COVID-19 LABORATORY TEST STRATEGY IN SRI LANKA
VERSION 02

WHAT ARE THE CHANGES IN THIS VERSION?

The algorithm for overseas returnees (Annex 6) revised splitting into two algorithms as overseas returnees from low-risk countries (Annex 6a) and overseas returnees from high-risk countries (Annex 6b). The timing of tests also changed accordingly.

PREPARED BY THE EPIDEMIOLOGY UNIT OF THE MINISTRY OF HEALTH AND INDIGENOUS MEDICAL SERVICES
WITH THE CONTRIBUTION OF CONSULTANT VIROLOGISTS

VERSION 01: 09 MAY 2020
VERSION 02: 30 MAY 2020
**Introduction**

In managing the pandemic caused by SARS CoV-2, early diagnosis of acute infection in both symptomatic and asymptomatic patients plays a major role in containing the transmission of this infection in the community. Early diagnosis in combination with contact tracing and quarantining of exposed contacts remains the main strategy in preventing wide community spread of the SARS CoV-2 infection.

**Laboratory diagnosis of COVID-19**

SARS CoV-2 RT-PCR (on respiratory specimens) is the mainly available diagnostic method at present to diagnose acute infection to fulfill above strategic need of infection control and prevention. Being a laborious testing method consuming several resources, SARS CoV-2 RT-PCR needs to be used in a rational approach for its optimum usage to achieve best outcome in this crisis situation. Introduction of automated laboratory procedures is also a need to further expand the SARS CoV-2 RT PCR testing capacity in the laboratories.

Point-of-care molecular assays and immunochromatographic antigen assays are also being developed in the world with limited accessibility due to the issues in global supply chain. Once such methods are available in the country they can be used for acute diagnosis after a local laboratory verification process to evaluate their sensitivity and specificity compared to RT-PCR method. Some rapid antigen assays were already available but their performance were not adequate for the use according to the results of local verification process.

Antibody assays are not appropriate for acute diagnosis of the infection, but can be used to assess the exposures to the virus in surveillance purposes if satisfactory assays are available. All rapid antibody assays which were locally validated so far haven’t shown good performance for their routine use. Serosurveillance studies would be more feasible when validated serology ELISAs are available in the country.

COVID-19 testing strategy mentioned here is based on RT-PCR assay and designed to cater the needs of infection control and prevention of the outbreak in the prevailing epidemiological circumstances. In addition, it focuses on individual patient management, as well. As the situation of the pandemic is evolving globally and locally, this testing strategy may need regular review and change according to the new developments in relation to the SARS CoV-2 infection and associated factors in the country and the world.
COVID-19 Laboratory Test Strategy

For the overall RT-PCR test algorithm please refer to the Annex 1.

The current COVID-19 laboratory test strategy in Sri Lanka can be categorized as follows:

1. Case finding
   1.1. Passive Case Finding
   1.2. Active Case Finding

2. Epidemiological investigation
   2.1. Sentinel surveillance
   2.2. Random sampling of selected communities/settings
   2.3. Sero-prevalance studies

1. CASE FINDING

1.1. PASSIVE CASE FINDING
   1.1.1. All suspected patients that fit into the COVID-19 case definition (Admitted to isolation centers in designated hospitals) [Refer Annex 2]

1.2. ACTIVE CASE FINDING
   1.2.1. All close contacts of COVID-19 patients [Refer Annex 3]
   1.2.2. Second level contacts of COVID-19 patients identified from environments that has higher risk of transmission [patients from highly overcrowded areas/ patients who had very high mobility with large number of contacts/ people living in congregate settings like hostels/camps/ institutional care facilities] (large clusters) - ‘Hot Spots’ [Refer Annex 4]
   1.2.3. Random sampling of neighbourhood of confirmed COVID-19 cases [Refer Annex 5]
   1.2.4. Overseas returnees [Refer Annex 6]
   1.2.5. Healthcare workers and other frontline workers dealing with COVID-19 patients/communities with high risk exposures [Refer Annex 7]
   1.2.6. All patients admitted to hospitals (both Govt. and Private) with severe acute respiratory infection (SARI) not explainable by any other aetiology [Refer Annex 8]
   1.2.7. Inward patients (for management of other problems) that treating consultant decides need of exclusion of COVID-19 [Refer Annex 9]
   1.2.8. Deaths suspected due to COVID-19 pneumonia that may occur inward, on admission or in the community [Refer Annex 10]
2. Epidemiological Investigation

2.1. SENTINEL SURVEILLANCE - Patients presenting to OPD of the COVID-19 sentinel sites (~35 Hospitals island wide) with COVID-19 like symptoms (fever with respiratory symptoms). Test a random sample of 10 patients per day

2.2. RANDOM SAMPLING FROM COMMUNITIES in high-risk areas/ settings as determined by the Epidemiology Unit (including urban slum areas, estates, schools, pre-schools, healthcare workers, people living in hostels/ camps, market places etc.)

