GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – COVID-19 Instructions for using GeneXpert / Truenat-beta-CoV in the private sector in Kerala - Orders issued.

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HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No. 726 /2020/H&FWD Dated, Thiruvananthapuram, 16 /04 /2020.

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ORDER

The following orders for testing COVID-19 using GeneXpert / Truenat-beta- CoV in the private sector in Kerala is issued.

- ICMR recommends the use of US-FDA approved closed real time RT PCR GeneXpert (Xpert-SARS-CoV2-Cartridges) tests as a confirmatory test for COVID-19 . These systems are approved under emergency use.
- In addition, Truenat -beta -CoV test on True lab workstation validated by ICMR is recommended as a screening (PCR) 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.

DESIGNATED TESTING FACILITY for doing Truenat/ GeneXpert tests:

1. Laboratory willing to perform these tests should send proper application to covpsnodnat@gmail.com. State will evaluate the application, conduct inspection by an expert team and sanction written approval for the same. Laboratories without written permission from State Government are not allowed to perform this test.
2. These tests should only be performed in laboratories with availability of a BSL-2/ BSL-3 setup and a functioning and calibrated Bio safety cabinet class 2A2/ 2B/ 3.

3. Laboratories shall perform the tests only through proper request from Designated sample collection facilities signed by a Registered Modern Medicine Practitioner with TCMC.

4. Laboratories must ensure a tie up facility for confirmation of tests/RT PCR Test laboratory in case of positive results in Truenat- beta -CoV.

5. The laboratory has to be registered in both the portals created for this purpose by the Government of Kerala and ICMR. Registration with Govt. of Kerala for COVID-19 testing can be obtained on request to the email mentioned above, with all required documents.

6. The laboratory shall report results of all persons tested to the Department of Health and Family Welfare, Govt. of Kerala through the on line portal on real time basis. The link to the on line portal shall be provided after registration. The nodal officer for the laboratory shall abide to this process and fill all the mandatory fields on real time basis.

7. Report shall also be uploaded on the on line portal of ICMR

8. The laboratory shall sign a Non-Disclosure Agreement and send a scanned copy for completion of registration. **Annexure-1**

9. Laboratory shall agree to verification of records by Local Public Health Authority anytime

DESIGNATED SAMPLE COLLECTION FACILITY

- Throat/Nasal swabs to be collected only at Government approved Designated Sample Collection Facility. On expression of interests from private hospitals, District Medical Officer will approve Designated Sample Collection Facility.
- Sample Collection Facility shall collect Samples ONLY as per eligibility criteria based on proper request from Registered Modern Medicine Practitioner with TCMC.
- Designated sample collection facility shall have designated vehicle for transporting suspects to and from home and facility for disinfecting vehicles. Facility shall also have rooms and ICUs for isolating suspects of COVID-19 and agree to follow the guidelines and protocols issued by Government of Kerala.

- Facility shall maintain Clinical Information Format (CIF) for all patients from whom samples have been collected and requests tests in prescribed formats with all information duly filled definitions attached as **Annexure 2.**
- The sample collection shall be done using the recommended Personal Protective Equipment (PPE).
- Sample collection sites shall be disinfected regularly as per recommended procedures. All recommended bio safety and biosecurity precautions shall be implemented.
- Sample transport to the COVID-19 testing laboratory shall be ensured under proper cold-chain conditions and with triple layered packing.
- Details of sample collection process and transportation are available as **Annexure 3.**

CRITERIA FOR PATIENT SELECTION

The patient/person should have a test request form for COVID-19 testing issued by a registered Modern medicine practitioner at Designated Sample Collection Facility. Registered Medical Practitioner should prescribe these tests only for the categories of patients recommended by Government of Kerala. Available at: https://dhs.kerala.gov.in/wp-content/uploads/2020/04/Advisory-Addendum-to-revised-Testing-Admissoin-discharge-srategy.pdf

a) All symptomatic individuals who have undertaken international travel in the last 14 days

b) All symptomatic contacts of laboratory confirmed cases

c) All symptomatic health care workers

d) All patients with Severe Acute Respiratory Illness (fever AND cough and/or shortness of breath)

e) 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

f) All symptomatic from locality/area where clustering of cases/community transmission have been reported in last 14 days.

g) All symptomatic who attended mass gatherings, festivals, funerals in last 14 days where people from abroad are likely to have attended

The test request should include details on which category the patient belongs to. Since the guidance evolves periodically the latest revised version is to be followed.

