



GOVERNMENT OF KERALA

Abstract

Health & Family Welfare Department – COVID-19 Guidelines for conducting tests to identify community transmission -Orders issued.

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HEALTH & FAMILY WELFARE (F) DEPARTMENT

G.O.(Rt)No.709/2020/H&FWD Dated,Thiruvananthapuram, 11/04/2020

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ORDER

In connection with the recent out break of the Pandemic COVID-19 in the State of Kerala the Government have decided to identify the Community transmission of the disease and herd immunity in the population in the state. Accordingly the following guidelines are-issued for the conduct of community transmission.

Objective of the Testing Strategy:

To identify community transmission of COVID-19 in the population.

Management of the Antibodies testing:

The District Collector shall be over all charge of the implementation in the district regarding the logistics, sample selection mentioned below.

The ADHS Public Health and the District Surveillance Officers (COVID19) in the districts shall be responsible for the technical aspects regarding sample collection and testing and record keeping.

1) Selection criteria and priority grouping for Rapid Antibody Testing:

Priority group 1: All patient handlers among the health staff - doctors, nurses, paramedics and all those who are in direct contact with confirmed/potential patients. 25,000 kits shall be used to test this priority group. This group is further divided into two :

1. Healthcare personnel who have directly handled patients who were confirmed positive for infection using the RT-PCR based confirmatory test.

All personnel in the state belonging to this category must be tested.

10,000 kits shall be used for this category.

The kits must be divided among the 14 districts based on the actual numbers of such healthcare personnel, and the Director of Health Services (DHS) shall provide a district-wise list of such personnel to DSO to assist the District Collector for sample selection.

The kits shall be distributed to the districts based on this list.

The District Surveillance Officer (DSO) shall be responsible for the successful conduct of these tests.

The Sero-surveillance team for the district shall do appropriate arrangement regarding collecting samples from the respective institutions from the list of healthcare personnel prepared at the district-level.

2. Healthcare personnel working in healthcare institutions that DO NOT deal with RT-PCR confirmed positive patients.

Randomised samples of healthcare working in such institutions shall be drawn and tested.

15,000 kits shall be used in this category.

Test kits shall be distributed to the districts in the proportion of positive cases that each district has.

The DSO of each district shall be responsible for the implementation of these tests.

The DSO shall draw a random sample of Primary Health Centers (PHCs), Community Health Centers (CHCs), Taluk Headquarters Hospitals (THQs), District Hospitals (DHs) and General Hospitals (GHs) in the district in the proportion of the actual distribution of these various healthcare institutions in each district.

Test kits shall then be distributed to these institutions in the following numbers:

PHCs: 5 test kits per PHC.

CHCs: 10 test kits per CHC.

THQs, DHs, GHs: 20 test kits per institution.

A randomised sample of healthcare personnel at each institution shall be drawn by the head of each institution with equal numbers representing the following three categories:

Doctors, Nurses, Other healthcare personnel

The Sero-surveillance team for the district shall visit each of these institutions and collect samples from healthcare personnel thus selected.

Priority group 2: 25,000 kits shall be used to test this priority group.

A. Government/associated functionaries with maximum public contact - policemen on enforcement duty, field-level health workers, personnel deployed by the Local Self Government Department, Anganwadi Workers.

20,000 kits shall be used for this purpose.

The District Collectors of various districts shall be responsible for the implementation of this phase of testing.

The kits shall be divided equally among the 14 districts. (approx. 1800 kits per district).

The kits sent to each district shall be used to test the various field-level functionaries in the following proportion:

Police personnel: 500 Kits

Health workers: 500 kits

LSGD functionaries: 500 kits

Anganwadi workers: 300 kits

The District Collector shall draw a randomised list of these personnel in consultation with the District Police Chief, the District Medical Officer, the Deputy Director of Panchayats and the District Women and Child Officer.

The District Collector shall ensure that there is a reasonably uniform representation from personnel across the district.

These randomly selected personnel shall report to the nearest Taluk Headquarters Hospital (THQH) for testing.

The Sero-surveillance team for the district shall, in consultation with the District Collector and DSO, develop a staggered schedule for testing so as to complete all such taluk-level testing camps within the minimum possible time.

