus lysis buffer to be provided along with the kit.
- All States who immediately intend to initiate Truenat[™] beta CoV test on Truelab[™] workstation are advised the following:
 - The proposed sites of Truelab[™] workstation do not require approval of ICMR.
 - The States may appoint a core team of experts for assessing facilities with the Truelab[™] workstation for feasibility of initiating COVID-19 testing in the existing setup.
 - Based on the evaluation of the core team, the designated officer of each state may accord approval for testing.
 - Procurement of the cartridges for existing machines and other logistics should be done through the Central TB Division.
 - Sample collection should only be done using the virus lysis buffer provided by the supplier. This is essential to avoid any biosafety / biosecurity concerns.
 - ICMR guidelines for testing (available at <u>www.icmr.nic.in</u>) 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 email for obtaining login credentials to the ICMR COVID-19 portal is:

support.dmu@bmi.icmr.org.in

 Please note any request for login credentials on the ICMR COVID-19 portal must be accompanied by the formal approval document accorded by the state authorities. This should be shared by email at the ID mentioned above.

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

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Date: 19/04/2020

Additional Guidelines for TrueNat testing for COVID-19

In addition to existing guidelines for testing for COVID-19 (including the biosafety precautions for sample collection and transportation); TrueNat being a screening test for COVID-19, following procedures may be followed for registration of laboratories on ICMR portal –

- 1. Since TrueNat is a screening test, therefore a confirmatory test is necessary. Accordingly, for Government laboratories, where ever TrueNat is planned to be used as a standalone unit; it must be mapped with an existing laboratory registered with ICMR for real time RT-PCR testing for COVID-19. In such a case, the -
 - Negative test results uploaded by the TrueNat laboratory will be deemed as final for that episode of testing; and
 - Positive test results uploaded by the TrueNat laboratory will be deemed as provisional and will be considered as confirmatory only after uploading of real time RT-PCR test results by the concerned / mapped laboratory registered for COVID-19 real time RT-PCR testing; and
 - Transportation of the sample(s), on positive result by TrueNat, for further confirmation by RT-PCR will be the responsibility of the concerned TrueNat laboratory
- 2. For Private laboratories, the TrueNat test will be permitted only if the TrueNat machines are installed in the same laboratory that is already registered with ICMR for real time RT-PCR testing as per guideline.

Standard Operating Procedure No: MPX 6.7

Components of SOP: Molecular Biology: Mol Diagnostic RT.-PCR

Title	Multiplex Real-Time PCR for detection of SARS-CoV-2 using TaqPath COVID-19 Combo Kit (Applied Biosystems).
Document code	SARS-CoV-2 -mol-multiplex RT PCR –diagnostic-MPX 6.7
Implementation Date	07.04.2020

1. Introduction:

The purpose of this document is to provide interim guidance to laboratories involved in laboratory testing of patients who meet the definition of suspected case of pneumonia associated with a novel coronavirus identified in Wuhan, China.

TaqPath[™] COVID-19 Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider. TaqPath[™] COVID-19 Combo Kit is for use only under Emergency Use Authorization (EUA).

2. SourceReference:

https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0019181_TaqPath_COVID-19_IFU_EUA.pdf

3. Testing criteria/Objective:

Detection of SARS-CoV-2 in human clinical specimens using TaqPath COVID-19 Combo Kit (Applied Biosystems)

4. Principle:

The real time assay uses the TaqMan fluorogenic probe based chemistry that uses the 5' nuclease activity of Taq DNA polymerase and enables the detection of a specific PCR product as it accumulates during PCR cycles.

COVID-19 Real Time PCR Assay Multiplex-Multiplexed assays that contain three primer/probe sets specific to different SARS-CoV-2 genomic regions and primers/probes for phage MS2 (Internal process control for nucleic acidextraction).

- 5. Safety procedures: According to Laboratory Safety Manual. (WHO,2011)
- 6. Sample requirements: 250µl of specimen or as per recommendedkit.

7. Standard andcontrols:

(1) Positive control (Supplied withKit)

(2) Water is used as no template control(NTC).

8. Scope and definition:

Highly specific and efficient detection of SARS-CoV-2 by Multiplex Real Time PCR.

9. Requirements:

Equipment	Consumables	Reagents and samples
Water bath, Bio Safety Cabinet	Mask, gloves, Lab Coats sterile filter	TaqPath COVID-19 Combo Kit
clean laminar flow hood with	tips, tissue paper, 0.2 ml, 0.5 ml and	(Applied Biosystems), Milli Q
micro-centrifuge with plate rotor	1.5 ml micro centrifuge tubes, micro	Water, Extracted viral Nucleic
and vortex, MiniSpin. Pipette set,	tips, 0.5-10 µl, 20-200 µl and 1000 µl	samples,
Real Time PCR machine.	tips. Real Time PCR Plates and	_
	sealers or tubes and strips	
	-	

10. TestProcedure:

- *Add 10 μL MS2 Phage Control to each sample well and to the Negative Control well during extraction and perform RNA extraction of clinical samples using your laboratory protocol. Extracted RNA will be the starting point for thereaction.
- 2. Prepare real time PCR worksheets (KGMU- VIRO-RTM-MPX-PCR-PP-6.7-copy attached at theend)
- 3. Perform multiplex real time PCR reaction as shown in table1 for corona ORF1ab gene, N gene, S gene and MS2 (Internal process control for nucleic acid extraction) in a single tube (as per manufacturers instruction).
- 4. Determine the number of reactions (N) to set up per assay. In addition, include Negative control & Positive control in thetest.
- 5. Prepare excess reaction cocktail to account for pipettingerror.

If number of samples (n) including controls = 1 to 10, then N = n + 2

6. In the **clean reagent preparation room** prepare the MasterMix:

Calculate the amount of each reagent to be added for each set reaction master mix.

Table 1: The calculations are as follows:

S.No.	Component	Volume for one reaction(N=1)	Volumefor(N=)
1.	TaqPath [™] 1-Step Multiplex MasterMix(NoROX [™])(4X)	6.25 μL	
2.	COVID-19 Real Time PCR Assay Multiplex	1.25 μL	
3.	Nuclease-free Water	12.50 μL	
	Total Reaction Mix volume	20.0 μL	

- 7. Mix reaction mixtures by pipetting up anddown.
- Centrifugefor 5-10secto collect contents at bottomofthetube, and then place the tube incoldrack.
 Set up reaction strip tubes or plates in 96-well cooler rack.
- 9. Dispense 20µl of each master mix into each well as per the plate setup.
- 10. Before moving the plate to the nucleic acid handling area. Pipette 5ul of the nuclease free water into NTCwells.
- 11. In the nucleic acid extraction room, add 5ul of each sample and 5ul of extraction control into respective wells as per the setup.
- 12. Capthecolumn or cover the plate with tissue papertowhich the samples and control has been added.
- 13. Finally, pipette 5 µl of positive viral template control (Positive Control) into wells in positive control addition area. Cap VTC wells/ or seal the plate with optical sealer. Centrifuge the plate for 10 seconds. Make sure that bubbles are eliminated from the bottom of the reactiontubes.
- 14. For real time PCR set up follow the instructions given by the Real-time PCR system manual for plate set up. Save your platesetup!
- 15. The reaction volume is 25μ l.

Table 2: Program the run method as follows:

Step	Temperature	Time	Number of cycles
UNG incubation	25°C	2 minutes	1
Reverse transcription	53°C	10 minutes	1
Activation	95°C	2 minutes	1
Denaturation	95°C	3 seconds	
Anneal/extension*	60°C	30 seconds	45

*Fluorescence data should be collected during the 60°C incubation step.

Table 3: Target Genes & Reporter dyes

Reporter dye	Detector
FAM	ORF1ab
VIC	N gene
ABY	S gene
JUN	MS2

16. After completion of the run, save the run and analyze the collecteddata.

11. Recording & reporting and Interpretation of theresults:

Interpretation of the results is performed by the Applied Biosystems COVID-19 Interpretive Software (Optional).

One Negative Control and one Positive Control are processed with each run.

ORF1ab	N gene	S gene	MS2	Status	Result	Action
NEG	NEG	NEG	NEG	Invalid	NA	Repeat test. If the repeat result remains invalid, consider collecting a new specimen.
NEG	NEG	NEG	POS	Valid	SARS-CoV-2 Not Detected	Report results to healthcare provider. Consider testing for other viruses.
Only one S = POS	SARS-CoV	7-2 target	POS or NEG	Valid	SARS-CoV-2 Inconclusive ^[#]	Repeat test. If the repeat result remains inconclusive, additional confirmationtesting should be conducted if clinicallyindicated.
Two or mo targets	ore SARS-	CoV-2	POS or NEG	Valid	Positive SARS- CoV-2	Report results to healthcare provider and appropriate public health authorities.

Table 4: Result interpretation for patient samples

[#] Samples with a result of SARS-CoV-2 Inconclusive shall be retested one time.

12. Quality control procedures:

For the results to be valid positive control must be positive; NTC must be negative. Check MS2 (if added during RNA Extraction) for all the samples. All the sample should have MS2 Positive. Otherwise, laboratory in charge must be informed and repeat testing is performed. Another experienced staff must countercheck all results.

13. Limitations

- 1. Analysts should be trained and familiar with testing procedures and interpretation of results prior to performing theassay.
- **2.** A false negative result may occur if inadequate numbers of organisms are present in the specimen due to improper collection, transport orhandling.
- 3. This assay doesn't provide control over quality of samplecollected.

Note:

MS2 (Internal process control for nucleic acid extraction) testing can be ignored as it will not reflect the quality of sample collected. Hence, laboratories which have machine with no calibrated JUN dye filter or without JUN filter should not add MS2 control during extraction. MS2 control is for only for extraction procedure and if your machine doesn't support the JUN dye you can omitthis.

It is recommended that separate RNase P or any other human house-keeping gene for which primers & probe are available in your laboratory should be run parallel in a separate tube for RT PCR assay. This will check both the quality of sample collected and nucleic acid extractionprocedure.

Report: Communicate the result on daily basis to ICMR

Report Format

Sample ID	Patient State & place	Category of Patient	received	Severity/ condition of patient	Result for SARS-CoV- 2 virus
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Worksheet for Multiplex Real-Time PCR for detection of SARS-CoV-2 using TaqPath COVID-19 Combo Kit (Applied Biosystems).

(One Step Reaction)

ReactionmixPreparation:

Corona ORF1ab Gene Probe:Reporter- FAM,

Corona S Gene Probe: Reporter- ABY

Total Volume: 25µl (for one reaction) Corona N Gene Probe: Reporter- VIC MS2-IC Probe: Reporter-JUN

S.No.	Item	Quantity(N=1)	Quantity(N=)	Done
1.	TaqPath [™] 1-Step Multiplex Master Mix (No ROX [™]) (4X)	6.25 μL		
2.	COVID-19 Real Time PCR Assay Multiplex	1.25 μL		
3.	Nuclease-free Water	12.50 μL		
	Total Reaction Mix volume	20.0 μL		

Addition of Template

Template (TNA/RNA)	5 μl	
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Sample details (sample ID):

	1	2	3	4	5	6	7	8	9	10	11	12
Α												
В												
С												
D												
E												
F												
G												
Н												

Results for SARS-CoV-2:

	1	2	3	4	5	6	7	8	9	10	11	12
A												
В												
С												
D												
E												
F												
G												
Н												

Comments:

Done by:

Checked by:

SARS Coronavirus – 2 Real Time RT-PCR

Manufacturer – BGI Real time Fluorescent RT-PCR kit for detecting 2019-nCoV

As per kit protocol

Target gene – ORF1ab for SARS CoV-2 Duplex assay (ORF1ab and Internal Control)

Master-mix preparation:

All reagents provided in the kit. Master-mix prepared in a single tube. 30 μl reaction volume

	Component	Volume for 1 reaction
1	2019-nCoV Reaction Mix	18.5 μl
2	2019-nCoV Enzyme Mix	1.5 μl
	Template RNA	10 μl
	Total	30 μl

Kit content- Blank control and Positive control (pooled PC for 2019-nCoV ORF1ab and IC)

Target dyes:

	Target gene	Dyes used
Duplex assay	ORF1ab	FAM
	Internal Control	VIC/ HEX

Passive reference - None

Cycling condition:

Reverse Transcription	50°C for 20 min
Initial denaturation	95°C for 10 min
PCR amplification	95°C for 15 sec
(40 cycles)	60°C for 30 sec *(data collection)

Analysis & Interpretation:

Positive Control - Ct value \leq 32 and sigmoid curve Internal Control - Ct value \leq 32 and sigmoid curve

Test specimen – Positive - Ct value < 38 and sigmoid curve

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 13/04/2020

Advisory on feasibility of using pooled samples for molecular testing of COVID-19

Background: Number of COVID-19 cases in India is rising exponentially. In view of this, it is critical to increase the numbers of tests conducted by laboratories. Positivity rate in cases is still low. Hence, it may help to use the pooled samples for screening. A pooled testing algorithm involves the PCR screening of a specimen pool comprising multiple individual patient specimens, followed by individual testing (pool de-convolution) only if a pool screens positive. As all individual samples in a negative pool are regarded as negative, it results in substantial cost savings when a large proportion of pools tests negative.

Objectives: To increase capacity of the laboratories to screen increased numbers of samples using molecular testing for COVID-19 for the purpose of surveillance.

Methods & Results: A feasibility study was conducted at DHR/ICMR Virus Research & Diagnostic Laboratory (VRDL) at King George's Medical University (KGMU), Lucknow. It has been demonstrated that performing real-time PCR for COVID-19 by pooling 5 samples of TS/NS (200 ul/sample) is feasible when the prevalence rates of infection are low. All individual samples in a negative pool to be regarded as negative. Deconvoluted testing is recommended if any of the pool is positive. Pooling of more than 5 samples is not recommended to avoid the effect of dilution leading to false negatives.

Recommendations for sample pooling for real-time RT-PCR screening for COVID-19 are as follows (based on the KGMU study):

- 1. Use only in areas with low prevalence of COVID-19 (initially using proxy of low positivity of <2% from the existing data. Still a watch should be kept on increasing positivity in such areas
- 2. In areas with positivity of 2-5%, sample pooling for PCR screening may be considered only in community survey or surveillance among asymptomatic individuals, strictly excluding pooling samples of individuals with known contact with confirmed cases, Health Care Workers (in direct contact with care of COVID-19 patients). Sample from such individuals should be directly tested without pooling
- Pooling of sample is not recommended in areas or population with positivity rates of >5% for COVID-19

Preferable number of samples to be pooled is five, though more than two samples can be pooled, but considering higher possibility of missing positive samples with low viral load, it strongly discouraged to pool more than 5 samples, except in research mode.

Contributors:

- Dr. Shantanu Prakash, Dr. Amita Jain, DHR/ICMR VRDL, KGMU, Lucknow
- Dr. Kiran Rade, WHO-India

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 19/04/2020

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

- 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 <u>https://www.fda.gov/media/136314/download</u>.
- 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: Medical Microbiologists 1 or more with experience of work in Molecular Virology.
 - ii. Technicians At least 2-3 with relevant experience of work in Molecular Virology.
 - 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

Guidance on Rapid antibody kits for COVID-19

Not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test comes positive after 7-10 days of infection
- The test remains positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection

These tests are not recommended for diagnosis of COVID-19 infection

List of CE-IVD approved antibody based rapid kits

- 1. *COVID-19 IgM-IgG Dual Antibody Rapid Test* (**CE-IVD**): **BioMedomics** (+1- 9198903070, info@biomedomics.com, USA)
- One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold) (CE-IVD): Getein Biotech (+86-25-68568594, <u>sales@getein.com</u>, <u>overseas@getein.com.cn</u>, Nanjing, China)
- 3. COVID 19 Rapid Test Kit (IgM/IgG) (CE-IVD) (Sensing Self Ltd, Singapore,), also validated by NIV, Pune
- 4. *COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)* (**CE- IVD**): **Hangzhou Biotest Biotech** Co.,Ltd. (info@alltests.com.cn, +86-57- 158120625, China)
- 5. COVID-19 IgM/IgG test kit (CE-IVD) (AmonMed Biotechnology Co. Ltd, info@amonmed.com)
- 6. *COVID-19 Antibody (IgG/IgM)Test Kit* (**CE-IVD**) (<u>Beijing Abace Biology Co., Ltd., huanyi.cheng@rd.abace-biology.com</u>)
- 7. *Tigsun COVID-19 Combo IgM/IgG Rapid Test* (**CE-IVD**) (<u>Beijing Tigsun Diagnostics</u> <u>Co.Ltd., hu.duan@tigsun.com</u>)
- 8. 2019-nCoV IgG/IgM Rapid Test Cassette (CE-IVD) (BIOMAXIMA S.A, Poland, export@biomaxima.com)
- 9. OnSite COVID-19 IgG/IgM Rapid Test (CE-IVD) (CTK Biotech, Inc., USA, sparker@ctkbiotech.com)
- 10. COVID-19 IgG/IgM Detection Kit (Colloidal Gold) (CE-IVD) (<u>Hunan Lituo</u> <u>Biotechnology Co., Ltd.</u>,)
- 11. VivaDiag SARS-CoV-2 IgM/IgG rapid test. (**CE-IVD**) **Vivacheck** Lab (91- 4448544811, <u>info@vivacheck.com</u>, <u>vivachek.india@gmail.com</u> India office: Tamil Nadu)
- 12. COVID-19 Antibody Kit Serological Test. (CE-IVD) GenSure Biotech Inc., https://www.ozo.life (+91 7021901240, tarshant@ozo.life India Office: Bangalore

Antibody based rapid kit are validated by ICMR-NIV, Pune

1. SARS-CoV-2 Antibody Test: Wondfo (+86-3032296083, <u>sales@wondfo.com.cn</u>, China), validated by NIV, Pune

This is an evolving list, and kits which will get CE/FDA approval or validated by NIV Pune will be added.

INDIAN COUNCIL OF MEDICAL RESEARCH

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.

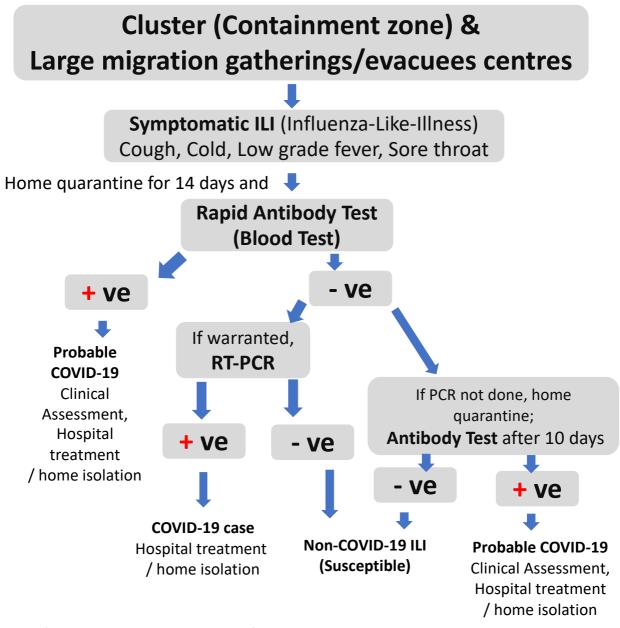
If symptoms worsen, refer to designated COVID-19 hospitals. When home quarantine is not feasible, consider facility-based quarantine.

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

Guidance on Rapid antibody kits for COVID-19

Not recommended for diagnosis of COVID-19 infection

- Can be done on blood/serum/plasma samples
- Test result is available within 30 minutes
- Test comes positive after 7-10 days of infection
- The test remains positive for several weeks after infection
- Positive test indicates exposure to SARS-CoV-2
- Negative test does not rule out COVID-19 infection

These tests are not recommended for diagnosis of COVID-19 infection

Till date, 23 antibody based rapid tests have been validated at NIV Pune, and the following were found to be satisfactory. 9 of these kits are manufactured in India.

