**COVID-19 Outbreak Control and Prevention State Cell**

**Health & Family Welfare Department**

**Government of Kerala**

## Advisory on using Chemiluminescent Immunoassay (CLIA) based serology test in Containment Zone (MALAPPURAM DISTRICT)

No 31/ F2/2020/ Health- 28th June2020

### Background

Sentinel Surveillance system using RT PCR has been established by Government of Kerala to detect community transmissions and to pick up early warning signals. Antibody based sero surveillance is also established to widely test selected groups in the community. In containment zones where cases have been picked up through sentinel surveillance, additional surveillance activity are essential for gaining deeper insights to epidemiology of the transmission.

Immunoassay tests are intended for qualitative detection of antibodies to SARS-CoV-2 in human serum. The test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The CLIA based serology test has an overall specificity greater than 99.8% and overall sensitivity of 100% in detection of antibodies including IgG (14 days post-PCR confirmation). The high specificity of the test is crucial to determine reliably if a person has been exposed to the virus and if the patient has developed antibodies.

**Objective**: To detect any local transmission in specific containment zones

To provide epidemiological insights at specific clusters and trace the source when required.

**Setting:** The samples are to be collected from the population described below from the Containment Zones and buffer zones identified by the district authorities based on the recent epidemiology.

**Description of population**

Samples need to be collected from the following groups of people in clusters where confirmed COVID cases are found through sentinel surveillance.

**Group 1:** All Primary and Secondary Contacts of the confirmed COVID cases who came in contact with the case in last 14 days from the day of symptom onset of case till the period of isolation. (500 Numbers)

**Group 2**: People with high social exposure in the cluster containment zones (500 Numbers)

These include ASHA, LSG volunteers, Policemen, Local shop vendors, Peoples representatives etc.

**Group 3**: Vulnerable sections of the population- above 60 years in the cluster containment zones. (250 Numbers)

**Group 4**: Health care workers including field staff in public and private sector in cluster containment zones (250 Numbers)

DSO may decide number of tests to be used in each containment zones depending on the number of containment zones and number of contacts traced. Epidemiological Investigation team to technically support the DSO in sampling. 500 kits are reserved exclusively for epidemiological investigation.

The numbers of sample are indicative. It may be appropriately decided. The first batch of 1000 samples may be collected. Based of the results, next batch of 1000 tests should be done.

**Sample Collection**

5ml of blood sample should be collected from every identified individual in red cap vacutainers/clot activater tubes (for serum) or purple capped/EDTA vacutainers (for plasma)

A trained team including Lab Technician need to collect the samples following all standard precautions and additional precautions for COVID.

The samples are to be **labelled** using unique identifiers as follows.

(**LSG name** /CLIA/DATE/SAMPLE number). Eg: **Perinthalmanna** /CLIA/ 28-06-2020/004

**PACKING, STORAGE AND TRANSPORTAITON**

The labelled samples shall be packed and stored in **COLD CHAIN** to ensure no spillage and to maintain adequate temperate 2-8$^0$ C. The samples shall be transported in cold chain to the designated laboratory provided in the **annexure-1** through the DSO.

**TESTING:**

The Designated Laboratory shall receive the samples sent from the health facility and allow serum separation by allowing blood sample to stand still for 30 minutes or by centrifugation at 1200-1500 rpm for 10 minutes. Laboratory need to run the current CLIA test on Roche's cobas e analysers. 20 microlitre/12 microlitre of the serum so separated is to be tested using CLIA Based antibody kits for SARS CoV2 observing good laboratory practices based on the equipment available (20µl for cobas e 411 analyser and cobas e 601/602 modules; 12 µl for cobas e 801 module). The remaining serum from positive samples are to be transferred to cryovials and stored in deep freezers at -20C in facilities as decided by DSO for future use. The laboratory should be well equipped for spill management with 1-2% of sodium hypochlorite(contact time of 15-20 minutes).

**Designated Laboratory for Malappuram District:**

1. Govt. Medical College Kozhikode

**Recording and Reporting:**

Report all tests in antibody test reporting healthmon.kerala portal/ antibody under the heading Immunoassay.

**Administration & Management**

The DMO Malapuram shall supervise the implementation of the serosurveillance activity. The COVID District Surveillance Officers (COVID-DSOs) shall co-ordinate, implement and follow up the activity with the laboratory. The Laboratory Technician (LT) at MCH Kozhikode shall supervise, monitor and maintain stock and logistics.

**Principal Secretary**

**Annexure 1**

**Government of Kerala**

**COVID-19 SEROSURVEILLANCE USING CLIA ANTIBODY TEST FOR COVID-19**

**SAMPLE ID NO: _____/CLIA/ _____ /_____** (LSG name /CLIA/DATE/SAMPLE NO.)

[ eg. Perinthalmanna /CLIA/ 18-04-2020/ 004]

| | | |
|---|---|---|
| **Name** | | **LSG** |
| **Age:** | | **Gender: Male/ Female/ Other** |
| **Phone Number** | | |
| **District** | | |
| **Address** | | |

a. Symptomatic: Yes/No
b. If Yes: Date of onset of symptoms:_____
c. Has the person come to kerala from outside Kerala/Country in last 14 days. Yes/NO.....
c. Has the person travelled outside the **containment zone in the last 14 days**: Yes/No
d. If yes:_____
e. Contact with any **COVID suspect**: Yes/No
f. Has the person previously been diagnosed with COVID-19: Yes/No

| | **Category** | **Details/ Remarks** |
|---|---|---|
| 1 | Contacts | Primary Contact<br>Secondary Contact |
| 2 | People with high social exposure | Occupation:..... |
| 3 | Vulnerable Individuals | - |
| 4 | Health Care Workers | Place of work:..... |