REPORTING OF THE TEST RESULTS:

1) The nodal officer of the laboratory shall ensure that *all the relevant* information are collected from the patient/ doctor requesting the test during the time of receipt of sample itself so that all the relevant data can be entered on the on line portal.

2) Test results shall be verified by the microbiologist/lab-in-charge at the designated private lab.

3) Details of all tests conducted and results must be entered on real time basis to the on-line portal of Department of Health and Family Welfare, Govt. of Kerala. The daily testing summary should be entered in the separate sheet provided in the link at 9 am every day for the number of samples received and tested the previous day (even if no tests were done).

4) Weekly utilisation certificates of Chips/cartridges need to be submitted every Saturday 6:00 PM.

5) The results (positive or negative) must not be disclosed to the patient by the laboratory. The results will be informed to the patient on the same day of reporting by the Department of Health and Family Welfare and take further necessary steps.

6) The District/Local Health authorities (District Surveillance Officer /Medical Officer Primary Health Centre) shall inform the patient/person and the treating physician and take appropriate public health action. Further testing, admission, isolation and quarantine shall be as per the existing guidelines for COVID-19 available at www.dhskerala.gov.in

7) The results shall be disclosed to the treating physician/ patient only after approval from the Department of Health and Family Welfare Govt. of Kerala.

8) Reporting to ICMR shall be as per ICMR guidelines.

RATE OF TEST:

The following directions were issued by the Honourable Supreme Court of India in Writ petition (civil) Diary No.(s).10816/2020 dated 13/04/2020.

(i) Free testing for COVID-19 shall be available to persons eligible under Ayushman Bharat Pradhan Mantri Jan Aarogya Yojana as already implemented by the Government of India, and any other category of economically weaker sections of the society as notified by the Government for free testing for COVID-19, hereinafter.

(ii) The Government of India, Ministry of Health and Family Welfare may consider as to whether any other categories of the weaker sections of the society e.g. workers belonging to low income groups in the informal sectors, beneficiaries of Direct Benefit Transfer, etc. apart from those covered under Ayushman Bharat Pradhan Mantri Jan Aarogya Yojana are also eligible for the benefit of free testing and issue appropriate guidelines in the above regard also within a period of one week.

(iii) The private Labs can continue to charge the payment for testing of COVID-19 from persons who are able to make payment of testing fee as fixed by ICMR.

(iv) The Government of India, Ministry of Health and Family Welfare may issue necessary guidelines for reimbursement of cost of free testing of COVID-19 undertaken by private Labs and necessary mechanism to defray expenses and reimbursement to the private Labs.

(v) Central Government to give appropriate publicity to the above, and its guidelines to ensure coverage to all those eligible.

For the Truenat test the charge is fixed as Rupees One thousand five hundred only per test as per the reference number F.No.Z.28015/23/2020-EMR Dated 21/3/2020 GOI Ministry of H&FWD. The Truenat test for BPL patients having Karunya Arogya Suraksha Padhathi (KASP) card will be done free of cost and the Private Labs may reimburse the cost from Karunya Arogya Suraksha Padhathi (KASP). Xpert-SARS-COV Test is not yet licensed for commercial use. The rate of Xpert-SARS-COV Test will be fixed on approval for commercial use. The directions of the Honourable Supreme Court, ICMR, Government of India and the State with regard to the rates are to be followed strictly.

ANNEXURE- 1: Non- Disclosure Form

DEPARTMENT OF HEALTH AND FAMILY WELFARE, GOVT. OF KERALA.

NON- DISCLOSURE AGREEMENT ON TESTING FOR COVID-19

I, ……(Name of Lab in Charge), …… ……. (Name and address of Lab), with registration number for Testing for COVID-19 …….. and NABL reg. no……., hereby declare that the results of the Testing for COVID-19 shall be disclosed to the patient/person who had undergone the test and the treating physician/referring practitioner only after approval from the Department of Health and Family Welfare, Government of Kerala.

I shall not disclose the results to any other person/ colleagues/ head of institution or any organization without the permission of the Department of Health and Family Welfare, Government of Kerala.

All necessary measures to ensure confidentiality, privacy and security of patient information shall be maintained. Good laboratory practices shall be ensured.

I hereby declare that I shall abide by all the stipulations of ICMR and Department of Health and Family Welfare, Government of Kerala.

Signature of Lab in Charge with date :_____

Name of Lab in Charge :_____

TCMC Registration:_____

Formal Address:_____

ANNEXURE-2: Definition of COVID suspect, High and Low risk contact.