S.No.	Kit Detail	*Lot no./Batch no.
1.	SARS-CoV-2 Antibody test (Lateral flow method): Guangzhou Wondfo Biotech,	
	Mylan Laboratories Limited (CE-IVD)	
	M R Roofs Private Ltd	W19500309
		W19500302
	Abbott Laboratories	W19500351
	Zydus Cadilla	W19500338
2.	COVID-19 IgM IgG Rapid Test: BioMedomics (CE-IVD)	20200226
3.	COVID-19 IgM/IgG Antibody Rapid Test: ZHUHAI LIVZON DIAGNOSTICS (CE-IVD)	CK2003010410
4.	New Coronavirus (COVID-19) IgG/IgM Rapid Test: Voxtur Bio Ltd, India	PCCV200301S
5.	COVID-19 IgM/IgG Antibody Detection Card Test: VANGUARD Diagnostics, India	RCOVID200301T
6.	Makesure COVID-19 Rapid test: HLL Lifecare Limited, India	CVCT030420 CVCT0204203 CVCT0104202
7.	YHLO iFlash-SARS-CoV-2 IgM and IgG detection kit (additional equipment required): CPC Diagnostics	20200206
8.	ACCUCARE IgM/IgG Lateral Flow Assay kit: LAB-CARE Diagnostics (India Pvt. Ltd)	CVC 200401
9.	Abchek COVID-19 IgM/IgG Antibody Rapid Test: NuLifecare	NUL/COV- 19/R&D/001
10.	One Step Corona Virus (COVID-19) IgM/IgG Antibody Test: ALPINE BIOMEDICALS	A10420 A20420
11.	COVID 19 IgM/IgG Rapid Test Kit; Medsource Ozone Biomedicals (ver 2.0)	COV-002
12.	Immuno Quick Rapid Test for Detection of Novel Coronavirus (COVID-19) IgM/IgG Antibodies: Immuno Science India Pvt. Ltd	E142001
13.	Standard Q Covid -19 IgM/IgG Duo test – One Step Rapid Antibody test: SD Biosensors	E054002 E054004
14.	COVID-19 IgG/IgM Rapid Test Kit Rafael Diagnostic: BMT Diagnostics	COV20030059 COV20030059-1

*Above listed kits are validated with the mentioned batch number only. Responsibility for batch to batch consistency lies with the manufacturer.

Guidance on Rapid antibody kits for COVID-19

Antibody based rapid tests which are CE-IVD approved

The complete list of CE-marked rapid SARS-CoV-2 antibody tests is available at (<u>https://www.finddx.org/covid-19/pipeline/</u>). CE-IVD approved kits can be used directly after due marketing approval from DCGI.



प्रोफेसर (डा.) बलराम भार्गव, पदम श्री

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

> सचिव, भारत सरकार स्वास्थ्य अनुसंघान 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



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 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
- 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 Bakan &

(Balram Bhargava)

Enclosed: As above

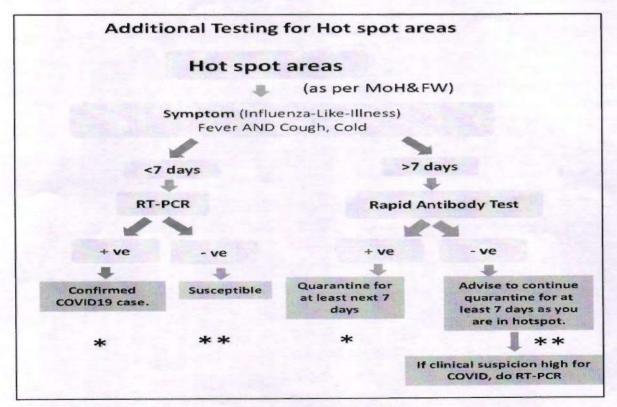
CC: Chief Secretary/Administrators

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)

Balan Braggen

F.No.R.15015/03/2020-HR Government of India Ministry of Health & Family Welfare (Department of Health Research)

2nd Floor, IRCS Building, Red Cross Road, New Delhi – 110001 Dated the 20th March, 2020

OFFICE MEMORANDUM

Subject: National Labs identified for COVID-19 testing to remain open all 7 days a week – regarding.

With a view to contain the spread of COVID-19, it has been decided that all the notified National Labs for COVID-19 testing, including Viral Research & Diagnostic Laboratories (VRDLs) and other Labs, spread across the country shall remain open all the 7 days a week. List of Labs is enclosed as Annexure-I.

2. For this purpose a duty roster may be prepared and followed strictly.

This issues with the approval of competent authority.

Encl: As above.

(D.K. Meena) Deputy Secretary to the Govt. of India Tel.: 23736901

To

1. All the Principal Investigators/ in-charges of the VRDLs and other National Labs identified for COVID-19 testing.

Copy to:

- 1. Secretary, Department of Health & Family Welfare, New Delhi.
- 2. The Principal Health Secretaries of all the States/ UTs with a request to kindly ensure that all the notified labs for COVID-19 testing remain operational all the seven days a week.

ANNEXURE-I

	_	COVID -19 Testing Sites
State/UT		Name of Laboratories
Andhra	1.	Sri Venkateswara Institute of Medical Sciences, Tirupati
Pradesh	2.	Rangaraya Medical College, Kakinada
	3.	Sidhartha Medical College, Vijayawada
	4.	GMC, Anantapur, AP
Andaman & Nicobar islands	5.	Regional Medical Research Centre, Port Blair, Andaman and Nicobar
Assam	6.	Gauhati Medical College, Guwahati
	7.	Regional Medical Research Center, Dibrugarh
	8.	Silchar Medical College, Silchar
	9.	Jorhat Medical College, Jorhat
Bihar	10.	Rajendra Memorial Research Institute of Medical Sciences, Patna
	11.	Darbhanga Medical College, Darbhanga
Chandigarh	12.	Post Graduate Institute of Medical Education & Research, Chandigarh
Chhattisgarh	13.	All India Institute Medical Sciences, Raipur
	14.	Late Sri BaliramKashyap Memorial Govt. Medical College, Jagdalpur
Delhi-NCT	15.	All India Institute Medical Sciences, Delhi
	16.	Lady Hardinge Medical College, New Delhi
	17.	Army Hospital (R&R), New Delhi
Gujarat	18.	BJ Medical College, Ahmedabad
	19.	M.P.Shah Government Medical College, Jamnagar
	20.	Govt. Medical College, Surat
	21.	Govt.Medical College, Bhavnagar
	22.	Pt. B.D. Sharma Post Graduate Inst. of Med. Sciences, Rohtak, Haryana
Haryana	23.	BPS Govt Medical College, Sonipat
Himachal	24.	Indira Gandhi Medical College, Shimla, Himachal Pradesh
pradesh	25.	Dr.Rajendra Prasad Govt. Med. College, Kangra, Tanda, HP
Jammu and	26.	Sher-e- Kashmir Institute of Medical Sciences, Srinagar
Kashmir	27.	Government Medical College, Jammu
	28.	Government Medical College, Srinagar
	29.	Command Hospital, Udhampur
Jharkhand	30.	MGM Medical College, Jamshedpur
Karnataka	31.	Bangalore Medical College & Research Institute, Bangalore
	32.	National Institute of Virology Field Unit Bangalore
-	33.	Mysore Medical College & Research Institute, Mysore
-	34.	Hassan Inst. of Med. Sciences, Hassan, Karnataka
	35.	Shimoga Inst. of Med. Sciences, Shivamogga, Karnataka
	36.	Command Hospital, Bengaluru
Kerala	37.	National Institute of Virology Field Unit, Kerala

	38.	Govt. Medical College, Thriuvananthapuram, Kerala			
	39.	Govt. Medical College, Kozhikhode, Kerala			
	40.	Govt. Medical College, Thrissur			
Madhya	41.	All India Institute Medical Sciences, Bhopal			
Pradesh	42.	National Institute of Research in Tribal Health (NIRTH), Jabalpur			
	43.	MGM, Indore			
Meghalaya	44.	NEIGRIHMS, Shillong, Meghalaya			
Maharashtra	45.	Indira Gandhi Government Medical College, Nagpur			
	46.	Kasturba Hospital for Infectious Diseases, Mumbai			
	47.	Armed Forces Medical College, Pune			
	48.	NIV Mumbai Unit			
	49.	Seth G S Seth Medical College & KEM Hospital, Mumbai			
Manipur	50.	J N Inst. of Med. Sciences Hospital, Imphal-East, Manipur			
	51.	Regional Institute of Medical Sciences, Imphal			
Odisha	52.	Regional Medical Research Center, Bhubaneswar			
Puducherry	53.	Jawaharlal Institute of Postgraduate Medical Education & Research Puducherry			
Punjab	54.	Government Medical College, Patiala, Punjab			
	55.	Government Medical College, Amritsar			
Rajasthan	56.	Sawai Man Singh, Jaipur			
	57.	Dr. S.N Medical College, Jodhpur			
	58.	Jhalawar Medical College, Jhalawar, Rajasthan			
	59.	RNT Medical College, Udaipur			
	60.	SP Med. College, Bikaner, Rajasthan			
	61.	AIIMS, Jodhpur			
Tamil Nadu	62.	King's Institute of Preventive Medicine & Research, Chennai			
	63.	Government Medical College, Theni			
	64.	Tirunelveli Medical College, Tirunelveli			
	65.	Govt. Medical college, Thiruvarur			
	66.	Madras Medical College, Chennai			
	67.	Govt. Kumar Manglam Govt. Medical College, Salem			
	68.	Coimbatore Medical College, Coimbatore			
Tripura	69.	Government Medical College, Agartala			
Telangana	70.	Gandhi Medical College, Secunderabad			
<u> </u>	71.	Osmania Medical College, Hyderabad			
Uttar Pradesh	72.	King's George Medical University, Lucknow			
	73.	Institute of Medical Sciences, Banaras Hindu University, Varanasi			
	74.	Jawaharlal Nehru Medical College, Aligarh			

	75. Command Hospital, Lucknow		
Uttarakhand	76.	Government Medical College, Haldwani	
West Bengal	77.	National Institute of Cholera and Enteric Diseases, Kolkata	
	78.	IPGMER, Kolkata	

79. National Centre of Disease Control, New Delhi

Government of India Ministry of Health and Family Welfare Department of Health Research

Dated the, 15th April, 2020

<u>ORDER</u>

In view of the need to increase the daily testing capacity of the public sector labs and the ever increasing number of labs and their widening geographical spread, the current model of inventory stocking and distribution will have to be scaled up significantly. Currently, ICMR has two major stocking and dispatch centers at NIMR, Delhi and NIV, Pune where the orders placed to different suppliers are being received and stored in the cold container units.

2. The stock is being distributed to the six regional depots - NIRRH, Mumbai; NIE, Chennai; NICED, Kolkata; RMRC, Dibrugarh; NIREH, Bhopal and NIN, Hyderabad. As the volumes go on increasing it will be challenging for the existing manpower and infrastructure to meet the requirements. Therefore the existing depots are being strengthened in terms of manpower, resources and infrastructure. To further decentralize the distribution, it is New to set-up additional depots in the following locations in addition to the above mentioned depots.

- 1. KJMU, Lucknow -Uttar Pradesh
- 2. PGI, Chandigarh Punjab, Chandigarh, Himachal, Jammu-Kashmir and Ladakh
- 3. NIIRNCD, Jodhpur Rajasthan
- 4. NIOH, Ahmedabad Gujarat
- 5. RMRC, Bhubaneshwar Orissa
- 6. RMRI, Patna Bihar
- 7. NIV Field Unit, Bangalore -Karnataka
- 8. GMC, Guwahati

3. Once these units/depots become fully functional state-wise allocation of each depot is shall be as below:

S.no.	DEPOT LOCATION	Туре	Existing allocation of states	New allocation of States
1	NIMR, DELHI	Existing	Delhi, Haryana, Himachal, Uttarakhand, Jammu & Kashmir, Punjab, Uttar Pradesh, Rajasthan, Patna, Chandigarh, Gujarat, Bihar, Jharkhand	Dełhi, Western UP (NCR), Uttarakhand, Haryana
2	PGI, CHANDIGARH	New		Punjab, , J&K, Himachal Pradesh, , Ladakh, Chandigarh

3	KJMU, LUCKNOW	New	***	Uttar Pradesh
4	RMRI, Patna	New		Bihar
5	NIIRNCD, Jodhpur	New		Rajasthan
6	NIOH, Ahmedabad	New		Gujarat, Dadra & Nagar Haveli and Daman and Diu
7	NIREH, BHOPAL	Existing	Madhya Pradesh	MP, Vidharbha Region
8	NICED, KOŁKATA	Existing	West Bengal, Chhattisgarh, Orissa	West Bengal, Tripura, Jharkhand, Sikkim, Andaman& Nicobar
9	RMRC, Bhubaneshwar	New		Orissa, Chhattisgarl
10	NIRRH, MUMBAI	Existing	Maharashtra	Maharashtra (othe than Vidarbha), Dadra & Nagar Haveli and Daman and Diu
11	NIV, Pune	Existing	Goa, Karnataka	Goa
12	NIV Filed Unit, Bangalore	New		Karnataka
13	NIN, HYDERABAD	Existing	Telangana	Telangana
14	NIE, CHENNAI	Existing	Kerala, Tamil Nadu, Puducherry, Andhra Pradesh, Andaman	Tamil Nadu, Andhra Pradesh, Puducherry, Kerala Lakshadweep
15	RMRC, DIBRUGARH	Existing	All NE states	Arunachal, Assam (Upper Assam) , Meghalya
16	GMC, Guwahati	New		Manipur, Mizoram Nagaland

4. As per the new system the requisition and indents will be placed directly to the Depots by the labs. These depots will process, analyze and decide the distribution of testing commodities in line with the requirements placed by the lab, usage by them so far and the likely forecast of requirement of the testing commodities.

5. ICMR will monitor the working of these depots and ensuring no request is pending for more than 24-48 hours. For this purpose, an inventory portal is functional which can capture these requirements. A dashboard view of the available inventory across labs in each state has been created for the Health Secretary of the respective state. The State Governments shall also be able to view the requests made, the response of the depot and the date of dispatch and receipt once the request is processed.

6. Thus, the primary responsibility of ensuring adequate supplies at the lab level shall be the primary responsibility of the depots based on the indents received from them. Overall coordination with the depots will be handled by a central team supervised by Dr. G.S. Toteja, Additional Director General, ICMR. The Director at each of these institutes shall be responsible for ensuring that the work specified as part of the Inventory Management Plan are carried out effectively and adequate and timely supplies to each lab is ensured.

7. The depots will be augmented in terms of manpower and resources to enable real time feedback on the inventory availability and to plan lab-wise distribution. The depots will be provided following assistance in order to become a self-functioning unit:

- Manpower requirement be enhanced to ensure there is adequate staff for manning 2/3 shifts during the day.
- Technical team staffed by ICMR scientists, experts and lab technicians
- Packaging material and regular supply of essential items required to maintain the cold chain.
- Management Team to be manned by MBA students from IIMs, Consultants from KPMG/PWC/EY/BCG etc. to be deployed for operationalizing the Inventory Portal and giving real time feedback and streamlining of the entire inventory management plan.
- Packaging team to ensure packing of material as per Bio-safety and IATA standards.
- Inventory team to maintain stock and inventory data receipt/dispatch
- Logistics partner- each depot to have a field office of Department of Post which will prepare the dispatch plan as per requirement communicated and ensure delivery of the consignment to the lab by the fastest mode.

(Shailendra Singh) Additional Secretary, DHR

Copy to:

- 1. PS to Secretary, D/o of Health Research
- 2. DG, ICMR
- 3. Sr. DDG, Admn. ICMR
- 4. Dr. G. S. Toteja, Addl. ICMR
- 5. Dr. R. R. Gangakhedkar, Head ECD, ICMR
- 6. JS (AN), DHR
- 7. JS(GN), DHR
- 8. DS(KT)
- 9. DS(ABS), DHR

INDIAN COUNCIL OF MEDICAL RESEARCH NEW DELHI

Date: April 19, 2020

Subject: Regional Depots for storage and transportation of COVID KITS

The daily COVID-19 testing capacity at various laboratories in the country is being increased and is expected to reach to 1 lakh tests per day by 31st May 2020. To meet the increased requirement of testing material with increasing number of tests, the current model of inventory stocking and distribution is being scaled up significantly.

Accordingly a total of 16 regional depots are being set up and are modelled into self-contained units by strengthening manpower, resources and infrastructure. Besides 16 Regional Depots; Depots at NIMR, New Delhi and NIV, Pune would also function as Central Depots.

The Roles and Responsibilities of Regional Depots are as follows:

- 1. Receiving stock from central depots and repackaging for lab-level and state-level consignments as per ICMR guidelines and commodity requirements.
- 2. Processing lab-level and state-level stock requests and deciding quantity and items to be dispatched to each linked state and lab.
- 3. Mapping commodity specifications with lab-level infrastructure (machine type, available storage etc.) and deciding appropriate commodities for labs.
- 4. Assisting labs on technical issues related to testing by receiving, understanding and disseminating ICMR / central depot guidelines
- 5. Preparing consignments by repackaging stock received from national nodes and considering special requirements such as refrigeration and packing.
- 6. Coordinating logistics with recipient state, Government and private service provider (such as India Post, Indian Railways, Jeena Logistics etc.)
- 7. Keeping tab on inventory level and dispatch trends, and requesting stock well in advance of a potential stock-out.
- 8. Daily data entry of dispatch and inventory details on ICMR MIS.

Designation	Function
Depot Supervisor	Overall Supervision
Administrators	 Nodal person for signing off the receipts and authorizing dispatch. Keeping tab on inventory level and dispatch trends, and requesting stock well in advance of a potential stock-out with the assistance of Management team. Ensuring daily data entry of dispatch and inventory details on ICMR MIS by data entry operators. Supervision of Management Team deputed at the depot location for processing lab-level and state-level stock requests and deciding quantity and items to be dispatched to each linked state and lab.
Technical Team	 Mapping commodity specifications with lab-level infrastructure (machine type, available storage etc.) and deciding appropriate commodities for labs. Assisting labs on technical issues related to testing by receiving, understanding and disseminating ICMR / central depot guidelines

The manpower structure for the Regional Depots is as follows:

Packaging Coordinator	 Receiving stock from central depots and repackaging for lab-level and state-level consignments as per ICMR guidelines and commodity requirements Preparing consignments by repackaging stock received from national nodes and considering special requirements such as refrigeration and packing. 	
Logistics Coordinator		

The details of the Regional Depots are given below:

1. National Institute for Cholera and Enteric Diseases (NICED), KOLKATA

Designation	Name	Contact Details
		Phone No and email address
Depot Supervisor	Dr. Shanta Dutta	Phone: 9830152971
	Director	E-mail: drshantadutta@gmail.com
Administrators	Dr. Mamta Chawla Sarkar	Phone: 9830660999
	Scientist F	E-mail: chawlam70@gmail.com
	Dr. Provash Chandra	Phone: 9830546338
	Sadhukhan Scientist E	E-mail: provash2000@gmail.com
Technical Team	Dr. Asish K. Mukhopadhyay	Phone: 9830468362
	Scientist F	E-mail: asish1967@gmail.com
	Dr. Sandipan Ganguly	Phone: 9830064739
	Scientist F	E-mail: sandipanganguly@hotmail.com
	Dr. S. S. Das	Phone: 9830160665
	Scientist F	E-mail: santasabujdas@yahoo.com
Packaging Coordinator	Dr. Alok Kr. Deb	Phone: 9831149779
	Scientist F	E-mail: adeb02@yahoo.com
	Dr. Hemanta Koley	Phone: 9831031307
	Scientist E	E-mail: hemantakoley@hotmail.com
Logistics Coordinator	Dr. Ranjan Kr. Nandy	Phone: 9433525652
	Scientist F	E-mail: nandyrk.niced@gov.in
	Dr. Debjit Chakraborty	Phone: 8296875975
	Scientist D	E-mail: djsmile_1979@yahoo.com

2. National Institute for Implementation Research on Non-Communicable Diseases (NIIR-NCD), Jodhpur

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. G.S.Toteja Director	Phone: 9868368075 E-mail: gstoteja@gmail.com

Administrators	Dr. S. S. Mohanty Scientist E	Phone: 8058642995 E-mail: <u>ssnimr@gmail.com</u>
	Er. Ramesh Hudda Scientist B	9602755600 ramesh.hudda@gmail.com
Technical Team	Dr. Suresh Yadav Scientist C Dr. Elantamilan Scientist C	9426211724 syadavdmrc@gmail.com 8794726173 dentamilan@gmail.com
Packaging Coordinator	Dr. Ramesh Sangwan Scientist B	9416857243 ramesh219879@gmail.com
Logistics Coordinator	Dr. Mahender Thakore Scientist B	8511194590 MAHENDRA15519@GMAIL.COM

