LABORATORY STRATEGY
FOR COVID-19 IN SRI LANKA

JUNE 2020

Ministry of Health
Sri Lanka College of Microbiologists
World Health Organization
Sri Lanka
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FOR COVID-19 IN SRI LANKA

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CONTRIBUTORS

Dr. B. V. S. H. Beneragama,
Deputy Director General Laboratory Services

Dr. Rohitha Muthugala
Consultant Virologist, National Hospital Kandy

Dr. Nadeeka Janage
Consultant Virologist, Medical Research Institute, Sri Lanka

Dr. Shirani Chandrasiri
President, Sri Lanka College of Microbiologists

Dr. Jeevatharan Hamsananthy
Consultant Community Physician, DDG LS Unit

Dr. Maleetha Pathiraja
Medical Officer, DDG LS Unit

Dr. Kanchana Jayamanna
Medical Officer, DDG LS Unit

Dr. Manjula Samarakoon
Medical Officer Health Informatics, DDG LS Unit

Dr. Nalika Gunawardena
National Professional Officer, World Health Organization, Sri Lanka
Sri Lanka’s response to the COVID-19 pandemic has been swift, decisive, and coordinated, and using a whole-of-society approach, it has yielded successful results. The availability of valid and accurate laboratory testing has been identified as imperative to a country’s success in controlling the pandemic. In Sri Lanka, the timely built up of virology laboratory testing capacity in Sri Lanka in the recent past enabled the country to rapidly and optimally support the national response with laboratory testing for diagnostics and surveillance. This, in turn, can be considered the cornerstone of the country’s successful response to COVID-19.

This document, Laboratory Strategy for COVID-19 in Sri Lanka, provides a description of how COVID-19 testing was initiated and established in the country, current testing strategies, testing capacity, maintenance plans, and the projected expansion of testing during the future steady-state of transmission.

It is expected to serve as guidance to laboratories involved in COVID-19 virus testing and to stakeholders on requirements to maintain and expand the laboratory testing services for COVID-19 in Sri Lanka.

I congratulate all those who had contributed. I am confident that this will be a valuable source of information to the ongoing efforts of the country to continue to combat the COVID-19 pandemic successfully.

Dr B. V. S. H. Beneragama
Deputy Director General Health (Laboratory Services)
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INTRODUCTION

On 30 January 2020, the World Health Organization (WHO) declared coronavirus disease 2019 (COVID-19) a public health emergency of international concern. On 11 March, WHO made the assessment that COVID-19 can be characterized as a pandemic. The key principle of controlling the COVID-19 outbreak is for countries to increase their level of preparedness, alert, and response, to identify, manage, and care for new cases. With the declaration of the pandemic, WHO advocated for each country to assess its risk and rapidly implement the necessary measures at the appropriate scale, and to prepare for a testing and clinical care surge to reduce both COVID-19 transmission and economic, public health, and social impacts. Laboratory testing is an integral part of this strategy.

From the onset of this public health crisis, the need for rapid and accurate laboratory testing was clear; laboratory scientists responded by developing the first diagnostic tests for COVID-19 within days of the release of the viral genome sequence. On 25 January 2020 the National Influenza Centre of the Department of Virology, Medical Research Institute (MRI) in Sri Lanka, under the guidance of Director General of Health Services and Deputy Director General of Laboratory Services (DDG LS) of the Ministry of Health and Indigenous Medical Services (MOHIMS), established an in-house molecular test for SARS-CoV-2 virus and validated
the method through the WHO coronavirus reference laboratory, University of Hong Kong, as per WHO recommendations for quality assurance. Results revealed a 100% concordance with the reference laboratory results. Thereafter, Professor Malik Pieris, the Chair Professor, Department of Microbiology, Faculty of Medicine, University of Hong Kong, donated primers and probes and provided technical advice to establish the assay at MRI, National Hospital Kandy, and University of Sri Jayewardenepura. Professor Andreas and his team from Robert Koch Institute, Germany, also donated reagents to conduct testing at National Hospital Kandy and North Colombo Teaching Hospital, Ragama. This initial support fulfilled the early testing requirements in Sri Lanka at a time when commercial assays were not freely available.

This prompt action paved the way for the successful expansion of COVID-19 testing to fourteen laboratories of the MOHIMS, four laboratories of the Medical Faculties of Universities and four laboratories of the private-sector as of 1 June 2020. This expansion successfully catered to the testing requirements of Sri Lanka’s COVID-19 response.

02 AIMS

This document, Laboratory Strategy for COVID-19 in Sri Lanka, provides a description of how COVID-19 testing was initiated and established in the country, current testing strategies, testing capacity, maintenance plans, and the projected expansion of testing during the future steady-state of transmission.

It is expected to serve as guidance to laboratories involved in COVID-19 virus testing and to stakeholders on requirements to maintain and expand the laboratory testing services for COVID-19 in Sri Lanka.
03
LABORATORY TESTS FOR COVID-19 VIRUS

3.1 REAL-TIME REVERSE-TRANSCRIPTION POLYMERASE CHAIN REACTION (RT-PCR) TEST FOR COVID-19 VIRUS

Routine confirmation of cases of COVID-19 is based on the detection of unique sequences of the SARS CoV-2 RNA by nucleic acid amplification tests (NAAT) such as real-time reverse-transcription polymerase chain reaction (RT-PCR). The viral genes targeted so far include the N, E, S, and RdRP genes.

An account on the global recommendation of the RT-PCR test kits to diagnose COVID-19 is presented in Annex I.

At a time with severe global shortages, to cater to the demand to expand testing in the country, the National Medicines Regulatory Authority (NMRA) uses several parameters to issue waivers of registration of the diagnostic kits to be used in Sri Lanka. These are:

- PCR-test kits included in the WHO Emergency Use Listing (EUL)
- PCR-test kits evaluated and listed for use by the Foundation for Innovative New Diagnostics (FIND), a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology
- PCR test kits under International Medical Device Regulators Forum (IMDRF) jurisdiction based on the approval of agencies such as the Food and Drug Administration (FDA) of USA, the Therapeutic Goods Administration of Australia (TGA) and Health Canada.
- Kits that were validated by Sri Lankan laboratories and found to be performing well with acceptable sensitivity, specificity, and efficacy.

Below is a list of PCR kits that the NMRA has issued a Waiver of Registration (WOR) for, as of 1 June 2020; providing the basis for them to be listed in the IMDRF jurisdiction (Table 1).

<table>
<thead>
<tr>
<th>SERIAL NO.</th>
<th>PRODUCT NAME</th>
<th>LOCAL AGENT /IMPORTER</th>
<th>MANUFACTURER / DONOR</th>
<th>BASIS FOR THE WAIVER OF REGISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>New Corona Virus 2019-nCo nucleic acid detection kit</td>
<td>Asiri Surgical Hospital</td>
<td>Primer Design Limited, UK</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>2.</td>
<td>VIASURE SARS -CoV-2 Real Time PCR Detection kit</td>
<td>Microtech Biological</td>
<td>Certest Biotec SL - Spain</td>
<td>Listed in TGA</td>
</tr>
<tr>
<td>3.</td>
<td>Altona RealStar SARS – CoV-2 RT-PCR Kit1</td>
<td>Avon Pharma (Pvt) Ltd</td>
<td>Labgenomics Co. Ltd, Korea for Siemens Healthcare, India (Donation to MOH)</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>SERIAL NO.</td>
<td>PRODUCT NAME</td>
<td>LOCAL AGENT /IMPORTER</td>
<td>MANUFACTURER / DONOR</td>
<td>BASIS FOR THE WAIVER OF REGISTRATION</td>
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<td>------------------------------</td>
<td>-------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>5.</td>
<td>IVD Real Time Detection Test Kit (PCR) (Standard M nCov Real Time Detection Kit)</td>
<td>George Starts Health (Pvt) Ltd</td>
<td>George Starts Health (Pvt) Ltd</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>6.</td>
<td>1 copy COVID-19 qPCR Multi Kit</td>
<td>Biomedite (Pvt) Ltd</td>
<td>1 Drop Inc, Korea</td>
<td>Listed in Health Canada</td>
</tr>
<tr>
<td>7.</td>
<td>Quantivirus SARS Cov-2 test</td>
<td>Dowell Medico (Pvt) Ltd</td>
<td>Diacarta Inc, USA</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>10.</td>
<td>iAMP Covid-19 detection kit</td>
<td>Apcot Marketing (Pvt) Ltd</td>
<td>Atila Biosystem Inc, USA</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>11.</td>
<td>(Note: this kit eliminates the need for RNA extraction)</td>
<td>Biomedite (Pvt) Ltd</td>
<td>Osang Healthcare Co. Ltd, Korea</td>
<td>Emergency Use Authorization in USA</td>
</tr>
<tr>
<td>12.</td>
<td>GeneFinder COVID-19 Plus RealAmp</td>
<td>Nawaloka Hospital</td>
<td>Shanghai Geneo Dx Biotech Ltd, China</td>
<td>Validated by Sri Lankan laboratories</td>
</tr>
<tr>
<td>13.</td>
<td>New Corona Virus-2019 n-Cov nucleic acid detection kit</td>
<td>MOHIMS</td>
<td>Jack Ma Foundation</td>
<td>Validated by Sri Lankan laboratories</td>
</tr>
<tr>
<td>14.</td>
<td>COVID-19 Nucleic acid diagnostic kit</td>
<td>MOHIMS</td>
<td>From the Government of China as a donation</td>
<td>Validated by Sri Lankan laboratories</td>
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<td>15.</td>
<td>COVID-19 Nucleic acid diagnostic kit PCR (fluorescence) probing</td>
<td>Through medical supplies division</td>
<td>China Sinopharm International Corporation, China</td>
<td>Validated by Sri Lankan laboratories</td>
</tr>
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</table>
3.2 XPERT XPRESS SARS-CoV-2

The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens. The test runs on the GeneXpert Dx and GeneXpert Infinity systems Xpress systems. The Xpert Xpress SARS-CoV-2 test is authorized for emergency use by the FDA. Sri Lanka possesses 36 GeneXpert machines, installed in laboratories used for the diagnosis of tuberculosis (Annex 2). Officially the country has decided to utilize this test in surveillance activities; however, global shortages of the Xpert Xpress SARS-CoV-2 kits have prevented its use, up to date.

3.3 SEROLOGICAL TESTS

3.3.1 Detection of antibodies

Detection of IgM/IgG antibodies to diagnose SARS CoV-2 using rapid diagnostic tests (RDT) has its advantages; it is easy to test, produces rapid results, and can be used as a point of care test. Antibody detection rapid tests have been eligible to undergo WHO assessments for emergency use since 17 April 2020. WHO is in receipt of a few expressions of interest for an antibody detection RDT, but none have been recommended for the purpose of diagnosis, as of 1 June 2020.

The RDTs available in the market at present pose the following challenges in use as a diagnostic test:

1. Due to a late antibody response (7-10 days after onset of symptoms), it is not useful for early diagnosis to determine isolation and individual patient management. In the heavily affected populations of immunocompromised individuals and the elderly, it will take a longer time to develop antibodies, and many may not develop antibodies at all. Those with early infection and those with poor antibody development will be missed as false negatives, which poses the serious risks of incorrectly reassuring people that they do not have COVID-19, and therefore increasing the spread of infection within the community.

2. If the testing target is not a neutralizing antibody, the detection of antibodies may not confirm immunity to infection.

3. As several other human coronaviruses are also co-circulating in the community, the test cannot exclude cross-reactivity, which will lead to a substantial number of false-positive results.

4. There is a considerable variation in sensitivity level across different brands of rapid antibody test kits.

Therefore, antibody detection tests are not considered an alternative diagnostic test for early case detection and preventing community transmission in Sri Lanka. Nevertheless, Sri Lanka acknowledges that the antibody tests may have a place in the following indications and purposes (Table 2).

Table 2: Indications for antibody tests and its purposes

<table>
<thead>
<tr>
<th>INDICATIONS</th>
<th>PURPOSE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspected symptomatic patients if PCR negative, antibody testing can be done after day 7 of symptoms</td>
<td>Clinical decision making</td>
</tr>
<tr>
<td>Asymptomatic quarantine individuals, antibody can be tested with Acute (1st exposure) and convalescent (day 10-12) samples (facilitate asymptomatic contact screening) Kits with quantitative detection of antibodies are preferred</td>
<td>Public health decision making</td>
</tr>
<tr>
<td>Serostatus of positive patients after complete recovery</td>
<td>In Experimental studies</td>
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<tr>
<td>Past exposure(IgG) to the virus (community surveillance)</td>
<td>Epidemiological purposes</td>
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</tbody>
</table>
3.3.2 Detection of antigens

One type of rapid diagnostic test (RDT) detects the presence of viral proteins (antigens) expressed by the COVID-19 virus in a sample from the respiratory tract of a person. The antigen(s) detected are expressed only when the virus is actively replicating; therefore, such tests are best used to identify acute or early infection.

How well the tests work depends on several factors, including the time from onset of illness, the concentration of virus in the specimen, the quality of the specimen collected, the procedure followed in processing the specimen, and the precise formulation of the reagents in the test kits. If any of the antigen detection tests that are under development demonstrate adequate performance, they could potentially be used as triage tests to rapidly identify patients who are very likely to have COVID-19, reducing the need for expensive molecular confirmatory testing.

With limited data available, WHO does not currently recommend the use of antigen-detecting rapid diagnostic tests for patient care; although research into their performance and potential diagnostic utility is highly encouraged.

3.3.3 Viral sequencing

In addition to confirming the presence of the virus, regular sequencing of a percentage of specimens from clinical cases can be used to monitor and detect viral genome mutations that might affect the performance of medical countermeasures, including diagnostic tests. Virus whole-genome sequencing can also inform molecular epidemiology studies.

