General Circular Letter No: 01-47/2021

Deputy Director General - NHSL, NH Kandy
All the heads of Line Ministry Institutions
Provincial and Regional Directors of Health Services
Heads of Institutions of Provincial Healthcare Institutions
All other Heads of Institutions and COVID-19 PCR testing Laboratories

Request form and the Instructions to send the samples for SARS CoV-2 gene sequencing testing

In the current context of SARS-CoV-2, it is necessary to detect newly emerging variants entering and spreading in Sri Lanka. Therefore, the Healthcare institutions and other PCR testing laboratories situated in the following provinces are instructed to send the samples for gene sequencing to the designated laboratory using the attached request form.

<table>
<thead>
<tr>
<th>Designated Gene Sequencing Facility</th>
<th>Catering Province</th>
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</thead>
<tbody>
<tr>
<td>Virology Laboratory - MRI</td>
<td>Western, Sabaragamuwa, North Western</td>
</tr>
<tr>
<td>Molecular laboratory - MRI</td>
<td>Western, Sabaragamuwa, North Western</td>
</tr>
<tr>
<td>Virology Laboratory - NH/Kandy</td>
<td>Northern, Central, Uva, North Central</td>
</tr>
<tr>
<td>Virology laboratory - TH/Karapitiya</td>
<td>Eastern, Southern</td>
</tr>
</tbody>
</table>

Please discuss with the designated gene sequencing laboratory/PCR laboratory prior to sending the samples to ensure acceptance. ONLY a selected limited number of priority samples will be tested depending on the availability of resources. Include all relevant details to decide on the priority of testing. ALL requests should come from the relevant Consultant or Regional Epidemiologist with their signature and the stamp. Results will not be available immediately as this is a reference test done at regular intervals.

Indications for SARS CoV-2 variant detection gene sequencing testing

1. SARS CoV-2 PCR positive samples from overseas returnees and foreign travelers detected on arrival testing or quarantine exit screening.

2. PCR positive samples of tourists/overseas visitors with highly suspicious should be sent irrespective of the Ct value.

3. Samples from critically ill COVID-19 patients in ICU or HDU with priority given for young patients/severe disease in the absence of comorbidities.
4. Moderate to severe symptomatic inward/ICU patients who are SARS CoV-2 PCR positive despite having the full course of COVID-19 vaccination (Infection after completion of 2 weeks from the second dose of COVID-19 vaccination).

5. Possible SARS-CoV-2 reinfection presenting again with suspected moderate to severe symptoms and positive SARS CoV-2 PCR after the initial recovery and discharge

6. Family or community clusters with an unusually high proportion of severe COVID-19 complications or fatalities.

7. Newly developing clusters with high SARS CoV-2 PCR positive rate (about more than 20%) with Ct values less than 25.

8. Few samples from COVID deaths with priority given for young deaths, deaths in the absence of comorbidities, or deaths despite complete COVID vaccination (onset of diseases after 2 weeks from the second dose of COVID vaccination)

Instructions for sending samples:

1. Samples must be transported to the PCR laboratory on ice on the same day of collection. Then it should be properly stored at -80°C freezer and maintained the cold chain until reaching the sequencing facility. The samples should not be repeatedly freeze-thawed.

2. Each sample tube should be clearly labelled.

3. The samples should be safely packed in a triple-packing system and the package must be clearly labeled as the samples for gene sequencing to prevent the mixup of packages for PCR and sequencing.

4. Patient information sheet should be filled for each sample.

5. Please fill out all the details required in the request on sending samples for SARS CoV-2 gene sequencing to the Gene sequencing laboratories.

6. Please liaise with Regional Epidemiologist and the relevant Gene Sequencing laboratory/PCR laboratory (Contact Consultant Incharge or Medical Officers at the laboratory) before sending samples.

Please refer to the instructions stated in the back of the request form and adhere to the instructions to fill out the details required when sending samples for SARS CoV-2 gene sequencing testing.

Dr. Asela Gunawardena
Director General of Health Services

CC:
1. Secretary of Health
2. Additional Secretary (Medical Services)
3. Deputy Director General (Laboratory Services)
4. Deputy Director General - MS I, MS II, PHS I, PHS II
5. Chief Epidemiologist
6. Director (Laboratory Services)
MINISTRY OF HEALTH
GENE SEQUENCING TESTING OF SARS-CoV-2 REQUEST FORM
(Please fill the request form and send it with the sample to the PCR laboratory)

1. PCR laboratory: .................................................................
2. Gene Sequencing Testing Laboratory: MRI-Virology laboratory / MRI-Molecular Laboratory / NH-Kandy/TH-Karapitiya.................................................................
3. Place of Samples collection: Hospital/MOH/ PCR Laboratory.................................
4. Date of Sample collection: .......... /......... /20..
5. Storage temperature till the dispatch: .................................................................
6. Patient Details
   6.1 Name: .................................................................................
   6.2 NIC/BHT no. /Passport No............................................................
   3.3 Age: ................., Y
   3.4 Gender: Male/ Female
   3.5 Address: .................................................................................

7. Indications for Testing (Please refer categories mentioned on next page) Category :

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<table>
<thead>
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<tbody>
<tr>
<td>1</td>
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<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
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</tbody>
</table>

If any other, please specify: .................................................................................

If 1 or 2 mention the country: .................................................................

8. Clinical Details (if relevant) underline
Regarding current COVID-19 infection: Asymptomatic/ Symptomatic
If symptomatic,
Date of onset: .................................................................................
Specify symptoms: .................................................................................
Category of severity: .................................................................................
O₂ requirement (if any): .................................................................................
Comorbidities (if any): .................................................................................
Past Hx of COVID-19: None / Asymptomatic / Symptomatic (mild/moderate/severe)
Date of past COVID-19: ................................................................................. (If COVID-19 positive in the past)

9. COVID-19 vaccination history
Type of vaccine obtained: .................................................................................
Date of 1st dose: .......... /......... /20..
Date of 2nd dose: .......... /......... /20..

10. Laboratory investigations of current infection (fill if relevant)

<table>
<thead>
<tr>
<th>Date</th>
<th>COVID-19 Antigen results</th>
<th>PCR test results with CT value</th>
<th>COVID-19 Antibody results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Target 1</td>
<td>Target 2</td>
</tr>
</tbody>
</table>

Date: .......... /......... /20..

Contact Number: .................................................................

Signature of Consultant/Regional Epidemiology
[OFFICIAL STAMP]
Please read the instructions before sending the samples

Gene sequencing testing service to Enhanced surveillance of SARS-CoV-2 for newly emerging variant

Please note this is a reference test used only to draw conclusions for epidemiological purposes. With the current level of evidence, SARS CoV-2 gene sequencing for the detection of variants hasn’t got an additional advantage over other routinely available laboratory diagnostic tools in clinical management and infection prevention and control.

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FOR LABORATORY USE ONLY

SAMPLE ID:

Date of sample received: ................................................................. Received By: .................................................................

Properly labeled: Yes/No
In the triple package :Yes/No
Condition of the sample: Leaking /Not labeled : ..............................

RESULTS:

...........................................................................................................

...........................................................................................................