The Sero-surveillance team shall travel to each such designated THQH according to this schedule so as to complete sample collection from one taluk per day.

- B. Special categories from among the public with maximum exposure.**
 Persons belonging to this category shall be classified into three groups:
- (i) Persons working at ration shops.
 - (ii) Persons involved in delivering food and grocery.
 - (iii) Persons involved in running community kitchens.

5000 kits shall be used for this purpose. The kits shall be equally distributed among all 14 districts (approx. 350 kits per district). The District Collector of each district shall be responsible for the implementation of this phase of testing.

The District Collector shall identify a list of persons belonging to these categories in consultation with the Deputy Director of Panchayats, the District Supply Officer and representatives of delivery services such as Swiggy and Zomato.

The selected persons shall be intimated to come to the District Hospital/General Hospital on a certain date and time (to be decided in consultation with the DMO).

The Sero-surveillance team for each district shall visit this center at the pre-fixed time and collect samples.

Priority group 3:

Persons put under home quarantine. 25,000 kits shall be used for this purpose.

The kits shall be distributed in the proportion of the number of quarantined persons in each district, and this number shall be computed by the Health Department, and kits distributed to various districts in this proportion.

The District Surveillance Officer of each district shall be responsible for this phase of the testing process.

The DSO shall draw a random sample of quarantined persons from the total list of quarantined persons in the district, so as to maintain an equal distribution of kits across panchayats.

The Sero-surveillance team for each district shall then visit each of these persons at their homes and collect samples for testing. The team shall prepare a Block-wise route map to complete the sample collection process within the minimum possible time and ensuring maximum efficiency.

Priority group 4:

Vulnerable sections of the population - persons above 60 years of age.

A random sample of persons belonging to this category shall be tested in each district.

20,000 kits shall be used for this purpose.

The Director of Social Justice shall prepare a district-wise list of persons above 60 years of age and the available test kits shall be distributed among various districts in this proportion.

The concerned District Collector shall draw a random sample of individuals belonging to this category using this list and maintaining an equal distribution of kits across panchayats.

The Sero-surveillance team for each district shall then visit each of these persons at their homes and collect samples for testing. The team shall prepare a Block-wise route map to complete the sample collection process within the minimum possible time and ensuring maximum efficiency.

2) Serological Surveillance of SARS-COV-2 using Antibody Tests - Guidelines for Validation

With the arrival of 1,00,000 kits of the Antibody detection kits, it is important to first validate the accuracy of these kits in the Kerala setting. This process will be important in understanding the applicability of these tests as a complimentary tool to actual diagnosis of the infection/illness using the approved technique of RT-PCR. The process of validation involves using these kits in patients who have already been confirmed to have the infection using the RT-PCR and are at various stages of the illness, as well as on persons who can be considered to be at high risk of contracting/having contracted the infection from these confirmed positive patients. 5000 kits shall be used for this purpose.

1. For the purpose of validation, the target population mentioned above can be classified into five categories so as to aid the interpretation of the results of the antibody test. For this purpose, it is important to correlate serological findings with the various stages of the infection/illness. Persons belonging to this target group can be divided into FIVE categories:
 - a. Cat-1: PCR-positive Cured/Recovered Patients
 - b. Cat-2: PCR-positive Extremely Ill Patients in ICU
 - c. Cat-3: PCR-positive Moderately Ill Patient
 - d. Cat-4: PCR-positive Mildly Ill Patients (Early diagnosed)
 - e. Cat-5: PCR-negative/undiagnosed Close Primary Contacts of PCR-positive patients. This category can be further classified into the following three sub-categories:
 - i. Persons with first contact less than 7 days ago
 - ii. Persons with first contact between 7 and 14 days
 - iii. Persons with first contact more than 14 days ago
2. All PCR-positive patients in the state shall be included in the validation study.
3. The number of persons belonging to the fifth category shall be 25% of the total PCR-positive patients in Kerala. They shall be equally divided into the three sub-categories.
4. A line list of the above mentioned persons shall be finalised and provided by the Director of Health Services.
5. All persons in the fifth category (PCR-negative/undiagnosed Close Primary Contacts) who are detected positive using the Antibody test shall be subjected to the RT_PCR test to confirm presence of infection.
6. A Sero-surveillance team shall be formed for each district by the concerned District Medical Officer. This Sero-surveillance team shall consist of the following members appointed by the DMO from Health Department personnel belonging to each district:
 - a. One doctor
 - b. One nurse (with added experience in collecting a pharyngeal swab for PCR analysis)
 - c. One lab technician to perform the Antibody test
 - d. One assistant
 - e. One driver