In Sri Lanka, MRI, in collaboration with HKU and the Centre for Dengue Research in Sri Jayewardenepura, have carried out the whole genomic sequencing of virus strains detected in Sri Lanka. The data is stored in the National Center for Biotechnology Information databases, which is accessible to the public.
From the start, testing for COVID-19 has been performed under the strict guidance of the Epidemiology Unit of the MOHIMS. The Epidemiology Unit is the premier organization of the MOHIMS, which directs the country on the prevention and control of communicable diseases. Its guidance on the initial case definitions to identify those to be tested based on the clinic-epidemiological pattern of the COVID-19 outbreak experienced by the country is indicated in the circulars DDG(PHS I) DO2/12-9/2019/10 -26 Jan 2020 (Annex 3a), DDG(PHS I) DO2/12-9/2010/10 -06 Feb 2020 (Annex 3b), and EPID/400/n- CoV 07 April 2020 (Annex 3c). The definitions were further modified to suit the current clinic-epidemiological pattern, as published in the Testing Strategy of the Ministry of Health and Indigenous Medical Services, version 2.0 on 30 May 2020¹.

The following is a summary account of the present COVID-19 laboratory test strategy in Sri Lanka by the Epidemiology Unit of the MOHIMS on 30 May 2020. The overall RT-PCR test algorithm is shown below in Figure 1.

The test strategy in Sri Lanka can be categorized by purpose: for case findings, and for epidemiological investigations.

[Diagram of the overall RT-PCR testing algorithm]

Source: Epidemiology Unit, Ministry of Health, Sri Lanka

4.1 CASE FINDINGS

The strategy calls for testing for both passive and active case findings.

4.1.1 Passive case finding

Passive case finding is the testing all suspected patients that fit the COVID-19 case definition (A-E) (admitted to isolation centers in designated hospitals)

A. A person with ACUTE RESPIRATORY ILLNESS (cough, shortness of breath (SOB), sore throat) with a history of FEVER (at any point of time during this illness), returning to Sri Lanka from ANY COUNTRY within the last 14 days

B. A person with ACUTE RESPIRATORY ILLNESS AND having been in close-contact* with a confirmed or suspected COVID-19 case during the 14 days prior to the onset of symptoms

* Close-contact: A person staying in an enclosed environment for >15 minutes (e.g. same household/ workplace/social gatherings/travelling in the same vehicle).

C. A person with a history of FEVER (at any point of time during this illness), with a history of travel or residence in a location designated as an area of high-risk transmission of COVID-19 disease as defined by the Epidemiology Unit, MOHIMS, during the 14 days prior to symptom onset

D. A patient with acute pneumonia (not explainable by any other aetiology) regardless of travel or contact history as decided by the treating Consultant

E. A patient with fever and respiratory distress as evident by RR>30 per min, SpO2 <90% on room air, regardless of travel or contact history and without a definable cause, as decided by the treating Consultant

F. Any person, irrespective of the presence of symptoms, with an epidemiological link to a confirmed COVID-19 case who needs testing, as decided by the Regional Epidemiologist or the Central Epidemiology Unit

4.1.2 Active case findings

Active case finding is the testing of all suspected patients that fit into the below specified (A-H) criteria.

A. All close contacts of COVID-19 patients

B. Second-level contacts of COVID-19 patients identified from environments that have a higher risk of transmission [i.e., patients from overcrowded areas/ patients who had very high mobility with a large number of contacts/ people living in congregate settings like hostels/ camps/ institutional care facilities/ large clusters - 'Hot Spots', etc.]

C. Random sampling from the neighborhoods of people who have tested positive for COVID-19

D. Overseas returnees (an update of the criteria is given in circular DQ/06/2020 dated 3 June 2020)

E. Healthcare workers and other frontline workers dealing with COVID-19 patients/ communities with high-risk exposures

F. All patients admitted to hospitals (both Government and Private) with severe acute respiratory infection (SARI) not explainable by any other aetiology

G. Inward patients for the management of other problems, were the treating consultant decides there is a need for exclusion of COVID-19

H. Deaths suspected due to COVID-19 pneumonia that may occur inward, on admission or in the community
Measures to be adopted at airports in Sri Lanka during COVID-19 was updated by the MOHIMS as specified by the circular DQ/06/2020 dated 3 June 2020 (Annex 4). It calls for mandatory RT-PCR testing of passengers for COVID-19, at the airport, on arrival to Sri Lanka. The logistical arrangements for sample collection and transport to the testing laboratories have been assigned to the Airport and Aviation Services Sri Lanka Limited. The mandatory testing of airline crew members based on different circumstances is specifically indicated in the circular.

Mandatory testing for all members of the Diplomatic Staff of the Foreign Missions based/attached in Colombo, Diplomatic Missions, the Representation Offices of the United Nations and its Specialized Agencies, International Organizations, Honorary Consulates residing in Colombo through diplomatic channels is governed by the circular issued by the Ministry of Foreign Affairs Ref No.: PR/CP/MISC/2020 dated 4 June 2020 (Annex 5).

4.2 EPIDEMIOLOGICAL INVESTIGATION

The strategy also specifies three types of epidemiological investigations that require testing.

A. Sentinel Surveillance - Patients presenting to Out-Patient Departments (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.

B. 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, marketplaces etc.)

C. 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.

WHO recommends two negative PCR tests, at least 24 hours apart, in a clinically recovered patient to discharge himself/herself from a hospital setting. Sri Lankan Provisional Clinical Practice Guidelines on COVID-19 suspected and confirmed patients in March 2020, by Ceylon College of Physicians and Epidemiology Unit Version 4 of 31 March 2020 recommends the same.

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06

SPECIMEN COLLECTION AND TRANSPORT

Provisional Clinical Practice Guidelines on COVID-19 suspected and confirmed patients specifies the specimens to be collected, safety procedures during specimen collection and packaging, and transport of clinical specimens.

6.1 SAMPLE COLLECTION

The type of sample depends on the clinical presentation of the patient. For patients with mild upper respiratory tract infection, both throat and nasopharyngeal swabbing should be done. The swabs should be transported in Viral Transport Medium (VTM). For those who produce sputum, a sputum sample is preferable, and it should be collected in a sterile, leak-proof, screw-cap container with VTM.

In patients with more severe respiratory disease, endotracheal aspirate or bronchoalveolar lavage collected in VTM are recommended. Tissue from biopsies or autopsies, including those from the lungs, should also be transported in VTM.

As a measure to meet the increasing demand for sample collection materials, the MRI of the MOHIMS initiated production of VTM in April 2020. At the same time, the MRI collaborated with the Sri Lanka Institute for Nanotechnology (SLINTEC) to locally manufacture sample collection swabs. Both of these products were subjected to stringent validation procedures locally to ensure validity; they are also registered at NMRA for use in Sri Lanka.

6.1.1 Safety procedures during specimen collection

It is important to ensure that healthcare workers (HCWs) who collect specimens follow the standard precautions and use the recommended personal protective equipment (PPE). HCWs should perform procedures in an adequately ventilated room and follow the steps of donning and doffing of PPE. Perform hand hygiene before and after contact with the patient and his or her surroundings and after PPE removal. Rational use of PPE and Infection Prevention and Control of COVID-19: Minimum recommendations in Sri Lanka of 15 May 2020 by Sri Lanka College of Microbiologists, Epidemiology Unit, MOHIMS, and World Health Organization, Sri Lanka³ specifies the PPE recommended for specimen collection.

6.2 PACKAGING AND TRANSPORT OF CLINICAL SPECIMENS

Specimens should be properly labelled. Samples should be transported to the testing laboratory as soon as possible with ice (4°C). If there is a delay in transport, the sample can be stored in a refrigerator (4°C) for up to 48 hours. Do not freeze the sample.

Ensure that personnel who transport specimens are trained in safe handling practices and spill decontamination procedures. Samples should be transported in triple package to fulfill the requirements of the national or international regulations for the transport of dangerous goods (infectious substances).

The request form relevant to the sample needs to be completed in full (Annex 6a-6d). Notify the laboratory as soon as possible that the specimen is being transported. PPE is not necessary for people who transport specimens that are in the triple package.

6.1.1 Description of the triple package

• **Primary receptacle**

This should be a watertight, leak-proof receptacle containing the specimen; it should be properly labeled. The receptacle should be wrapped in enough absorbent material to absorb all fluid in case of breakage. For disposal purposes, please choose a suitable plastic container as a primary receptacle.

• **Secondary receptacle**

This should be a durable, watertight, leak-proof receptacle to enclose and protect the primary receptacle(s). Several wrapped primary receptacles for the same laboratory test may be placed in one secondary receptacle. Enough additional absorbent material must be used to cushion multiple primary receptacles.

• **Outer package**

This is the container in which the secondary receptacle is placed. This is the outer-most package that protects the receptacle and its contents from outside influences, such as physical damage and water, while in transit.

07 DECONTAMINATION AND DISPOSAL OF WASTE

Interim Biosafety Guidelines for laboratories for personnel handling samples or materials associated with 2019-nCoV of the MOHIMS, Sri Lanka of 7 February 2020 specifies the process to be adopted for decontamination and the disposal of waste.

• After specimens are processed, decontaminate work surfaces with 0.1% hypochlorite.

• The contact time is at least 10 minutes. Alcohol (e.g. isopropyl 70%, ethyl alcohol 60%) can be used to wipe down surfaces where the use of bleach is not suitable (e.g., metal).

• Equipment should be disinfected according to the manufacturer’s instructions, using appropriate disinfectants. 70% alcohol can also be used for equipment surfaces.

• For spillages, use 1% hypochlorite. The contact time is at least 10 minutes.

• All disposable waste should be autoclaved and incinerated. If an incinerator is available within the premises, waste could be sent directly for incineration.

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Control samples should be examined prior to the interpretation of results. SARS CoV-2 results will be in the following four formats from the COVID-19 testing laboratories:

• **SARS CoV-2 RNA Detected** –
  At least two SARS CoV-2 RNA targets, of which one target is specific for SARS CoV-2, are detected within the Ct values defined by the COVID testing laboratory.

  Before issuing **positive results**, the clinical and epidemiological information provided in request forms should be evaluated, and, if required, further inquiries should be made from clinical and epidemiology teams to verify that the positive results are in accordance with the clinical and or epidemiological features.

  The positive result is interpreted as molecular evidence of SARS CoV-2 infection.

• **SARS CoV-2 RNA Not Detected** –
  Both SARS CoV-2 RNA targets are clearly negative, but inhibition control is positive.

  Before issuing negative results from samples from individuals with a background that puts them at high-risk of COVID-19 infection, the clinical and epidemiological information provided in the request form should be evaluated, and, if required, further inquiries should be made from clinical and epidemiology teams to verify that the negative results are in accordance with the individual’s clinical and or epidemiological features.

  For several reasons, the RT-PCR assay can be negative in a patient with a true infection.

  When the clinical or and epidemiological suspicion is high, it advisable to do follow-up testing. If the patient is producing sputum, follow-up testing can be done on a sputum sample, if the initial negative result is from an upper respiratory tract sample.

  The negative result is interpreted as not having molecular evidence of SARS CoV-2 infection, at the time of obtaining the sample.

• **SARS CoV-2 RNA result: Inconclusive** –
  When there is some reactivity in both or either of the SARS CoV-2 RNA targets, which is not within the defined Ct values.

  This requires a repeat test with the re-extraction of the same sample or and testing a follow-up sample.

• **SARS CoV-2 RNA result: Invalid** –
  When the test has not properly worked for the sample; therefore, the situation is similar to a situation where the test has not been performed for the sample. This requires a repeat test with the re-extraction of the same sample or and testing a follow-up sample.

### 8.1 NOTIFICATION OF RESULTS AND DISSEMINATION

All of the testing laboratories in Sri Lanka are mandated to immediately communicate positive test results to the Epidemiology Unit of the MOHIMS. This is to enable containment measures to prevent further spread from the individual identified as having COVID-19 infection.

In addition, the aggregated data of all of the tests performed in a day is entered into an online data platform of the MOHIMS by all testing laboratories. Based on this data, a daily update of the collated laboratory data of the country is disseminated to key stakeholders.

Plans are also underway to integrate laboratory data of COVID-19 to the existing National COVID-19 surveillance system of Sri Lanka.
GUIDELINES FOR PRIVATE SECTOR LABORATORIES PERFORMING COVID-19 TESTING

Performance of COVID-19 PCR testing by private sector medical laboratories is governed by the circular EPID/400/2019/nCoV date 10 March 2020 (Annex 7). The circular specifies that all private laboratories should strictly adhere to testing suspected COVID-19 cases based on the case definitions published by the MOHIMS. directly for incineration.

QUALITY ASSESSMENT SCHEMES

Performing internal and external quality assessments is imperative to ensuring the validity of the results of laboratory tests in a country.

As for internal quality assessments, each test run must be validated technically, and an assessment of the clinical features and epidemiological factors conducted, before the authorization of results. Whenever a new protocol commences or new commercial kits are introduced into the testing market, each laboratory should validate and verify the kits performance based on analytical sensitivity, specificity, and repeatability. Furthermore, when using a new lot of previously approved commercial kits, individual laboratories should carry out verification of the performances prior to using the kits on clinical samples.

With the support of WHO Sri Lanka, arrangements were made for Sri Lankan testing laboratories to participate in external quality assessment schemes. Four state sector laboratories successfully completed the WHO SARS-CoV-2 External Quality Assessment Programme by the University of Hong Kong in May/June 2020 with a score of 100%. The four laboratories assured for quality are:

1. The National Influenza Centre, department of virology, MRI
2. Virology laboratory of the Teaching Hospital Karapitiya
3. Virology laboratory of the National Hospital Kandy
4. Virology laboratory of the Teaching Hospital Anuradhapura
Another 21 state sector laboratories have been registered to participate in the WHO SARS-CoV-2 External Quality Assessment Programme by accredited laboratories in Australia in July/August 2020.

