LICENCE CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE MOLECULAR SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-CoV-2) TESTING FOR CORONAVIRUS DISEASE 2019 (COVID-19)

IMPOSED UNDER SECTION 13(1) OF THE HEALTHCARE SERVICES ACT 2020

1 Application

1.1 These licence conditions ("**LCs**") apply to all persons: -

(a) licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service; and

(b) providing, or intend to provide, as part of that service, Molecular Severe Acute Respiratory Syndrome Coronavirus 2 ("**SARS-CoV-2**") testing for COVID-19 ("**SARS-CoV-2 testing**") ("**Licensees**").

1.2 For avoidance of doubt, the defined terms as used in these LCs shall have the meanings ascribed to them in the HCSA and any Regulations made thereunder, unless otherwise stated.

1.3 These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Service Licensees Providing or Intending to Provide Molecular Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Testing for Coronavirus Disease 2019 (COVID-19)' issued on 10 August 2022.

1.4 A breach of these LCs may result in regulatory action being taken against the Licensee under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's clinical laboratory service licence;

(b) shortening of the term of the Licensee's clinical laboratory service licence;

(c) a direction for the Licensee to rectify the contravention, or prevent a recurrence of the contravention; and/or

(d) a direction for the Licensee to pay a financial penalty.

1.5 For avoidance of doubt, these LCs do not override a healthcare professional's duty to make clinical decisions that are in the best interests of each patient.

1.6 For avoidance of doubt, the requirements in these LCs are without prejudice, and in addition to the requirements imposed under the HCSA as well as any Regulations and other applicable licensing conditions, directions and codes of practice made thereunder.

2 Quality Management System

2.1 Subject to paragraph 2.2, the Licensee shall ensure that its Clinical Laboratory Service ("**Laboratory**") participates in and performs satisfactorily in the national proficiency test for SARS-CoV-2 testing conducted by the National Public Health Laboratory **before** patient testing.

2.2 Paragraph 2.1 **does not** apply to Licensees performing molecular SARS-CoV-2 tests **solely** in the context of clinical trial. Instead, the licensee shall participate in and perform satisfactorily in a relevant and established external quality assessment (EQA) programme **before** the commencement of molecular SARS-CoV-2 testing.

3 Testing Requirements

3.1 The Licensee shall ensure that the following are in place prior to the commencement of offering polymerase chain reaction ("**PCR**") tests for SARS-CoV-2 to the public:

(a) Appropriate facilities for biological containment and proper handling of specimens, including emergency facilities such as emergency showers and eyewashes, and biological spill kits;

(b) Laboratory safety policies for the proper handling of samples that contain or are suspected to contain SARS-CoV-2, and adequate biosafety training for laboratory personnel who will handle these samples;

(c) Instrument validation / commissioning, if applicable;

(d) Test evaluation. At minimum, accuracy and precision shall be evaluated against the manufacturer's claims with sample size of 10 positives and

10 negatives. For off-label use and laboratory-developed tests, the limit of detection and analytical specificity shall be established;

(e) Quality control measures and EQA programme. In the case where an established EQA programme is unavailable, the Licensees shall arrange for inter-laboratory comparison with another licensed clinical laboratory;

(f) Standard operating procedures for PCR tests for SARS-CoV-2; and

(g) Staff training and competency assessment for laboratory personnel who will conduct PCR tests for SARS-CoV-2.

3.2 The Licensee shall ensure that its Laboratory tests no more than 200 samples per day for the first 5 days after the commencement of the provision of PCR tests for SARS-CoV-2. Subsequently, the Licensee shall ensure that its Laboratory tests no more than 400 samples per day on Day 6 and Day 7 after the commencement of the provision of PCR tests for SARS-CoV-2.

3.3 The Licensee shall ensure that its Laboratory's capacity, for conducting SARS-CoV-2 tests, is commensurate with its resources (e.g. equipment and reagents) and competencies for the proper and efficient performance of the testing.

3.4 The Licensee shall ensure that its Laboratory conducts SARS-CoV-2 testing in a safe, accurate and timely manner.

4 Laboratory Practices

Specimen handling and transportation

4.1 The Licensee shall ensure that all samples/materials used in SARS-CoV-2 testing are triple-packed. The primary and/or secondary container must be break-proof and leak-proof, and the external packaging must be labelled with the biohazard logo.

4.2 The Licensee shall ensure, in transporting the samples/materials used in SARS-CoV-2 testing, that its Laboratory complies with the following:

(a) Public transport should not be used to transport any samples and/or materials used in SARS-CoV-2 testing; and

(b) Conduct a comprehensive risk assessment and implement appropriate risk control measures for the handling of all samples/materials, including transportation. Where hand-delivery is indicated by risk assessment,

samples/materials used in SARS-CoV-2 testing shall be delivered by hand in an upright position at all times. For the avoidance of doubt, the licensee should ensure chain of custody of all samples/materials used in SARS-COV-2 testing by keeping proper documentation.