7. The DMO shall provide a vehicle for the team to visit the selected individuals at their respective healthcare facilities/homes for sample collection.
8. The DMO shall ensure that the team is equipped with adequate protective equipment (PPEs, N95 masks etc.) and are trained to use them properly.
9. The team will visit the concerned healthcare institution/home and draw blood into pre-marked/barcoded vials.
10. The DMO shall provide the team with adequate equipment/material for sample collection as well as for safe transportation of the samples to a central facility in the district.
11. The collected samples must be tested by the lab technician at a central facility in the district, arranged for by the DMO.
12. The IT Mission shall provide a Bar-coding system to each team to ensure that the samples collected are de-identified to ensure the privacy and anonymity of the person.
13. The IT Mission shall also provide an IT platform (mobile app etc.) for the team to directly input details related to sample collection into the application, as well as to record along with the sample details a brief clinical history of the concerned person.
14. The doctor on the team shall record an accurate clinical history of the person is on this application, along with supervising the sample collection process and accurate entry of details related to this on the application.
15. In the case that a Cat-5 (PCR-negative/undiagnosed Close Primary Contact) is detected to be positive for Antibodies upon performing the Antibody test, the team shall return to the home/institution of the person and collect a pharyngeal swab sample. The doctor shall oversee proper conduct of this process, after which the sample shall be sent to the nearest/pre-assigned government lab specifically designated to perform a PCR test for diagnosis of COV-2 infection.
16. The result of such a test shall be followed up by the doctor and entered accurately on the IT platform.
17. Upon completion of this process in every district, the results shall be passed on to a Validation Committee. This committee shall be specifically constituted for this purpose by the Health Department, and shall consist of:
 - a. One Infectious Disease expert
 - b. One Epidemiologist
 - c. One Microbiologist

The results of the validation process, along with the interpretations and conclusions drawn by the Validation Committee shall be confidentially submitted to the Health Department, which shall then use these recommendations to design a protocol for the interpretation of the results of this Antibody test that on further selected cohorts. These testing protocols should be in adherence to the general guidelines laid down for Antibody based rapid testing issued by the

Department of Health and Family Welfare, Government of Kerala on 27th March 2020 vide circular no. 31/F2/2020/Health.

3) Sero-surveillance teams:

Separate District-level dedicated Sero-surveillance teams shall be formed for each of priority groups. These Sero-surveillance teams shall be formed for each district by the concerned District Medical Officer. Each Sero-surveillance team shall consist of the following members appointed by the DMO from Health Department personnel belonging to each district:

One doctor

One nurse (with added experience in collecting a pharyngeal swab for PCR analysis)

One lab technician to perform the Antibody Test

One Assistant

One Driver

The DMO shall provide a vehicle for each team to visit the selected individuals/groups at their respective healthcare facilities/homes for sample collection. The DMO shall ensure that the team is equipped with adequate protective equipment (PPEs, N95 masks etc.) and are trained to use them properly. The DMO shall provide the team with adequate equipment/material for sample collection as well as for safe transportation of the samples to a central facility in the district.

The team will visit the concerned healthcare institution/home and draw blood into pre-marked/barcoded vials. The collected samples must be tested by the lab technician in the respective Sero-surveillance team at a central facility in the district, arranged for by the DMO.

4. Role of IT Mission:

The IT Mission shall provide a Bar-coding system to each team to ensure that the samples collected are de-identified to ensure the privacy and anonymity of the person. The IT Mission shall also provide an IT platform (mobile app etc.) for the team to directly input details related to sample collection into the IT based application and ensure real-time and accurate collection of data which is in sync with Covid Tracker dashboard.

The access to the IT Platform system shall be limited and appropriately decided by the Department of Health & Family Welfare.