COVID Suspect:

A patient with acute respiratory illness (fever and at least one sign/symptom of respiratory disease (e.g. cough, shortness of breath or diarrhoea), AND a history of travel to or residence in a country/area or territory reporting local transmission (See NCDC/WHO website for updated list) of COVlD-19 disease during the 14 days prior to symptom onset;

OR

A patient/health care worker with any acute respiratory illness AND having been in contact with a confirmed COVID-19 case in the last 14 days prior to onset of symptoms;

OR

A patient with severe acute respiratory infection {fever and at least one sign/symptom of respiratory disease (e.g. cough, shortness breath)} AND requiring hospitalization AND with no other etiology that fully explains the clinic presentation;

OR

A case for whom testing for COVID-19 infection is inconclusive

High Risk (HR) Contact:

1. Contact with a confirmed case of COVID-19.
2. Travellers who visited a hospital where COV1D-19 cases are being treated
3. Travel to a locality where active COVID-19 Community Spread is suspected or clustering of COVID-19 cases are detected in the last 14 days.
4. Touched body fluids of patients (respiratory tract secretions, blood, vomitus, saliva, urine, faeces).
5. Had direct physical contact with the body of the patient including physical examination without PPE.
6. Touched or cleaned the linens, clothes or dishes of the patient
7. Close contact, within 3 feet (1 metre) of the confirmed case
8. Co-passengers in an airplane /vehicle seated in the same row, 3 rows in front and behind of a confirmed COVID19 case

Low Risk (LR) Contact:

1. Shared the same space (same classroom/same room for work or similar activity and not having high risk exposure to the confirmed/suspected case)
2. Travel in the same environment (bus/train) but not having high risk exposure as cited above.
3. Any traveller from abroad not satisfying high risk criteria

ANNEXURE-3: GUIDE TO SAMPLE COLLECTION & TRANSPORTATION

Collection of samples

For initial diagnostic testing for COVID-19, an upper respiratory specimen is preferred. Nasopharyngeal specimen is the preferred choice for swab-based SARS-CoV-2 testing. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or b
- An anterior nares (nasal swab; NS) specimen collected by a healthcare professional

For NS, a single polyester swab with a plastic shaft should be used to sample both nares. NS or NMT swabs should be placed in a transport tube containing viral transport medium with virus lysis buffer provided along with the kit by the supplier.

If both NP and OP swabs both are collected, they should be combined in a single tube to maximize test sensitivity and limit testing resources

A. Upper respiratory tract

Nasopharyngeal (NP) swab/oropharyngeal (OP) swab

Use only synthetic fibre swabs with plastic shafts. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 mL of viral transport media. If both swabs are used, NP and OP specimens should be combined at collection into a single vial. OP swabs remain an acceptable specimen type.

Nasopharyngeal swab: Insert a swab into nostril parallel to the palate. Swab should reach depth equal to distance from nostrils to outer opening of the ear. Leave swab in place for several seconds to absorb secretions. Slowly remove swab while rotating it. *Oropharyngeal swab (e.g., throat swab):* Swab the posterior pharynx, avoiding the tongue.

B. Lower respiratory tract [Only if recommended by ICMR]

.Bronchoalveolar lavage, tracheal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Sputum

Have the patient rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Packing of Samples: Basic triple packaging system

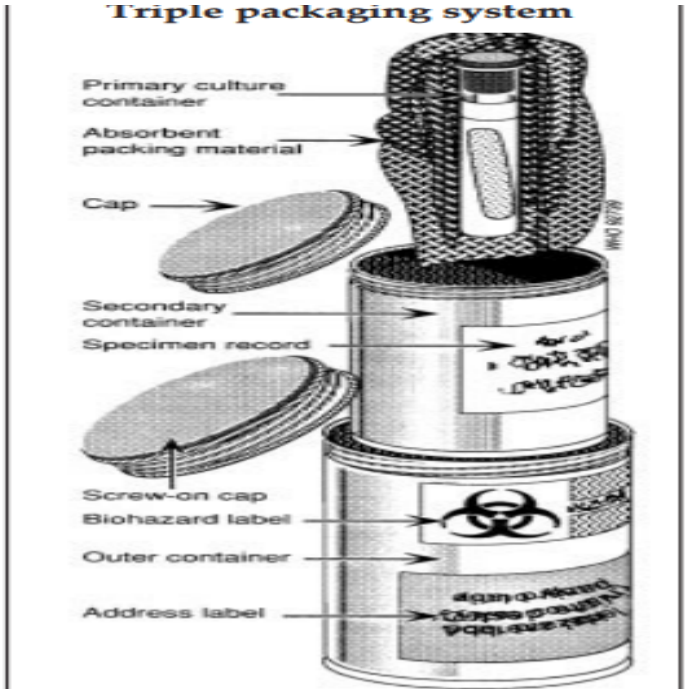
The system consists of three layers as follows.