4.3 The Licensee shall ensure that virus isolates or cultures confirmed to contain the virus are packaged and transported in accordance with the Biological Agents and Toxins (Transportation) Regulations.

4.4 The Licensee shall ensure that there are effective measures in place in order to ensure the following:

(a) The safety of its Laboratory staff; and

(b) The quality of the samples used for SARS-CoV-2 testing.

Partnerships with Approved Swab Providers

4.5 The Licensee shall ensure that the laboratory only processes swab samples that were obtained by Approved Swab Providers.

Serology testing

4.6 The Licensee shall use only test kits for SARS-CoV-2 testing that are able to differentiate between the immunoglobulins against the receptor-binding domain (RBD) of the spike (S) protein and nucleocapsid (N) protein, i.e. that are able to provide distinction between anti-N and anti-S.

5 Reporting Requirements

5.1 The Licensee shall ensure that its Laboratory has in place a system that is linked to the following external systems, unless otherwise exempted or stated by MOH in writing:

(a) A MOH-approved system to electronically receive information on patients on which it has conducted the Testing, e.g. Patient Risk Profile Portal (PRPP), iConnect.COVID, Swab Registration System (SRS); and

(b) The Covid-19 Testing Repository ("**CTR**").

5.2 The Licensee shall ensure that all SARS-CoV-2 testing results are submitted to the CTR accurately, securely and as soon as reasonably practicable.

5.3 The Licensee shall ensure that, where the Licensee outsources or sub-contracts any SARS-CoV-2 testing to another Licensee ("**Licensee B**") in any way, Licensee B transmits the test results to the CTR.

5.4 The Licensee shall ensure that, for pooled samples, its Laboratory works with approved swab providers to separate each individual sample from the pooled SARS-CoV-2 testing results and to upload all such test results into its Laboratory's LIS for transmission to the CTR in the format prescribed by MOH.

5.5 The Licensee shall ensure that its Laboratory transmits the Cycle Threshold (CT) value of the SARS-CoV-2 testing results to the CTR when it transmits the results for those SARS-CoV-2 testing results whenever possible.

5.6 The Licensee shall ensure that the completeness of information and SARS-CoV-2 testing results transmitted to the CTR conform to the list of mandatory data fields set out in **Annex A**.

5.7 In the event that new data fields and/or values are required to support any operations, particularly in its Laboratory's LIS, the Licensee shall submit a written request to MOH (via ihis.ctr.ops@ihis.com.sg) at least three (3) working days before the intended date of inclusion of the new data fields and/or values. The Licensee shall only include new data fields and/or values after receiving MOH's written approval to do so.

5.8 The Licensee shall inform MOH in writing of its intention to adopt SARS-CoV-2 testing technologies other than PCR or serology at least 30 days before the start of its adoption of any such testing technology. Director-General of Health reserves the right to revise the LCs applicable to the Licensee or impose new LCs in relation to such testing technologies.

Reporting of serology results

5.9 The Licensee shall ensure that information about the immunoglobulins against the viral proteins (Anti-N / Anti-S) and type of immunoglobulins (IgG, IgM, Total antibody) of the test kits shall be transmitted to the CTR during the test code submission and review.

5.10 The Licensee shall comply with the following requirements when transmitting quantitative serology results to CTR:

(a) For serology tests, two test codes shall be transmitted: one for qualitative result (i.e. positive / negative), and one for quantitative results (e.g. 0.8 U/ml); and

(b) The manufacturer's name is to be provided in the interpretation note field.

5.11 A Licensee whose clinical laboratory performs SARS-CoV-2 tests solely in the context of a clinical trial (where no clinical diagnosis is made) is exempted from the conditions set out at paragraphs 5.1 to 5.10 above.

Annex A

LIST OF MANDATORY DATA FIELDS FOR SUBMISSION OF COVID-19 RESULTS TO CTR

S/N	Field name
1	**Patient_id**
2	**controlHeader_srcInstitution**
3	**controlHeader_msgDateTime**
4	**controlHeader_msgID**
5	**lab_accession_no**
6	**lab_specimenReceivedDate***
7	**lab_examinationDate***
8	**lab_result_status**
9	**labitem_item_text_value***
10	**labitem_item_numeric_value***
11	**Labitem_item_name_code**
12	**Patient Nationality**

*Only 1 field required to be submitted based on lab workflow.