3. National Institute of Occupational Health (NIOH), Ahmedabad

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. Kamalesh Sarkar, Director	Phone: 9432674230 E-mail: director-nioh@gov.in kamalesh.sarkar@gmail.com
Administrators	Dr. P. Sivaperumal Scientist D	Phone: 9904721778 E-mail: sivaperumal.p@gov.in sivaperum2003@yahoo.co.in
	Dr Kuldeep Upadhyay Scientist B	Phone: 8780829397 drkuldip_upadhyay@rediffmail.com
Technical Team	Dr. Mahesh Sahu Scientist B	7008709597; 9439154436 sahu.maheshc@icmr.gov.in mchsahu@gmail.com
	Dr. Avinash Pagdhune Scientist B	9975629029; 9405030435 pagdhune.av@icmr.gov.in dravinashpd@gmail.com
Packaging Coordinator	Dr. Rakesh B. Scientist D	9535228260 rakesh.bal@icmr.gov.in balachandar.rakesh@gmail.com
Logistics Coordinator	Dr. Ankit Viramgami Scientist B	9998191447 drapviramgami86@yahoo.in

4. National Institute for Research in Environmental Health (NIREH), Bhopal

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. R. R. Tiwari, Director	Ph: 9427958747 email: tiwari.rr@gov.in
Administrators	Dr. Anil Prakash, Sc G	Ph:9425403828 email: anilprakashin@yahoo.co.in
	Dr. Y. D. Sabde, Sc E	Ph: 9926329273 email: sabdeyogesh@gmail.com

Technical Team	Dr. D. K. Sarma, Sc C	Ph:7002117201 email: dkbiotek@gamil.com
	Dr. Manoj Kumar, Sc C	Ph: 8121450098 email: manoj15micro@yahoo.co.in
Packaging Coordinator	Dr. Rajase- karan, Sc E	Ph:8675460006 email:rajasekarphd@gmail.com
Logistics Coordinator	Dr. Rajesh Ahirwar, Sc B	Ph: 8839848215 email: rahirwar1209@gmail.com

5. National Institute For Research In Reproductive Health (NIRRH), Mumbai

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. Vainav Patel, Scientist E	+912224192020 +919819037910 vainavp@gmail.com
Administrators	Dr Rajendra Katkam, Sr Technical Officer III	katkamrajendra@gmail.com +919967416155
	Dr Kiran Munne, Scientist B	dr.kiranmunne@gmail.com +919923334435
Technical Team	Ms. Shobha Sonawane, Sr. Technical Officer (2)	shobhapotdar@rediffmail.com +919869648950
	Ms. Gayatri Shinde, Sr. Technical Officer (1)	gayatri_shinde@yahoo.com +919869052711
Packaging Coordinator	Mr. Sunil Choraghe, Lower Division Clerk	<u>chorgesunil1988@gmail.com</u> +919967692616
Logistics Coordinator	Mr. Kunal Pawar, Lower Division Clerk	kunalpawar1995@gmail.com +919820912591

Helpline No. +912224192168; +912224192170 Technical Queries: <u>depotnirrh@gmail.com</u>

6. National Institute of Virology (NIV), Pune

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. Priya Abraham, Director	91-20-26006290-Ext 201 director.niv@icmr.gov.in
Administrators	Dr. Varsha Potdar Scientist D & HOD Dr. M L Choudhary Scientist D	9890307757 Potdarvarsha9@gmail.com 9923516108 mlchoudhary@gmail.com
Technical Team	Mrs Sheetal Jadhav Technical Assistant MallicaLavania Scientist D	9011529385 sheetalk86@gmail.com
Packaging Coordinator	Mrs Veena Vipat Sr. Technical Officer Dr Viren Meena	9545029290 veenavipat@gmail.com 7875824740

	Scientist B	viren.meena2709@gmail.com
Logistics Coordinator	Satish Ranawade, Sr.Technical officer	9822634080 ssranawade1963@gmail.com
	Y Ghodke, Sr. Technical Officer	
	Madhukar Kambe Sr Technician	
	Sarang Kamble, Technician	
	Shirsh Vaidya, Technician	

Email ID for Technical queries: niv.influenza @gmail.com Helpline no: 91-20-26006260, 26006273, 26006270

7. Regional Medical Research Centre (RMRC), Bhubaneswar

Designation	Name	Contact Details
		Phone No and email address
Depot Supervisor	Dr. Sanghamitra Pati,	Phone:- 9437093306
	Director	Email: drsanghamitra12@gmail.com
Administrators	Dr.G Bulliyya, Scientist-F	Phone:- 9861321469
		Email: <u>gbrmrcicmr@gmail.com</u>
	Dr S K Palo, Scientist-D	Phone: 8763590449
		Email: drpalsubrat@gmail.com
Technical Team	Dr M S Bal, Scientist-D	Phone: 8895265160
		E mail; <u>balmadhusita@gmail.com</u>
	Dr. B K Mishra, Scientist-C	Phone: 9238409917
		E mail; <u>bijaydrster@gmail.com</u>
Packaging Coordinator	Dr P K Sahoo, Scientist-C,	Phone: 9583931077
		Email; <u>shuvaprakash@gmail.com</u>
	Dr N N Mandal, Sr TO-II	
		Phone; 9437749067
		Email: mandalrmrc@yahoo.com
Logistics Coordinator	Dr S K Kanungo Scientist- C	Phone: 9307932643
		Email; srikantak109@gmail.com
	Dr K C Sahoo, Scientist-C	
		Phone; 8658889942
		Email; <u>sahookrushna@yahoo.com</u>

8. Regional Medical Research Centre (RMRC), Dibrugarh

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. Kanwar Narain, Director	+91-94353-34901 kanwar_narain@hotmail.com
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	Dr. S.J. Patgiri Scientist C	+91-94355-32250 saurav.patgiri@gmail.com
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Logistics Coordinator	Dr. S.K. Sharma, Scientist G	+91-94351-31953 sksharma.rmrcne@gov.in

9. Rajendra Memorial Research Institute of Medical Sciences (RMRIMS), Patna

Designation	Name	Contact Details Phone No and email address
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	Director	Email: drpradeep.das@gmail.com
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	Scientist C	Email: ashish2k8@gmail.com
	Dr. Manas R Dikhit	Phone: 9304657119
	ICMR-PDF	Email: manasranjandikhit@gmail.com
Technical Team	Dr. Kumar Abhisek	Phone:7903307749
	ICMR-Research Associate	Email: abhisinghbhu41@gmail.com
	Mr. N. K. Sinha	Phone: 9661716113
	S.T.O. 1	Email: nksinha_rmri@yahoo.com
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	Mr. Tapas Kumar	Phone: 8809967416
		Email: tapasmaity99@gmail.com
Logistics Coordinator	Mr. Kundan Kunal	Phone: 9099289191
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10. National Institute of Nutrition (NIN), Hyderabad

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	Dr. P. Uday Kumar Scientist G	Phone: 9247339143 E-mail: putchaaudaykumar@yahoo.com
	Dr. A Laxmaiah, Scientist G	Phone: 9395113419 E-mail: laxmanavula09@gmail.com
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	Dr. B. Santosh Kumar, Scientist C	Phone: 9885767609 E-mail: drsantoshkumar999@gmail.com
	Mr. V. Raju Naik	Phone: 9912468972 E-mail: vrajunaik@live.com

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Logistics	Dr. M. V. Surekha, Scientist D	Phone: 9490969496
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	Dr. Sreenu Pagidouju	
		Phone: 9866081252
		E-mail: pagidoju@gmail.com
	Dr. Raji Reddy	
		Phone: 9885547855
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11. NIV Unit, Bangalore

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Logistics Coordinator	Mr Srinivas Vilasagaram	9581808969 Vilasagar.srinivas@gmail.com

12. National Institute of Malaria Research (NIMR), New Delhi

Designation	Name	Contact Details Phone No and email address
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	Mr. Sanjeev Kumar TO-C	sanjeevgupta40@gmail.com 991117398
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	Dr. Prashank Mallick, Sc.C	pkmmrc@gmail.com 9999657602
	Dr. Mradul Mohan, Sc.B	mradul_mohan@yahoo.com

		8860253935
	Dr. CP Yadav,Sc.B	cpyadav123@gmail.com 8010153329
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	Dr. Kumar Vikram TO-B	kvikram82@yahoo.com 9212740238
Logistics Coordinator	Dr. Ram Das, Sc.C	ramdas9@gmail.com 9958883739
	Mr. Yogesh Kumar, Administrative Officer	aonimr@gmail.com yktyagi@icmr.gov.in 9340657917

13. Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh

Designation	Name	Contact Details Phone No and email address
Depot Supervisor	Dr. Jagat Ram Director PGIMER, Chandigarh	pgimer-chd@nic.in
Administrators	Dr Mini P Singh Professor, Department of Virology	Email: <u>minipsingh@gmail.com</u> 9357784144
	Dr Kapil Goyal Assistant Professor	Email: <u>kapilgoyalpgi@gmail.com</u> 8872288864
Technical Team	Dr Arnab Ghosh Assistant Professor	Email: arnabghosh2002@gmail.com 9873354117
	Dr. Subhabrata Sarkar Research Scientist-II	Email: <u>subhabrata5426@gmail.com</u> 6291816201
Packaging Coordinator	Dr Ishani Bora Assistant Professor	Email: <u>ishanibora16@gmail.com</u> 9435147632, 8638646547
Logistics Coordinator	Dr Gursimran Kaur Mohi Assistant Professor	Email: <u>gkmohi@gmail.com</u> 8427850107, 9337300001

14. King George's Medical University (KGMU), Lucknow

Designation	Name	Contact Details Phone No and email address
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Technical Team	Prof. Jyoti Choprta Professor Department of Anatomy Dr. M.K. Ahmad	Phone: 9415404144 Email: chopra71jyoti@yahoo.co.in Phone: 9452181357

	Associate Professor Department of Biochemistry	Email: kaleembaksh@gmail.com
Packaging Coordinator	Dr. Navin Kumar Associate Professor Department of Radiotherapy	Phone: 9140726847 Email: navinkgmu@gmail.com
Logistics Coordinator	Dr. Kushagr Gaurav Assistant Professor	Phone: 8932985717 Email: <u>amita602002@yahoo.com</u>

15. National Institute of Epidemiology (NIE), Chennai

Designation	Name	Contact Details Phone No and email address
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	Dr.S.M.Jeyakumar	9440520475
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Logistics	Dr.B. Ganesh	7810943585
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16. Gauhati Medical College and Hospital (GMC), Guwahati

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	Professor	dinaraja2016@gmail.com
	Dr. Shashank Sekhar, Assistant	9435033258
	Professor	drshashank79@gmail.com
Technical Team	Dr. Manjuri Kataki	9508162103
	Associate Professor	ravarty@ymail.com
	Dr. Sthapana Sharma	9435042593
	Assistant Professor	dr.sthapana@gmail.com
Packaging	Dr. Raktim Pratim Tamuli	9707557154
Coordinator	Assistant Professor	raktimt81@gmail.com
Logistics	Dr. Pran Pratim Saikia,	9435569350
Coordinator	Demonstrator	spranpratim@gmail.com

Advisory for Procurement of Reagents for Labs doing Real Time (RT)-PCR of Throat and Nasal Swab for diagnosis of COVID-19

In order to ensure uninterrupted supply of reagents for COVID-19 testing, ICMR has formulated the following guidelines.

- Each state is requested to identify a nodal officer to coordinate with the State Resident Commissioner stationed at Delhi for procurement /supply of reagents/primers/probes and other related supplies to respective ICMR recognized labs for the diagnosis of COVID-19 in their states.
- 2. All labs certified by ICMR will procure VTM & RNA Extraction kits through States.
- 3. Resident Commissioner will be in touch with Addl Secretary **Mr Shailendra Singh** (Ph. No. 9555305052), Dept of Industrial Policy & Promotion(DIPP) stationed at ICMR for the **purpose.**
- 4. ICMR will provide the Primers, Probes and Master Mix for RT-PCR, to selected labs (the list of Govt labs (123) which will receive reagents from ICMR as well as a separate list of Govt labs (6) which will not receive reagents from ICMR is placed on the weblink <u>www.icmr.nic.in</u>), while state will ensure the supply of VTM, RNA Extraction kits and other consumables as required.
- All labs involved in COVID-19 testing irrespective of receipt of reagents from ICMR should register themselves with ICMR (contact point is Dr Harpreet Singh, Ph 9999496965). All data on COVID-19 testing should be essentially entered in to the online portal of ICMR on daily and real time basis.

Steps	Reagents Required	Procurement	Manufactures/Sources [#]
Step 1	VTM for sample	BY State Govt	Suppliers of Viral Transport Media with
	collection (2 swabs-		swabs include:
(Sample Collection)	throat and Nasal swab		1. Hi Media
	should be put in 1 VTM		2. BD universal viral transport (UVT)
	tube)		system
			3. Viral Transport kit (TM Media)
			4. Medireach Viral Transport kit
Step 2	RNA Extraction Kit	By State Govt	1. QIA amp VIRAL RNA MINIKIT
			(52904) BY QIAGEN
(RNA Extraction)			2. PureLink™ RNA Mini Kit (Invitrogen),
			3. GenElute™ Total RNA Purification Kit,
			4. ReliaPrep™ RNA Miniprep System
			5. RNASure [®] Virus Kit (250)
Step 3	Primers	ICMR	All real-time PCR kits approved by US-
	Probes	through Resident	FDA and European CE and approved by
RT-PCR	Master Mix	Commissioner &	CDSCO can be procured and used. In
	Positive Control	State Nodal Officer	addition, real time RT-PCR kits validated
	RNAseP		by ICMR-NIV, Pune are:
			1. Seegene 2. Altona 3. MyLab 4. SD
			Biosensor

6. Following steps are involved in testing a sample. Types of reagents required and their procurement process is as follows:

#This is not an exhaustive list

All Private Labs and select Govt labs involved in testing for COVID-19 will procure all reagents of their own.

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 12/04/2020

Augmented plan to fast-track the COVID-19 testing laboratory scale-up

ICMR has taken cognizance of the need to expeditiously expand COVID-19 testing facilities in all parts of the country. Following efforts are being made:

- 1. Proactive search of potential laboratories which could be enabled for COVID-19 testing.
- 2. Inviting applications from all eligible Private and Government Medical Colleges.
- 3. As per directives of Hon'ble Union Minister of Home Affairs & Union Minister of Health & Family Welfare, under a core team of Director, All India Institute of Medical Sciences (AIIMS), Delhi; Director and Director General, ICMR, a total of 14 Centres of Excellence have been designated. These Centres have been delegated a responsibility of mentoring all the Govt. & Private Medical Colleges in their catchment area and eventually create state-of-art molecular virology setups.

The list of mentor Institutes and designated Medical Colleges are annexed.

Prof. (Dr.) Bairam Bhargava Secretary, DHR & DG.ICMR Goverment of India Ministry of Health & Family Welfare Member, Board of Governors Medical Council of India



Prof. (Dr.) Randeep Guleria Director, AllMS, New Delhi Goverment of India Ministry of Health & Family Welfare Member, Board of Governors Medical Council of India

MOST IMMEDIATE

D.O.No.VIR/4/2020/ECD-I 10th April, 2020

Dear All Directors (List) attached

It has been directed by Hon'ble Union Minister of Home Affairs & Hon'ble Union Minister of Health & Family Welfare to increase capacity for COVID-19 testing in all Government and Private Medical Colleges of the country on urgent basis.

This work will involve significant due diligence, interaction with various Medical Colleges, training and handholding. Therefore, it has been decided to distribute the responsibility evenly across various Institutions of eminence all across the country. These Institutions are expected to serve as mentors of the Medical Colleges in their allotted area and facilitate the establishment of COVID-19 testing facilities in the respective States. All these Institutions will work in close coordination with the respective State Governments.

You have been designated as mentor Institution for your nearby States. Please find enclosed the following Annexures for reference :

- List of proposed Mentor Institutes along with allocated States: Annexure-I
- Terms of Reference of the Mentor Institutes : Annexure-2
- Detailed guidance on requirements for infrastructure and consumables for real –time RT-PCR Laboratory : Annex-3
- Suggestive list of good quality consumables: Annexure-4
- List of mentor Institutes along with allocated States & Medical Colleges: Annexure-5
- Existing COVID-19 testing laboratories in Government & Private Medical Colleges: Annexure-6

You are requested to start the designated activities at the earliest in close coordination with the State Govt.

Yours sincerely,

With best regards,

(Prof.Randeep Guleria)

Enclosed: As above

1. Principal Secretay to Hon'ble Prime Minster of India

2.Home Secretary, Govt. of India

3.Secretary, Health & F.W., Govt. of India

Secretary General, Medical Council of India – for urging all medical colleges accordingly

5. Principal Secretary (Health) of all States

6.PS to Hon'ble Union Minister for Home, Govt. of India –for information of Hon'ble Home Minister 7.PS to Hon'ble Union Minister of Health, Govt . of India-for information of Hon'ble H&FW Minister

Balran BRougen

(Prof.Balram Bhargava)

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NEIGRIHMS
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14. Dr. K. Manohar,
Nizam's Institute of Medical Sciences (NIMS),
Punjgutta, Hyderabad - 500082,
Telangana, INDIA.
Email: director@nims.edu.in

List of mentor Institutes alongwith allocated States:

S. No.	Name of the Mentor Institute	States Allocated		
1.	Post Graduate Institute of Medical Education & Research (PGIMER), Chandigarh	Jammu & Kashmir, Ladakh, Punjab, Haryana, Himachal Pradesh, Chandigarh, Uttarakhand		
2.	All India Institute of Medical Sciences (AIIMS), Delhi	Delhi & Bihar		
3.	All India Institute of Medical Sciences (AIIMS), Jodhpur	Rajasthan & Gujarat		
4.	Armed Force Medical College (AFMC), Pune	Mumbai & Pune		
5.	All India Institute of Medical Sciences (AIIMS), Nagpur	Remaining Maharashtra & Goa, Dadra & Nagar Haveli, Daman & Diu		
6.	National Institute of Mental Health & Neurosciences (NIMHANS), Bengaluru	Karnataka		
7.	Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvanathapuram	Kerala, Andaman & Nicobar Islands, Lakshwadeep		
8.	Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Puducherry	Tamil Nadu, Andhra Pradesh, Telangana, Puducherry		
9.	All India Institute of Medical Sciences (AIIMS), Bhubaneshwar	Odisha & West Bengal		
10.	King George Medical University (KGMU), Lucknow	Uttar Pradesh		
11.	All India Institute of Medical Sciences (AIIMS), Bhopal	Madhya Pradesh		
12.	All India Institute of Medical Sciences (AIIMS), Raipur	Chattisgarh & Jharkhand		
13.	North-Eastern Indira Gandhi Regional Institute of Health & Medical Sciences (NEIGRIHMS), Shillong	Assam, Megahlaya, Sikkim, Tripura, Manipur, Mizoram, Arunachal Pradesh, Nagaland		
14.	Nizam's Institute of Medical Sciences (NIMS), Punjgutta, Hyderabad - 500082, Telangana, INDIA.	Telangana		

Terms of Reference of Mentor Institutes:

- To constitute a core team of Director, Microbiologists, other faculty, administrators and other relevant staff (as deemed appropriate) to conduct site assessments and mentor the allocated Government & Private Medical Colleges for setting up COVID-19 diagnostic facility.
- To conduct a comprehensive review of the allocated Government and Private Medical Colleges to assess the feasibility of setting up a real-time RT-PCR testing facility for COVID-19 as per the requirements laid down by ICMR.
- To prepare a comprehensive list of available and deficit infrastructure, space, staff, expertise, equipments and consumables at each of the designated Medical Colleges and submit it to the respective State Governments for fulfilment of necessary gaps.
- 4. To maintain a daily follow-up of all the allocated Institutions to monitor progress of work in-terms of setting up a COVID-19 diagnostic facility.
- To conduct onsite / offsite trainings of all designated staff of the proposed COVID-19 testing facility on the following aspects:
 - Appropriate laboratory biosafety and biosecurity procedures.
 - Respiratory sample collection and processing
 - RNA extraction and setting up of real-time RT-PCR experiment
 - Appropriate disinfection and decontamination of laboratory spaces
- To give approval to the respective State Government Medical College Laboratories to start testing.
- 7. To ensure expansion of COVID-19 testing facilities as per geographic distribution.
- To ensure data entry by the designated testing laboratories into the central portal of MoH&FW/ICMR.
- 9. To assign dedicated space and staff to maintain a stockpile of testing reagents [Viral Transport Media (VTM), swabs, RNA extraction kits, real-time PCR kits etc) in the specified temperature through sources indicated by the State Govt.
- 10. To provide the reagents / kits to allocated functional laboratories, maintain a logbook of supplies and replenish supplies of reagents / kits from sources earmarked by the State Government.
- 11. To develop plan for QA/QC of the allocated laboratories and implement it.
- 12. To conduct regular safety audits of the allocated laboratories.