1. Primary receptacle. A labelled primary watertight, leak-proof receptacle containing the specimen. The receptacle is wrapped in enough absorbent material to absorb all fluid in case of breakage.

2. Secondary receptacle. A second durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles may be placed in one secondary receptacle. Sufficient additional absorbent material must be used to cushion multiple primary receptacles.

The requisition form with patient details to be put in a self-lock cover and placed outside the second receptacle encompassing it.

3. Outer shipping package. The secondary receptacle is placed in an outer shipping package which protects it and its contents from outside influences such as physical damage and water while in transit.



Transportation and Storage of samples:

For transport of samples for viral detection, use VTM (viral transport medium)with virus lysis buffer provided along with the kit by the supplier.

Samples should be safely packed as described above and transported under cold chain (4°C) to the testing laboratory with prior intimation. Before dispatching the sample, disinfect the outer surface of container using 1: 100 dilution of bleach or 5% Lysol solution.

• Sample containing vials should be kept in good quality plastic bags tied with rubber bands so that inside material if leaks should not come out of bag. The plastic bag should be kept in another container which should be sealed with adhesive tape. This carrier should be placed in another plastic bag sealed with rubber bands and placed in thermocol / vaccine carrier containing ice. The case sheets with complete information should be placed in plastic bag and should be pasted outside the container.

• Samples should be transported at 4°C if they arrive at the laboratory with 48 hours; The sample must be stored at – 70°C if storage is required for longer periods.

• 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”** .

ANNEXURE 4. LINE LIST OF TESTS PERFORMED FOR ONLINE REPORTING

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q
1	DISTRICT	NAME OF THE LAB/INSITUTION	PATIENT CATEGORY: 1.A,1.B, 2A, 2B,2C	DATE OF TEST	NAME	AGE	SEX	OP/IP number if applicable	ADDRESS	DSITRICT OF RESIDENCE	PHONE NUMBER	NEAREST PHC AREA	VILLAGE	PANCHAYATH	Any Govt. Valid ID number	OCCUPATION	Special Category
2																	
3																	
4																	

	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	AD
1	OCCUPATION	Special Category	HEALTH CARE WORKER YES/NO	HISTORY OF TRAVEL OUTSIDE COUNTRY OR KERALA STATE SINCE MARCH 5, 2020 (YES/NO), MENTION PLACE(S)	WHETHER ARRIVED FROM ANY COUNTRY/STATE OR COVID AFFECTED AREA IN THE LAST 14 DAYS-YES/NO	IF YES MENTION PLACES OF TRAVEL	ANY CONTACT WITH A COVID SUSPECT OR CONFIRMED CASE (YES/NO)	WHETHER ON QUARANTINE (YES/NO)	SYMPTOMATIC OR ASYMPTOMATIC	DATE OF ONSET: MENTION SYMPTOMS;	NAME OF TEST KIT USED, WITH BATCH NUMBER	Result ([Positive/ Negtive/ Invalid/ Indeterminate)		IF ANY PREVIOUS TESTS FOR COVID WAS DONE; RESULT WITH DATE OF SAMPLE COLLECTION	Remarks

Annexure 5: LINK TO GUIDELINES

Revised guidelines for testing, quarantine, hospital admission and discharge:

https://dhs.kerala.gov.in/wp-content/uploads/2020/03/reg_12032020.pdf

Addendum to revised testing, quarantine, admission and discharge:

https://dhs.kerala.gov.in/wp-content/uploads/2020/04/Advisory-Addendum-to-revised-Testing-Admissoin-discharge-srategy.pdf

Interim treatment guidelines:

https://dhs.kerala.gov.in/wp-content/uploads/2020/03/interim_24032020.pdf

(BY ORDER OF THE GOVERNOR)
Dr. RAJAN KHOBRAGADE
Principal Secretary to Government

To

The Director of Medical Education, Thiruvananthapuram.
The Director of Health Services Thiruvananthapuram
All District Collectors
All District Medical Officers (through DHS)
The Director, IT Mission
The Managing Director, KMSCL, Thiruvananthapuram
The Drugs Controller, Thiruvananthapuram
Information and Public Relations (Web & New Media) Department.
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Section Officer.

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PS to Minister Health & Social Justice
Special Secretary to Chief Secretary
PA to Additional Chief Secretary Home & Vigilance
PA to Principal Secretary Planning and Economic Affairs
PA to Principal Secretary Health &Family Welfare