2.3. SERO-PREVALENCE STUDIES [Antibody testing based on the availability of validated test]. Study populations to be selected based on the epidemiological pattern of the disease at the time of testing

Special notes: -

1. All samples for screening of asymptomatic cases should be collected according to the indications in annexures 3-7 and the request should be made in the format demonstrated in annexure 11. It should be completely filled with all requested information and clear identification and contact details of the requesting officer. Otherwise testing laboratory may not accept the samples for screening

2. Samples for screening of asymptomatic cases and surveillance purposes may be considered for pooled sample analysis according to a validated laboratory protocol in future. But such practice will not be used for the samples tested for clinical diagnostic purposes.
COVID-19 PCR TESTING ALGORITHM

HOSPITAL
- COVID-19 suspected cases
- Pneumonia of unknown origin & SARI in absence of alternative diagnosis
- Covid-19 suspected deaths
- Healthcare staff-high-risk exposure to covid-19 patient/s
- Close contact/s of a COVID-19 patient
- Patients from a high risk geographic area (Area with reported cases within last 14 days or area with epidemiological risk is declared)

COMMUNITY
- Close contacts of positive cases (Based on epidemiological links)
  - High risk communities
  - “hot-spots”
    - Areas where with high risk transmission experienced
  - Random samples

RT PCR TEST

POSITIVE
- Transfer to Covid-19 treatment hospitals

NEGATIVE#
- Two consecutive PCR test negative (24hrs apart)
- Discharge
  - If QC person/s, close contact/s and treated patient/s
  - Home quarantine for 14 days
  - Patients with COVID 19 signs and symptoms
  - No further action is required*

OTHERS
- No further signs and symptoms
- Inform relevant public health officers to follow up if necessary (this is applicable to Home Quarantine also)

* Epidemiology Unit, Ministry of Health, Sri Lanka
PASSIVE CASE FINDING

CASES WITH COVID-19 LIKE SYMPTOMS FROM THE COMMUNITY THAT FIT INTO SUSPECTED CASE DEFINITION\(^1\)

- Admit to hospital with no isolation facility/ Not a COVID-19 Center
- Admit to isolation ward in the COVID-19 Center

**RT-PCR**

- Negative
  - Discharge with advice for home isolation and necessary review as indicated
- Further evaluate if indicated – strongly indicated by treating clinicians
- Repeat RT-PCR
  - Negative
  - Admit to COVID-19 treatment center
- POSITIVE

\(^1\) Refer Updated interim case definitions on COVID-19 and advice on initial management of patients (version dated 04. 04. 2020) [Available at: www.epid.gov.lk]
CLOSE CONTACTS OF COVID-19 PATIENT

CLOSE CONTACT OF COVID-19 PATIENT

COVID-19 like symptoms present
- Admit to Isolation ward in the COVID-19 Center
  - RT-PCR
    - POSITIVE
      - Admit to COVID-19 treatment center
    - Negative
  - RT-PCR

COVID-19 like symptoms absent
- Home quarantine OR institutional quarantine for 14 days
  - Symptoms appear before end of 14 days
    - RT-PCR
      - POSITIVE
    - Negative
  - Asymptomatic
    - Day 10-14 of the quarantine period
      - RT-PCR
        - POSITIVE
        - Negative
      - Discharge at the end of the quarantine period advising home quarantine for 14 more days
EXTENDED CONTACTS OF COVID-19 PATIENTS FROM HOT SPOTS

Home quarantine OR institutional quarantine for 14 days

Select a group (sample) of second level contact with high epidemiological risk

RT-PCR

One or more cases POSITIVE

Admit POSITIVE cases to COVID-19 treatment center

RT-PCR

Expand testing based on the pattern of case reporting

Continue Home quarantine OR institutional quarantine in negative cases for 14 days

Do random sampling for RT-PCR at the end of the quarantine period (10-14 days) and consider to discharge accordingly

All Cases are negative
RANDOM SAMPLING OF NEIGHBOURHOOD OF CONFIRMED COVID-19 CASES

Confirmed COVID-19 cases

Select a group (sample) of neighbourhood with high epidemiological risk

RT-PCR

One or more cases POSITIVE

Admit POSITIVE cases to COVID-19 treatment center

All Cases are negative

No further action required

Home quarantine OR institutional quarantine of neighbourhood for 14 days

RT-PCR

Expand testing based on the pattern of case reporting

Do random sampling for RT-PCR at the end of the quarantine period 10-14 days and consider to discharge accordingly
OVERSEAS RETURNEES: LOW-RISK COUNTRIES