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Pre-requisites for establishing COVID-19 testing facility in Government and Private Medical Colleges:

It is proposed to establish real-time RT-PCR testing facility in all the existing Government & Private Medical Colleges of India with help of the network of Medical Institutes of Eminence.

Following infrastructure and expertise is essentially required:

- i. 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.
- ii. Availability of cold centrifuge/microfuge for RNA extraction
- iii. Availability of a functioning and calibrated real-time PCR machine.
- iv. Staff and expertise requirements:
 - A. Availability of following minimum staff is required (for 8 hours shift / day):
 - Medical Microbiologists 1 or more with experience of work in Molecular Virology.
 - Technicians Atleast 4-6 (2-3/shift) with relevant experience of work in Molecular Virology.
 - Multi-Task Staff 1 or more for washing / cleaning

*The staff requirements will change based on numbers of shifts.

- B. Desired expertise of the staff:
 - Good understanding of laboratory biosafety and biosecurity, trained for handling respiratory samples for viral diagnosis, RNA extraction and real-time PCR.
 - Experience of work in virology and handling clinical specimens, especially respiratory samples.
- v. A robust Institutional policy on biomedical waste management of human origin.
- vi. Well defined arrangement for segregation and discarding of biomedical waste.

Additionally, for all applicants from Private Medical Colleges, it is essential to submit a copy of the NABL accreditation certificate and scope of accreditation for real-time PCR for RNA viruses.

Separate information should be provided on each of the above component (i to vi).

II. Desired Laboratory workspaces for setting up a real-time RT-PCR laboratory for infectious pathogens:

- Separate sample receiving area
- Handwashing & PPE donning/doffing zone
- Designated area for Biosafety cabinet and sample handling
- Designated pre-PCR (RNA extraction & template addition), PCR (for running the assay) and post PCR (for result interpretation & analysis) rooms.
- Separate autoclave facility.
- Space for handling biomedical waste

EQUIPMENT AND CONSUMABLE REQUIREMENTS FOR SETTING UP A REAL TIME PCR TESTING FACILITY

On-site requirements of equipment (installed, calibrated and functional)

- Biosafety cabinet (BSC) class 2A (calibrated)
- -20 °C deep freezer with UPS, for storage of reagents (primers/ probes/ positive controls)
- -80°C deep freezer with UPS, for storage of aliquoted samples/ viral RNA in cryovials
- 4°C refrigerator (for storage of viral transport medium, and for short term storage of samples and extracted RNA)
- UPS (2 nos., 2KVA each, with 2 hours back-up, for real time PCR instrument and nucleic acid extraction systems – if not available, then to be carried); and confirm about power backup for the two deep freezers (check about duration of power outages, if any)
- Real-time PCR machine calibrated for the fluorophore dyes which are present on the probes.
- Microcentrifuge / Refrigerated Centrifuge

Required consumables

- I. For sample collection:
 - a. Personal protective equipment (PPE)
 - b. Viral Transport Medium (VTM)
 - c. Flocked Dacron swabs (2 swabs/ sample collection from 1 patient)

II. During processing

- a. Personal protective equipment: N95 masks, coveralls (protective against blood and body fluids), nitrile gloves, shoe cover, head cover
- b. Vortex mixer
- c. Microcentrifuge (Cold centrifuge)
- d. Cryovials (2 ml)
- e. Cryobox
- f. Pipette aid
- g. Disposable plastic pipettes
- h. Sprit lamp
- i. Forceps (if no spirit lamp, then disposable forceps for each sample)
- j. 70 % ethanol (also required for next stage, i.e., extraction)
- k. 1% sodium hypochlorite (4% stock, to be freshly reconstituted daily to 1% with water)
- I. Discarding jars
- m. Biomedical waste disposal (BMW) bags (with ties for sealing; preferably autoclavable, if discarding autoclave is available/ used locally) and bins
- n. Iceboxes with gel packs or regular ice supply in laboratory (from icemaker)
- o. Tube rack (15 ml tubes)
- p. For tube / cryovial labelling Marker pens, cellotape, or label printouts (printer with label maker)

III. Nucleic acid extraction

- a. Manual extraction using kits for Viral RNA extraction: Viral RNA mini kits (Qiagen) or other viral RNA extraction kits for manual extraction
- b. 1.7 ml Eppendorf tubes (separate ones also required for next step)
- c. Cryovial/ Eppendorf tube rack (separate ones also required for next step)
- d. Microcentrifuge (small equipment)
- e. Micropipettes- 100-1000ul, 20-200ul (additional separate micropipettes of required volumes also listed for next stage, i.e. real time PCR)
- f. Filter barrier tips: 1000ul, 200ul
- g. Tissue rolls
- h. Hand sanitizers
- i. Biohazard labels

IV. Real time PCR

- a. Reagents for setting up Real-time
 - PCR primers and probes specific for SARS-CoV2 targets
 - PCR master mix reagents (e.g., Thermo Fisher/ Invitrogen AgPath/ Superscript III Platinum real time PCR reagents) with buffer and enzyme
- b. PCR reagents
 - Primers for E gene screening and
 - Probes for E gene screening and RDRP/ ORF 1b targets
 - PCR Buffer and enzyme mix
 - Positive control
- c. PCR workstations 1 for mastermix preparation; 1 for RNA addition
- d. Cryovial racks
- e. PCR tubes/ PCR plates
- f. PCR plate adhesive seals and plate sealer
- g. Micropipettes- 0.5-10ul (2 nos., 1 for PCR master mix and 1 for RNA addition), 2-20ul, 20-200ul
- h. Filter barrier tips 10ul, 20ul, 200ul
- i. Microspin (small equipment)
- j. Plate centrifuge (small equipment)
- k. Electronic micropipette (optional small equipment, but convenient and reduces time duration of testing)

5

- I. Nuclease free water for PCR
- m. RNaseP

List of various brands of Real time PCR machine, RNA extraction kit, Automated RNA extractor and Viral transport medium, which may be suggested for a facility planning on starting real-time PCR for SARS-CoV2 testing.

Real Time PCR Machine	RNA Extraction Kit	Automated RNA Extractor	Viral Transport Medium
Thermofisher Scientific: 7500, 7500Dx, Quant Studio 5	QIA amp VIRAL RNA MINIKIT by Qiagen	Thermofisher: Kingfisher automated RNA extractor	Hi-Media: Hi-Viral Transport Kit
Biorad= CFX96 Touch Real-Time PCR Detection System	PureLink RNA Mini kit (Invitrogen)	QIAGEN QIACube	BD universal viral transport (UVT) system
Abbott: M2000	GenElute Total RNA Purification Kit	Eppendorf ep <i>Motion</i>	Viral Transport kit (TM Media)
Eppendorf: Master Cycler epRealPlex	ReliaPrep RNA Miniprep System	Roche: MagnaPune	Medireach Viral Transport kit
Roche: Light Cycler 480	RNASure Virus Kit		Note: VTM for sample collection (2 swabs, throat and Nasal swab should be put in 1 VTM tube)
Qiagen: Rotor gene			

NOTE: This is not a comprehensive list and is based on personal experience of various laboratories who have used these.

Annexure 5

List of Mentor Institutes alongwith allocated States and Medical Colleges

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
1.	PGIMER,	Ladakh: No Medical College
	Chandigarh	Jammu & Kashmir:
		1. Government Medical College, Anantnag (G)
		2. Government Medical College, Baramulla (G)
		3. Acharya Shri Chander College of Medical Sciences, Jammu (P)
	12 10 10 10	4. Government Medical College, Kathua (G)
	1000	5. Government Medical College & Associated Hospital, Rajouri (G)
		Himachal Pradesh:
		1. Pt. Jawahar Lal Nehru Government Medical College, Chamba (G)
		2. Dr. Radhakrishnan Government Medical College, Hamirpur (G)
	10 S. 10	3. Shri Lal Bahadur Shastri Government Medical College, Mandi (G)
		4. Government Medical College, Nahan, Sirmour (G)
		5. Maharishi Markandeshwar Medical College & Hospital, Solan (P)
		Punjab:
		1. Sri Guru Ram Das Institute of Medical Sciences and Research, Sri Amritsar (P)
		2. Adesh Institute of Medical Sciences & Research, Bhatinda (P)
		3. Punjab Institute of Medical Sciences, Jalandhar (P)
		4. Christian Medical College, Ludhiana (P)
		5. Dayanand Medical College & Hospital, Ludhiana (P)
		Haryana:
		1. Maharaja Agrasen Medical College, Agroha (P)
		 Markandeshwar Institute of Medical Sciences & Research, Mullana, Ambal (P)
		3. Al Falah School of Medical Sciences & Research Centre, Faridabad (P)
		4. Employees State Insurance Corporation Medical College, Faridabad (G)
		5. Faculty of Medicine and Health Sciences, Gurgaon (P)
	1.	6. World College of Medical Sciences & Research, Jhajjar (P)
		7. Kalpana Chawala Govt. Medical College, Karnal (P)
	1.2.1.2.1.1.1	8. N.C. Medical College & Hospital, Panipat (P)
		9. Shaheed Hasan Khan Mewati Government Medical College, Nalhar (P)
		10. Adesh Medical College and Hospital, Shahabad, Kurukshetra (P)
	12000	Chandigarh: NIL
		Uttarakhand:
	Distrig Cart	1. Doon Medical College, Dehradun (G)
		2. Shri Guru Ram Rai Institute of Medical & Health Sciences, Dehradun (P)
		3. Himalayan Institute of Medical Sciences, Dehradun (P)
		4. Veer Chandra Singh Garhwali Govt. Medical Sc. & Research Instt, Srinagar, Pauri Garhwal (P)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
2.	AIIMS, Delhi	Delhi:
		1. University College of Medical Sciences & GTB Hospital, New Delhi
		2. Hamdard Institute of Medical Sciences & Research, New Delhi North Delh
		Municipal Corporation Medical College,
		3. Dr. Baba Saheb Ambedkar Medical College, Rohini, Delhi
		Bihar:
		1. Jawaharlal Nehru Medical College, Bhagalpur (G)
		2. Anugrah Narayan Magadh Medical College, Gaya (G)
		3. Katihar Medical College, Katihar Mata Gujri Memorial Medical College
		Kishanganj (P)
		4. Madhubani Medical College, Madhubani (P)
		5. Vardhman Institute of Medical Sciences, Pawaripuri, Nalanda (G)
		6. Nalanda Medical College, Patna (G)
		7. All India Institute of Medical Sciences, Patna (G)
•		8. Narayan Medical College & Hospital, Sasaram (P)
		9. Lord Buddha Koshi Medical College and Hospital, Saharsa (P)
		10. Government Medical College, Bettiah (G)
3.	AIIMS,	Gujarat:
	Jodhpur	1. Ahmedabad Municipal Coporation Medical Education Trust Medical College
		Ahmedabad (G)
		2. Dr. M.K. Shah Medical College & Research Centre, Ahmedabad (P)
		3. GCS Medical College, Ahmedabad (P)
		4. Smt. N. H. L Municipal Medical College, Ahmedabad (G)
		5. Shantabaa Medical College, Amrelli (P)
		6. Pramukhswami Medical College, Karmsad (P)
		7. Banas Medical College and Research Institute, Palanpur (P)
		8. Gujarat Adani Institute of Medical Sciences, Bhuj (P)
		9. Zydus Medical College and Hospital Dahod (P)
		10. GMERS Medical College, Dharpur Patan (G)
		11. GMERS Medical College, Gandhinagar (G)
		12. GMERS Medical College, Gotri, Vadodara (G)
		13. GMERS Medical College, Junagadh (G)
	200	14. GMERS Medical College, Hadiyol, Himmatnagar Patan (G)
		1S. GMERS Medical College, Sola, Ahmedabad (G)
		16. GMERS Medical College, Vadnagar, Mehsana (G)
		17. GMERS Medical College, Valsad (G)
		18. Nootan Medical College and Research Centre, Mehsana (P)
		19. Dr. N.D. Desai Faculty of Medical Science and Research, Nadiad (P)
		20. Surat Municipal Inst. of Medical Education & Research Center, Surat (G)
	S	21. CU Shah Medical College, Surendra Nagar (P)
		22. Parul Institute of Medical Sciences & Research, Vadodara (P)
		23. SBKS Medical Inst. and Research Center, Vadodara (P)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
		Rajasthan:
		1. Government Medical College, Barmer (G)
		2. American International Institute of Medical Sciences, Bedwas (P)
		3. Government Medical College, Bharatpur, Rajasthan (G)
		4. Government Medical College, Bhilwara, Rajasthan (G)
		5. Government Medical College, Churu (G)
		6. Government Medical College, Dungarpur (G)
	A-1915	 Jaipur National University Institute of Medical Sciences and Research Centre Jagatpura, Jaipur (P)
		8. Mahatma Gandhi Medical College and Hospital, Jaipur (P)
		9. National Institute of Medical Science & Research, Jaipur (P)
		10. RUHS College of Medical Sciences, Jaipur (G)
		11. Government Medical College, Pali (G)
		12. Ananta Institute of Medical Sciences & Research Centre, Rajsamand (P)
		13. Geetanjali Medical College & Hospital, Udaipur (P)
	Sec. 1	14. Pacific Institute of Medical Sciences, Umarda, Udaipur (P)
		15. Pacific Medical College & Hospital, Bhilo Ka Bedla, Udaipur (P)
4.	AFMC, Pune	Maharashtra including Mumbai & Pune:
		 H.B.T. Medical College & Dr. R.N. Cooper Municipal General Hospital, Juhu, Mumbai (G)
		2. KJ Somaiyya Medical College & Research Centre, Mumbai (P)
		3. Lokmanya Tilak Municipal Medical College, Sion, Mumbai (G)
	1	4. Seth GS Medical College, Mumbai (G)
		5. Mahatma Gandhi Missions Medical College, Navi Mumbai (P)
		6. Padmashree Dr. D.Y.Patil Medical College, Navi Mumbai (P)
		 Rajiv Gandhi Medical College and Chhatrapati Shivaji Maharaj Hospital, Thane (G)
	The second second	8. Topiwala Medical College, Mumbai (G)
		9. Terna Medical College, Navi Mumbai (P)

C

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
5.	AIIMS,	Rest of the Maharashtra:
	Nagpur	1. Dr. Vithalrao Vikhe Patil Foundations Medical College & Hospital Ahmednagar (P)
		2. Dr. Panjabrao Alias Bhausaheb Deshmukh Memorial Medical College Amravati (P)
	-	3. Mahatma Gandhi Missions Medical College, Aurangabad (P)
	19.7	4. Government Medical College & Hospital, Baramati (G)
		5. Government Medical College, Chandrapur (G)
		6. ACPM Medical College, Dhule (P)
		7. Dr. Ulhas Patil Medical College & Hospital, Jalgaon (P)
		8. Government Medical College, Jalgaon (G)
		9. Indian Institute of Medical Science & Research, Jalna (P)
		10. Krishna Institute of Medical Sciences, Karad (P)
		11. Dr. D Y Patil Medical College, Kolhapur (P)
		12. Rajashree Chatrapati Shahu Maharaj Government Medical College, Kolhapu (G)
		13. Government Medical College, Latur (G)
		14. Maharashtra Institute of Medical Sciences & Research, Latur (P)
		15. Rural Medical College, Loni (P)
		16. N.K.P. Salve Instt. of Medical Sciences and Research Centre and Lat Mangeshkar Hospital, Nagpur (P)
		17. Dr. Shankarrao Chavan Govt. Medical College, Nanded (G)
		18. Dr. Vasantrao Pawar Med. Col. Hosp. & Research Centre, Nasik (P)
		19. Bharati Vidyapeeth University Medical College, Pune (P)
		20. Dr. D Y Patil Medical College, Hospital and Research Centre, Pimpri, Pune (P)
		21. B.K.L. Walawalkar Rural Medical College, Ratnagiri (P)
		22. Bharati Vidyapeeth Deemed University Medical College & Hospital, Sangli (P
		23. Prakash Institute of Medical Sciences & Research, Sangli (P)
		24. Ashwini Rural Medical College, Hospital & Research Centre, Solapur (P)
		25. Dr Vaishampayan Memorial Medical College, Solapur (G)
		26. Jawaharlal Nehru Medical College, Sawangi (Meghe), Wardha (P)
		27. Mahatma Gandhi Institute of Medical Sciences, Sevagram, Wardha (P)
		28. Shri Vasant Rao Naik Govt. Medical College, Yavatmal (G)
		29. Smt. KashibaiNavale Medical College and Hospital, Pune (P)
		30. SMBT institute of Medical Insitutes Sciences and Research Center, Nashik (P
		31. SRTR Medical College, Ambajogai (G)
		32. Vedanata Institute of Medical Sciences , Palghar (P)
		Goa:
		Only one Medical College is functional
		Dadra & Nagar Haveli:
1		Only one Medical College is functional
		Daman & Diu:
	The second second	No Medical College