The MOHIMS has officially requested that private sector laboratories performing COVID-19 tests cross-validate their performance with one of the state laboratories that has been quality assured by the WHO SARS-CoV-2 External Quality Assessment Programme.
11
SUPPLY CHAIN MANAGEMENT FOR PCR TESTING FOR COVID-19

Existing networks of institutions and established procedures of the MOHIMS to efficiently ensure an adequate supply of required drugs, devices, including medical equipment, and all other required materials are being used to manage the supply chain for PCR testing for COVID-19. The main institutions and their function in the chain are as follows.

11.1 MEDICAL SUPPLIES DIVISION (MSD)

The key institution involved in estimating, forecasting, ordering, stock maintaining, and distributing PCR kits and consumables to healthcare institutions is the MSD. Supplies from donors and UN agencies are also coordinated by the MSD.

11.2 NATIONAL MEDICINES REGULATORY AUTHORITY (NMRA)

NMRA is the authorized key institution to ensure the optimum quality, required efficacy/effectiveness, and safety of PCR kits and consumables.

11.3 STATE PHARMACEUTICAL CORPORATION (SPC)

As the major procurement agency of supplies to MSD, it is the responsibility of the SPC to ensure the timely supply of PCR kits and consumables to the MSD as per the orders placed with them. At present, the supply chain management is under close monitoring by the Secretary, MOHIMS, to ensure an uninterrupted supply of consumables and reagents for COVID-19 PCR testing. The status of PCR testing capacity and logistics for each of the testing laboratories in the country are entered into a Google sheet daily. Using this Google sheet, data on the estimated maximum number of PCR tests that can be performed on the following day by respective laboratories is communicated to the Epidemiology Unit for reference when distributing samples for testing.
EXPANSION OF TESTING FOR COVID-19 TO MEET PROJECTED TESTING REQUIREMENTS

Existing networks of institutions and established procedures of the MOHIMS to efficiently ensure an adequate supply of required drugs, devices, including medical equipment, and all other required materials are being used to manage the supply chain for PCR testing for COVID-19. The main institutions and their function in the chain are as follows.

12.1 BUILDING UP OF VIROLOGY LABORATORY CAPACITY IN SRI LANKA

Over the past two to three years approximately 5,000 million LKR has been spent, under the guidance of DDG LS, on the strengthening of laboratory services in Sri Lanka. Five virology laboratories, indicated below, were built during this period.

1. Teaching Hospital Jaffna
2. Teaching Hospital Anuradhapura
3. Teaching Hospital Kurunegala
4. Teaching Hospital Karapitiya
5. National Institute for Cancer - Apeksha Hospital

Furthermore, the following institutions were provided with substantial equipment to strengthen the laboratory service of the country: the National Institute for Cancer - Apeksha Hospital, National Hospital Kandy, Teaching Hospital Rathnapura, National Hospital of Sri Lanka Colombo, District General Hospital Nuwareliya, District General Hospital Negombo, Colombo South Teaching Hospital, Colombo North Teaching Hospital, National Hospital for Respiratory Diseases, and Teaching Hospital Kuliyapitiya.
13
SITUATIONAL ANALYSIS OF LABORATORY CAPACITY AND OTHER REQUIREMENTS TO MEET THE PROJECTED EXPANSION OF COVID-19 TESTING

Since setting up laboratory testing for COVID-19 in January 2020, the MOHIMS has expanded the laboratory testing capacity to its planned target capacity of being able to perform 2,500 RT-PCRs per day. The following laboratories perform PCR testing in the country, as of 1 June 2020. Table 3, below, indicates the maximum capacity of PCR tests in government sector laboratories in Sri Lanka as of 1 June 2020.

13.1 CURRENT PCR TESTING INSTITUTIONS IN SRI LANKA

Government Institutions:
1. Medical Research Institute
2. National Hospital Kandy
3. National Institute of Infectious Diseases
4. Teaching Hospital Anuradhapura
5. North Colombo Teaching Hospital
6. Teaching Hospital Karapitiya
7. National Institute for Cancer - Apeksha Hospital
8. Teaching Hospital Jaffna
9. Teaching Hospital Batticaloa
10. Provincial General Hospital Badulla
11. Teaching Hospital Rathnapura
12. District General Hospital Nuwaraeliya

Laboratories of Universities:
13. Faculty of Medicine - University of Sri Jayewardenepura
14. Faculty of Medicine - Kothalawala Defence University (KDU)
15. Faculty of Medicine - University of Colombo
16. Faculty of Medicine - University of Jaffna

Private Institutions:
17. Asiri Genetic Laboratory
18. Durdans Hospital
19. Nawaloka Hospital (pvt) Ltd.
20. Lanka Hospital (pvt) Ltd.

13.2 DETAILS OF THE PCR TESTING CAPACITY OF LABORATORIES CONDUCTING RT-PCR FOR COVID-19

There are different brands of RT-PCR systems available in different laboratories. As indicated above, the PCR kits are machine-specific. Manufacturers of SARS CoV-2 RT-PCR kits specify the compatibility of the kits with specific brands of RT-PCR systems. Therefore, it is necessary to check the compatibility of SARS CoV-2 RT PCR kits with the available RT-PCR machines in laboratories. The capacity of a COVID-19 testing laboratory is also dependent on several other factors such as the availability and capacity to automate processes, other necessary equipment (e.g., number of biosafety cabinets for nucleic acid extraction), trained human resources, space to accommodate more equipment, and the capacity of existing equipment (e.g., number of samples per run in a centrifuge), amongst other factors. Further, capacity is dependent on that laboratory’s commitments to provide other testing services as well. Accordingly, different laboratories have different capacities to perform testing. Table 3 below describes the maximum capacity of the various laboratories as of 1 June 2020.
Table 3: Details of the PCR testing capacity of laboratories conducting RT-PCR for COVID-19 as of 1 June 2020

<table>
<thead>
<tr>
<th>INSTITUTE</th>
<th>RT-PCR MODEL</th>
<th>PCR KIT USED</th>
<th>MAX. CAPACITY PER DAY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Research Institute (MRI)</td>
<td>ABI Step one</td>
<td>Altona/ IDT</td>
<td>600</td>
</tr>
<tr>
<td></td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ABI 7500</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td>National Hospital Kandy</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td>Teaching Hospital Karapitiya</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>150</td>
</tr>
<tr>
<td></td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td>North Colombo Teaching Hospital</td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td>92</td>
</tr>
<tr>
<td>Teaching Hospital Rathnapura</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>120</td>
</tr>
<tr>
<td>Teaching Hospital Batticaloa</td>
<td>ABI 7500</td>
<td>Altona/ IDT</td>
<td>150</td>
</tr>
<tr>
<td>National Institute of Infectious Diseases</td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td>250</td>
</tr>
<tr>
<td>Teaching Hospital Anuradhapura</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>150</td>
</tr>
<tr>
<td>Provincial General Hospital Badulla</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>70</td>
</tr>
<tr>
<td>National Institute for Cancer-Apeksha Hospital</td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td>80</td>
</tr>
<tr>
<td>Faculty of Medicine - University of Colombo</td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td>186</td>
</tr>
<tr>
<td>Faculty of Medicine - University of Jaffna</td>
<td>Applied BioSystem</td>
<td>CDC</td>
<td>60</td>
</tr>
<tr>
<td>Faculty of Medicine - University of Sri Jayewardenepura</td>
<td>ABI 7500</td>
<td>Altona/ IDT</td>
<td>360</td>
</tr>
<tr>
<td></td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td>Faculty of Medicine - Kothalawala Defence University (KDU)</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td>40</td>
</tr>
<tr>
<td>Teaching Hospital Jaffna</td>
<td>Rotor Gene</td>
<td>Altona/ IDT</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ABI Step one plus</td>
<td>CDC</td>
<td>48</td>
</tr>
<tr>
<td></td>
<td>ABI Con studio 3</td>
<td>CDC</td>
<td></td>
</tr>
<tr>
<td>District General Hospital Nuwaraeliya</td>
<td>Bio rad</td>
<td>Altona/ IDT</td>
<td>30</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td><strong>2,526</strong></td>
</tr>
</tbody>
</table>
13.3
THE REQUIRED REAGENTS AND CONSUMABLES TO PERFORM 20,000 SAMPLES WITH RT-PCR

To efficiently support daily testing capacity, it is essential to maintain a continuous and uninterrupted reagent supply for COVID-19 testing laboratories. Approximate estimates of the needed quantities of different consumables to test 20,000 samples with RT-PCR are outlined in Table 4.

Table 4: Requirement of reagents and consumables for performing 20,000 samples with RT-PCR

<table>
<thead>
<tr>
<th>RT-PCR MODEL</th>
<th>QTY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial COVID-19 Real Time PCR diagnostic kit (the comprehensive kit, including all primer/probe mix, enzymes, molecular reagents, inhibition control, and positive controls) to detect SARS CoV2 in respiratory specimens (96 reactions/kit)</td>
<td>250</td>
</tr>
<tr>
<td>Commercial Viral RNA extraction kit to extract viral RNA in respiratory specimens (250 reactions/kit)</td>
<td>80</td>
</tr>
<tr>
<td>Commercial virus transport medium with 2 swabs (VTM)</td>
<td>20,000</td>
</tr>
<tr>
<td>Viral swab for in-house prepared VTM (sterile dacron or rayon swabs with plastic shafts)</td>
<td>10,000</td>
</tr>
<tr>
<td>0.1 ml PCR tubes in strips with caps RNase/DNase free (250 strips/pk)</td>
<td>100</td>
</tr>
<tr>
<td>0.2 ml PCR tubes in strips with flat cap RNase/DNase free</td>
<td>30,000</td>
</tr>
<tr>
<td>0.2 ml PCR tubes with flat cap RNase/DNase free</td>
<td>30,000</td>
</tr>
<tr>
<td>1.5 ml microcentrifuge tubes RNase/DNase free</td>
<td>40,000</td>
</tr>
<tr>
<td>100 μl – 1,000 μl RNase/DNase free filter tips Rack packed (96tips/box)</td>
<td>500</td>
</tr>
<tr>
<td>20μl - 200μl RNase/DNase free filter tips Rack packed (96tips/box)</td>
<td>500</td>
</tr>
<tr>
<td>2μl – 20μl RNase/DNase free filter tips Rack packed (96tips/box)</td>
<td>200</td>
</tr>
<tr>
<td>0.5μl – 10μl RNase/DNase free filter tip Rack packed (96tips/box)</td>
<td>500</td>
</tr>
<tr>
<td>Powder-free gloves (100/pack)</td>
<td>1000</td>
</tr>
<tr>
<td>100% Ethanol, molecular grade</td>
<td>150 L</td>
</tr>
<tr>
<td>Cryovials 2 ml RNase/DNase free</td>
<td>20,000</td>
</tr>
<tr>
<td>Cryo-storage boxes</td>
<td>50</td>
</tr>
<tr>
<td>Pasteur pipettes 3 ml (individually wrapped)</td>
<td>20,000</td>
</tr>
<tr>
<td>Disposable long-sleeved lab cots</td>
<td>20,000</td>
</tr>
<tr>
<td>Head caps</td>
<td>20,000</td>
</tr>
<tr>
<td>N95 masks</td>
<td>1000</td>
</tr>
<tr>
<td>Medical Mask</td>
<td>1000</td>
</tr>
<tr>
<td>Goggles/face shield</td>
<td>200</td>
</tr>
<tr>
<td>Yellow bags large</td>
<td>500</td>
</tr>
<tr>
<td>Discard jar bags</td>
<td>500</td>
</tr>
<tr>
<td>Lab shoes (pairs)</td>
<td>50</td>
</tr>
</tbody>
</table>

Prepared by Sri Lanka College of Microbiologists - 06.04.2020
13.4
SPECIFICATIONS FOR REAGENTS AND CONSUMABLES FOR PERFORMING RT-PCR

A supply of the correct and relevant consumables of good quality is critical to maintaining the accuracy of the results generated in COVID-19 testing laboratories. Specifications of different reagents and consumables needed for COVID-19 testing are shown in Table 5.

