GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – Antigen Test – Fixing of cost per test in Private Sector – Sanction accorded – Orders issued.

HEALTH &FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.1295/2020/H&FWD Dated,Thiruvananthapuram, 15/07/2020

Read 1 Advisory issued by ICMR dated 23/6/2020

2 G.O(Rt) No. 1236/2020/H&FWD Dated 2/7/2020

ORDER

In order to augment the testing through Private Laboratories, Government as per the ICMR guidelines had already given permission to the Laboratories and Private Hospitals to do COVID testing. Government have given permission for RTPCR, XpertNAT, TrueNAT tests and fixed the costs as per the GO read as 2nd paper above.

As per the paper read as 1st above, the ICMR has recommended rapid point of care antigen detection test for diagnosis of COVID-19. This is a point of care rapid chromatographic immunoassay for qualitative detection of specific antigens to SARS-CoV-2. The assay approved at present by Indian Council of Medical Research (ICMR) is known as “Standard Q COVID-19 Ag kit” to detect Covid -19 infection.

Government after examining the matter in detail are pleased to give permission to Private Laboratories approved by the ICMR for Antigen testing by fixing the cost at Rs.625/- per test for those Private

Laboratories / Private Hospitals complied with the detailed guidelines for Antigen testing.

Detailed guidelines for the Antigen testing is appended as Annexure 1 and non-disclosure agreement as Annexure 2.

(By order of the Governor)
RAJAN NAMDEV KHOBRAGADE
PRINCIPAL SECRETARY

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 Drugs Controller, Thiruvananthapuram
The I&PRD(Web&New Media) Department
Stock File / Office Copy

Forwarded /By order

Section Officer

Annexure 1

1. **CRITERIA FOR HOSPITALS AND LABORATORIES**

The private hospital/private laboratory should meet the following criteria for conducting rapid point of care antigen detection test:

1. National Accreditation Board for Hospitals & Healthcare (NABH) accreditation
2. National Accreditation Board for Laboratories (NABL) accreditation
3. ICMR registration as a COVID-19 testing Lab
4. Registration and approval from the Department of Health and Family Welfare, Govt. of Kerala

2. **REGISTRATION PROCESS AND ADMINISTRATION**

Registration with Indian Council of Medical Research (ICMR)

The registration and approval with ICMR can be obtained on request. Institutions may send their request on the following email id's: The login credentials for data entry can be obtained from ICMR. The requests are to be sent to the following email ID:

ag-pvthosp-nabh@icmr.gov.in

All data of testing needs to be entered into the ICMR portal on a real time basis. Detailed video is available on ICMR website at http://www.icmr.gov.in/video/Data_Entry_Antigen_v4.mp4.

Registration with Department of Health and Family Welfare, Govt. of Kerala

The registration and approval from Department of Health and Family Welfare, Govt. of Kerala can be obtained on request through the following email ID:

covidpsnodedme@gmail.com

The following valid documents (scanned copy) are to be attached with the email request for the purpose of approval:

1. National Accreditation Board for Hospitals & Healthcare (NABH) accreditation

2. National Accreditation Board for Laboratories (NABL) accreditation
3. ICMR registration and approval as a COVID-19 testing Lab
4. Non-Disclosure agreement provided in the annexure-2
5. MoU with the nearest ICMR approved RT-PCR COVID-19 testing laboratory for testing symptomatic patients tested negative
6. Details of Nodal Person liaising with the State Government.

Administration

A Medical Officer (Nodal person) should be identified for the Hospital/Laboratory for the purpose of administration and communications. He/she shall liaison with ICMR and the State Government and act as the nodal person for the purpose of testing in their institution. The nodal person shall sign the non-disclosure agreement and the MoU with the lab having RT-PCR testing facility on behalf of the private Hospital/Laboratory

1. **SAMPLE COLLECTION AND TESTING**

Eligibility of persons/patients

The persons/patients should have a prescription from a registered medical practitioner for COVID-19 testing.