	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
6.	NIMHANS,	Karnataka
	Bengaluru	 S. Nijalingappa Medical College & HSK Hospital & Research Centre, Bagalkot (P)
	and the second	2. BGS Global Institute of Medical Sciences, Bangalore (P)
		 Bowring & Lady Curzon Medical College & Research Institute, Bangalore (G) Dr BR Ambedkar Medical College, Bangalore (P)
	All and the second	5. East Point College of Medical Sciences & Research Centre, Bangalore (P)
		6. Employees State Insurance Corporation Medical College, Bangalore (G)
	199 19 191	 7. Kempegowda Institute of Medical Sciences, Bangalore (P)
	A CONTRACTOR	8. M S Ramaiah Medical College, Bangalore (P)
		9. MVJ Medical College and Research Hospital, Bangalore (P)
		10. Rajarajeswari Medical College & Hospital, Bangalore (P)
		11. Sapthagiri Institute of Medical Sciences & Research Centre, Bangalore (P)
		12. Sri Siddhartha Institute of Medical Sciences & Research Centre, Bangalore (P)
		13. St. Johns Medical College, Bangalore (P)
		14. Belagavi Institute of Medical Sciences, Belagavi (G)
		15. Jawaharlal Nehru Medical College, Belgaum (P)
		16. Adichunchanagiri Institute of Medical Sciences Bellur (P)
		17. The Oxford Medical College, Hospital & Research Centre, Bangalore (P)
		18. Bidar Institute of Medical Sciences, Bidar (G)
		19. Al-Ameen Medical College, Bijapur (P)
		20. Chamrajnagar Institute of Medical Sciences, Chamrajnagar (G)
		21. Basaveswara Medical College and Hospital, Chitradurga (P)
		22. JJM Medical College, Davangere (P)
		23. S S Institute of Medical Sciences& Research Centre, Davangere (P)
		24. Akash Institute of Medical Sciences & Research Centre, Devanhalli Bangalore (P)
		25. SDM College of Medical Sciences & Hospital, Sattur, Dharwad (P)
		26. Gadag Institute of Medical Sciences, Mallasamudra, Mulgund Road, Gada (G)
		27. Khaja Bandanawaz University - Faculty of Medical Sciences, Gulbarga (P)
		28. Mahadevappa Rampure Medical College, Gulbarga (P)
		29. Employees State Insurance Corporation Medical College, Gulbarga (G)
		30. Karwar Institute of Medical Sciences, Karwar (G)
		31. Kodagu Institute of Medical Sciences, Kodagu (G)
		32. Sambharam Institute of Medical Sciences & Research, Kolar (P)
		33. Sri Devaraj URS Medical College, Kolar (P)
		34. Koppal Institute of Medical Sciences, Koppal (G)
		35. Mandya Institute of Medical Sciences, Mandya (G)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
		36. A J Institute of Medical Sciences & Research Centre, Mangalore (P)
		37. Father Mullers Medical College, Mangalore (P)
	1000	38. K S Hegde Medical Academy, Mangalore (P)
		39. Yenepoya Medical College, Mangalore (P)
		40. Kasturba Medical College, Mangalore (P)
		41. Kanachur Institute of Medical Sciences, Mangalore (P)
	100	42. Kasturba Medical College, Manipal (P)
		43. JSS Medical College, Mysore (P) Navodaya Medical College, Raichur (P)
		44. Navodaya Medical College, Raichur (P)
		45. Raichur Institute of Medical Sciences, Raichur (G)
		46. Subbaiah Institute of Medical Sciences, Shimoga, Karnataka (P)
		47. Srinivas Institute of Medical Research Centre, Srinivasnagar (P)
		48. K V G Medical College, Sullia (P)
		49. Shridevi Institute of Medical Sciences & Research Hospital, Tumkur (P)
		50. Shri B M Patil Medical College, Hospital & Research Centre Vijayapura(Bijapur) (P)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
7.	SCTIMST,	Kerala:
	Thiruvanath	1. T D Medical College, Alleppey (Alappuzha) (G)
	apuram	2. Amrita School of Medicine, Elamkara (P)
		3. Government Medical College, Ernakulam (G)
		4. Sree Narayana Instt. of Medical Sciences, Chalakka, Ernakulam (P)
		5. Kannur Medical College, Kannur (P)
		6. Malankara Orthodox Syrian Church Medical College, Kolenchery (P)
		7. Azeezia Instt of Medical Science, Meeyannoor, Kollam Kerala (P)
	1 15 - 11	8. Government Medical College, Parippally, Kollam (G)
		9. Travancore Medical College, Kollam (P)
		10. Government Medical College, Kottayam (G)
		11. KMCT Medical College, Kozhikode, Calicut (P)
		12. Malabar Medical College, Kozhikode (P)
		13. Government Medical College, Manjeri, Malapuram Dist (G)
	1.1	14. M E S Medical College, Perintalmanna Malappuram (P)
	ALCON	15. Government Medical College (Institute of Integrated Medical Sciences), Yakkara, Palakkad (G)
		16. Karuna Medical College, Palakkad (P)
		17. P K Das Institute of Medical Sciences, Palakkad (P)
		18. Academy of Medical Sciences, Pariyaram, Kannur (P)
	- AN	19. Mount Zion Medical College, Chayalode, Ezhamkulam Adoor, Pathanamthitta (P)
		20. Believers Church Medical College Hospital, Thiruvalla (P)
		21. Dr. Somervel Memorial CSI Hospital & Medical College, Karakonam, Thiruvananthapuram (P)
		22. Medical College, Thiruvananthapuram (G)
		23. S.R. Medical College & Research Centre, Akathumjuri, Vennicode, Varkala, Thiruvananthapuram (P)
		24. Al-Azhar Medical College and Super Speciality Hospital, Thodupuzha (P)
		25. Amala Institute of Medical Sciences, Thrissur (P)
		26. Jubilee Mission Medical College & Research Institute, Thrissur (P)
		27. Pushpagiri Institute of Medical Sciences and Research Centre, Tiruvalla (P)
		28. Sree Gokulam Medical College Trust & Research Foundation, Trivandrum (P)
		29. Sree Uthradom Thiurnal Academy of Medical Sciences, Trivandrum (P)
		30. DM Wayanad Institute of Medical Sciences, Wayanad (P)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility		
		Andaman & Nicobar Islands:		
-		1. Andaman And Nicobar Institute of Medical Sciences, Port Blair (G)		
		Lakshwadeep:		
		No Medical College		
8.	JIPMER, Puducherry	 Puducherry Aarupadai Veedu Medical College, Pondicherry (P) Mahatma Gandhi Medical College & Research Institute, Pondicherry (P) Pondicherry Institute of Medical Sciences & Research, Pondicherry (P) Sri Lakshmi Narayana Institute of Medical Sciences, Pondicherry (P) Sri Manakula Vinayagar Medical College & Hospital, Pondicherry (P) Sri Venkateswaraa Medical College, Hospital & Research Centre, Pondicherry (P) Vinayaka Missions Medical College, Karaikal, Pondicherry (P) 		
		8. Indira Gandhi Medical College & Research Institute, Puducherry (G)		
		Andhra Pradesh:		
		 ACSR Government Medical College, Nellore (G) All India Institute of Medical Sciences, Mangalagiri, Vijayawada (G) Alluri Sitaram Raju Academy of Medical Sciences, Eluru (P) Andhra Medical College, Visakhapatnam (G) Apollo Institute of Medical Sciences and Research, Chittoor (P) Dr. P.S.I. Medical College, Chinoutpalli (P) FathimaInstt. of Medical Sciences, Kadapa (P) Gayathri Vidya Parishad Institute of Health Care & Medical Technology, Visakhapatnam (P) GITAM Institute of Medical Sciences and Research, Visakhapatnam (P) Great Eastern Medical School and Hospital, Srikakulam (P) GSL Medical College, Rajahmundry (P) Katuri Medical College, Guntur (P) Konaseema Institute of Medical Sciences, Vizianagaram (P) Narayana Medical College, Nellore (P) Nimra Institute of Medical Sciences, Visakhapatnam (P) Nariyana Medical College, Nellore (P) Nimra Institute of Medical Sciences, Visakhapatnam (P) Rajiv Gandhi Institute of Medical Sciences, Ongole, AP. (G) Rajiv Gandhi Institute of Medical Sciences, Srikakulam (G) P E S Institute Of Medical Sciences and Research, Kuppam (P) 		
-	Real Providence	22. Viswabharathi Medical College, Kurnool (P)		

t	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
		Tamil Nadu:
		1. Rajah Muthiah Medical College, Annamalainagar (G)
		2. Kanya Kumari Government Medical College, Asaripallam (G)
		3. Chengalpattu Medical College, Chengalpattu (G)
-		4. ACS Medical College and Hospital, Chennai (P)
		5. ESI-PGIMSR, ESI Hospital, K.K Nagar, Chennai (G)
		6. Kilpauk Medical College, Chennai (G)
		7. Madha Medical College and Hospital, Thandalam, Chennai (P)
		8. SreeBalaji Medical College and Hospital, Chennai (P)
		9. Sri Muthukumaran Medical College, Chennai (P)
		10. Stanley Medical College, Chennai (G)
		11. Tagore Medical College and Hospital, Chennai (P)
		12. Government Medical College & ESIC Hospital, Coimbatore (G)
		13. Karpagam Faculty of Medical Sciences & Research, Coimbatore (P)
		14. KMCH Institute of Health Sciences and Research, Coimbatore (P)
		15. PSG Institute of Medical Sciences, Coimbatore (P)
		16. Government Dharmapuri Medical College, Dharmapur (G)
		17. Shri SatyaSai Medical College and Research Institute, Kancheepuram (P)
		18. Meenakshi Medical College and Research Institute, Enathur (P)
		19. SRM Medical College Hospital & Research Centre, Kancheepuram (P)
		20. Chettinad Hospital & Research Institute, Kanchipuram (P)
		21. Melmaruvathur Adiparasakthi Instt. Medical Sciences and Research, Kanchipuram (P)
		22. SreeMookambika Institute of Medical Sciences, Kanyakumari (P)
		23. Government Medical College, Karur (G)
		24. Velammal Medical College Hospital and Research Institute, Madurai (P)
		25. KarpagaVinayaga Institute of Medical Sciences, Maduranthagam (P)
		26. Government Medical College, Omandurar (G)
		27. Dhanalakshmi Srinivasan Medical College and Hospital, Perambalur (P)
		28. Government Medical College, Pudukottai (G)
		29. Annapoorna Medical College & Hospital, Salem (P)
		30. Vinayaka Missions KirupanandaVariyar Medical College, Salem (P)
		31. Government Sivagangai Medical College, Sivaganga (G)
		32. Government Thiruvannamalai Medical College, Thiruvannamalai (G)
		33. Trichy SRM Medical College Hospital & Research Centre, Trichy (P)
		34. Thoothukudi Medical College, Thoothukudi (G)
		35. Government Vellore Medical College, Vellore (G)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
	Nizam's	Telangana:
	Institute of	1. Rajiv Gandhi Institute of Medical Sciences, Adilabad (G)
	Medical Sciences	 Employees State Insurance Coporation Medical College, Sanath Nagar, Hyderabad (G)
	(NIMS),	3. Deccan College of Medical Sciences, Hyderabad (P)
	Telangana	 Shadan Institute of Medical Sciences, Research Centre and Teaching Hospital Peerancheru (P)
	and the second second	5. Mallareddy Medical College for Womens, Hyderabad (P)
		6. Mediciti Institute Of Medical Sciences, Ghanpur (P)
	112	7. Prathima Institute of Medical Sciences, Karimnagar (P)
		8. Chalmeda Anand Rao Institute Of Medical Sciences, Karimnagar (P)
		9. Mamata Medical College, Khammam (P)
		10. Government Medical College, Mahabubnagar (G)
	1	11. S V S Medical College, Mehboobnagar (P)
		12. R.V.M. Institute of Medical Sciences and Research Centre, Medak (P)
		13. Maheshwara Medical College, Chitkul, Patancheru, Medak (P) Mamata
		Academy of Medical Sciences, Bachupally (P)
		14. Government Medical College, Nalgonda (G)
		15. Bhaskar Medical College, Yenkapally (P)
		16. Dr. Patnam Mahender Reddy Institute of Medical Sciences, Chevella, Rangareddy (P)
	1	17. Ayaan Institute of Medical Sciences, Teaching Hospital & Research Centre, Kanaka Mamidi, R.R. District (P)
		18. Dr. VRK Womens Medical College, Aziznagar (P)
		19. MNR Medical College & Hospital, Sangareddy (P)
		20. Government Medical College, Siddipet (G)
		21. Surabhi Institute of Medical Sciences, Siddipet, Telangana (P)
		22. Government Medical College, Suryapet (G)
		23. Mahavir Institute of Medical Sciences, Vikarabad (P)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility Odisha:						
9.	AIIMS,							
	Bhubanesh war	 Government Medical College & Hospital (Renamed as Bhima Bhoi Medica College & Hospital), Balangir (G) 						
	and the second	 Government Medical College & Hospital (Renamed as Fakir Mohan Medica College & Hospital), Balasore (G) 						
	24.20	3. Pt. Raghunath Murmu Medical College and Hospital, Baripada (G)						
		4. MKCG Medical College, Berhampur (G)						
	and the	5. Hi-Tech Medical College & Hospital, Bhubaneswar (P)						
	DESERTOR	6. Instt. Of Medical Sciences & SUM Hospital, Bhubaneswar (P)						
	Carlos Array 1	7. Kalinga Institute of Medical Sciences, Bhubaneswar (P)						
		8. Veer Surendra Sai Institute of Medical Sciences and Research, Burla (G)						
		West Bengal:						
		1. Bankura Sammilani Medical College, Bankura (G)						
		2. Rampurhat Government Medical College & Hospital, Rampurhat (G)						
	and the second	3. Burdwan Medical College, Burdwan (G)						
		4. Coochbehar Government Medical College & Hospital, Coochbehar (G)						
		5. Raiganj Government Medical College & Hospital, Raiganj (G)						
	Sale Sale	6. Calcutta National Medical College, Kolkata (G)						
	1000	7. College of Medicine and Sagore Dutta Hospital, Kolkata (G)						
		8. Medical College, Kolkata (G)						
	1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1. 1	9. Nirlatan Sircar Medical College, Kolkata (G)						
		10. RG Kar Medical College, Kolkata (G)						
		11. Jagannath Gupta Institute of Medical Sciences & Hospital, Kolkata (P)						
		12. KPC Medical College, Jadavpur, Kolkata (P)						
		13. Murshidabad Medical College & Hospital, Murshidabad (G)						
		14. College of Medicine and JNM Hospital, Kalyani(G)						
		15. Diamond Harbour Government Medical college & Hospital (G)						
		16. Gouri Devi Institute of Medical Sciences and Hospital, Dugapur (P)						
		17. Shri Ramkrishna Institute of Medical Sciences & Sanaka Hospitals, Durgapu (P)						
		18. IQ-City Medical College, Burdwan (P)						
		19. ICARE Institute of Medical Sciences & Research, Haldia, Purba Midanpore (P)						
		20. Employees State Insurance Corporation Medical College, Joka (G)						

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
10.	KGMU,	Uttar Pradesh:
	Lucknow	1. F.H. Medical College & Hospital, Etamdapur, Agra (P)
		2. Mahamaya Rajkiya Allopathic Medical College, Ambedkarnagar
		3. Venkateshwara Institute of Medical Sciences, Gajraula (P)
	1	4. Government Medical College & Super facility Hospital, Azamgarh
		5. Government Allopathic Medical College, Banda
		6. Hind Institute of Medical Sciences, Barabanki (P)
	1.000	7. Mayo Institute of Medical Sciences, Barabanki (P)
	-	8. Rajshree Medical Research Institute, Bareilly (P)
		9. Shri Ram Murti Smarak Institute of Medical Sciences, Bareilly (P)
	-	10. Rohilkhand Medical College & Hospital, Bareilly (P)
		11. Government Medical College, Rampur, Basti
		12. Rajkiya Allopathic Medical College, Bahraich
		13. Uttar Pradesh University of Medical Sciences, Etawah
		14. Government Medical College, Badaun
		15. Government Medical College, Faizabad
		16. Major S D Singh Medical College and Hospital, Fathehgarh, Farrukhaba (P)
	1.	17. Government Medical College, Firozabad
		18. School of Medical Sciences & Research, Greater Noida (P)
	S IN THE R	19. Santosh Medical College, Ghaziabad (P)
		20. Manyavar Kanshi Ram Ji Government Allopathic Medical College, Jalau
	1.20	21. Saraswati Institute of Medical Sciences, Hapur (P)
		22. G.S. Medical College & Hospital, Hapur, UP (P)
		23. Rama Medical College Hospital and Research Centre, Hapur (P)
		24. Government Medical College, Kannauj
		25. Rama Medical College and Hospital , Kanpur (P)
		26. GSVM Medical College, Kanpur
		27. Era Lucknow Medical College, Lucknow (P)
		28. Prasad Institute of Medical Sciences, Lucknow G.C.R.G. Institute of
		Medical Sciences, Lucknow (P)
	Contraction and	29. T S Misra Medical College & Hospital, Amausi, Lucknow (P)
		30. Integral Institute of Medical Sciences & Research, Lucknow (P)
		31. Career Instt. of Medical Sciences & Hospital, Lucknow (P)
		32. Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow Krishna
		Mohan Medical College & Hospital, Mathura (P)
		33. K.D. Medical College Hospital & Research Centre, Mathura (P)
		34. Subharti Medical College, Meerut (P)
		35. Mulayam Singh Yadav Medical College & Hospital, Meerut (P)
	1000	36. Teerthanker Mahaveer Medical College, Moradabad (P)
	Malla Int	37. Muzaffarnagar Medical College, Muzaffarnagar (P)
		 38. Glocal Medical College, Super Specialty Hospital & Research Center, Saharanpur (P)
		39. Shaikh-UL-Hind Maulana Mahmood Hasan Medical College, Saharanpu
		40. Varun Arjun Medical College, Banthra, Shahjahanpur (P)
		40. Varun Aljun Medical College, Bantina, Shahjahanpur 41. Government Medical College, Shahjahanpur
	1	41. Government Medical College, Shanjahanpur 42. Hind Institute of Medical Sciences, Sitapur (P)
	The second	42. Hind institute of Medical Sciences, Stapur (P) 43. Heritage Institute of Medical Sciences, Varanasi(P)
		44. Sitapur Saraswati Medical College, Unnao (P)
		44. Sitaput Salaswati Meulcal College, Offiao (F)

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility							
11.	AIIMS,	Madhya Pradesh:							
	Bhopal	1. Chirayu Medical College and Hospital, Bairagarh, Bhopal (P)							
		L.N. Medical College and Research Centre, Bhopal (P)							
		3. Peoples College of Medical Sciences & Research Centre, Bhanpur, Bhopal (P)							
		4. RKDF Medical College Hospital & Research Centre, Jatkhedi, Bhopal (P)							
		5. Government Medical College, Chhindwara (G)							
	Star Star	6. Government Medical College, Datia (G)							
		Amaltas Institute of Medical Sciences, Dewas (P)							
		8. Index Medical College Hospital & Research Centre, Indore (P)							
		9. Sri Aurobindo Medical College and Post Graduate Institute, Indore (P)							
		10. Netaji Subhash Chandra Bose Medical College, Jabalpur (G)							
		11. Sukh Sagar Medical College and Hospital, Jabalpur (P)							
		12. Government Medical College, Khandwa (G)							
		13. Government Medical College, Ratlam (G)							
		14. Shyam Shah Medical College, Rewa (G)							
		15. Bundelkhand Medical College, Sagar (G)							
		16. Government Medical College, Shahdol (G)							
		17. Government Medical College, Shivpuri (G)							
		 Ruxmaniben Deepchand Gardi Medical College, Ujjain (P) Government Medical College, Vidisha (G) 							
12.	AIIMS,	Chattisgarh:							
	Raipur	1. Shri Shankaracharya Institute of Medical Sciences, Bhilai (P)							
		2. Chhattisgarh Institute of Medical Sciences, Bilaspur (G)							
		3. Chandulal Chandrakar Memorial Medical College, Durg (P)							
		4. Late Shri Lakhi Ram Agrawal Memorial Govt. Medical College, Raigarh (G)							
		5. Pt. J N M Medical College, Raipur (G)							
		6. Raipur Institute of Medical Sciences (RIMS), Raipur (P)							
		7. Government Medical College (Bharat Ratna Shri Atal Bihari Vajpyee							
		Memorial Med. Col.), Rajnandgaon (G)							
		8. Government Medical College, Ambikapur (Surguja), Chhattisgarh (G)							
		Jharkhand:							
		1. Patliputra Medical College, Dhanbad (G)							
		2. Dumka Medical College, Dighi (G)							
		3. Hazaribagh Medical College, Hazaribagh (G)							
		4. Palamu Medical College, Palamu (G)							
13.	NEIGRIHMS,	Manipur:							
	Shillong	All Medical Colleges operational							
	1.1	Nagaland							
		No Medical College							
		Mizoram							
		Only Medical College is operational							
		Meghalaya							
		Only Medical College is operational							

S. No.	Name of the Mentor Institute	Names of Medical Colleges (Govt. & Private) with no COVID-19 testing facility
	20.50	Agartala
-	1	1. Tripura Medical College and Dr. BRAM Teaching Hospital, Agartala (P)
		Sikkim
		1. Sikkim Manipal Institute of Medical Sciences, Gangtok (P)
		Assam
		1. Assam Medial College, Dibrugarh
		2. Tezpur Medical College & Hospital, Tezpur
	1212	Arunachal Pradesh
		1. Tomo Riba Institute of Health & Medical Sciences, Naharlagun (G)

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 10/04/2020

Total Operational (initiated independent testing) Government Laboratories reporting to ICMR 146 + 3 collection sites:

S. No.	Names of States	Names of Medical Colleges			
1.	Andhra Pradesh (6)	 Sri Venkateswara Institute of Medical Sciences, Tirupati Rangaraya Medical College, Kakinada Sidhartha Medical College, Vijaywada Govt. Medical College, Ananthpur Guntur Medical College, Guntur Rajiv Gandhi Institute of Medical Sciences, Kadapa 			
2.	Assam (5)	 Gauhati Medical College, Guwahati Regional Medical Research Center, Dibrugarh Jorhat Medical College, Jorhat Silchar Medical College, Silchar Fakkhruddin Ali Ahmed Medical College, Barpeta 			
3.	Bihar (4)	 Rajendra Memorial Research Institute of Medical Sciences, Patna Indira Gandhi Institute Medical Sciences, Patna Patna Medical College, Patna Darbhanga Medical College, Darbhanga 			
4.	Chandigarh (2)	 Post Graduate Institute of Medical Education & Research, Chandigarh Govt. Medical College, Chandigarh 			
5.	Chhattisgarh (2)	 All India Institute of Medical Sciences, Raipur Late Baliram Kashyap M Govt. Medical College, Jagdalpur 			
6.	Delhi (7)	 All India Institute Medical Sciences Lady Hardinge Medical College National Centre for Disease Control Ram Manohar Lohia Hospital Institute of Liver & Biliary Sciences Army Hospital Research & Referral Maulana Azad Medical College 			
7.	Gujarat (6)	 BJ Medical College, Ahmedabad MP Shah Govt Medical College, Jamnagar Govt. Medical College, Surat Govt. Medical College, Bhavnagar Govt. Medical College, Vadodara Govt. Medical College, Rajkot NHL Medical College, Ahmedabad 			
8.	Goa (1)	34. Goa Medical College, Goa			
9.	Haryana (2)	 Pt. B.D. Sharma Post Graduate Inst. Of Med. Sciences, Rohtak, Haryana BPS Govt. Medical College, Sonipat 			
10.	Himachal Pradesh (2)	 Br 5 Govt. Medical College, Solipat Indira Gandhi Medical College, Shimla Dr. Rajendra Prasad Govt. Medical College, Tanda 			
11.	Jammu & Kashmir	39. Govt. Medical College, Jammu			