OVERSEAS RETURNEES FROM LOW-RISK COUNTRY*

Symptomatic on arrival

Admit to a COVID-19 isolation hospital

Asymptomatic on arrival

Institutional quarantine for 14 days

RT-PCR

POSITIVE

Transfer to COVID-19 treatment center

At the end of 14 days

RT-PCR

POSITIVE

Continue management appropriately

Symptoms appear before end of 14 days

Admit to COVID-19 treatment center

Day 10-14 of the quarantine period

RT-PCR

POSITIVE

Discharge

No symptoms

RT-PCR

POSITIVE

Discharge from home quarantine at end of 14 days

Symptoms appear before end of 14 days

No symptoms

RT-PCR

POSITIVE

Discharge

Negative

Symptoms appear before end of 14 days

RT-PCR

POSITIVE

Discharge from home quarantine at end of 14 days

Negative

No symptoms

RT-PCR

POSITIVE

Discharge

Negative

* The risk level of the country will be determined by the Epidemiology Unit
OVERSEAS RETURNEES FROM HIGH-RISK COUNTRY

Symptomatic on arrival

- Same management as of overseas returnees from low-risk countries [Refer Annex 6a]
  - Admit to COVID-19 treatment center
    - RT-PCR
      - POSITIVE
      - Negative
    - RT-PCR
      - POSITIVE
      - Negative
    - RT-PCR
      - POSITIVE
      - Negative

Asymptomatic on arrival

- Institutional quarantine for 14 days
  - RT-PCR [Day 1-2 after arrival]
    - POSITIVE
    - Negative
    - RT-PCR
      - POSITIVE
      - Negative
      - Home quarantine for further 14 days
      - Discharge from home quarantine at end of 14 days
      - Admit to COVID-19 treatment center

* The risk level of the country will be determined by the Epidemiology Unit
HEALTHCARE WORKERS OR OTHER FRONTLINE WORKERS DEALING WITH COVID-19 PATIENTS OR HIGH-RISK COMMUNITIES

High or Moderate risk exposure[2]
- Home quarantine OR institutional quarantine for 14 days
  - Symptoms appear before end of 14 days
    - RT-PCR
      - POSITIVE: Admit to COVID-19 treatment center
      - Negative: Continue quarantine
        - RT-PCR
          - POSITIVE: Admit to COVID-19 treatment center
          - Negative: Day 10-14 of the quarantine period
  - Asymptomatic
    - RT-PCR
      - POSITIVE: Admit to COVID-19 treatment center
      - Negative: Discharge at the end of the quarantine period

Low risk exposure[2]
- Continue routine work & monitor for symptoms for 14 days
  - Symptoms appear during 14 days
    - RT-PCR
      - POSITIVE: Admit to COVID-19 treatment center
      - Negative: Continue monitoring
  - Asymptomatic
    - RT-PCR
      - POSITIVE: Admit to COVID-19 treatment center
      - Negative: Discharge at the end of the quarantine period

[Available at: www.epid.gov.lk]
SARI PATIENTS NOT EXPLAINED BY ANY OTHER AETIOLOGY

ALL PATIENTS ADMITTED TO HOSPITALS (BOTH GOVERNMENT AND PRIVATE) WITH SEVERE ACUTE RESPIRATORY INFECTION (SARI) NOT EXPLAINABLE BY ANY OTHER AETIOLOGY

RT-PCR

- POSITIVE
  - Transfer to COVID-19 treatment center

- Negative
  - Manage appropriately
    - Clinically improved
    - No clinical improvement
      - Repeat RT-PCR
        (As decided by the Consultant)
        - POSITIVE
          - Manage appropriately
        - Negative
          - Manage appropriately

[3] Patient should be resuscitated and stabilized before transferring. Receiving end consultant should be contacted and discussed about the patient before transferring.
OTHER INWARD PATIENTS

INWARD PATIENTS ADMITTED FOR THE MANAGEMENT OF OTHER PROBLEMS

Treating clinician’s request for RT-PCR[4]

Assessed by a team (including treating Consultant, Consultan Physician and Consultant Microbiologist/Virologist)

RT-PCR not indicated

RT-PCR indicated

RT-PCR

POSITIVE

Transfer to COVID-19 treatment center (after appropriate management)

NEGATIVE

Manage appropriately

[4] Patient’s routine management should never be compromised due to not doing RT-PCR test or non-availability of RT-PCR test results. Proper patient care should be ensured, if necessary, wearing appropriate Personal Protective Equipment (PPE)
DEATHS

DEATHS SUSPECTED DUE TO COVID-19

- Inward
- On admission
- In the community

Obtain post-mortem respiratory samples
(Handling of the body as suspected COVID-19 patient)[5]

RT-PCR

- POSITIVE
  - Disposal of the body according to COVID-19 dead body disposal criteria[5]

- Negative
  - Risk to be assessed by a team (JMO/treating clinician/Microbiologist/Virologist) to decide on method of dead body disposal

# NOVEL CORONAVIRUS (COVID-19) PCR REQUEST FOR SCREENING OF ASYMPTOMATIC CASES

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