COVID-19 LABORATORY TEST STRATEGY IN SRI LANKA

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

09 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. Serology 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
- Sentinel sites for COVID-19
  - Random sampling of ILI

**NEGATIVE#**
- Two consecutive PCR test negative (24hrs apart)
- Discharge

If QC person/s, close contact/s and treated patient/s
- Patients with COVID 19 signs and symptoms
  - Home quarantine for 14 days
  - Epidemiology Unit, Ministry of Health, Sri Lanka
  - Inform relevant public health officers to follow up if necessary (this is applicable to Home Quarantine also)

Others
- No further action is required*

* Inform relevant public health officers to follow up if necessary (this is applicable to Home Quarantine also)
PASSIVE CASE FINDING

CASES WITH COVID-19 LIKE SYMPTOMS FROM THE COMMUNITY THAT FIT INTO SUSPECTED CASE DEFINITION

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

- Admit to isolation ward in the COVID-19 Center

- Negative

- RT-PCR

- Further evaluate if indicated – strongly indicated by treating clinicians

- Discharge with advice for home isolation and necessary review as indicated

- Repeat RT-PCR

- Negative

- POSITIVE

- Admit to COVID-19 treatment center

[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

COVID-19 like symptoms absent

Home quarantine OR institutional quarantine for 14 days

RT-PCR

Symptoms appear before end of 14 days

Asymptomatic

POSITIVE

Day 10-14 of the quarantine period

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

EXTENDED CONTACTS OF COVID-19 PATIENT 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

1. Confirmed COVID-19 cases
   - Select a group (sample) of neighbourhood with high epidemiological risk

2. RT-PCR
   - One or more cases POSITIVE
     - Admit POSITIVE cases to COVID-19 treatment center
   - All Cases are negative
     - No further action required

3. Home quarantine OR institutional quarantine of neighbourhood for 14 days
   - RT-PCR
     - Expand testing based on the pattern of case reporting

4. Do random sampling for RT-PCR at the end of the quarantine period 10-14 days and consider to discharge accordingly
OVERSEAS RETURNEES

Symptomatic on arrival

RT-PCR

- POSITIVE: Admit to COVID-19 treatment center
- Negative: Institutional quarantine for 14 days

Asymptomatic on arrival

RT-PCR

- Positive: Symptoms appear before end of 14 days
- Negative: No symptoms

Institutional quarantine for 14 days

Day 10-14 of the quarantine period

RT-PCR

- Positive: Discharge at the end of the quarantine period
- Negative: Home quarantine for further 14 days

Symptoms appear before end of 14 days

RT-PCR

- Positive: Discharge from home quarantine at end of 14 days
- Negative: No symptoms

No symptoms

Discharge at the end of the quarantine period

Home quarantine for further 14 days

Discharge from home quarantine at end of 14 days
TESTING AFTER RISK EXPOSURE

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
  - Asymptomatic

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
  - Day 10-14 of the quarantine period
    - RT-PCR
      - POSITIVE
        - Continue monitoring
      - 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[^3]
- 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, Consultant 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 SUSPECTED DUE TO COVID-19

Inward

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

On admission

In the community

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

## Community and Quarantined Samples

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<thead>
<tr>
<th>Testing after high risk exposures</th>
<th>Area</th>
<th>Name of Requesting Officer</th>
<th>Designation</th>
<th>Contact No</th>
<th>Email</th>
<th>Signature</th>
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<tbody>
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<td>Extended contacts from Hot spots</td>
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<td>Samples from neighbourhood of a case</td>
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<td>Quarantined patient samples</td>
<td>Home</td>
<td>yes/no</td>
<td>Quarantine centre</td>
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## Table

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<th>Gender</th>
<th>Nationality</th>
<th>Occupation</th>
<th>Address and Contact No</th>
<th>Date of Quarantine</th>
<th>Reason for Quarantine</th>
<th>Date of Sample Collection</th>
<th>Overseas Returnee or Returnee from High Risk Area</th>
<th>Close Contact with Diagnosed or Suspected Case</th>
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## Additional Information

- Overseas returnee or returnee from high risk area
- Close contact with diagnosed or suspected case
- Nature of exposure (Family contact, work place, neighbourhood, etc.)
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<tr>
<th>Serial No</th>
<th>Name</th>
<th>Age</th>
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<th>Occupation</th>
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<th>Reason for quarantine</th>
<th>Date of sample collection</th>
<th>Overseas returnee or returnee from high risk area</th>
<th>Close contact with diagnosed or suspected case</th>
<th>Arrival/ returned date</th>
<th>Country/ High risk area</th>
<th>Date/period of contact</th>
<th>Index case symptomatic/asymtomatic (or cluster exposure)</th>
<th>Nature of exposure (Family contact/ work place/ neighbourhood etc..)</th>
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