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S. No.	Names of States	Names of Medical Colleges			
	(4)	40.	40. Command Hospital (NC) Udhampur		
		41.	Sher-i-Kashmir Institute of Medical Sciences, Srinagar		
		42.	Govt. Medical College, Srinagar		
12.	Jharkhand (2)	43.	MGM Medical College & Hospital, Jamshedpur		
		44.	Rajendra Institute of Medical Sciences, Ranchi		
13.	Karnataka (11)	45.	Hassan Inst. Of Med. Sciences, Hassan		
		46.	Mysore Medical College & Research Institute, Mysore		
	R	47.	Shivamogga Institute of Medical Sciences, Shivamogga		
		48.	Command Hospital (Air Force), Bengaluru		
		49.	Bangalore Medical College & Research Institute Bengaluru		
		50.	National Institute of Virology, Bangalore Field Unit Bengaluru		
		51.	Gulbarga Institute of Medical Sciences, Gulbarga		
		52.	Vijaynagar Institute of Medical Sciences, Bellary		
		53.	National Institute of Mental Health and Neuro Sciences, Bangalore		
		54.	Wenlock District Hospital, Mangalore		
		55.	Karnataka Institute of Medical Sciences, Hubli		
14.	Kerala (10)	56.	National Institute of Virology, Field Unit, Allapuzzha		
		57.	Govt. Medical College, Thiruvanathapuram		
		58.	Govt. Medical College, Kozhikode		
		59.	Govt. Medical College, Thrissur		
		60.	Rajiv Gandhi Center for Biotechnology		
			Thiruvanathapuram		
		61.	Sree Chitra Tirunal Institute of Medical Sciences		
	-		Thiruvanathapuram		
		62.	State Public Health Laboratory, Trivandrum		
		63.	Inter University, Kottayam		
	a set of the set	64.	Malabar Cancer Center, Thalassery		
		65.	Central University of Kerala, Periye, Kasaragod		
15.	Maharashtra (16)	66.	National Institute of Virology, Pune		
		67.	Seth GS Medical College & KEM Hospital, Mumbai		
		68.	Kasturba Hospital for Infectious Diseases, Mumbai		
		69.	National Institute of Virology Field Unit, Mumbai		
		70.	Armed Forces Medical College, Pune		
		71.	BJ Medical College, Pune		
	12	72.	Indira Gandhi Govt. Medical College, Nagpur		
		73.	Grant Medical College & Sir JJ Hospital, Mumbai		
		74.	Govt. Medical College, Aurangabad		
		75.	V. M. Government Medical College, Solapur		
	the state of the second	76.	Haffkine Institute, Mumbai		
		77.	Shree Bhausaheb Hire Govt. Medical College, Dhule		
		78.	Government Medical College, Miraj		
		79.	All India Institute of Medical Sciences, Nagpur		
		80.	Nagpur Veterinary College, MAFSU, Nagpur		
		81.	Tata Memorial Centre ACTREC, Mumbai		
16.	Madhya Pradesh	82.	All India Institute of Medical Sciences, Bhopal		
	(6)	83.	National Institute for Research on Tribal Health		

S. No.	Names of States					
		1.2	Jabalpur			
		84.	Mahatma Gandhi Memorial Medical College, Indore			
		85.	Gandhi Medical College, Bhopal			
		86.	36. Bhopal Memorial Hospital & research Centre, Bhopal			
	and the second	87.	Gajra Raja Medical College, Gwalior			
17.	Manipur (2)	88.	Jawaharlal Nehru Institute of Med. Sciences, Imphal-			
		1.00	East, Manipur			
		89.	Regional Institute of Medical Sciences, Imphal			
18.	Meghalaya (1)	90.	North Eastern Indira Gandhi Regional Institute of			
			Health & Medical Sciences, Shillong, Meghalaya			
19.	Mizoram (1)	91.	Zoram Medical College			
20.	Odisha (3)	92.	Regional Medical Research Centre, Bhubaneshwar			
		93.	All India Institute of Medical Sciences, Bhubaneshwar			
_		94.	SCB Medical College and Hospital, Cuttack			
21.	Puducherry (1)	95.	Jawaharlal Institute of Postgraduate Medica Education & Research, Puducherry			
22.	Punjab (3)	96.	Govt. Medical College, Amritsar			
	runjus (5)	97.	Govt. Medical College, Patiala			
		98.	Guru Gobind Singh Medical University, Faridkot			
23.	Rajasthan (8)	99.	Sawai Man Singh Medical College, Jaipur			
23.	Rejestiten (of	100.	Dr. Sampurnan and Medical College, Johpur			
		100.	Jhalawar Medical College, Jhalawar			
		101.	RNT Medical College, Udaipur			
		102.	SP Medical College, Bikaner			
	-	103.	All India Institute of Medical Sciences, Jodhpur			
	1	104.	JLN Medical College, Ajmer			
		105.	Govt. Medical College, Kota			
24.	Tamil Nadu (11)					
24.		107.	King Institute of Preventive Medicine & Research Chennai			
	1000	108.	Madras Medical College, Chennai			
		109.	Govt. Theni Medical College, Theni			
	22.2	110.	Tirunelveli Medical College, Tirunelveli			
	10000	111.	Govt. Medical College, Thiruvarur			
		112.	Kumar Mangalam Govt. Medical College, Salem			
		113.	Coimbatore Medical College, Coimbatore			
	Section 1	114.	Govt. Medical College, Villupuram			
		115.	Madurai Medical College, Madurai			
		116.	K A P Viswanatham Govt. Medical College, Trichy			
		117.	Perundurai Medical College, Perundurai			
25.	Telangana (5)	118.	Gandhi Medical College, Secunderabad			
	2 1 1 2 2 1	119.	Osmania Medical College, Hyderabad			
		120.	Sir Ronald Ross of Tropical & Communicable Diseases Hyderabad.			
	and the second second	121.	Nizam's Institute of Medical Sciences, Hyderabad			
		122.	Institute of Preventive Medicine, Hyderabad			
		123.	Centre for Cellular & Molecular Biology, Hyderabad			
26.	Tripura (1)	124.	Government Medical College, Agartala			
27.	Uttar Pradesh	125.	King George Medical University, Lucknow			
	(12)	126.	Institute of Medical Sciences, Banaras Hindu			

S. No.	Names of States	Names of Medical Colleges			
		University, Varanasi			
		127. Jawaharlal Nehru Medical College, Aligarh			
		128. Command Hospital, Lucknow			
		129. Lala Lajpat Rai Memorial Medical College, Meerut			
		130. Sanjay Gandhi Post Graduate Institute, Lucknow			
		131. MLN Medical College, Allahabad			
		132. Uttar Pradesh University of Medical Sciences (Formerly Uttar Pradesh RIMS), Saifai			
		133. MLB Medical College, Jhansi			
		134. Regional Medical Research Centre, Gorakhpur			
		135. SN Medical College, Agra			
		136. RML Hospital, Lucknow			
28.	Uttarakhand (2)	137. Govt. Medical College, Haldwani			
		138. All India Institute of Medical Sciences, Rishikesh			
29.	West Bengal (6)	139. National Institute of Cholera & Enteric Diseases, Kolkata			
		140. Institute of Post Graduate Medical Education & Research, Kolkata			
		141. Midnapore Medical College, Midnapore			
		142. North Bengal Medical College, Darjeeling			
		143. School of Tropical Medicine, Kolkata			
		144. Malda Medical College & Hospital, Malda			
30.	Andaman & Nicobar Islands (1)	145. Regional Medical Research Centre, Port Blair			
31.	Dadra & Nagar Haveli	146. Shri Vonoba Bhave Civil Hospital, Silvassa			
		Collection sites only			
31.	Sikkim (1)	147. Sir Thutob Namgyal Memorial (STNM), Gangtok			
32.	Ladakh (1)	148. Sonam Norboo Memorial Hospital (SNMH), Leh			
33.	Arunachal Pradesh (1)	149. Tomo Riba Institute of Health & Medical Sciences (TRIHMS), Naharlagun			

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Guidance on expansion of SARS-CoV-2 testing platforms:

- ICMR recommends the use of US-FDA approved closed real time RT PCR systems like GeneXpert and Roche COBAS-6800/8800. These systems are approved under emergency use.
- 2. In addition, TruenatTM beta CoV test on TruelabTM workstation validated by ICMR is recommended as a screening test. All positives through this platform will need to be reconfirmed by confirmatory assays for SARS-CoV-2. All negatives may not be processed further.
- 3. Truenat beta CoV test should only be performed with all biosafety precautions in BSL-2 or BSL-3 setups at laboratories. Performing this test for SARS-CoV2 in mobile test units without proper biosafety level 2 checks is not recommended.
- 4. This is in addition to the previously issued guidelines and subsequent addendums.

LIST OF VRDLS AND THEIR CONTACT DETAILS

S.No.	State/UT	Level of VRDL		LIST OF VRDLs	Contact details of PI
1	Andaman	State Level	1	Regional Medical Research Centre, Port Blair	Dr. P. Vijyachari Mb.No – 9932083226;
					vijayacharip@yahoo.com
2	Andhra Pradesh	State Level	2.	Sri Venkateswara Institute of Medical	Dr.Usha Kalawat,
				Sciences, Tirupati, Andhra Pradesh	Email: <u>ukalawat@yahoo.com</u>
					Mob: 09493547709
		Medical College	3.	Siddhartha Medical College,	Dr. R. Lakshmi Kumari,
		Level		Vijayawada	Email: <u>rlakshmikumari@gmail.com</u>
					vrdlsmcvja@gmail.com
					Mob: 9290092848
		Medical College	4.	Government Medical College,	Dr. Swarnalatha
		Level		Anantapur	Email: vrdlgmcatp@gmail.com
					Mob: 9849499761
		Medical College	5	Rajeev Gandhi Institute of Medical	Dr.SasidharMajeti,
		Level		Sciences, Kadapa	Email: <u>sasidharmajeti@hotmail.com</u>
					microrimskadpa@gmail.com
					Mob: 9247899544
		Medical College	6.	Rangaraya Medical College, Kakinada	Dr. D.S Murthy
		Level			Mb.No - 9440341099
					murtyds@gmail.com
		State Level	7.	Guntur Medical College, Guntur	Dr. Prasanthi Kohli
					Email: <u>vrdlgunturmedicalcollege@gmail.com</u>
					Mob: 09848173034
		Medical college	8	Andhra Medical college,	Dr.P.Kamala,
		Level		Vishakhapatnam	9246667885; 9492820244
					drkamalavirology@gmail.com

2	Assam	Regional level	9.	Regional Medical Research Centre, Dibrugarh	Dr.Biswa Borkakoty, Email: biswaborkakoty@gmail.com Mob: 09435131316
		State Level	10	Gauhati Medical College, Guwahati	Dr. Ajanta Sharma, Email: virologygmch@gmail.com, ajantasharma2002@yahoo.com Mob: 9435011202
		Medical College Level	11	Silchar Medical College, Silchar	Dr.Dipa Baido Email: vrdl.silchar@gmail.com Mob: 09706031102
		Medical College Level	12	Jorhat Medical College, Jorhat	Dr. Purnima Barua, Email: drpbm29@gmail.com drpurnimabarua@gmail.com Mob: 9435141989
		Medical College Level	13	Tezpur Medical College, Tezpur	Dr.Kalpana Bezborah, Email: vrdltmch@gmail.com kalpanabezborah1@gmail.com Mob: 09954264923
		Medical College Level	14	Fakhruddin Medical College, Barpeta	Dr. Elmy Samsun rasul Email: elmyrasul@yahoo.com Mob: 9864065956
3	Bihar	Medical College Level	15	Patna Medical College, Patna	Dr. Satyendra Narayan Singh, Email: <u>vrdlpmc@gmail.com</u> Mob: 09430829788
		Medical College Level	16	Darbhanga Medical College, Darbhanga	Dr. R. S. Prasad, drrspd.57@gmail.com, vrdldmc@gmail.com Mob: 9430850201, 07762860386

		Medical College Level	17	S K Medical College, Muzaffarpur	Dr. Ranjeet Kumar, Email:hodmicrobiologyskmcmui@gmail.com Mob: 09835279484
		Medical College Level	18	Rajendra Memorial Research Institute of Medical Sciences, Patna	Dr. Pradeep Das, Email: drpradeep.das@gmail.com Mob:09431012380
4	Chandigarh	Regional level	19	PGIMER, Chandigarh	Dr. R. K. Ratho, 08360680627 rathopgi@yahoo.com
		Medical College Level	20	Government Medical College & Hospital, Chandigarh	Dr.Jagdish Chander Email: jchander@nic.in/jchander@hotmail.com Mob: 9646121570
5	Chhattisgarh	Medical College Level	21	Late Sri BaliramKashyap Memorial Govt. Medical College, Jagdalpur	Dr. Devajyothi Majumdar, Email: dmsmims@gmail.com Mob: 7869698550
		State Level	22	All India Institute of Medical Science (AIIMS) Raipur, Chhattisgarh.	Dr. Anudita Bhargava, Email: <u>nuditabhargava@gmail.com</u> Mob: 08518881903
6	Delhi-NCT	Regional Level	23	All India Institute of Medical Sciences, New Delhi- 110029	Dr. Lalit Dar, Email: <u>lalitdaraiims@gmail.com,</u> Mob:9818137078
		Medical College Level	24	Lady Hardinge Medical College, New Delhi	Dr. Manoj Jais, Email: <u>serologyhailhmc@gmail.com;</u> drmanojjais@yahoo.co.in Mob: 9868961269
7	Gujarat	State Level	25	B.J. Medical College, Ahmedabad	Dr. M.M. Vegad, Email: mahendravegad@rediffmail.com Mob: 09825067308

		Medical College Level	26	M.P. Shah Medical College, Jamnagar	Dr Summaiya Mullan, Email: mullasummaiya@gmail.com Mob: 09825319755
		Medical College Level	27	Government Medical College, Surat	Dr. Neeta Khandelwal, Email: neetashokk@gmail.com Mob: 9925276950
		Medical College Level	28	GMC, Bhavnagar	Dr. Kairavi J Desai, Mob: 9825469106 Email: drkairavi@yahoo.in
		Medical College Level	29	PDU GMC, Rajkot	Dr. Prakash Modi, Mob: 8780262489 Email: mcrmicro@gmail.com
		Medical College Level	30	Government Medical College & SSG Hospital, Vadodara	Dr. Tanuja Javadekar, Email: drtanuja24@gmail.com Mob: 9824919676
8	Haryana	Medical College Level	31	PGIMS, Rohtak	Dr. Paramjeet S. Gill, Email: <u>pjsgill@rediffmail.com</u> Mob: 9896296249
		Medical College Level	32	BPS Government Medical College for Women, Sonepat	Dr. Sarita Yadav, Email: yadav78sarita@yahoo.com Mob: 9416978208
9	Himachal Pradesh	State Level	33	Indira Gandhi Medical College, Shimla	Dr. Santwana Verma, Email: santwana1812@gmail.com Mob: 09418451123
		Medical College Level	34	Dr.Rajendra Prasad Government Medical College, Tanda	Dr.S C Jaryal, Email: drscjaryal@gmail.com Mob: 9418115596
10	Jammu and Kashmir	State Level	35	Sher-i-Kashmir Institute of Medical Sciences, Srinagar	Dr. Bashir Ahmad Fomda, Email: bashirfomda@gmail.com Mob:09419001701
		Medical College Level	36	Government Medical College, Jammu	Dr. Shashi Sudan Sharma, Email: drshashisharma.micro@gmail.com

					Mob: 9419197344
		Medical College Level	37	Government Medical College, Srinagar	Dr. Anjum Farhana, Email: anjumfarhana1@yahoo.in Mob: 9419016207
11	Jharkhand	Medical College Level	38	Rajendra Institute of Medical Sciences, Ranchi	Dr. Manoj Kumar, Email: icmrvirologyrims@gmail.com Mob: 8986880889
		Medical College Level	39	MGM Medical College, Jamshedpur	Piyali Gupta <mark>.</mark> Email: <u>mgmvrdl@gmail.com</u> Mob: 9470153537
12	Karnataka	State Level	40	Bangalore Medical College & Research Institute, Bangalore	Dr. Shantala G., Email: drshantalagb@gmail.com Mob: 09448078081
		Medical College Level	41	Mysore Medical College & Research Institute, Mysore	Dr. Amurtha Kumari B., Email: amrutakb@yahoo.co.in Mob: 9900571039
		Medical College Level	42	Vijayanagar Institute of Medical Science, Bellary	Dr. Krishna S., Email: <u>drkrishnas68@gmail.com</u> Mob: 9448415781
		Medical College Level	43	Hassan Institute of Medical Sciences, Hassan	Dr. Venkatesha D.T., Email: <u>Venkatdt2002@yahoo.co.in</u> Mob: 9448262118
		Medical College Level	44	Shimoga Institute of Medical Sciences	Dr. Siddesh K.C., Email: drsiddeshkc@gmail.com , simsvrdlshivamogga@gmail.com Mob: 9448324483
		Medical College Level	45	Gulbarga Institute Of Medical Sciences, Gulbarga	Dr. Nawaz Umar, Email: microbiologygims123@gmail.com, drnawazumar@gmail.com Mob: 99452701149

13	Kerala	Regional Level	46	Government Medical College, Kozhikode	Dr. Beena Philomina J., Email: drbeenapj@gmail.com Mob: 09446161949
		State Level	47	National Institute of Virology, Alappuzha	A.P. Sugunan, apsugunan@gmail.com Mob: 9400235828
		Medical College Level	48	Government Medical College, Trivandrum	Dr. Sarada Devi, Email: sdevikl23@gmail.com Mob: 9495244081
		Medical College Level	49	Government Medical College, Thrissur	Dr. Beena Paul Email: <u>vrdlthrissur@gmail.com</u> Mob: 07907261883
14	Madhya Pradesh	Regional level	50	AIIMS, Bhopal	Dr. Debasis Biswas, Email: aiimsbhopalvrdl@aiimsbhopal.edu.in debasis.microbiology@aiimsbhopal.edu.in Mob: 07747010312
		Medical College Level	51	Bundelkhand Medical College, Sagar	Dr. Shoeb Akhtar Khan, Email: <u>shoebakin@yahoo.co.in</u> Mob: 09827047392
		Medical College Level	52	MGM Medical College, Indore	Dr. Anitha Mutha, Email: dranitamutha@gmail.com Mob: 9826170789
		Medical College Level	53	Gajra Raja Medical College, Gwalior	Dr. Vaibhav Mishra, Email: <u>vmmicro@gmail.com</u> drvaibhavmisra74@gmail.com Mob: 9826778524
		State Level	54	National Institute for Research in Tribal Health(NIRTH), Jabalpur	Dr. P. V. Barde, Email: <u>pradip_barde@hotmail.com</u> Phone: 0761- 2370800/2370818/2673807/3204738

		Medical College Level	55	S.S Medical College, Rewa	Dr. Amresh Puri Email: dramarns@gmail.com Mob: 09972563939
15	Maharashtra	Medical College Level	56	Indira Gandhi Government Medical College, Nagpur	Dr. Sharmila Raut, Email: sharmilakuber@gmail.com, vrdliggmcnagpur@gmail.com Mob: 7721910747
		Medical College Level	57	Government Medical College, Miraj, Sangli	Dr.Vanita Kulkarni Email: vanitak24@yahoo.com, gmcmirajmicro@gmail.com Mob: 9881861154
		Medical College Level	58	Kasturba Hospital for Infectious Diseases, Mumbai	Dr. Jayanthi Shastri Email: jsshastri@gmail.com Mob:09820549156
		Medical College Level	59	Seth GS Medical College & KEM Hospital , Mumbai	Dr. Nayana Ingole, Email: nayanaingole@gmail.com; gitanataraj@gmail.com Ph: 9821471788
		State Level	60	Government Medical college, Nagpur	Dr. Sandeep. V. Kokate Mob: 9833216792 drsandeepkokate@gmail.com
		Medical College Level	61	Government Medical College, Aurangabad	Dr. Jyoti Iravane, Email: jairavane@gmail.com Mob: 09823233245
		Medical College Level	62	V. M. Government Meical College, Solapur	Dr. Nasira Sheik, Email: <u>vmgmcmicro@gmail.com</u> Mob: 09422653930

