



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – COVID-19 Antibody Testing (IgG and IgM) in the private sector in Kerala - Orders issued.

HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.725/2020/H&FWD

Thiruvananthapuram, Dated 16/04 /2020.

Read: Advisory. No.31/F2/2020/H&FW dated 27/03/2020.

ORDER

In connection with the recent outbreak of the Pandemic COVID-19 the Government have issued advisory vide reference read above. In addition to the above Advisory the following order is issued for Antibody Testing (IgG and IgM) in the private sector in Kerala.

CRITERIA FOR SELECTING LABORATORIES TO CONDUCT COVID-19 ANTIBODY TEST:

1. The laboratory has to be NABL accredited for basic serology.
2. The laboratory must be recognized by ICMR for COVID-19 Antibody Testing.
3. 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, with all required documents. Requests are to be sent to covidpsnodedme@gmail.com.
4. The laboratory shall report results of persons tested to the Department of Health and Family Welfare, Govt. of Kerala through the online portal for real time reporting. The link to the on line portal shall be provided after registration. The nodal officer for the laboratory shall ensure this process.
5. The laboratory shall sign a Non-Disclosure Agreement and communication protocol and send a scanned copy for completion of registration as in **Annexure-1**.

CRITERIA FOR SELECTION OF ANTIBODY TEST KIT:

The test kits have to be recommended by ICMR. The list of approved antibody kits are available on ICMR, Govt. of India website <https://www.icmr.nic.in/content/covid-19>. Continue checking the ICMR website for updates.

The Drugs Controller of Kerala shall take random samples periodically to validate the antibody test kits used by the Private Laboratories for the screening of COVID-19 cases.

CRITERIA FOR PATIENT SELECTION FOR ANTIBODY TEST:

1. The patient/person should have a prescription for COVID-19 testing issued by a registered modern medicine practitioner with TCMC Kerala.

2. Tests may be performed on persons who have returned from foreign countries or the contact of persons returned from the foreign countries.
3. Tests may be performed on COVID-19 suspects or symptomatic high risk contacts that were negative by RT-PCR. The definition of COVID-19 suspects and High risk and Low risk are provided in **Annexure-2**.
4. Tests may be performed on high risk individuals like health care workers who work in COVID-19 designated treating facilities who are involved in providing direct care to COVID positive patients.
5. Tests may be done in a locality where a cluster of Severe Acute Respiratory Infection (SARI) cases without a diagnosis has been reported.
6. Tests may be performed on individuals who have recovered from SARI without a diagnosis.
7. Tests may be performed on asymptomatic direct and high-risk contacts, secondary contacts of a confirmed case.
8. Tests may be performed on persons who have participated in large migration gatherings / evacuees centres.
9. Tests may be performed on the symptomatic person who have attended mass gathering, festivals, funerals etc in the last fourteen days where people from abroad / COVID suspects or confirmed cases are likely to have attended.
10. Tests may be performed from locality / area where clustering of cases have been reported in the last fourteen days.

The prescription should include the exposure history to COVID-19 if any. Since the guidelines evolves periodically the latest revised version of the guidelines are to be followed.

WHEN TO TEST?

1. Ideally ANTIBODY TEST should be done 7 days after symptom onset in symptomatic cases.
2. Asymptomatic persons in home quarantine - ANTIBODY TEST should be done on 14th day of quarantine.
3. Asymptomatic health workers involved in direct COVID-19 care - At the end of mandatory quarantine period.
4. Asymptomatic direct and high-risk contacts of a confirmed case can be tested by antibody test 7-10 days after coming in his/her contact.
5. 7-14 days after participation in large gatherings, migrations, festivals, funerals, evacuees centres etc.