Table 5: Specifications for reagents and consumables for performing RT-PCR

| ITEM |
| ITEM WITH SPECIFICATIONS |
|---|---|
| 1. | Should be Real Time PCR format |
| 2. | Approved for in vitro diagnostics (CE IVD or equivalent). Locally validated kits, that are already being used at virology laboratories in the MOHIMS, may also be considered to maintain the supply chain. |
| 3. | Should have at least 2 SARS CoV-2 RNA targets (N gene, E gene, ORF gene, etc.); both specific for SARS CoV-2 virus or one specific for beta coronaviruses and the other one specific for SARS CoV 2 virus. |
| 4. | Should have an extraction control, preferably an endogenous human gene target (e.g., RNase P gene). |
| 5. | Compatible with a wide range of thermal cyclers (Rotor Gene Q 5plex, Applied Biosystems 7500, Bio Rad CFX96, Applied Biosystems Quantstudio, and Applied Biosystems step one plus platforms); please specify. |
| 6. | Detection dyes should be compatible with commonly available thermal cyclers in the country (Rotor Gene Q 5plex, Applied Biosystems 7500, Bio Rad CFX96, Applied Biosystems Quantstudio, and Applied Biosystems step one plus platforms); |
| 7. | Multiplex format is preferable with all targets detected in one reaction tube |
| 8. | Should not take excessively long to complete the cycles |
| 9. | Very good sensitivity and specificity |
| 10. | Kit should not detect common human Coronaviruses |
| 11. | Preferably should provide all reagents and consumables necessary for the RT-PCR test (enzymes, primers, probes, dNTPs, buffers, nuclease-free water, etc.) |
| 12. | Should be able to perform using equipment available in a general molecular laboratory |
| 13. | Storage conditions should be specified |
| 14. | Stability after opening the kit should be specified |
| 15. | Kit should be with positive and negative controls for quality control |
| 16. | Should be compatible with a wide range of extraction methods/ kits |
| 17. | Should have adequate stocks available to be used for a considerable time and ensure a continuous supply. |
| 18. | Should provide kit insert and product details with protocols for evaluation |
| 19. | Should provide a sample kit free of charge if requested for laboratory verification |
| 20. | When a kit is selected, expiry date of the supplied kit should be reasonable and conveyed for agreement with the end-user |
| 21. | Kits should be supplied according to a delivery schedule agreed to with the end-user |
| 22. | Any issue of kit performance during large scale use will factor into a review regarding further procurement |
1. Should be of spin column format
2. Should be able to extract viral RNA or both viral DNA and RNA
3. Should be able to utilize a wide range of respiratory samples (sputum, nasopharyngeal and oropharyngeal swabs in VTM, tracheal aspirates, BAL, etc.)
4. Should have a high yield with a minimal amount of sample
5. Eluted nucleic acid should be ready to use in amplification reactions
6. Purified nucleic acid should be free of proteins, nucleases, and other impurities
7. Kit should be complete with all consumables included in sufficient quantities to perform the indicated reaction number (extraction columns, collection tubes, carrier RNA, lysis buffer, wash buffer, elution buffer, etc.)
8. Test should be able to perform using standard clinical laboratory equipment (centrifuge, heat block, etc.)
9. Procedure should not take excessively long
10. Reconstituted solutions in the kit should be stable long-term
11. Should have easy storage conditions with instructions
12. Should have adequate stocks available to be used for a considerable time and ensure a continuous supply.
13. Should be compatible with a wide range of real-time PCR kits
14. Should provide kit insert and product details with protocols for evaluation
15. Should provide a sample kit free of charge if requested for laboratory verification
16. When a kit is selected, the expiry date of the supplied kit should be reasonable and conveyed for agreement with the end-user
17. Kits should be supplied according to a delivery schedule agreed to with the end-user
18. Any issue of kit performance during large scale use will factor into a review regarding further procurement
<table>
<thead>
<tr>
<th>Viral Transport Media and Swabs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. VTM should be suitable to transport respiratory samples</td>
</tr>
<tr>
<td>2. At least 3 ml should be available</td>
</tr>
<tr>
<td>3. Should be able to maintain virus yield and should not have any effect on the PCR reaction</td>
</tr>
<tr>
<td>4. Should keep the virus stable at least 48 hours in +4oC until the sample reaches the laboratory</td>
</tr>
<tr>
<td>5. Should be leak-proof, screw-capped, plastic tubes</td>
</tr>
<tr>
<td>6. Preferably, the tube should be around 10cm long to accommodate the swab with the shaft</td>
</tr>
<tr>
<td>7. Preferably, should have 2 plastic swabs with dacron or rayon tip. One swab with a long flexible shaft for nasopharynx and one with a thick shaft for oropharynx</td>
</tr>
<tr>
<td>8. Should be safe to insert into nose and throat</td>
</tr>
<tr>
<td>9. Should have a long shelf life in room temperature</td>
</tr>
<tr>
<td>10. Should be easy to store</td>
</tr>
<tr>
<td>11. Should have adequate stocks available to be used for a considerable time and ensure a continuous supply.</td>
</tr>
<tr>
<td>12. Should provide product details with protocols for evaluation</td>
</tr>
<tr>
<td>13. Should provide a few samples of the item free of charge if requested for verification</td>
</tr>
<tr>
<td>14. When a VTM (with swabs) is selected, the expiry date of the supplied VTM should be reasonable and conveyed for agreement with the end-user</td>
</tr>
<tr>
<td>15. VTM should be supplied according to a delivery schedule agreed to with the end-user</td>
</tr>
<tr>
<td>16. Any issue of performance of VTM during large scale use will factor into a review regarding further procurement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Absolute ethanol</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Molecular biology-grade (analytical-grade could also be considered in the absence of molecular-grade)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Microcentrifuge tubes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Should be virgin polypropylene</td>
</tr>
<tr>
<td>2. Must have a safe lock</td>
</tr>
<tr>
<td>3. DNase and RNase free</td>
</tr>
<tr>
<td>4. Should be Sterile</td>
</tr>
<tr>
<td>5. Should be clear or colourless</td>
</tr>
<tr>
<td>6. Volume capacity of 1.5ml</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cryovials</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial stands without holder, externally threaded screw-capped, autoclavable, can be frozen at -80 C, bulk packed, volume 1.8ml</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PCR tubes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Optical grade, 0.2 ml (DNase and RNase free), clear tubes in strips (8 tubes) with 8 strip caps for Real time PCR machine, the lid should be a flat shape</td>
</tr>
<tr>
<td>Optical grade, 0.1 ml (DNase and RNase free), clear tubes in strips (4 tubes) with 4 strip caps for Real Time PCR</td>
</tr>
<tr>
<td>Optical grade, Flat-shaped lids, size 0.2 ml individual tubes, sterile, (DNase and RNase free)</td>
</tr>
<tr>
<td>Micropipette tips</td>
</tr>
<tr>
<td>------------------</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Disposable plastic pasteur pipette</td>
</tr>
</tbody>
</table>

Special note
- Should provide product details with catalogue numbers of all items for evaluation
- Should provide a few samples of each item free of charge if requested for evaluation
- All items should have a reasonable period for expiration on delivery, this should be conveyed for agreement with the end-user
- All items should be delivered in accordance with a delivery schedule, as specified in the purchase order

13.5 GUIDANCE ON PLANNING TO INITIATE THE COVID-19 RT-PCR TESTING SERVICE IN NEW FACILITIES

Any clinical diagnostic laboratory should function under clinical governance to assure the delivery of clinically relevant accurate results with good clinical liaison. The same principles apply for COVID-19 testing laboratories. COVID-19 testing laboratories should adhere to stringent infection prevention and control measures (biosafety and biosecurity measures), including the proper management and disposal of clinical and laboratory waste.

COVID-19 RT-PCR test results are very important when making decisions in the following clinical and epidemiological contexts:

1. The exclusion of suspected patients from hospital isolation wards
2. Cohort isolation of positive patients together for further management
3. Contact tracing and contact quarantining procedures

Therefore, the following points should be strictly considered and assessed before providing permission for new facilities to start COVID-19 RT-PCR testing services.

1. Availability of the onsite service of a Consultant Medical Microbiologist/Virologist is essential for the initiation of COVID-19 RT-PCR diagnostic services in new facilities. Therefore, when expanding the COVID-19 RT-PCR diagnostic service, priority should be given to laboratories where a Consultant Medical Microbiologist/Virologist is already available. In the absence of an onsite service, the first priority would be to officially arrange coverage services from a Consultant Medical Microbiologist/Virologist.

2. Arrangements should be available for Consultant Microbiologists to liaise with a designated Consultant Virologist in providing COVID-19 RT-PCR diagnostic services in their facilities.

3. Availability of a feasible mechanisms for the supply of reagents/consumables and personnel protective equipment to guarantee uninterrupted service.
4. Availability of adequate laboratory space, molecular laboratory format, and the needed equipment for this testing service.

5. Availability of adequate trained staff with experience in PCR work or potential staff to undergo training.

6. Availability of a clinical waste management policy and system with incineration or autoclave facilities.

7. Feasibility of result authorization and clinical liaison under the responsibility of the Consultant Medical Microbiologist/Virologist in routine work.

8. Feasibility of efficient result delivery method to end-users.
1. In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid Emergency Use Listing of IVDs https://www.who.int/diagnostics_laboratory/200428_final_pqt_ivd_347_instruction_ncov_nat_eul.pdf?ua=1

2. In vitro diagnostics (IVDs) Detecting Antibodies to SARS-CoV-2 virus Emergency Use Listing of IVDs https://www.who.int/diagnostics_laboratory/200417_pqt_ivd_eul_requirements_ncov_rdt_antibody.pdf?ua=1hg

3. Laboratory testing for Coronavirus diseases (COVID-19) in suspected human cases diseases https://www.dropbox.com/sh/6ds51omvuzijnxp/AACb_f46TSX5u_F6S7eogrya?dl=0&preview=20200319+Laboratory+testing+for+coronavirus+disease.pdf


Annex 1

RT-PCR TEST KITS TO DIAGNOSE CORONAVIRUS DISEASE (COVID-19)

With the announcement of the pandemic of 2019-nCoV, numerous commercial PCR diagnostic kits were supplied to the global market.

WHO’S EMERGENCY USE LISTING (EUL)

With the intention of guiding countries to select suitable diagnostic products, WHO invited the manufacturers of diagnostic kits to submit applications to be included in the WHO’s Emergency Use Listing (EUL). EUL is a procedure used by WHO in emergencies to expedite the availability of diagnostic kits. Based on a minimum set of available quality, safety, efficacy, and performance data, WHO will decide on whether the product evaluated is eligible to be included in the EUL or not. The EUL is an indicator of the suitability of the diagnostic product; it can be used by interested countries and procurement agencies.

Since February 2020, 34 applications have been received for evaluation. As of 1 June 2020, the nine products indicated below have been listed as eligible for WHO procurement based on their compliance with WHO EUL requirements. Global Fund mandates that country requests for RT-PCR kits with its support should mandatorily identify one of the listed nine. However, it should be noted that WHO EUL RT-PCR kits are machine-specific, and not all laboratories in Sri Lanka possess such compatible machines.
## RT-PCR kits included in the WHO Emergency Use Listing

<table>
<thead>
<tr>
<th>DATE LISTED</th>
<th>PRODUCT NAME</th>
<th>PRODUCT CODE(S)</th>
<th>MANUFACTURER</th>
</tr>
</thead>
<tbody>
<tr>
<td>03 Apr 20</td>
<td>cobas SARS-CoV-2 Qualitative assay for use on the cobas 6800/8800 Systems</td>
<td>09175431190 and 09175440190</td>
<td>Roche Molecular Systems, Inc.</td>
</tr>
<tr>
<td>09 Apr 20</td>
<td>Abbott Realtime SARS-CoV-2</td>
<td>09N77-090 and 09N77-080</td>
<td>Abbott Molecular Inc.</td>
</tr>
<tr>
<td>24 Apr 20</td>
<td>PerkinElmer® SARS-CoV-2 Real-time RT-PCR Assay</td>
<td>SY580</td>
<td>SYM-BIO LiveScience Co., Ltd</td>
</tr>
<tr>
<td>07 May 20</td>
<td>Real-time fluorescent RT-PCR kit for detecting 2019-nCoV</td>
<td>MFG030010</td>
<td>BGI Europe A/S</td>
</tr>
<tr>
<td>21 May 20</td>
<td>FTD SARS-CoV-2</td>
<td>11416300</td>
<td>Fast Track Diagnostics Luxembourg S.à.r.l.</td>
</tr>
<tr>
<td>22 May 20</td>
<td>Novel Coronavirus (SARS-CoV-2) Real Time Multiplex RT-PCR Kit</td>
<td>RR-0485-02</td>
<td>Shanghai ZJ Bio-Tech Co., Ltd</td>
</tr>
<tr>
<td>05 Jun 20</td>
<td>SARS-CoV-2 Nucleic Acid Test (Real-time PCR)</td>
<td>KH-G-M-574-48</td>
<td>Shanghai Kehua Bioengineering Co., Ltd</td>
</tr>
<tr>
<td>11 Jun 20</td>
<td>Novel Coronavirus 2019-nCoV Nucleic Acid Detection Kit (Real Time PCR)</td>
<td>GZ-D2RM25</td>
<td>Shanghai GeneoDx Biotechnology Co., Ltd</td>
</tr>
<tr>
<td>23 Jun 20</td>
<td>Xpert® Xpress SARS-CoV-2</td>
<td>XPRSARS-COV2-10</td>
<td>Cepheid AB</td>
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</tbody>
</table>

### Foundation for Innovative New Diagnostics (FIND), a WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology, evaluates and publishes the performance results of the PCR test kits; offering another source of scientific information to use when choosing RT-PCR kits. The list of 14 PCR kits (as of 18 May 2020) that are selected based on scoring criteria are listed below.