		Medical College Level	63	Shri Bhausaheb Hire Government Medical College, Dhule	Dr. Dr. Supriya Malvi Email: supriya.malvi@gmail.com Mob:08605807795
		Medical College Level	64	Government Medical College and Hospital & Superspeciality Hospital, Akola	Dr.Nitin A, Email: nitinaambhore@gmail.com / naambhore@rediffmail.com Mob:09921414350
16	Manipur	State Level	65	Regional Institute of Medical Sciences, Imphal	Dr. Sulochana Devi, Email: sulo_khu@rediffmail.com Mob: 09436037996
		Medical College Level	66	JNIMS, Imphal	Dr. R.K.Manoj kumar Singh, Email: rkmksingh@gmail.com Mob: 8974025306
17	Meghalaya	State Level	67	NEIGRIHMS, Shillong	Dr. A.C. Phukan Email: dranilphukan@yahoo.co.in Mob: 09436336370
18	Odisha	Regional level	68	RMRC, Bhubaneswar	Dr. Jyoti Turuk, Email:drjyotirmayuturuk@gmail.com; vrdlrmrcbbsr@gmail.com Mob: 7653915589
		State Level	69	SCB Medical College, Cuttack	Dr. Dharitri Mohapatra dr.dharitri@rediffmail.com Mob. 9861336505 Dr. Nirupauma Chayani Email: nirupama.chayani@gmail.com Mob: 09437310666
19	Puducherry	Regional level	70	JIPMER, Puducherry	Dr. Rahul Dhodapkar, Email: rahuldhodapkar@gmail.com Mob: 09791933708

		Medical College Level	71	Indira Gandhi Medical College & Research Institute, Puducherry	Dr. S. Srinivasan, Email: drsriniv@gmail.com Mob: 9444149424, 9787728177
20	Punjab	Medical College Level	72	Government Medical College, Amritsar	Dr. Shailpreet Sidhu and Dr. Kanwardeep Dhingra, Email: <u>shail78@hotmail.com</u> , kdmicrojmcasr@gmail.com Mob: 9814309793; 09876148560
		Medical College Level	73	Government Medical College, Patiala	Dr. Rupinder Bakshi, Email: rupindergill1@yahoo.co.in Mob: 9815320300
21	Rajasthan	State Level	74	SMS Medical College, Jaipur	Dr. Bharti Malhotra, Email: drbhartimalhotra@gmail.com Mob: 09414042040
		Medical College Level	75	Dr. S.N. Medical College, Jodhpur	Dr. P.K. Khatri, Email: drpkkhatri@yahoo.co.in Mob: 9460481236
		Medical College Level	76	RNT Medical College, Udaipur	Dr. Anshu Sharma, Email: anshu69sharma@gmail.com Mob: 9414238909
		Medical College Level	77	S.P. Medical College & Associated Group of Hospitals, Bikaner, Rajasthan	Dr. Anjali Gupta, Email: bkgbkn@rediffmail.com Mob: 9414452393
		Medical College Level	78	Jhalawar Medical College, Jhalawar, Rajasthan	Dr. Yogendra Kumar Tiwari, Email: yogendratiwari2012@gmail.com Mob: 9414550771
		Regional level	79	AIIMS, Jodhpur	Dr. Vijaya Lakshmi Nag, Email: vijayalakshmi005@gmail.com Mob: 08003996874
22	Tamil Nadu	Medical College Level	80	Madurai Medical College, Madurai	Dr. C. Sugumari, Email: doctorsugumari@yahoo.com Mob: 9842953380

		Medical College Level	81	Government Medical College, Theni	Dr.S. Lalitha Email: <u>gtmcmicrobiology@gmail.com;</u> drlallithiagu@gmail.com Mob: 9787594487
		Medical College Level	82	Government Mohan Kumaramangalam Medical College, Salem	Dr. S. Rajesh, Email: sengodan.rajesh1974@gmail.com microsalem30@gmail.com Mob: 9443321151
		Medical College Level	83	Government Medical College, Thiruvarur	Dr. V.Vasuki, Ph No: 9442351350 Email: micro_vasuki@yahoo.co.in
		Medical College Level	84	Government Medical College, Villupuram	Dr. P Shankar Email: <u>pshankx@gmail.com</u> Mob: 09940856010
		Medical College Level	85	Tirunelveli Medical College, Tirunelveli	Dr. V P Amudha Ema <u>il: vpamudha@yahoo.co.in</u> Mob: 09443429641
		State Level	86	Coimbatore Medical College, Coimbatore	Dr. Mythily Nagasundaram Email: mythilynmicro@gmail.com Mob: 09488990741
		State Level	87	King Institute of Preventive Medicine and Research, Chennai, Tamil Nadu	Dr. K. Kaveri, Email: kaveri_raj1967@yahoo.com Mob: 988485519
		Medical College Level	88	Madras Medical College, Chennai, Tamil Nadu	Dr. T. Sabeetha, Email: sabitha@iitm.ac.in tndmepd@gmail.com Mob: 94426-69001
23	Tripura	Medical College Level	89	Government Medical College, Agartala	Dr. Tapan Majumdar, Email: drtapan1@rediffmail.com Mob: 9436120498

24	Telangana	Medical College Level	90	Osmania Medical College, Hyderabad	Dr. G. Jyothi Lakshmi Email: drgjyothilakshmi@yahoo.com Mob: 9848097635
		Medical College Level	91	Kakatiya Medical College, Nizampura, Warangal	Dr. Jyothi Kundru Email: jyothikunduru08@gmail.com Mob: 7337070094
		State Level	92	Gandhi Medical College, Secunderabad	Dr. K. Nagamani, Email: nagamaniy2k03@rediffmail.com Mob: 09966533327
25	Uttar Pradesh	State Level	93	King George Medical University, Lucknow	Dr. Amita Jain, Email: amita602002@yahoo.com Mob: 09415023928
		Medical College Level	94	J N Medical College, Aligarh	Dr. Haris Mazoor Mb.No 9897752620 vrdlaligarh2016@gmail.com
		Medical College Level	95	UPUMS,(Formerly UPRIMS) Saifai	Dr. Rajesh Kumar Verma, Email: rshverma@gmail.com Mob: 8477973359
		State Level	96	Institute of Medical Sciences, Banaras Hindu University, Banaras	Dr. Gopal Nath, Email: gopalnath@gmail.com Mob: 09335058394
26	Uttarakhand	Medical College Level	97	Government Medical College, Haldwani	Dr. Vinita Rawat, Email: drvinitarawat@gmail.com Mob: 8954630885
		State Level	98	AIIMS, Rishikesh	Dr. Pratima Gupta 8475000272 pratima.micro@aiimsrishikesh.edu.in
		Medical College Level	99	Doon Government Medical College, Dehradun	Dr. Shekhar Pal, 09997679392 E-mail:drshekharpal@gmail.com

27	West Bengal	Regional level	100	NICED Virus Unit, Kolkata	Dr. Shanta Dutta Email: shanta1232001@yahoo.co.in, <u>shanta.niced@icmr.gov.in</u> vrdln.niced@gmail.com Mob: 09830152971
		Medical College Level	101	IPGMER, Kolkata	Dr. Raja Ray, Email: rjrm1175@gmail.com Mob: 943332345
		Medical College Level	102	Murshidabad Medical College & Hospital, Murshidabad, Berhampur, West Bengal	Dr. Manas Sarkar, Email: manashsarkar98@yahoo.in Mob: 9433396315
		Medical College Level	103	Midnapore Medical College & Hospital, Midnapore	Dr. ParthaSarathi Satpathi, Email: vrdlmmch@gmail.com Mob: 9332145545
		Medical College Level	104	North Bengal Medical College, Darjeeling	Dr. Arunabhao Sarkar, Email: micro.nbmc@gmail.com 9932214173
		Medical College Level	105	Malda Medical College, Malda	Dr.Puranjay Saha, Email: drpuranjoysaha@gmail.com Mob: 9434167080
		Medical College Level	106	RG Kar Medical College, Kolkata	Prof. Mitali Chatterjee, Email: chatterjeemitali5@gmail.com.; vrdlrgkar@gmail.com Mob: 9831086552

INDIAN COUNCIL OF MEDICAL RESEARCH

DEPARTMENT OF HEALTH RESEARCH

Guidance document for State Nodal & Testing VRDLs for nCoV

You have been identified as the State Nodal Laboratory for ensuring collection and transport of suspected nCoV sample to ICMR-NIV, Pune. In addition, you are also identified as a testing laboratory for nCoV.

Your roles and responsibilities are as follows:

- You are supposed to make phone calls to VRDLs in your State (list of VRDLs and contact numbers are attached) and inform them the following:
 - If they collect any suspect samples of nCoV directly or through State Health Authorities/IDSP, they should inform you immediately (on real time basis).
 - As soon as you get the information about a sample collected from suspect case, you are supposed to contact Sequel Logistics or World Courier and arrange pick up of samples from the respective sites. Contact details of the relevant agencies are placed at **Annexure 1**.
- Once the courier agency picks up the sample, you need to coordinate with the concerned courier agency for getting the sample(s) delivered to NIV, Pune by the shortest route in shortest time.
- Pick up of the sample by the courier agency will be directly from the VRDL where the sample has been collected and stored. You are not supposed to ask any VRDL to ship the sample to your centre.
- Once the sample is shipped, immediate notification of dispatch of sample along with details should be sent to:
 - Dr. Sumit Bharadwaj <u>sumitduttbhardwaj@gmail.com;</u>
 - DHR-ICMR vrdltechnicalevaluation@gmail.com and
 - Whatsapp group (DHR-ICMR VRDLs).

For State Nodal VRDLs who are also the testing sites, following are the directives:

- Till the time you receive the reagents, nCoV primers and probes from NIV Pune, you should ship the samples to ICMR-NIV, Pune.
- Once you receive the reagents, you have to acknowledge on the Whatsapp group (Preparedness for nCoV) immediately. After the receipt of samples before opening a positive control, first aliquot reagents and primers. Then aliquot positive control. Run the PCR assay with appropriate positive and negative controls (as indicated in the SOP), and share the results with NIV, Pune within 24 hrs. The results should include the gel doc pictures showing the molecular ladder and the band for the positive control.
- After the Positive Control PCR results are verified by NIV, Pune, your VRDL must initiate the **testing of respiratory samples collected from suspected nCoV cases**.
- After initiation of testing for nCoV at your VRDL, aliquots of all respiratory samples tested POSITIVE for nCoV must be shared with NIV, Pune. Minimum volume of 2 ml of positive respiratory sample needs to be shared with NIV, Pune.
- In addition, the first 10 respiratory samples tested negative must also be shared with NIV, Pune for verification of results. Minimum volume of 1 ml of negative respiratory sample should be sent to NIV, Pune.
- Shipment of all the positive respiratory samples and the first 10 negative respiratory samples to NIV, Pune needs to be on a real-time basis.
- In case you get any positive result by testing suspect nCoV respiratory sample, you are not supposed to disclose the results to anyone. You should only advise the treating clinician to isolate the patient in an appropriate facility and follow all biosafety precautions till further confirmation. In such situations you should immediately send an aliquot of sample to ICMR-NIV, Pune for nCoV reconfirmation. A positive result (if any) would only be declared by NIV, Pune after reconfirmation.
- In case of a negative respiratory sample, results should be reported as tentative clearly mentioning that confirmation is awaited from NIV, Pune.

- Blood samples (whole blood in EDTA vacutainer and yellow serum vacutainer for serum) should also be collected from all suspected cases.
- Blood samples from cases tested positive for nCoV need to be shipped to NIV, Pune on a real-time basis.
- For any positive cases, a convalescent serum sample needs to be collected after 2 weeks.
- Blood samples (serum and plasma) from negative cases should be frozen after aliquoting and then sent to NIV, Pune in batches.
- Ensure proper precautions to prevent cross-contamination and ensure PCR quality. Some of the important precautions are as follows-
 - Ensure proper calibration of Micropipettes.
 - Make multiple aliquots of primers, nuclease free water for PCR and for the Positive control plasmids.
 - Strictly ensure uni-directional workflow in the molecular biology laboratory.
 - Ensure that the reagents for the nCoV assay are stored separately from the Positive control.
 - Positive Control should be added in a separate area than the extracted sample RNA.
 - Ensure proper disinfection measures as well as avoiding crosscontamination by cleaning all work surfaces in the molecular biology laboratory with bleach followed by 70% ethanol.
 - Strictly follow SOP shared by NIV Pune and include positive control and negative controls as per the instructions.
- Please Note: No results for nCoV should be reported on NIE portal. However, other respiratory virus screening should be reported as usual.

You are requested to read the advisories on following web-links:

https://mohfw.gov.in/diseasealerts/novel-corona-virus

http://niv.co.in/SOP Specimen Collection 2019-nCoV.pdf

http://niv.co.in/Specimen referral form.pdf

Annexure 1

Sequel Logistics:

Deba Prasad Sahoo – 9019642443 Hardik Shah – 7738350002

World Courier:

Mr. Pradeep - 9004367878

Real Time PCR machines supplied to Government Labs

As a part of strengthening the COVID-19 testing across the country, following Virus Research and Diagnostic Labs (approved under the Department of Health Research scheme "Establishment of a Network of Laboratories for Managing Epidemics and Natural Calamities") have been provided with Real Time PCR machine to enable testing at these labs at the earliest possible.

S. No.	Name of VRDL
1.	Guntur Medical College, Guntur
2.	Patna Medical College, Patna
3.	Lady Hardinge Medical College, New Delhi
4.	Government Medical College & Hospital, Chandigarh
5.	GMC, Bhavnagar
6.	PDU GMC, Rajkot
7.	Government Medical College & SSG Hospital, Vadodara
8.	Rajendra Institute of Medical Sciences, Ranchi
9.	Bundelkhand Medical College, Sagar
10.	Gajra Raja Medical College, Gwalior
11.	S.S Medical College, Rewa
12.	Government Medical College, Miraj, Sangli
13.	Seth GS Medical College & KEM Hospital , Mumbai
14.	Government Medical college, Nagpur
15.	Government Medical College, Aurangabad
16.	V. M. Government Meical College, Solapur
17.	Shri Bhausaheb Hire Government Medical College, Dhule
18.	Government Medical College and Hospital & Super Specialty Hospital, Akola
19.	AIIMS, Rishikesh
20.	Murshidabad Medical College & Hospital, Murshidabad, Berhampur, West Bengal
21.	Malda Medical College, Malda
22.	Government Medical College, Surat
23.	Madras Medical College, Chennai, Tamil Nadu
24.	UPUMS,(Formerly UPRIMS) Saifai
25.	RG Kar Medical College, Kolkata

संचालनालय, वैद्यकीय शिक्षण आणि संशोधन, मुंबई

कीय दंत महाविद्यालय व रुग्णालय इमारत चौथा मजला, सेंट जॉर्जेंस रुग्णालय आवार, पी. डीमेलो रोड, फोर्ट, मुंबई - ४०० ००१ - >२६२०३६१-६५/२२६५२२५१/५७/५९. टेलीग्राम: "MEDUCATNSEARCH" फॅक्स:+९१-२२-३२६२०५६२/२२६५३१६८ Hanter hup www.dmer.org

क. संवैशिवसं/कोव्हीड-१९/प्रयोगशाळा/जिल्हानिहाय/९७९ /२०२०/अ,

प्रति. मा सचिव. वैद्यकीय शिक्षण व औषधी द्रव्ये विभाग. गो.ते.रुग्णालयाची नवीन इमारत, 9वा मजला, नवीन मंत्रालय, लोकमान्य टिळक मार्ग, मुंबई ४०० ००१.

- विषय कोव्हीड-१९ संदर्भातील प्रयोशाळांची जिल्हानिहाय सूची प्रसिध्द करणेबाबत.
- संदर्भ संचालनालयाचे पत्र क्रमांक संवैशिवसं/कोव्हीड-१९/प्रयोगशाळा/ 08.08.2020, दिनांक जिल्हानिहाय/०१६/२०२०/२-अ, ०९.०४.२०२० आणि १७.०४.२०२० रोजीचे पत्र.

राज्यात कोव्हीड-१९ या विषाणूच्या निदान व चाचणीकरिता आय.सी.एम.आर. च्या मान्यतेने प्रयोगशाळांना परवानगी देण्यात आलेली आहे. संचालनालयाच्या संदर्भीय पत्रान्वये सदर प्रयोशाळांचे जिल्हानिहाय वाटप करुन त्या त्या जिल्हयातील रुग्णांन नमूने नेमून दिलेल्या प्रयोगशाळांकडे पाठविण्यासंदर्भातील जिल्हानिहाय प्रयोगशाळांची सूची सादर करण्यात आली होती व त्यानुसार सूची प्रसिध्द करण्यासंदर्भातील विनंती करण्यात आली होती. आज दिनांक १७.०४.२०२० रोजी नव्याने सुरु झालेल्या प्रयोगशाळा अंतर्भत करुन नव्याने जिल्हानिहाय प्रयोगशाळांची सूची सोबत सादर करण्यात येत आहे. शासनास विनंती करण्यात येते की, सदर सुधारीत सूची प्रसिध्द करण्याबातची पुढील परवानगी द्यावी, विनंती.

(डॉ.टी.पी.लहाने) संचालक तथा नोडल अधिकारी (कोव्हीड-१९) वैद्यकीय शिक्षण व संशोधन, मुंबई

सोबत – सुधारीत सूची (दिनांक १७.०४.२०२०)

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जिल्हानिहाय व संस्थानिहाय कोव्हीड-१९ निदान व तपासणी प्रयोगशाळा

दिनांक - १७.०४.२०२०

अ.क.	प्रयोगशाळा	जिल्हयाची नावे व महानगरपालिका
٤.	कस्तुरबा रुग्णालय, मुंबई	
२.	के ई एम रुग्णालय, परळ, मुंबई	१. बृहन्मुंबई महानगरपालिका
Э.	नॅशनल इन्स्टीटयुट फॉर रिसर्च ऑन रिप्रोडक्टीव्ह हेल्य्, मुंबई	
۲.	रारा मेमोरिअल मेंटर ACTREC. मंबई	१. रायगड, २. नवी मुंबई महानगरपालिका,
ц.	ग्रॅन्ट शासकीय वैद्यकीय महाविद्यालय व सर ज.जा.समूह रुग्णालय, मंबई	३. अंबरनाथ नगरपालिको, ४. बेपलानू ११२
ξ.	राजीव गांधी वैद्यकीय महाविद्यालय, कळवा, ठाणे	१. ठाण, २. ठाण महानगरपारिका १. पालघर, २. मिरा-भाईदर महागनगरपालिका,
હ.	हाफकिन प्रशिक्षण, संशोधन व चाचणी संस्था, परळ, मुंबई	३. वसई विरार महानगरपालिका
٤.	नॅशनल इन्स्टिटयुट ऑफ वायरॉलॉजी, मुंबई युनिट, मुंबई	१. कल्याण डोबिवली महानगरपालिका, २. उल्हासनगर महानगरपालिका, ३. भिवंडी नगरपालिक
٩.	बै.जी. शासकीय वैद्यकीय महाविद्यालय व ससून सर्वोपचार रुग्णालय, पुणे	१. सातारा, २. नाशिक (मालेगाव, सटाणा तालूका वगळून) १. पुणे जिल्हा, २. पुणे महानगरपालिका,
80.	नॅशनल इन्स्टिटयुट ऑफ वायरॉलॉजी, पुणे	्र लिंग्नी चिंचतद महानगरपालिको, ८. फोएल रू
११.	नंशनल सेंटर फॉर सेल सायन्सेस, पुणे	३. पिपरा पिपपुंच करने करने होता प्रभाग १. अहमदनगर, २. संरक्षण विभागांतर्गत प्रभाग
१२.	आर्म्ड फोर्स मेडिकल कॉलेज, पुणे	९ गांगली २ रत्नागिरी ३. सिध्दुग
१३.	आस्ड कास नाउपर महाविद्यालय व रुग्णालय, मिरज, जि. सांगली	१. सोलापूर, २. लातूर, ३. उस्मानाबाद, ४. बीड
१४ .	डॉ.वैशंपायन स्मृती शासकीय वैद्यकीय महाविद्यालय, सोलापूर	१. धुळे, २. जळगाव, ३. नंदुरबार,
શ્બ.	श्री.भाऊसाहेब हिरे शासकीय वैद्यकीय महाविद्यालय, धुळे	४. नाशिक (मालेगाव व सटाणा तालुका)
१६.	शासकीय वैद्यकीय महाविद्यालय, औरंगाबाद	१. औरंगाबाद, २. जालना, ३. परभणी, ४. हिंगोली, ५. नांदेड
१७.	ऑल इंडिया इन्स्टिटयुट ऑफ मेडिकल सायन्सेस, नागपूर	१. नागपूर जिल्हा व महानगरपालिका
86.	इंदिरा गांधी शासकीय वैद्यकीय महाविद्यालय, नागपूर	१. गडचिरोली, २. गोंदिया, ३. भंडारा, ४. चंद्रपूर
89.	शासकीय वैद्यकीय महाविद्यालय, नागपूर	१. अकोला, २. बुलढाणा, ३. वाशिम,
२०.	शासकीय वैद्यकीय महाविद्यालय, अकोला	४. अमरावती, ५. यवतमाळ
२१.	नागपूर कॉलेज ऑफ व्हेटरनरी, नागपूर	१. वर्धा

- टिप १. वरील नमूद प्रयोगशाळांपैकी एखादी प्रयोगशाळा काही कारणास्तव बंद पडल्यास, कृपया जिल्हयालगतच्या प्रयोगशाळेकडे नमुने पाठविण्यात यावेत.
 - २. कोव्हीड-१९ रुग्णांची व परिस्थितीचा आढावा घेवून विभागीय आयुक्त यांच्या स्तरावरील त्यांच्या अंतर्गत येणाऱ्या जिल्हयातील लॅबनिहाय फेरवाटप करु शकतात.