SAMPLE COLLECTION MECHANISM:

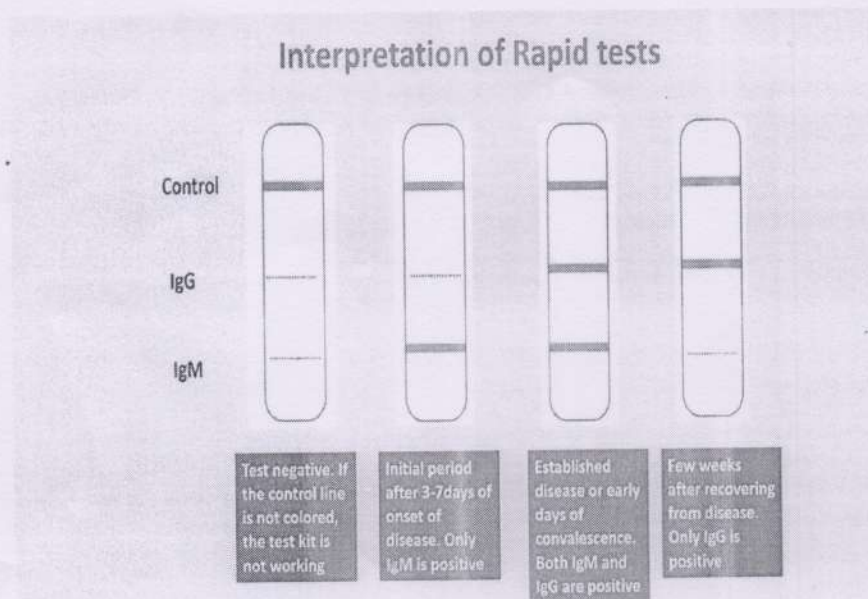
OPTION -1: Dedicated COVID-19 sample collection areas in laboratories/Hospitals are to be provided. These areas should be identified where there is plenty of natural cross ventilation (ideally 6-10 air exchanges per hour). Air conditioned rooms or air conditioned areas are **NOT** to be used for this purpose. There should be a proper queue management to avoid overcrowding and to maintain social distancing so as to reduce the chance of transmission. Health education should be given to the people coming to COVID-19 area in the Laboratory. Hand washing / hand sanitization facilities should be made available at the facility.

OPTION-2: Sample collection from homes. This method ensures that the samples are collected at the point where the patient/person is residing (home). A trained field team needs to be constituted for home collection from each testing laboratory. Prior communication needs to be provided to the person before field collection. All standard safety precautions

such as mask and PPE should be worn and Bio-Medical waste management protocols should be ensured.

The guide to the technical aspects of sample collection are given in **Annexure-3**.

INTERPRETATION OF TEST RESULT:



Please see the kit inserts of the kits used for further information.

REPORTING OF THE TEST RESULTS:

1. The nodal officer of the laboratory should ensure that all the relevant information is collected from the patient beforehand so that all the relevant data can be entered on the online portal- see **Annexure-4**.
2. ANTIBODY TEST results should be verified by the microbiologist/lab-in-charge at the designated private lab.
3. Test results both positive and negatives (IgG / and IgM) must be entered on real time basis to the online portal of Department of Health and Family Welfare, Govt. of Kerala, as demonstrated in **Annexure-4**. The daily testing summary should be entered in the separate sheet provided in the same link at 9 a.m. every day for the number of samples received and tested the previous day (even if no tests were done).
4. The results (positive or negative) must not be disclosed to the patient. The results will be informed to the patient on the same day of reporting by the Department of Health and Family Welfare and further necessary steps will be taken.
5. The District/Local Health authorities (District Surveillance Officer/Medical Officer of Primary Health Centre) shall inform the patient/person and the treating physician and take appropriate action. Further action, testing, admission, isolation and quarantine shall be as per the existing guidelines for COVID-19. Refer-**Annexure-5** Matrix for patient category, testing and follow up action.
6. The results should be disclosed to the treating physician only after approval from the Department of Health and Family Welfare Government of Kerala.
7. Reporting to ICMR should be as per ICMR guidelines.

RATE OF ANTIBODY 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 ANTIBODY TEST the charge is fixed as Rupees Eight Hundred only per patient as per the recommendation of the Sector Committee. The ANTIBODY 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). 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 RAPID ANTIBODY TESTING FOR COVID-19

I,(Name of Lab in Charge),
.....(Name and address of Lab), with ICMR
registration number for Rapid Antibody Test for COVID-19 and
NABL reg. no....., hereby declare that the results of
the Rapid Antibody Test 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 COVID-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 COVID-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

SAMPLE COLLECTION:

Blood sample collection should be undertaken by a trained phlebotomist (at a blood collection centre) wearing all standard PPE as per the guidelines (Ref: Sample Testing, Collection and Transportation Guidelines for laboratory Diagnosis of Novel Coronavirus infection- 1st February 2020, Health & Family Welfare Department, Govt. of Kerala) and maintaining adequate social distancing. 5 ml of blood is to be collected in vacutainers. Both serum and plasma are acceptable for testing. Clot activator tubes/red cap vacutainers to be used for serum collection. EDTA tubes (purple cap vacutainers) are to be used for plasma collection.