---

### FIND evaluated RT-PCR test kits

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>GENE TARGET</th>
<th>PRODUCT NO.</th>
<th>PRODUCT NAME</th>
<th>LOT NO.</th>
<th>PCR PLATFORM</th>
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<td><strong>Altona Diagnostics</strong></td>
<td>E</td>
<td>821003/821005</td>
<td>RealStar® SARS-CoV-2 RT-PCR Kit 1.0</td>
<td>023567</td>
<td>BioRad CFX96 deep well</td>
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<tr>
<td><strong>Atila BioSystems Inc.</strong></td>
<td>ORF1ab N</td>
<td>iAMP-COVID-100-ROU</td>
<td>Atila iAMP COVID-19 Detection (isothermal detection)</td>
<td>COVID20200320</td>
<td>BioRad CFX96 deep well</td>
</tr>
<tr>
<td><strong>BGI Health (HK) Co. Ltd</strong></td>
<td>ORF1</td>
<td>MFG030010</td>
<td>Real-time Fluorescent RT-PCR kit for detection 2019-nCOV (CE-IVD)</td>
<td>62202000305</td>
<td>Roche LightCycler 480</td>
</tr>
<tr>
<td><strong>Boditech Med. Inc.</strong></td>
<td>E RdRP</td>
<td>UFPK-4</td>
<td>ExAmplar COVID-19 real-time PCR kit (L)</td>
<td>WLQCB02L</td>
<td>BioRad CFX96 deep well</td>
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<tr>
<td><strong>CerTest Biotec</strong></td>
<td>ORF1ab N</td>
<td>VS-NC0112L VS-NC0212L</td>
<td>VIASURE SARS-CoV-2 Real Time PCR Detection Kit</td>
<td>NCO212L-023</td>
<td>BioRad CFX96 deep well</td>
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<tr>
<td><strong>DAAN Gene Co. Ltd</strong></td>
<td>ORF1 N</td>
<td>DA0930-DA0932</td>
<td>Detection Kit for 2019 Novel Coronavirus (2019-nCoV) RNA (PCR-Fluorescence Probing)</td>
<td>2020007</td>
<td>Roche LightCycler 480</td>
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<tr>
<td><strong>EUROIMMUN</strong></td>
<td>ORF1ab/N</td>
<td>MP 2606-0425</td>
<td>EURORealTime SARS-CoV-2</td>
<td>I200320AL</td>
<td>Light Cycler 480 II</td>
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<tr>
<td><strong>GeneFirst Limited</strong></td>
<td>ORF1 N</td>
<td>MPA-COVID19</td>
<td>The Novel Coronavirus (2019-nCoV) Nucleic Acid Test Kit</td>
<td>00072</td>
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</tr>
<tr>
<td><strong>KH Medical Co. Ltd</strong></td>
<td>S RdRP</td>
<td>RV008</td>
<td>RADI COVID-19 Detection Kit</td>
<td>V008.200202</td>
<td>BioRad CFX96 deep well</td>
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<tr>
<td><strong>R-Biopharm AG</strong></td>
<td>E</td>
<td>PG6815RUO</td>
<td>RIDA®GENE SARS-CoV-2 RUO</td>
<td>21120N</td>
<td>BioRad CFX96 deep well</td>
</tr>
<tr>
<td><strong>SD Biosensor Inc.</strong></td>
<td>E ORF1</td>
<td>M-NCOV-01</td>
<td>STANDARD M nCoV Real-Time Detection Kit</td>
<td>MNC00120005</td>
<td>Roche LightCycler 480</td>
</tr>
<tr>
<td><strong>Seegene Inc.</strong></td>
<td>E N RdRP</td>
<td>RP10244Y RP10243X</td>
<td>Allplex™ 2019-nCoV Assay</td>
<td>RP4520C24</td>
<td>BioRad CFX96</td>
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<tr>
<td><strong>Tib Molbiol</strong></td>
<td>E</td>
<td>53-0776-96 6754155001</td>
<td>ModularDx Kit SARS-CoV (COVID19) E-gene (Tib Molbiol) + LightCycler Multiplex RNA Virus Master (Roche)</td>
<td>48202019 48274100</td>
<td>Roche LightCycler 480</td>
</tr>
</tbody>
</table>
LISTED BY NATIONAL REGULATORY AUTHORITIES IN IMDRF JURISDICTIONS

The International Medical Device Regulators Forum (IMDRF) also maintains an emergency list of RT-PCR kits that it authorizes to be used by the countries. The list is updated weekly and can be accessed here: https://www.who.int/diagnostics_laboratory/200504_imdref_collated_table_4_may_2020.pdf?ua=1.
## GENEXPERT INSTALLATION DATABASE IN SRI LANKA

<table>
<thead>
<tr>
<th>CUSTOMER NAME</th>
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<tbody>
<tr>
<td>1 NTRL, Welisara</td>
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<tr>
<td>2 NTRL, Welisara</td>
<td>Microbiology Lab</td>
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<tr>
<td>3 The National Hospital of Sri Lanka</td>
<td>Microbiology Lab</td>
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<tr>
<td>4 Teaching Hospital, Kurunegala</td>
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<td>5 Teaching Hospital, Batticaloa</td>
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<tr>
<td>7 Provincial General Hospital, Badulla</td>
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<tr>
<td>10 District Chest Clinic, Kandy</td>
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<td>11 Chest Clinic, Jaffna</td>
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<tr>
<td>12 TH Kegalle</td>
<td>Microbiology Lab</td>
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<tr>
<td>13 National Institute of Health Science, Kalutara</td>
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<tr>
<td>14 NTRL, Welisara</td>
<td>Microbiology Lab</td>
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<tr>
<td>15 NTRL, Welisara</td>
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<td>16 The National Hospital of Sri Lanka</td>
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### Under National STD/AIDS Control Programme

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<td>34 STD Clinic, Mahamodara</td>
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### Other

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<tr>
<td>35 Apeksha Hospital,Maharagama</td>
<td>Haematology Lab</td>
</tr>
<tr>
<td>36 Sri Jayawardenapura General Hospital</td>
<td>Microbiology Lab</td>
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</tbody>
</table>
Annex 3
MINISTRY OF HEALTH AND INDIGENOUS MEDICAL SERVICE CIRCULAR DDG(PHS I)
DO2/12-9/2019/10 -26 JANUARY 2020

Provincial Directors of Health Services,
Regional Directors of Health Services,
Heads/Directors of Health Institutions,
Directors of National Hospital/Teaching Hospitals/Provincial &
District General Hospitals, Base Hospitals,
All Medical Superintendents of other Hospitals,
All Consultant Community Physicians,
All Regional Epidemiologists,

Interim Summary Guidelines for Clinical Management of patients with
novel coronavirus (2019-nCoV)

2019 Novel Coronavirus (2019-nCoV) is a virus (more specifically, a coronavirus) identified as the cause of an outbreak of respiratory illness first detected in Wuhan, China. Early on, many of the patients in the outbreak in Wuhan, China reportedly had some link to a large seafood and animal market, suggesting animal-to-person spread. However, a growing number of patients reportedly have not had exposure to animal markets, suggesting person-to-person spread is occurring. There is growing evidence that 2019-nCoV can spread from person to person in the community and in health care settings. At this time, it is unclear how easily or sustainably this virus is spreading between people.

Current disease situation
An increased number of cases infected with 2019-nCoV are reporting from the Hubei Province, number of other provinces and cities in China and also several other countries. As of 25th January, 2020, the World Health Organization has reported 1320 confirmed novel coronavirus cases of which 1297 cases are from China (including Taipei, Macau and Hong Kong). Out of 23 confirmed cases reported from other countries 21 had a travel history to Wuhan City. Four cases were reported from Thailand while Japan, Republic of Singapore, Australia and French Republic reported three cases in each country. United State of America, Republic of Korea and Viet Nam reported two cases in each country. One confirmed novel coronavirus case was reported in Nepal. Forty one deaths have been reported, all of them are from China.
The infectious agent

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). Novel coronavirus is a new coronavirus affecting people who have recently been in the area of Wuhan, Hubei Province, China. At the moment, this coronavirus is called 'novel coronavirus' or '2019-nCoV'. A novel coronavirus (n-CoV) is a new strain that has not been previously identified in humans.

Coronaviruses are zoonotic, meaning they are transmitted between animals and people. Detailed investigations found that SARS-CoV was transmitted from civet cats to humans and MERS-CoV from camels to humans. Several known coronaviruses are circulating in animals that have not yet infected humans.

Mode of transmission

Early reports indicated that most of the cases had prior contact with a seafood and live animal market, suggesting an animal source of the outbreak. However, more recently, some human to human transmission has been reported, in family clusters and in healthcare workers.

Human to human transmission is most likely to be through direct contact with case-patients, by respiratory droplets and by fomites (contaminated objects and surfaces), as is seen with other coronavirus infections including SARS and MERS.

People who are living or travelling to affected areas or who have had contact with other cases may be at risk of catching the disease. People with underlying illnesses that make them more vulnerable to respiratory disease, including those with diabetes, chronic lung disease, pre-existing kidney failure, or those who have suppressed immune systems, may be at a higher risk.

Clinical Presentation

Common signs of infection include respiratory symptoms, fever, cough, sore throat, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Chest radiographs showing invasive pneumonic infiltrates in both lungs.

Incubation period - 2-14 days
The following people should be investigated, tested and notified for nCoV(2019) infection

Case definitions for surveillance
1. Severe Acute Respiratory Infection (SARI) in a person, with history of fever and cough requiring admission to hospital, with no other etiology that fully explains the clinical presentation (clinicians should also be alert to the possibility of atypical presentations in patients who are immunocompromised); AND any of the following:
   a) A history of travel to Wuhan, Hubei Province China in the 14 days prior to symptom onset; or
   b) the disease occurs in a health care worker who has been working in an environment where patients with severe acute respiratory infections are being cared for, without regard to place of residence or history of travel; or
   c) the person develops an unusual or unexpected clinical course, especially sudden deterioration despite appropriate treatment, without regard to place of residence or history of travel, even if another etiology has been identified that fully explains the clinical presentation.
2. A person with acute respiratory illness of any degree of severity who presents, within 14 days before onset of illness, had any of the following exposures:
   a) close physical contact with a confirmed case of nCoV infection, while that patient was symptomatic; or
   b) a healthcare facility in a country where hospital-associated nCoV infections have been reported.

All suspected patients with 2019-nCoV need to be notify to Epidemiology Unit immediately by the treating physician by phone (0112695112, 011474049, 0114740490, 0114740492, 0112681548)

Treatment
There is no specific antiviral treatment recommended for 2019-nCoV infection. People infected with 2019-nCoV should receive supportive care to help relieve symptoms. There is no vaccine available to protect against 2019-nCoV.
Sample collection guideline for Novel Coronavirus (nCoV) testing

Criteria for testing

1) Patients with severe acute respiratory infection (fever, cough, and requiring admission to hospital), AND with no other etiology that fully explains the clinical presentation AND at least one of the following:
   a. History of travel to or residence in the city of Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or
   b. Patient is a health care worker who has been working in an environment where severe acute respiratory infections of unknown etiology are being cared for.

2) Patients with any acute respiratory illness AND at least one of the following:
   a. Close contact with a confirmed or probable case of 2019-nCoV in the 14 days prior to illness onset, or
   b. Visiting or working in a live animal market in Wuhan, Hubei Province, China in the 14 days prior to symptom onset, or
   c. Worked or attended a health care facility in the 14 days prior to onset of symptoms where patients with hospital-associated 2019-nCoV infections have been reported.

Information needed in the Lab Request Form

Brief history of the illness is mandatory.

a. Patient information (Name, Age, Sex)
   b. Clinical features / duration / treatment
   c. Presence of co-morbidities
   d. Travel history with specific dates
   e. Date and time of sample collection
   f. Sample type/s
   g. Other laboratory investigations

Sample collection procedure

Type of respiratory samples
   a. Nasopharyngeal and oropharyngeal swab
   b. Endotracheal aspirate, nasopharyngeal aspirate
   c. Bronchoalveolar lavage
   d. Tissue from biopsy or autopsy including from lung (not in formalin or alcohol)

Lower respiratory sample is strongly recommended in severe cases

Time of sample collection - On admission
Use VTM (viral transport medium) tubes
Sample storage
Store at +4°C (2-8°C) if any delay ≥ 48 hours store at -20°C

Sample transport
Transport in triple package system to laboratory within 48 hours

Before sending sample inform Department of Virology, MRI.

All specimens should be regarded as potentially infectious. Health Care Workers who collect, or transport clinical specimens should adhere to infection prevention and control guidelines and national regulations for the transport of dangerous goods (infectious substances) to minimize the possibility of exposure to pathogens.

For further information on sample collection and transport contact Dr. J. Jayamaha, Consultant Virologist, NIC, MRI

Infection Control and Waste Management

Droplet precautions should be added to standard precautions for any patients with suspected infection with 2019-nCoV infection. These infection prevention and control measures should be started when the patient enters triage with symptoms of acute febrile respiratory illness. Give suspect patient a surgical mask and direct patient to separate area, an isolation room if available. Organize the space and process to allow at least one meter distance between each patient with acute respiratory infections and other patients or other individuals not wearing Personal Protective Equipment (PPE). Ensure that triage and waiting areas are adequately ventilated. Instruct all patients to cover nose and mouth during coughing or sneezing with tissue or flexed elbow. Perform hand hygiene after contact with respiratory secretions. Airborne precautions should be used for aerosol-generating procedures.

Standard precautions
- Hand hygiene (i.e. wash hands well with soap and water before and after attending to the patient)
- Respiratory hygiene and cough etiquette (i.e. covering the mouth and nose during coughing or sneezing with a surgical mask, cloth mask, tissue, sleeve or flexed elbow)
- Use appropriate PPE
- Prevention of needle sticks/sharps injuries
- Cleaning and disinfection of the environment and equipment with routine disinfectants

Droplet precautions

Droplet precautions prevent large droplet transmission of respiratory viruses.
- Use a surgical mask of working within 1-2 meters of the patient.
- Place patients in single rooms, or group together those with the same epidemiological diagnosis. If an etiological diagnosis is not possible, group patients with similar clinical diagnosis and based on epidemiological risk factors, with a spatial separation.
When providing care in close contact with a patient with respiratory symptoms (e.g., coughing or sneezing), use eye protection (goggles), because sprays of secretions may occur.

Limit patient movement within the institution and ensure that patients wear surgical masks when outside their rooms.

Contact precautions

Droplet and contact precautions prevent direct or indirect transmission from contact with contaminated surfaces or equipment (i.e., contact with contaminated oxygen tubing/interfaces).