(डॉ.टी.पी.लहाने) संचालक तथा नोडल अधिकारी (कोव्हीड-१९) वैद्यकीय शिक्षण व संशोधन, मुंबई



INFORMATION DIRECTORATE OF MEDICAL EDUCATION & RESEARCH

Govt. Dental College & Hospital Building 4° floor, St. George's Hospital Compound, P.D'mello Road, Mumbai - 400 001. Tel. No. - +91-22-22620361-65/22652251/57/59. Telegram "MEDUCATNSEARCH" Fax - +91-22-22620562/22652168 Website : http://www.dmer.org

No.DMER/COVID-19/Lab/ 92 /2020 Urgent/Important

Date : 16 April, 2020

Dear Sir/Madam,

Subject: Timely reporting of Covid-19 Testing status on Designated Government Portals

Whereas the Government of Maharashtra, in exercise of the powers conferred under Section 2,3 & 4 of the Epidemic Diseases Act 1897 has framed Regulations for prevention and containment of COVID-19 under No.corona 2020/CR/58/Aarogya-5, dated 13th March 2020.

And where as Director of Medical Education and Research, has been declared as "Empowered Officer" and is empowered to take such measures as are necessary to prevent the outbreak of COVID-19 or spread thereof within his respective jurisdiction,

I Dr. T.P. Lahane, in the larger public interest and in exercise of the powers conferred upon me under Rule 10 of the said Regulations which permits me to implement measures of containment to prevent spread of the diseases, hereby direct all Government/Private Covid-19 Testing laboratory incharges in the State of Maharashtra, to report accurate daily information on the portal of Indian Council of Medical Research New Delhi (Coronavirus status in India) as well as to Maharashtra State IDSP Portals communicated through Public Health Department (email ID-<u>covid19labreport@gmail.com</u>, <u>ssumaharashtra</u> <u>@gmail.com</u>).

For any query in this regards, you may communicate the same to Dr Sumedh Andurkar, Assistant Director, Public Health Department (Mob: 9552532616). The information asked in the portals should be filled in daily without fail. Each laboratory should assign one responsible officer for the reporting process. It is responsibility of individual laboratory in-charge to do necessary timely reporting and Head of Institution will ensure that the reporting is made in time.

Yours sincerely,

5)e

(Dr.T.P. Lahane) Director & Nodal Officer Covid 19 Directorate of Medical Educaiton and Reserch Mumbai

To,

The Incharge of Covid-19 Testing Laboratories of -

- 1. National Institute of Virology, Pune
- 2. Seth GS Medical College & KEM Hospital, Mumbai
- 3. Kasturba Hospital for Infectious Diseases, Mumbai.
- 4. National Institute of Virology Field Unit, Mumbai.

- 5. Armed Forces Medical College, Pune
- 6. BJ Medical College, Pune
- 7. Indira Gandhi Govt. Medical College, Nagpur
- 8. Grant Medical College & Sir JJ Hospital, Mumbai
- 9. Govt. Medical College, Aurangabad
- 10. V. M. Government Medical College, Solapur
- 11. Haffkine Institute, Mumbai
- 12. Shree Bhausaheb Hire Govt. Medical College, Dhule
- 13. Government Medical College, Miraj
- 14. All India Institute of Medical Sciences, Nagpur
- 15. Nagpur Veterinary College, MAFSU, Nagpur
- 16. Tata Memorial Centre ACTREC, Mumbai
- 17. Govt. Medical College, Akola
- 18. National Institute for Research on Reproductive Health, Mumbai
- 19. National Centre for Cell Sciences, Pune
- 20. Government Medical College, Nagpur

Private Covid-19 Testing Laboratory

- 1. Thyrocare Technologies Limited, D37/1, TTC MIDC, Turbhe, Navi Mumbai
- 2. Suburban Diagnostics (India) Pvt. Ltd., 306, 307/T, 3rd Floor, Sunshine Bld., Andheri (W), Mumbai
- Metropolis Healthcare Ltd, Unit No. 409-416, 4th Floor, Commercial Building-1, Kohinoor Mall, Mumbai
- Sir H.N. Reliance Foundation Hospital and Research Centre, Molecular Medicine, Reliance Life Sciences Pvt. Ltd., R-282, TTC Industrial Area, Rabale, Navi Mumbai
- SRL Limited, Prime Square Building, Plot No 1, Gaiwadi Industrial Estate, SV Road, Goregaon, Mumbai
- 6. A.G. Diagnostics Pvt Ltd, Nayantara Building, Pune
- 7. KokilabenDhirubhai Ambani Hospital Laboratory, Four Bungalows, Mumbai
- InfeXn Laboratories Private Limited, A/131, Therelek Compound, Road No 23, Wagle Industrial Estate, Thane (W)
- 9. iGenetic Diagnostics Pvt Ltd, Krislon House, Andheri East, Mumbai
- 10. Tata Memorial Centre Diagnostic Services-Tata Memorial Hospital, Parel, Mumbai
- 11. Sahyadri Speciality Labs, Plot No 54, S.No. 89-90, Lokmanya Colony, Kothrud, Pune
- 12. Dr. Jariwala Lab & Diagnostics LLP, 1st Floor, Rasraj Heights, Rokadia Lane, Off Mandpeshwar Road, Borivli (W), Mumbai
- 13. Ruby Hall Clinic, Dept of Laboratory, Grant Medical Foundation, 40, Sassoon Road, Pune
- 14. Metropolis Healthcare Limited, Construction House, 796/189-B, Bhandarkar Institute Road, Pune
- 15. Qualilife Diagnostics, Balaji Arcade, 1st Floor, 544/A, Netaji Subhash Road, Mulund (W), Mumbai
- SRL Diagnostics Dr. AvinashPhadke (SRL Diagnostics Pvt Ltd), Mahalaxmi Engineering Estate, 2nd Floor, L.J. Cross Road No I, KJ Khilnani High School, Mahim (West), Mumbai
- 17. Sunflower Lab & Diagnostic Center, Keshav Kunj, Marve Road, Malad West, Mumbai

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

Date: 06/04/2020

"India COVID-19 Clinical Research Collaborative Network"

The National Task Force has recommended to establish the *"India COVID-19 Clinical Research Collaborative Network"* to be coordinated by the Indian Council of Medical Research. The goal of this network is to enhance the clinical understanding of COVID-19 in the country so as to develop specific clinical management protocols and further R&D for therapeutics. For this purpose, a central database of clinical and laboratory parameters of hospitalized COVID-19 cases is being created.

All hospitals currently managing COVID-19 patients are invited to become partners in the network. Those interested to join the network may fill the registration form available at the following link: <u>https://forms.gle/LHByZkR41UPHqX9FA</u>

Hospitals should continue to independently report concerned data to central/state health authorities as per current guidelines.

INDIAN COUNCIL OF MEDICAL RESEARCH DEPARTMENT OF HEALTH RESEARCH

3 April, 2020

Therapeutic trial for COVID-19

ICMR will collaborate with the World Health Organization for "public health emergency SOLIDARITY TRIAL – An international randomised trial of additional treatments for COVID-19 in hospitalised patients"

The trial will be coordinated in India by Dr. Sheela Godbole, Scientist F, ICMR-National AIDS Research Institute, Pune (email: <u>sgodbole@nariindia.org</u>, <u>sgodbole.nari@gov.in</u>)

DO.NO. Z-21020/16/2020-PH



Secretary

प्रीति सूदन, आईएएस ^{सचिव} PREETI SUDAN, IAS



भारत सरकार स्वास्थ्य एवं परिवार कल्याण विभाग स्वास्थ्य एवं परिवार कल्याण मंत्रालय Government of India Department of Health and Family Welfare Ministry of Health and Family Welfare

15.4.2020

Dear Colleague,

As you are aware Government of India has extended the national level lockdown till 3rd May to contain the spread of COVID-19 in the country. This period should be utilized effectively and there should be concerted effort for implementing containment measures in a focused manner.

As of now, based on reported cases, the districts can be classified as: Hotspots, Non-Hotspots districts reporting cases and districts which have not reported positive cases.

The criteria for classification of hotspots is listed at Annexure-I. With respect to these hotspots, the districts which need implementation of outbreak containment plan are at Annexure-II, and the districts where clusters of cases are noted are at Annexure-III. States also need to identify hotspots based on doubling rate of confirmed cases. This exercise of identification of hotspots has to be done on a weekly basis (every Monday) or earlier. Strict containment measures need to be implemented in these hotspots.

Further, for Non-Hotspots Districts Reporting cases (as in Annexure-IV) states need to ensure that containment measures are taken so as to ensure that case in these areas can be contained. States also need to undertake effective surveillance of SARI and ILI cases in districts not having any confirmed cases so far besides ensuring dedicated COVID hospitals.

The containment strategies are already available at MOHFW website <u>https://www.mohfw.gov.in/pdf/3ContainmentPlanforLargeOutbreaksofCOVID19Final.pdf</u> and <u>https://www.mohfw.gov.in/pdf/Containmentplan02042020.pdf</u>. The Micro Plan for containing Local Transmission of COVID-19 is available at <u>https://www.mohfw.gov.in/pdf/ModelMicroplanforcontainmentoflocaltransmissionofCOVID19.pdf</u>

Containment operation would be deemed over when there is no case reported in 28 days from an area after last case tests negative. Hotspots (designated red zones) will be assumed to be undertaking effective containment activities, if no case is reported in next 14 days (designated orange zones) and will be deemed successful in containment, if no case is reported for 28 days (designated green zones).

It is requested that states should utilize the extended lockdown period to the maximum extent to convert the hotspots (red) to orange and in turn green zones.

War marty Yours sincerely, (Preeti Sudan)

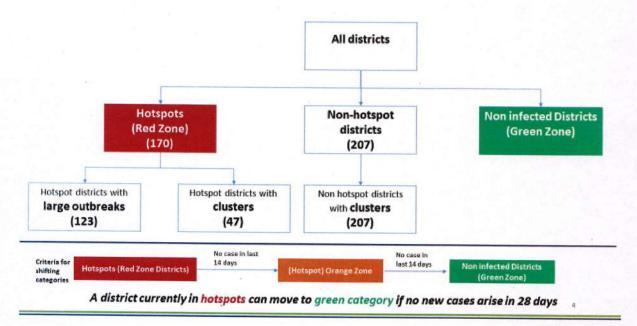
To, Chief Secretaries of all States/UTs C c lo (1) Secy. (17) Encl.: as above 'Hotspot (Red zone) classification'- to focus attention on districts/cities reporting large number of cases/high growth rate.

Inclusion Criteria -

- Highest case load districts contributing to more than 80% of cases in India or
- Highest case load districts contributing to more than 80% of cases for each state in India or
- Districts with doubling rate less than 4 days (calculated every Monday for last 7 days, to be determined by the state government)

Subject to the following exclusion criteria

No new confirmed cases for last 28 days (Green zone)



1

<u>Annexure II</u>

List of hotspot districts with large outbreaks

State	District
	Kurnool
5	Guntur
	Spsr Nellore
	Prakasam
	Krishna
Andhra Pradesh	Y.S.R.
	West Godavari
	Chittoor
	Visakhapatanam
	East Godavari
	Anantapur
Bihar	Siwan
Chandigarh	Chandigarh
Chhattisgarh	Korba
	South
	South East
	Shahdara
	West
Delhi	North
	Central
	New Delhi
	East
	South West

State	District
	Ahmadabad
1	Vadodara
Gujarat	Surat
	Bhavnagar
	Rajkot
	Nuh
University	Gurugram
Haryana	Palwal
	Faridabad
	Srinagar
	Bandipora
Jammu And Kashmir	Baramulla
	Jammu
	Udhampur
	Kupwara
	Bengaluru Urban
Karnataka	Mysuru
	Belagavi
	Kasaragod
	Kannur
Kerala	Ernakulam
	Malappuram
	Thiruvananthapuram
	Pathanamthitta

State	District
	Indore
	Bhopal
Madhya Pradesh	Khargone
	Ujjain
	Hoshangabad
	Mumbai
	Pune
	Thane
	Nagpur
	Sangli
Maharashtra	Ahmednagar
	Yavatmal
	Aurangabad
	Buldhana
	Mumbai Suburban
	Nashik
Odisha	Khordha
	S.A.S Nagar
Punjab	Shahid Bhagat Singh Nagar
	Jalandhar
	Pathankot

State	District
	Jaipur
	Tonk
	Jodhpur
-	Banswara
	Kota
Rajasthan	Jhunjhunu
	Jaisalmer
	Bhilwara
243 S. 1	Bikaner
	Jhalawar
	Bharatpur
	Chennai
	Tiruchirappalli
	Coimbatore
	Tirunelveli
	Erode
Tamil Nadu	Vellore
	Dindigul
	Villupuram
	Tiruppur
	Theni
	Namakkal
	Chengalpattu

State	District
	Madurai
	Tuticorin
	Karur
	Virudhunagar
	Kanniyakumari
Tamil Nadu	Cuddalore
	Thiruvallur
	Thiruvarur
	Salem
	Nagapattinam
	Hyderabad
	Nizamabad
	Warangal Urban
Telangana	Ranga Reddy
relangana	JogulambaGadwal
	MedchalMalkajgiri
	Karimnagar
	Nirmal
	Agra
	Gautam Buddha Nagar
Jttar Pradesh	Meerut
star i ruuesn	Lucknow
	Ghaziabad
	Saharanpur

State	District
-	Shamli
Uttar Pradesh	Firozabad
	Moradabad
Uttarakhand	Dehradun
	Kolkata
West Bengal	Howrah
	Medinipur East
	24 Paraganas North

Annexure III

List of hotspot districts with clusters

State	District
Andaman And Nicobar Islands	South Andamans
	Golaghat
	Marigaon
Assam	Nalbari
	Goalpara
<i>w</i> .	Dhubri
	Munger
Bihar	Begusarai
	Gaya
Chhattisgarh	Raipur
Delhi	North West
Gujarat	Patan
Haryana	Ambala
	Karnal
	Solan
	Una
Himachal Pradesh	Sirmaur
	Chamba
	Kangra
ammu And Kashmir	Shopian
	Rajouri
harkhand	Ranchi
	Bokaro
Karnataka	Dakshina Kannada

State	District
	Bidar
	Kalaburagi
Karnataka	Bagalkote
	Dharwad
Kerala	Wayanad
Ladakh	Kargil
Madhya Pradesh	Morena
	Kolhapur
Maharashtra	Amravati
	Palghar
Odisha	Bhadrak
	Mansa
Punjab	Amritsar
	Ludhiana
	Moga
Rajasthan	Udaipur
Felangana	Nalgonda
	Bulandshahr
Jttar Pradesh	Sitapur
	Basti
	Baghpat
Jttarakhand	Nainital
	Udam Singh Nagar

Annexure IV

Non-Hotspots Districts reporting cases

State Name	District Name
Arunachal Pradesh	Lohit
	Cachar
	Hailakandi
	Kamrup
Assam	Kamrup Metro
	Lakhimpur
46.1	South SalmaraMancachar
	Karimganj
	Gopalganj
	Nawada
	Bhagalpur
Bihar	Saran
	Lakhisarai
	Nalanda
	Patna
	Bilaspur
Chhattisgarh	Durg
	Rajnandgaon
Delhi	North East
Goa	North Goa
	South Goa
	Gandhinagar
Gujarat	Bharuch
	Anand

nchh	
CI	cheim

State Name	District Name
	Porbandar
	Chhotaudepur
	Mahesana
	GirSomnath
Sularat	Dohad
Gujarat	Jamnagar
	Morbi
	PanchMahals
	SabarKantha
	BanasKantha
	Panchkula
	Panipat
Haryana	Sirsa
	Sonipat
	Bhiwani
	Kaithal
ian yana	CharkiDadri
	Fatehabad
	Hisar
	Jind
	Rohtak
	Kurukshetra
ammu And Kashmir	Budgam
	Kulgam

Pulwama	

State	District
Jammu And Kashmir	Ganderbal
Jammu And Kashmir	Samba
	Hazaribagh
Jharkhand	Koderma
	Giridih
	Ballari
T 10	Mandya
	Bengaluru Rural
	Davangere
	Udupi
Karnataka	Gadag
6) 6)	Tumakuru
	Kodagu
	Vijayapura
	Chikkaballapura
	Uttara Kannada
	Thrissur
	Kollam
Kerala	Idukki
	Palakkad
	Kottayam
	Alappuzha
Ladakh	LehLadakh

Barwani
Vidisha

State	District
	Jabalpur
	East Nimar
	Dewas
	Chhindwara
	Gwalior
	Shivpuri
	Betul
Madhya Pradesh	Dhar
	Raisen
	Sagar
	Shajapur
	Mandsaur
	Ratlam
	Satna
	Sheopur
	Akola
	Latur
	Satara
Maharashtra	Ratnagiri
	Osmanabad
	Jalgaon
	Sindhudurg
all and the second s	

Raigad
Beed
Hingoli

State	Districts
	Jalna
	Washim
Maharashtra	Gondia
	Dhule
	Solapur
Meghalaya	East Khasi Hills
Mizoram	Aizawl
	Cuttack
	Dhenkanal
	Jajapur
Odisha	Kalahandi
	Kendrapara
	Puri
	Sundargarh
Duducharra	Pondicherry
Puducherry	Mahe
Right States	Hoshiarpur
	Rupnagar
Punjab	Barnala
	Faridkot
	Fatehgarh Sahib

Sangrur
Kapurthala
Patiala
Sri Muktsar Sahib

State	Districts
	Churu
35	Dausa
	Alwar
	Dungarpur
641 . H	Ajmer
	Karauli
Rajasthan	Pali
	Pratapgarh
	Barmer
	Dholpur
	Nagaur
	Sikar
	Hanumangarh
	Thanjavur
	Tiruvannamalai
	Kanchipuram
Tamil Nadu	Sivaganga
	The Nilgiris
	Kallakurichi
	Ramanathapuram

	Perambalur
	Ariyalur
	Suryapet
Telangana	Adilabad
	Mahabubnagar

State	District
	Kamareddy
	Vikarabad
	Sangareddy
	Medak
	Khammam
	BhadradriKothagudem
	Jagitial
	Jangoan
Telangana	JayashankarBhupalapally
	KumuramBheemAsifabad
	Mulugu
	Peddapalli
	Nagarkurnool
	Mahabubabad
	RajannaSircilla
	Siddipet
Ггірига	Gomati
прита	North Tripura
Jttar Pradesh	Kanpur Nagar

Varanasi
Amroha
Hapur
Maharajganj
Pratapgarh
Rampur

State	District
	Bareilly
	Ghazipur
	Azamgarh
	Hathras
	Muzaffarnagar
	Jaunpur
	Kheri
	Auraiya
	Banda
Uttar Pradesh	Budaun
	Hardoi
	Kaushambi
	Mathura
	Mirzapur
	Rae Bareli
	Pilibhit
	Barabanki
	Bijnor

Prayagraj
Shahjahanpur
Etawah
Haridwar
Almora
PauriGarhwal
Kalimpong

State	District
	Jalpaiguri
	Hooghly
	Nadia
West Bengal	PaschimBardhaman
	Medinipur West
	24 Paraganas South
	Darjeeling