



## GOVERNMENT OF KERALA

Abstract

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

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### HEALTH & FAMILY WELFARE (F) DEPARTMENT

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

Thiruvananthapuram, Dated 16/04 /2020.

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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](mailto: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.

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 14<sup>th</sup> 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:**

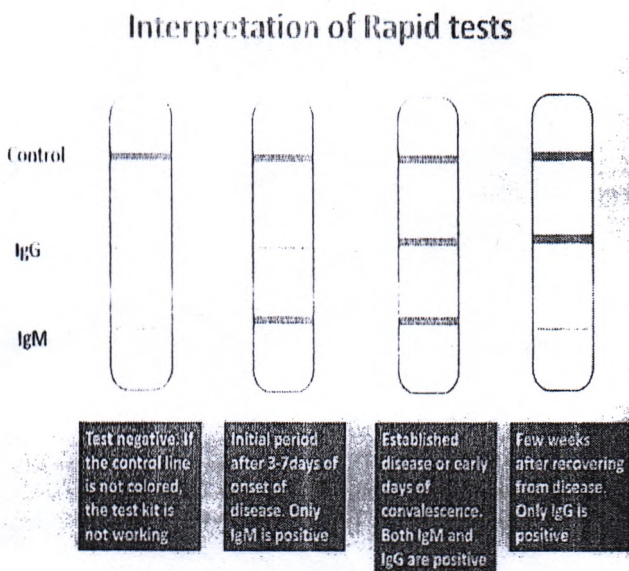
**OPTION -1:** Dedicated COVID-19 sample collection areas in laboratories/Hospitals are to be provided. These areas should be identified where there is plenty of natural cross ventilation (ideally 6-10 air exchanges per hour). Air conditioned rooms or air conditioned areas are **NOT** to be used for 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. (c) 10316/2020 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.