- Use PPE (medical mask, eye protection, gloves and gown) when entering into the isolation room and remove PPE when leaving the room.
- If possible, use dedicated equipment (e.g., stethoscopes, blood pressure cuffs and thermometers).
- If equipment needs to be shared among patients, clean and disinfect between each patient use.
- Ensure that healthcare workers refrain from touching their eyes, nose, and mouth with potentially contaminated gloved or ungloved hands.
- Avoid contaminating environmental surfaces that are not directly related to patient care (e.g., door handles and light switches).
- Ensure adequate room ventilation.
- Minimize movement of patients or transport.
- Perform hand hygiene.

Airborne precautions

Apply airborne precautions when performing an aerosol generating procedure.

- Ensure that healthcare workers performing aerosol-generating procedures (i.e., open suctioning of respiratory tract, intubation, bronchoscopy, cardiopulmonary resuscitation) use PPE, including gloves, long-sleeved gowns, eye protection, and particulate respirators (N95 or equivalent, or higher level of protection).
- Use adequately ventilated rooms when performing aerosol-generating procedures.
- Avoid the presence of unnecessary individuals in the room.

Use of N95 masks are recommended only during the aerosol generating procedures.

In addition to standard precautions, all individuals, including visitors, when in close contact (within 1 meter) or upon entering the room/cubicle of patients with nCoV infection should:

- Wear a surgical mask, wear eye protection (i.e., goggles or a face shield).
- Wear a clean, long-sleeved gown, apron and gloves.
- Perform hand hygiene before and after contact with the patient and his/her surroundings and immediately after removal of PPE.
Transportation of patients with 2019-nCoV infection

- Minimize the movement of patients out of the isolation room or area unless medically necessary. If transport is required, use routes of transport that minimize exposures of staff, other patients, and visitors.
- Inform the receiving area of the patient’s diagnosis and necessary precautions to take, as soon as possible before the patient’s arrival.
- Clean and disinfect patient-contact surfaces (e.g., bed) with routine disinfectants after use. Ensure that healthcare workers who transport patients wear appropriate PPE and perform hand hygiene afterwards.

Duration of infection control precautions for 2019-nCoV infection

The duration of infectivity for 2019-nCoV infection is still unknown. While standard precautions should continue to be applied throughout, additional precautions should be taken during the duration of symptomatic illness and continued for 24 hours after the resolution of symptoms.

Microbiologist of the Hospital is responsible to train all categories of health workers regarding the appropriate/rational use of PPE and infection control measures in accordance with the National guidelines.

In the event of a death from nCoV infection

1. Standard, droplet and airborne precautions should be used as relevant when handling deceased individuals from nCoV infection and when preparing bodies for autopsy or transfer to mortuary services.
2. It is advised that proper hand washing with soap and water is done when direct contact with the body occur during funeral proceedings.

Prevention

It is likely that general prevention measures used for other coronaviruses infections will also prevent infection with 2019-nCoV. The World Health Organization (WHO) recommends measures to reduce the general risk of acute respiratory infections while travelling in or from affected areas by:

- Avoiding close contact with people suffering from acute respiratory infections;
- Frequent hand-washing, especially after direct contact with ill people or their environment;
- Avoiding close contact with live or dead farm or wild animals;
- Travelers with symptoms of acute respiratory infections should practice cough etiquette (maintain distance, cover coughs and sneezes with disposable tissues or clothing, and wash hands).
Specific recommendations on managing a diseased patient with nCoV, further information could be obtained from Clinical management of severe acute respiratory infection when Novel coronavirus (2CoV) infection is suspected: Interim Guidance (https://www.who.int/diseases/2019-novel-coronavirus/home/en/)

Managing suspected traveller with Novel Corona Virus Infection at the Bandaranayake International Airport

Temperature screening

All passengers from flights originating from China need to screen. If a passenger with elevated temperature is detected, he/she should be given a surgical mask to wear and taken to the health office. The person handling the suspected patient should wear surgical mask and gloves.

Notification from the aircraft

APHIO (airport health office) Medical Officer should visit the aircraft and the ill traveller should be taken from the aircraft to an area suitable for further assessment/treatment by a medical escort with the assistance of the relevant staff of the AASI and Sri Lankan Airlines.

After a prompt assessment, APHIO is responsible to communicate immediately about the suspected 2019-nCoV case to the IHR Co-NFPs (Director Quarantine Unit and the Chief Epidemiologist/Epidemiology Unit of MoH) as soon as possible.

Health measures will be initiated under the leadership of the APHIO. Medical Officer/AASI at BIA is requested to take part fully in close collaboration with the APHIO.

Traveller who may be affected or suspected of carrying 2019-nCoV infection shall be transferred immediately to the Infectious Disease Hospital (IDH)/designated hospitals.

Medical screening by APHIO Medical Officer

All suspected 2019-nCoV patients need to be seen by APHIO medical officers. Consent for examination and further assessment should be obtained from the traveller or parent or guardian. If consent is not given, the traveller/s will be managed under the authority given by the Quarantine and Prevention of Diseases Ordinance.

If the traveller has a contact history and fever, signs and symptoms, the traveller should be transferred to IDH/designated hospitals.
Following hospitals are identified as designated hospitals for immediate admission / transferring of suspected patients and hospitals are advised to identify a mechanism for the isolation of patients, implement infection control measures and adhering to guidelines given for the maximum precautions in preventing transmission.

<table>
<thead>
<tr>
<th>IDH</th>
<th>T.H.Amaradhapura</th>
</tr>
</thead>
<tbody>
<tr>
<td>North Colombo Teaching Hospital</td>
<td>T.H.Jaffna</td>
</tr>
<tr>
<td>DGH Gampaha</td>
<td>T.H.Kumawatta</td>
</tr>
<tr>
<td>DGH Negombo</td>
<td>P.G.H.Ratnapala</td>
</tr>
<tr>
<td>National Hospital Kandy</td>
<td>T.H.Baticaloa</td>
</tr>
<tr>
<td>T.H.Karagiriya</td>
<td>P.G.H.Badulla</td>
</tr>
</tbody>
</table>

Director or a designated officer from these hospitals should immediately contact the Chief Epidemiologist and the T/O Quarantine and should immediately provide relevant patient information for required surveillance, prevention and further actions.

Details of travels including scanned copies of the patient detail checklist/s should be emailed to the Epidemiology Unit.

Contact tracing

Passenger Locator Form should be filled for those travellers with suspected nCoV seated in the same row and two rows in front and behind the index suspected case. The details should be communicated to the Epidemiology Unit. Epidemiology unit will carry out the community level contact tracing and house quarantine of asymptomatic contacts with the help of Regional Epidemiologist and MOOI.

Cleaning and disinfection

All surfaces and the Aircraft potentially contaminated by the ill traveller should be cleaned and disinfected by the relevant staff of the AASL under the guidance and supervision of the APHO.
Risk Communication

Health Promotion Bureau identified as the risk communication focal point. Risk communication working group with the representation of DGHS, DDGPHS, EPID unit, HPB Quarantine unit, DPRD, IDH will be established to strengthen the Risk communication system. Quick communication channel to be established within the working group to strengthen risk communication system.

Timely updates to be sent from Epidemiology unit and Quarantine unit to HPB for real-time public communication. Clearance chain for messages for public communication need to be defined. Identification and agree on spoke persons to media at each phase of risk communication (preparation phase, initial response phase, crisis phase, recovery phase, evaluation phase) and the details of spoke persons to be published. Public communication will be done through mass media, Health Promotion Bureau official facebook page and 24/7 swasthaya call center (0710107107) based on the technical inputs from epidemiology unit and quarantine unit. Rumor monitoring will be conducted by HPB on 24/7 basis and reported to DDG PHS I and communication working group for verification. Rumors will be managed based on the verification and guidance from DGHS/DDGPHS/Chief Epidemiologist.
Communication engagement with affected communities will be planned with Epidemiology unit and DPRD accordingly.

Please bring the contents of this guidelines to the notice of all relevant staff at your institution / district / province and immediately arrange to implement required actions.

Dr. Anil Jasinghe
Director General of Health Services

Cc:
Secretary Health
DDGPHS I and II
DDGMS I and II
DDGLS
Chief Epidemiologist
Director/MRI
Director/Quarantine
Director/HPB
Revision to Interim Summary Guidelines for Clinical Management of patients with novel coronavirus (2019- nCoV)

This is further to the Circular Letter dated 26.01.2020 with even number.

As of 5th February, 2020, the World Health Organization has reported 20,630 confirmed novel coronavirus cases of which 20,471 cases are from China (including Taipei, Macau and Hong Kong). Out of 159 confirmed cases reported from other countries majority had a travel history to Wuhan City. Cases were reported from Thailand Japan, Republic of Singapore, Australia, Republic of Korea, Vietnam, Indonesia, Malaysia, Cambodia, Philippines, Sri Lanka, India, USA, Canada, Finland, Germany, Italy, Russian Federation, Spain, Sweden, UK, United Arab Emirates and French Republic. Four hundred and twenty five deaths have been reported from China and one death reported from Philippines.

With the increasing new knowledge on the n-CoV infection the sections on Case definition and surveillance, Sample collection guideline for novel coronavirus (nCoV) testing and Prevention are revised as follows:

The following people should be investigated, tested and notified for nCoV (2019) infection

Case definitions for surveillance:

The case definitions are based on the current information available and might be revised as new information accumulates. Countries may need to adapt case definitions depending on their own epidemiologic situation.
Suspect case
A. Patient with severe acute respiratory infection (fever, cough, and requiring admission to hospital), AND with no other etiology that fully explains the clinical presentation AND a history of travel to or residence in China during the 14 days prior to symptom onset, OR
B. Patient with any acute respiratory illness AND at least one of the following during the 14 days prior to symptom onset:
   a) contact with a confirmed or probable case of 2019-nCoV infection, or
   b) worked in or attended a health care facility where patients with confirmed or probable 2019-nCoV acute respiratory disease patients were being treated.

Probable case
Probable case: A suspect case for whom testing for 2019-nCoV is inconclusive or is tested positive using a pan-coronavirus assay and without laboratory evidence of other respiratory pathogens.

Confirmed case
A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms.

All suspected patients with 2019-nCoV need to be notify to Epidemiology Unit immediately by the treating physician by phone (0112695112, 0114740490, 0114740491, 0114740492, 0112681548)

Sample collection guideline for Novel Coronavirus (nCoV) testing

Criteria for testing
Samples that are only fitting to case definition will be tested.

Information needed in the Lab Request Form

Brief history of the illness is mandatory.

a. Patient information (Name, Age, Sex)
   b. Clinical features / duration / treatment
   c. Presence of co-morbidities
   d. Travel history and date of arrival
   e. Date and time of sample collection
   f. Sample type/s
   g. Other laboratory investigations

Sample collection procedure
Type of respiratory samples
1. sputum (not saliva)
2. Endotracheal aspirate, nasopharyngeal aspirate
3. Bronchoalveolar lavage
4. Tissue from biopsy or autopsy including from lung
Lower respiratory samples are strongly recommended and should be collected wherever possible.

Nasopharyngeal and oropharyngeal swabs are low yield

- Time of sample collection
  - On admission
- Sample container
  - Pour VTM into a wide mouth, screw cap, plastic sterile (not glass) like a urine culture container before collecting sputum.
  - All other samples in VTM (viral transport medium) containers
  - All samples should be properly labeled before collection

Sample storage
Store at +4°C (2-8°C) if any delay ≥ 48 hours store at -70°C

Sample transport
Transport in triple package system to laboratory within 48 hours

Before sending sample inform laboratory, Department of Virology, MRI.

All specimens should be regarded as potentially infectious. Health Care Workers who collect, or transport clinical specimens should adhere to infection prevention and control guidelines and national regulations for the transport of dangerous goods (infectious substances) to minimize the possibility of exposure to pathogens.

For further information on sample collection and transport contact Dr. J. Jayamaha,
Consultant Virologist, NIC, MRI

Prevention

Recommendations for follow-up of contacts

Definition of contact

A contact is a person involved in any of the following:
- Providing direct care for 2019-nCoV patients, working with health care workers infected with novel coronavirus, visiting patients or staying in the same close environment of a 2019-nCoV patient.
- Working together in close proximity or sharing the same classroom environment with a 2019-nCoV patient.
- Traveling together with 2019-nCoV patient in any kind of conveyance.
- Sharing the same household as a 2019-nCoV patient within a 14-day period after the onset of symptoms in the case under consideration.

Monitoring of contacts of probable and confirmed cases

- Contacts should be monitored for 14 days from the last unprotected contact.
- Contacts should self-limit travel and movements.
- Monitoring by public health authorities, can be done through household or virtual visits or by telephone to check for symptoms.
- Any contact who becomes ill and meets the case definition becomes a suspect case and should be tested.
- Any newly identified probable or confirmed cases should have their own contacts identified and monitored.
Recommendations for follow-up of returnees from CHINA and affected areas of affected countries.
- Contacts should be monitored for 14 days from the date of arrival.
- Returnees should self-limit travel and movements.
- Monitoring by public health authorities can be done through household or virtual visits or by telephone to check for symptoms.
- Any returnee who becomes ill within 14 days of arrival and meets the case definition becomes a suspect case and should be tested.

It is likely that general prevention measures used for other coronavirus infections will also prevent infection with 2019-nCoV.

The World Health Organization (WHO) recommends measures to reduce the general risk of acute respiratory infections while travelling in or from affected areas by:
- avoiding close contact with people suffering from acute respiratory infections;
- frequent hand-washing, especially after direct contact with ill people or their environment;
- avoiding close contact with live or dead farm or wild animals;
- travellers with symptoms of acute respiratory infection should practice cough etiquette (maintain distance, cover coughs and sneezes with disposable tissues or clothing, and wash hands).