Dedicated COVID-19 sample collection corners (COVID Corner) in Laboratories/Hospitals are to be provided. A Walk in Sample Kiosks (WISK) model may be applied to facilitate safer sampling process. These areas should be identified where there is plenty of natural cross ventilation (ideally 6-10 air exchanges per hour). Air-conditioned rooms or 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 reduce the chance of transmission. Health education should be given to the people coming to COVID corner. Hand washing / hand sanitization facilities should be provided at the facility. All transmission-based precautions such as mask and PPE should be worn and Bio-Medical waste management protocols followed. Stigmatization of persons should not be done. Sample collection from patients/persons at home

and having prescription may be undertaken by **trained** field teams. A Mobile sample collection unit may be developed for the purpose. Prior communication needs to be provided to the persons before home/field collection.

The nodal person shall conduct necessary training to all the staff concerned in the process.

Testing

ONLY a nasopharyngeal swab should be taken for rapid antigen-based test using standard Q Ag-kit. Each test kit comes with an in built COVID antigen test device, viral extraction tube with viral lysis buffer and sterile swab for sample collection. The swab should be immersed and squeezed in the viral extraction buffer, provided with the kit. This buffer inactivates the virus thereby reducing biosafety and biosecurity requirements. The test does not work if the sample is collected in the usual Viral Transport Media (VTM), routinely used for collection of OP/NP swabs. The usual VTM or Modified VTM should not be used for sample collection. Once the sample goes into the extraction buffer, it should be mixed properly and the buffer tube cap needs to be replaced with a nozzle provided with the kit and 2-3 drops of the sample with buffer are to be put into the well of the test strip. The test can be interpreted as positive or negative after 15 minutes of putting the sample into the well by appearance of test and control lines, which can be read with a naked eye, requiring no specialized equipment. Maximum duration for interpreting a positive or negative test is 30 minutes. The results should be interpreted by a Senior Lab Technician/ Microbiologist/ Medical Doctor.

Further details can be obtained from the ICMR website:
https://www.icmr.gov.in/pdf/covid/strategy/Advisory_for_rapid_antigen_test14062020.pdf

Good Laboratory practices shall be observed throughout the process of sample collection and testing.

1. **INTERPRETATION OF TEST RESULTS**

All positive samples are to be treated as confirmed cases and manged as per the existing guidelines. Reconfirmation of the positive results with other tests is not required.

If the sample is negative in a **symptomatic person,** RT-PCR should be

performed on a fresh sample from the patient. All COVID suspects to complete their quarantine period even if the test result is negative.

2. REPORTING OF RESULTS

The results are to be reported online **and** real time, both to ICMR as well to the Department of Health and Family Welfare, Govt. of Kerala. The results are to be provided to ICMR using the credentials provided to them while registering with ICMR.

The results shall be reported to Department of Health and Family Welfare, Govt. of Kerala using the link https://healthmon.kerala.gov.in/rapidtest/#

The Private hospital/ Lab have to register themselves using the link above under "COVID-19 RAPID ANTIGEN ASSAY" and further approval and guidance shall be provided to the nodal person. All individual results of the tests conducted and the daily summary should be entered.

The results are to be reported to the referring registered Medical practitioner in the prescribed format provided by the Department of Health and Family Welfare, Govt. of Kerala.

Confidentiality and security of the data should be ensured

Annexure 2

DEPARTMENT OF HEALTH AND FAMILY WELFARE, GOVT. OF KERALA

Non-Disclosure Agreement On Rapid Point-of-Care Antigen Detection Test For COVID-19

I, …… (Nodal Officer) ……
……(Name and address of the Institution/ Laboratory) with ICMR Registration number for RAPID Point-of-care Antigen Detection Test for COVID-19 ……., hereby declare that the results of RAPID Point-of-care Antigen Detection Test for COVID-19 shall be disclosed to the patient/person/customer and the treating physician/ referring medical practitioner only after approval from the authorised personnel from the Department of Health and Family welfare, Government of Kerala.

The results will not be disclosed to any other person/ colleagues/head of institution or any organisation without the permission of the Department of Health and Family Welfare, Government of Kerala.

Good Clinical and 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 Nodal Officer with Date ……..

Name of the Nodal Officer ……

Formal Address……

Mail id.....

Mobile number.....