The needle used for collection has to be disposed as per Bio-Medical Waste management guidelines.

SAMPLE PROCESSING:

After sample collection, the tubes should be allowed to stand for 30 minutes and then centrifuged at 1200-1500 rpm for 10 minutes within one hour of sample collection. Transfer the serum/plasma into pre-labelled cryovials/serum vials. All standard precautions are to be taken by the lab technician while testing.

SAMPLE TESTING:

Samples are to be tested as per instructions in the kit insert accompanying the testing kit.

SAMPLE REPORTING AND INTERPRETATION:

After the recommended incubation period as per the kit insert, all kits have to be interpreted and reported by the Doctor/ Microbiologist.

DISPOSAL:

The used test kits, pipette tips, vacutainers, vials and negative serum/plasma after interpretation are to be disposed as per the Bio-medical waste management guidelines.

Disinfection of the work bench:

1% sodium hypochlorite must be used with a contact period of 15-20 minutes to disinfect the work benches.

Spill management:

Wear appropriate PPE. Cover the area immediately with absorbent material and flood the area with 1-2 % sodium hypochlorite for contact period of 15-20 minutes. The absorbent material is to be discarded in yellow bags. Then wipe, clean with disinfectant cleaning solution.

ANNEXURE-5: MATRIX FOR PATIENT CATEGORY, TESTING AND FOLLOW UP ACTION:

II	CATEGORY	SUB-CATEGORY	NATURE OF TESTING	ACTION POINT
1.	Symptomatic individuals	a. COVID SUSPECT	Do RT-PCR(current recommendation)	If RT-PCR Positive Treat it as COVID-19 case.
		b. Influenza Like Illness in general population NOT requiring hospitalization.	Rapid Antibody Test (After 7 days from onset of symptoms).	If RT PCR is Negative Rapid Antibody test can be used (After 7 days from onset of symptoms). If IgM Positive with or without IgG Treat as Probable COVID 19 If IgM Negative Isolate and repeat after 10 days of previous test. Only IgG Positive Immune from prior exposure
2.	Asymptomatic individuals	a. Health care workers involved in COVID-19 patient care	Rapid Antibody Test at end of mandatory quarantine period	Confirm with RTPCR. If RTPCR is not possible, put patient in home quarantine and repeat antibody test after 10 days. (-ve → non covid, +ve → probable COVID 19) Consider as probable COVID 19 and treat as per guidelines.
		b. Quarantined asymptomatic individuals	Rapid Antibody Test at the end of quarantine period	Do RT-PCR; if RT PCR Positive-treat as COVID-19, if negative 7 more days of isolation. Decision on period of quarantine as per risk stratification, refer guidelines.
		c. Non quarantined Asymptomatic direct and high-risk contacts, local contacts, others.	Rapid Antibody Test 7-10 days after suspected contact	Do RT-PCR; if RT PCR Positive-treat as COVID-19, if negative 7 more days of quarantine. Consider Immune and end period of quarantine Treat and isolate as Probable COVID 19. Quarantine based on exposure risk. Immune from prior exposure Treat and isolate as Probable COVID 19. Quarantine based on exposure risk. Immune from prior exposure

LINK TO GUIDELINES:**Advisory on using rapid antibody kits or COVID-19 diagnosis and****Surveillance:** https://dhs.kerala.gov.in/wp-content/uploads/2020/04/Advisory_Rapid-Test-.pdf.pdf**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-Admission-discharge-strategy.pdf>**Interim treatment guidelines:**https://dhs.kerala.gov.in/wp-content/uploads/2020/03/interim_24032020.pdf

(BY ORDER OF THE GOVERNOR)

Dr. RAJAN KHOBRADE

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 Director of Health Services)

The Director, IT Mission

The Managing Director, KMSCL, Thiruvananthapuram

The Drugs Controller, Thiruvananthapuram

The Information and Public Relations (Web & New Media) Department.

Stock File/Office Copy.

Forwarded/By Order



Section Officer.

Copy to : PS to Chief Minister

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 Department