Specific recommendations on managing a diseased patient with nCoV, further information could be obtained from Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance (https://www.who.int/docs/default-source/coronaviruse/clinical-management-of-novel-cov.pdf?sfvrsn=be7d4517_2&download=true)

Following hospitals are identified as designated hospitals for immediate admission / transferring of suspected patients and hospitals are advised to identify a mechanism for the isolation of patients, implement infection control measures and adhering to guidelines given for the maximum precautions in preventing transmission.

NIIDH
NIHSL
LRH
T. H. North Colombo
National Hospital Kandy

T.H.Karapitiya
T.H.Amiruthapura
T.H.Jaffna
T.H.Batikaloa
T.H.Kurunegala

P.G.H.Ratnapala
P.G.H.Badulla
DGH Gampaha
DGH Negombo

Dr Anil Jasinghe
Director General of Health Services

cc:
Secretary Health
DDG/PHS I and II
DDG/M five I and II
DDG/LS
Chief Epidemiologist
Director/MRI
Director/Quarantine
Director/IPH

All Deputy Director General of Health Services
All Provincial Directors of Health Services
All Regional Directors of Health Services
All Heads of the Institution

**Strengthening of COVID-19 Surveillance**

The COVID-19 Technical Committee has made a recommendation to expand testing for diagnosis of COVID-19 patients.

Considering this recommendation the decision has been taken to collect sampling and testing from following categories.

1. At least ten (10) samples per day from the patients presenting to the OPD of the COVID isolation and treatment hospitals (listed below) with COVID-19 like symptoms irrespective of contact or travel history.

2. Healthcare staff members self-quarantined following high or moderate risk exposure (Ref: Screening and management of health care workers following exposure to a confirmed or suspected case of COVID-19 patients, www.epid.gov.lk)

3. All severe acute respiratory infection (SARI) patients admitted to any of the hospital irrespective of the age

4. Community samples as decided by the public health staff in high risk areas (Early active case detection)

5. Any other patient where the treating clinician decides for exclusion of COVID-19

6. All deaths suspected due to pneumonia (inward, on admission or in the field)
Therefore following hospitals are identified as sentinel sites and laboratories have been allocated to respective hospitals to carry out this COVID-19 active case detection procedures at OPD settings and among inward patients.

Table 1: List of hospitals for COVID-19 surveillance

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Laboratory</th>
<th>Hospital</th>
<th>Laboratory</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 NHSL</td>
<td>MRI</td>
<td>09 Castle St Hos. Woman</td>
<td>MRI</td>
</tr>
<tr>
<td>2 Kandy NH</td>
<td>NH Kandy</td>
<td>10 TH Sri J’Pura</td>
<td>MRI/USJ</td>
</tr>
<tr>
<td>3 LRH</td>
<td>MRI</td>
<td>11 CEBH - Mulleriyawa</td>
<td>MRI/NIID</td>
</tr>
<tr>
<td>4 NIID</td>
<td>NIID/MRI/USJ</td>
<td>12 DGH Gampaha</td>
<td>MRI/CNTH</td>
</tr>
<tr>
<td>5 DMH</td>
<td>MRI</td>
<td>13 DGH Chilaw</td>
<td>MRI/TH Anuradh</td>
</tr>
<tr>
<td>6 CSTH (Kalubowila)</td>
<td>MRI</td>
<td>14 DGH Negambo</td>
<td>MRI/CNTH</td>
</tr>
<tr>
<td>7 NCTH (Ragama)</td>
<td>NCTH/MRI</td>
<td>15 TH Kurunegala</td>
<td>NH Kandy</td>
</tr>
<tr>
<td>8 BH Homagama</td>
<td>MRI/USJ</td>
<td>16 TH Jaffna</td>
<td>TH Jaffna</td>
</tr>
<tr>
<td>17 TH Rathnapura</td>
<td>MRI</td>
<td>25 DGH Hambantota</td>
<td>TH Karapitiya</td>
</tr>
<tr>
<td>18 TH Batticaloa</td>
<td>NH Kandy</td>
<td>26 TH Anuradhapura</td>
<td>TH Anuradhapura</td>
</tr>
<tr>
<td>19 PGH Badulla</td>
<td>NH Kandy</td>
<td>27 DGH Polonnaruwa</td>
<td>TH Anuradhapura</td>
</tr>
<tr>
<td>20 DGH Kalutara</td>
<td>MRI/USJ</td>
<td>28 Dr. Neville F. Hospital</td>
<td>MRI/USJ</td>
</tr>
<tr>
<td>21 DGH Matale</td>
<td>TH Karapitiya</td>
<td>29 TH Karapitiya</td>
<td>TH Karapitiya</td>
</tr>
<tr>
<td>22 GH Vavuniya</td>
<td>TH/Anuradhapura</td>
<td>30 BH Marawila</td>
<td>MRI/TH Anuradhapura</td>
</tr>
<tr>
<td>23 KDU Hospital</td>
<td>MRI/USJ</td>
<td>31 Chest Hospital, Welisara</td>
<td>MRI/CNTH</td>
</tr>
<tr>
<td>24 BH Welikanda</td>
<td>TH Anuradhapura</td>
<td>32 DGH Monaragala</td>
<td>TH Karapitiya/NH Kandy</td>
</tr>
</tbody>
</table>

Testing for active case detection should be done based on the following case definitions.

**Clinically Suspected Case:**

A. A person with ACUTE RESPIRATORY ILLNESS (with Cough, SOB, Sore throat; one or more of these) with a history of FEVER (at any point of time during this illness), returning to Sri Lanka from ANY COUNTRY within the last 14 days.

OR
B. A person with ACUTE RESPIRATORY ILLNESS (with Cough, SOB, Sore throat; one or more of these) AND having been in close-contact* with a confirmed or suspected COVID-19 case during the last 14 days prior to onset of symptoms;

*Close-contact: A person in an enclosed environment for >15 minutes (e.g. same household/workplace/social gatherings/travelling in same vehicle) OR who had direct physical contact.

OR

C. A person with ACUTE RESPIRATORY ILLNESS (with Cough, SOB, Sore throat; one or more of these) with a history of FEVER (at any point of time during this illness), with a history of travel to or residence in a location designated as an area of high transmission of COVID-19 disease as defined by the Epidemiology Unit, MoH, during the 14 days prior to symptom onset.

OR

D. A patient with acute pneumonia (not explainable by any other aetiology) regardless of travel or contact history as defined by the treating Consultants.

• A sample for the PCR test obtained and sent (not the patient) to a designated laboratory.

OR

E. A patient with fever and in respiratory distress as evident by RR >30 per minutes, SpO2 < 90% on room air, regardless of travel or contact history and without a definable cause, as decided by the treating Consultant.

• A sample for the PCR test obtained and sent (not the patient) to a designated laboratory.

F. Any person irrespective of the presence of symptoms, with an epidemiological link to a confirmed COVID-19 case who needs testing, as decided by the Regional Epidemiologist or the Central Epidemiology Unit.

Sample collection

➢ Identify a room/place at the OPO setting to collect samples for COVID-19 (nasopharyngeal or throat swabs) without admitting the patient.

➢ Viral Transport Media (VTM) / swabs to be obtained from the MRI.

➢ Collected samples should accompany with a request form with patients details (Name , age , BHT, Address, Date of sample collection, any signs and symptoms, onset of signs and symptoms, name of the institution, date and signature, [Ref www.epid.gov.lk]).
The head of the institution is responsible to assign a trained Medical Officer/ ICBOO/ NO for sample collection from patients / epidemiologically referred contacts.

The activities in this regard will be under the overall supervision of the Consultant Virologist/ Consultant Microbiologist of the institution or under any designated officer.

Regional Epidemiologist of the district will coordinate and monitor the activities at all sentinel sites under his/her purview.

Maintain a record or a register in each institution. Send a daily report (including name, age, sex, signs and symptoms, onset of signs and symptoms, address, contact no.) to the Epidemiology unit by email (chepid@slnet.lk) or fax (011-2696583).

Coordination of this case detection:
The process should be coordinated by the RE and provincial/district CCP with the help of the district and MOH team.

How to collect the samples?
The team should adopt the most convenient method for collection of the nasopharyngeal/throat samples.

This can be done by:
1) A team including the sample collecting officer, supporting staff and the driver who can reach the selected person in the community with the guidance of the MOH and staff.
2) This same team (defined in 01) can also visit the Quarantine Centre (QC) and collect the sample after liaising with the QC administration.
3) Once the samples have been collected transport in a triple package to the testing laboratory.

Sampling Procedure:
There could be 2 different swabs currently available in the sample collection kits.
1. If there are two swabs in the kit:
   a. Use both swabs – one for the nasopharyngeal swab and the other for the throat swab.
2. If there is a single swab in the kit:
   a. Collect the nasopharyngeal sample followed by the throat sample using the same swab

(Please note that sampling swab is too long to accommodate the VTM container, please adhere to the following procedure for convenience.)
Annex 4

MINISTRY OF HEALTH AND INDIGENOUS MEDICAL SERVICE CIRCULAR DQ/06/2020
DATED 03 JUNE 2020

MEASURES TO BE ADOPTED AT AIRPORTS OF SRI LANKA DURING THE PHASE OF COVID-19

1. Prerequisite for travellers before embarkation
   a) At the time of the issuing travel ticket, all passengers shall be given the Health Declaration Form (HDF) of Sri Lanka by the airline with the air ticket.
   b) The staff of Check-in counters shall ensure the availability of filled HDF with the air ticket of the passengers.
   c) Airline crew members also shall fill the HDF of Sri Lanka.
   d) Passengers and crew members without the filled HDF shall not be boarded to the flight.
   e) Civil Aviation Authority Sri Lanka (CAASL) should disseminate a communiqué amongst all airlines/travel agents to ensure the availability of HDF with travellers.

2. Measures to be followed at the airport in Sri Lanka
   - Temperature screening
     All incoming passengers and airline crew members should undergo temperature screening through thermal scanners. Travellers with a temperature of 37.4°C (99.3°F) or above should be referred to the Airport Health Office of Quarantine Unit. Their temperature will be re-checked after 15 minutes by the Airport Health Officer (Medical Officer) of the Airport Health Office and if the temperature is high, they will be transferred by Airport Health Officer to a designated hospital.
• Submission of the Health Declaration Form of Sri Lanka

All travellers should submit the HDF to the Health Counters set up at the airport. The Public Health Inspectors will scrutinize the HDF and travellers with high-risk conditions will be referred to the Airport Health Officer. Airport Health Officer (Medical Officer of Airport Health Office) will scrutinize the traveller, assess the risk condition and a decision will be made whether to permit disembarkation or transfer to a designated hospital.

• Face masks

All travellers should carry an adequate number of face masks with them. All travellers should wear a face mask throughout from the time of arriving at the departing airport until leaving the arriving airport. (Passengers with Chronic lung diseases/ any respiratory issue should inform the airline staff prior to embarkation)

If masks are needed for the travellers, Airport and Aviation Services Sri Lanka Limited (AASL) should provide masks at a cost at the arriving airport.

• Mandatory COVID-19 PCR testing at the airport on arrival in Sri Lanka

Passengers

a) All passengers should undergo the mandatory PCR testing on arrival at the airport on Day 1.

b) Testing laboratory should email all test results immediately to Epidemiology Unit of Ministry of Health (epidunit@at.net.lk and samiti@hotmail.com).

c) The AASL should make suitable logistic arrangements to set up the ‘sample collection facility’ and arrange the transport and delivering of samples to G.H. Negombo/testing laboratory.

Airline crew members

a) Crew members shall undergo PCR testing on Day 1 at arriving airport in Sri Lanka if disembarked in Sri Lanka except the below mentioned three categories.

b) PCR test on arrival at the airport in Sri Lanka is not needed for crew members of cargo flights/ ferry flights originated from Sri Lanka if no disembarkation is done in a foreign country.

c) PCR test on arrival at the airport in Sri Lanka is not needed for crew members of cargo flights/ ferry flights/ flights arriving for refuelling originated from foreign countries if no disembarkation in Sri Lanka.

d) PCR test on arrival at the airport in Sri Lanka is not needed for crew members of Turn Around flights originated from Sri Lanka.

385, Rev. Badddegama Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.
- **Crew members in foreign airlines**: will be allowed to go to their pre-determined hotels after the collection of samples for PCR. If results are not available during their departure, they should be allowed to leave the country. The PCR test results of the crew members of foreign airlines will be sent by the laboratory to CAASL (flightpermission@caas.lk) with a copy to Epidemiology Unit, Quarantine Unit (quarantinelk@gmail.com) and Airport Health Officer/ BIA (airporthealthofficer@gmail.com).

- **Crew members of Sri Lankan Airlines**: will be allowed to self-quarantine after the collection of samples for PCR at the airport. Repeat PCR is indicated on subsequent arrivals if the last PCR is done 7-10 days before. The PCR test results of the crew members shall be submitted by the laboratory to the Epidemiology Unit and Sri Lankan Airlines (anoma.jayasinghe@sri.lankan.com) with a copy to Quarantine Unit (quarantinelk@gmail.com) and Airport Health Officer/ BIA (airporthealthofficer@gmail.com). This will be applicable only under the following conditions:
  1. Shall wear appropriate PPE and all other preventive measures should be strictly adhered to.
  2. In a foreign country shall use only designated transport and stay in designated hotels.
  3. Shall not leave the hotel premises until departure.

**Diplomatic passport holders**

a) PCR test on arrival at the airport in Sri Lanka followed by 14 days of home quarantine.

b) Test results should be immediately informed to the Epidemiology Unit of Ministry of Health (epidunit@slnet.lk).