5. District Nodal Team:

A District Nodal Team shall be formed to monitor and ensure the smooth functioning of the Antibody-based testing process for the whole district. This team shall report the daily activities of the program to the District Collector and DMO. The District-level Nodal team shall be formed by the respective DMO, and shall comprise of:

1. One doctor
2. One health inspector
3. One data entry operator/technical assistant provided by the IT Mission

6. Role of District Collector:

The District Collector and District Surveillance Officer shall work together to ensure that the testing process is without glitches, and work to provide all necessary facilities to the Sero-surveillance teams. They shall ensure the following:

1. Selection of subjects

2. Appointment of personnel
3. Provision of vehicles for transportation
4. Facility for storage of kits
5. Provision of protective equipment and sample collection material in adequate quantities
6. Training of Sero-surveillance teams
7. Coordinating NIC/data entry teams
8. Timely and accurate data entry onto IT platform

All District Collectors shall prepare a District Testing Plan based on this and report to Addl DHS Public Health within 7 days of receiving instruction to do so.

7) Roles and responsibilities of Addl Director Health Services (Public Health):

Addl DHS Public Health will do follow up with all the stake holders and the district teams to ensure that the Antibodies testing is done as per the medical protocol by taking all the precautions and measures especially during sample collection, transportation and testing.

Addl DHS shall conduct a training of all the district teams, provide them the guidelines for conduct of the testing and reporting protocol.

Addl DHS shall prepare the MIS for monitoring the progress.

Addl DHS shall submit a daily report at 9 pm to Principal Secretary Health and Family Welfare.

8) Custodian and District Sero-Surveillance Team:

The custodian of the kits shall be the District Supply Officer (DSO). The DSO shall constitute a district level team (District Sero-Surveillance Team, DSST) with the District Laboratory Technician (DLT) as the team leader for the purpose of management and use of rapid antibody test kits. Stock position and separate register to be maintained by the District Laboratory Technician (DLT). The DLT shall take an active role in the management of rapid antibody testing including organization of testing at the community level (priority groups 1-4). The DSST should also constitute a field team consisting of a Doctor (1), Nurse (1), Lab technician (1), Assistant (1) and a driver. The number of DSST field teams can be decided by the DMO based on the available human resources. The District Medical Officer (DMO) and District Program Manager (DPM) should ensure that the teams are allocated an ambulance/ vehicle for mobility as and when required by the team.

The DMO and DPM shall ensure that adequate resources are provided to the DSST for the activities.

9) Process: The blood collection and testing should be performed by the DSST as per the annexure -1

10) Record keeping & Reporting:

1. The details of utilization shall be kept and updated daily by the DLT. The details of utilization are also to be kept at the point of testing wherever applicable by the nodal person/ superintendent/MO in charge/ Lab Technician in hospitals.
2. Where ever the Rapid kits are being done basic epidemiological and clinical features needs to be collected on the IT platform provided. The **DLT /superintendents/ MO** In charge shall ensure this process.

11) Follow up action

1. The follow up action for positive patients are as per the annexure-2.
2. The tests should be offered free of cost.

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 vaccutainers. Both serum and plasma are acceptable for testing. Clot activator tubes/red cap vaccutainers to be used for serum collection. EDTA tubes (purple cap vaccutainers) 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 MO/ Doctor/ Microbiologist.

DISPOSAL:

The used test kits, pipette tips, vaccutainers, 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 2

Priority Group	Category of Subjects	Nature of Testing	Action Points	
Priority groups 1-4	a. Priority group-1	Rapid Antibody Test at end of mandatory quarantine period	IgM Positive	Do RT-PCR; if RT PCR Positive-treat as COVID-19, if negative 7 more days of isolation.
			IgM & IgG Negative	Decision on period of quarantine as per risk stratification.
			IgM & IgG positive	Do RT-PCR; if RT PCR Positive-treat as COVID-19, if negative 7 more days of quarantine.
			IgM Negative & IgG Positive	Consider Immune and end period of quarantine
	b. Priority groups 2, 3, 4.	Rapid Antibody Test	IgM Positive with or without IgG	Treat and isolate as Probable COVID 19.
			IgM Negative	Quarantine based on exposure risk.
			Only IgG Positive	Immune from prior exposure.

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

To

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

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