---

Dr. Anil Jayasinghe
Director General of Health Services

Co:
Director General Ministry of Foreign Relations
Deputy Director General (Public Health Services)
Director/ Quarantine Unit
Chief Epidemiologist/ Epidemiology Unit
Dr. Bimal Dias/ Senior Civil Aviation Inspector/ CAASL

---

328, Rev. Baladewa Wimalawansa Thero Mawatha, Colombo 10, Sri Lanka.
Annex 5
MINISTRY OF FOREIGN AFFAIRS CIRCULAR PR/CP/MISC/2020
DATED 4 JUNE 2020

TPN No. : PR/0460/2020
Ref No. : PR/CP/MISC/2020

The Ministry of Foreign Relations of the Democratic Socialist Republic of Sri Lanka presents its compliments to all Diplomatic Missions, the Representation Offices of the United Nations and its Specialized Agencies, International Organizations, Honorary Consulates resident in Colombo and has the honour to inform that the Government of Sri Lanka has issued the following instructions with effect from 04th June 2020, to be followed by the members of the Diplomatic Staff of the Foreign Missions based/attached in Colombo when they enter/re-enter into Sri Lanka from today (04th June) onward in order to control and prevent the spread of Coronavirus.

(i) The respective diplomatic missions may inform the Ministry of Foreign Relations (MFR) by a Note Verbal, the details such as, name, designation, residential address, tentative travel dates, existing visa status, of the diplomats and their family members who are scheduled for entry/re-entry into Sri Lanka for the diplomatic assignments well in advance in order to obtain the prior approval from the concerned authorities.

(ii) The members of the Diplomatic staff and their family members need to submit PCR test reports obtained within 72 hours prior to their departure from respective countries.

(iii) If the members of the Diplomatic staff and their family members are unable to provide PCR test reports, they would be subjected to a mandatory PCR test at the Bandaranaike International Airport, Katunayake.

(iv) Heads of Mission and family members will self-quarantine at the Official Residences. All other arriving Diplomatic staff and their family members will have to follow quarantine procedures at a hotel, recommended by the Government of Sri Lanka (if independent/separate residences are not available), for a period of 14 days, subject to concurrence and supervision of the Heads of Mission.

(v) The Diplomatic Missions/Representations need to inform the Ministry of Foreign Relations once the 14-day home quarantine is completed and submit the second PCR test report done by the Mission before the Officer resumes duties in the Mission as per the measures taken by the Mission to control and prevent the spread of Coronavirus.

(vi) The Diplomatic Missions/Representations have to forward the travel details of the Diplomatic staff and their family members at least 48 hours prior to their departure to the Chief of Protocol, Email: corona@mf.gov.lk in order to share with information with relevant local Authorities.

The Diplomatic Missions/Representations may note that the above conditions are maintained only during the Global Pandemic period to ensure health security of Diplomatic and other rank officials of the Missions and all Sri Lankans.
The Ministry of Foreign Relations of the Democratic Socialist Republic of Sri Lanka avails itself of this opportunity to renew all Diplomatic Missions, the Representation Offices of the United Nations and its Specialized Agencies, International Organizations, Honorary Consulates resident in Colombo the assurances of its highest consideration.

Colombo, 09th June 2020

The Diplomatic Missions, the Representation Offices of the United Nations and its Specialized Agencies, International Organizations, Honorary Consulates resident in Colombo.
Annex 6a
COVID-19 PCR TEST REQUEST FORM - HOSPITAL DIAGNOSTIC PATIENTS

(A) Hospital Diagnostic Samples

COVID-19 PCR Test Request Form

Mode of transport: in viral transport medium, in ice, in triple package, within 48 hours of collection

<table>
<thead>
<tr>
<th>Institution:</th>
<th>Ward / Unit:</th>
<th>BHT No:</th>
</tr>
</thead>
</table>

### A. General Information
1. Name: 
2. Gender: M / F  3. Age: 
4. NIC No: 
5. Address: 
6. Occupation: 
7. Telephone: 
8. Date of Admission: 

### B. Involvement in COVID19 Response
1. Engaged in COVID response? 
   - [ ] Yes  
   - [ ] No
2. If so, in which capacity? 
   - [ ] Healthcare worker
   - [ ] Tri-forces
   - [ ] Other
3. Place of exposure:

### C. Travel History
1. History of travel abroad during last 30 days: 
   - [ ] Yes  
   - [ ] No
   - If so, countries visited: 
2. Travel to a risk area in Sri Lanka: 
   - [ ] Yes  
   - [ ] No
   - If so, areas visited: 
   - Date of visit: 

### D. Clinical Information
1. Duration of symptoms (Days):
2. Symptoms present: 
   - [ ] Fever
   - [ ] Cough
   - [ ] Sore throat
   - [ ] SOB
   - [ ] Diarrhoea
   - [ ] Other
3. Exposure to COVID19 confirmed/probable case: 
   - [ ] Yes  
   - [ ] No
   - Date of exposure:
4. Comorbidities: 
   - [ ] DM
   - [ ] COPD
   - [ ] HT
   - [ ] Other
5. Clinical/radiological features of acute pneumonia 
   - [ ] Present  
   - [ ] Absent
6. Patient category according to case definitions: 
   - See overlay for description
   - [ ] A
   - [ ] B
   - [ ] C
   - [ ] D
   - [ ] E
   - [ ] F
   - [ ] Other

### E. Sample Details
1. Date of sample collection: 
2. Sample type: 
   - [ ] NPA
   - [ ] Sputum
   - [ ] Tracheal aspiration
   - [ ] BAL
   - [ ] Nasopharyngeal swab
   - [ ] Oropharyngeal swab
   - [ ] Nasopharyngeal & oropharyngeal swab
3. Is this a post-mortem sample? 
   - [ ] Yes  
   - [ ] No

Name of the Doctor: ........................................
Contact Number: ........................................
Date: ........................................
Signature: ........................................

### F. For Laboratory Use Only
Date of sample receipt: 
Triple package: Y/N  In ice: Y/N
Properly labelled: Y/N  Sample leaking: Y/N
Reporting Date: 
Result: 
   - [ ] Positive
   - [ ] Negative
   - [ ] Inconclusive

Note: the request may be rejected if this form is not filled properly & the specimen is not transferred properly.
CASE DEFINITION OF A SUSPECTED PATIENT

A. A person with ACUTE RESPIRATORY ILLNESS (with Cough, SOB, Sore throat) with a history of FEVER (at any point of time during this illness), returning to Sri Lanka from ANY COUNTRY within the last 14 days.

OR

B. A person with ACUTE RESPIRATORY ILLNESS AND having been in close-contact* with a confirmed or suspected COVID-19 case during the last 14 days prior to onset of symptoms;

*Close-contact: A person staying in an enclosed environment for >15 minutes (e.g. same household/workplace/social gatherings/travelling in same vehicle).

OR

C. A person with a history of FEVER (at any point of time during this illness), with a history of travel or residence in a location designated as an area of high risk transmission of COVID-19 disease as defined by the Epidemiology unit, MoH, during the 14 days prior to symptom onset.

OR

D. A patient with acute pneumonia (not explainable by any other etiology) regardless of travel or contact history as decided by the treating Consultant.

OR

E. A patient with fever and respiratory distress as evident by RR>30 per min, SpO2 <90% on room air, regardless of travel or contact history and without a definable cause, as decided by the treating Consultant.

OR

F. Any person irrespective of the presence of symptoms, with an epidemiological link to a confirmed COVID-19 case who needs testing, as decided by the Regional Epidemiologist or the Central Epidemiology Unit.
Annex 6b
COVID-19 PCR TEST REQUEST FORM - FOR COVID-19 POSITIVE IN-WARD PATIENTS FOR MANAGEMENT AND DISCHARGE

(B) Follow-up Samples

Lab No.: 

Novel Coronavirus (COVID-19) PCR Test Request Form
(For COVID-19 diagnosed in-ward patients for management and discharge)

Mode of transport: in viral transport medium, in ice, in triple package, within 48 hours of collection

institution: .............................................. Ward / Unit: ........................................ BHT No. ..................

A. General Information
1. Name: 
2. Gender: ❑ Male ❑ Female
3. Age: 
4. NIC No. 
5. Telephone: 
6. Date of Admission: 

B. Clinical Information

<table>
<thead>
<tr>
<th>On Admission</th>
<th>At Present</th>
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<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Fever</td>
<td>Yes No</td>
</tr>
<tr>
<td>2. Cough</td>
<td>Yes No</td>
</tr>
<tr>
<td>3. Sore throat</td>
<td>Yes No</td>
</tr>
<tr>
<td>4. DOB</td>
<td>Yes No</td>
</tr>
<tr>
<td>5. Diarrhoea</td>
<td>Yes No</td>
</tr>
<tr>
<td>6. Other:</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

C. Information on Previous PCR Tests

<table>
<thead>
<tr>
<th>No</th>
<th>Date of PCR test</th>
<th>Sample type: (NPA/Sputum/Tracheal aspiration/ BAL/Nasopharyngeal &amp; oropharyngeal swab/Tissue biopsy)</th>
<th>Result</th>
<th>Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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<td>8</td>
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<td></td>
</tr>
</tbody>
</table>

D. Sample Details

1. Date of collection: 
2. Sample Type:
   ❑ NPA
   ❑ Sputum
   ❑ Tracheal aspiration
   ❑ BAL
   ❑ Nasopharyngeal swab
   ❑ Oropharyngeal swab
   ❑ Naso & oropharyngeal swab
3. Is a post-mortem sample? Yes / No 

Name of the Doctor: .............................................. Contact No. ..............................................

Date: .............................................. Signature: ..............................................

E. For Laboratory Use Only

Date of Sample Receipt:

<table>
<thead>
<tr>
<th>Triple Package: Y / N</th>
<th>In ice: Y / N</th>
<th>Properly labelled: Y / N</th>
<th>Sample leaking: Y / N</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

Reported Date: 

Result: ❑ Positive ❑ Negative ❑ Inconclusive

Note: the request may be rejected if this form is not filled properly & the specimen is not transferred properly.
## COVID-19 PCR Test Request Form

**Inclusion criteria:** Patients with respiratory symptoms given in section B, with or without fever

**Mode of transport:** in viral transport medium, in ice, in triple package, within 48 hours of collection

### A. General Information

1. Name:
2. OPD/Clinic No.
3. Gender: □ Male □ Female
4. Age:
5. NIC No.
6. Address:
7. Occupation:
8. Telephone:

### B. Clinical Information

1. Duration of symptoms (Days):
2. Symptoms present:
   - □ Fever
   - □ Cough
   - □ Sore throat
   - □ SOB

### C. Sample Details

1. Date of sample collection:
2. Sample type:
   - □ Nasopharyngeal swab
   - □ Nasopharyngeal & oropharyngeal swab
   - □ Oropharyngeal swab
   - □ Sputum

Name of the Doctor: ............................................  Contact No: .........................................................

Date: ..............................................................  Signature: ...........................................................

### D. For Laboratory Use Only

Date of Sample Receipt:

<table>
<thead>
<tr>
<th>Triple Package:</th>
<th>In ice:</th>
<th>Properly labelled:</th>
<th>Sample leaking:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y / N</td>
<td>Y / N</td>
<td>Y / N</td>
<td>Y / N</td>
</tr>
</tbody>
</table>

Reported Date:

Result: □ Positive □ Negative □ Inconclusive

Note: the request may be rejected if this form is not filled properly & the specimen is not transferred properly.
Annex 6d
COVID-19 PCR TEST REQUEST FORM - CONTACTS, OVERSEAS RETURNees, AND RANDOM COMMUNITY SAMPLES

<table>
<thead>
<tr>
<th>Serial No</th>
<th>NIC No/ Passport No</th>
<th>Name</th>
<th>Age</th>
<th>Gender</th>
<th>Address and contact No</th>
<th>Symptomatic/ Asymptomatic (symptoms if symptomatic)</th>
<th>Quarantined</th>
<th>Reason for testing</th>
</tr>
</thead>
<tbody>
<tr>
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</tr>
</tbody>
</table>

**Reason for testing**
- Overseas returnee or returnee from high risk area
- Close contact with diagnosed or suspected case
- Date of sample collection

**Overseas returnee or returnee from high risk area**
- Country/ High risk area
- Date of contact
- Index case symptomatic/asymptomatic
- Nature of exposure (family contact/ work place/ neighbourhood etc.)
- Nature of exposure (family contact/ work place/ neighbourhood etc.)
- Nature of exposure (family contact/ work place/ neighbourhood etc.)
All Private Laboratories

Re: Performance of COVID-19 PCR Testing at Private Sector Medical Laboratories

I would like to bring to your kind notice that all private laboratories should strictly adhere to the Circular guidelines issued by Ministry of Health regarding the performance of COVID-19 PCR testing (Interim Summary Guidelines for Clinical Management of patients with novel coronavirus (2019-nCoV) Letter No: DDG (PHS)1/DO2/12-9/2019/10 dated 26/01/2020) - Annex 1.

According to this guidelines, it was clearly mentioned that COVID-19 (novel coronavirus) PCR testing is indicated only to the suspected cases of COVID-19. Case definition for suspected COVID-19 patients was updated in the Circular Letter issued by the Ministry of Health on 04 March 2020 (Letter No: DDG (PHS)1/DO2/12-9/2019/10 dated 02/03/2020) - Annex 2.

According to the National guidelines all suspected patients need to be admitted to one of the 17 Hospitals with isolation facilities identified by the Ministry of Health. Therefore, there is no place and should not be used COVID-19 PCR test as a screening test.

Dr. Anil Jasinghe
Director General of Health Services

cc Secretary Health
DDG (PHS)1
DDG (Laboratory Services)
Chief Epidemiologist
Director Private Health Sector Development – For circulate among all private Hospitals & Laboratories