LICENCE CONDITIONS FOR
CLINICAL LABORATORY SERVICES

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

1 Application

1.1 These licence conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service ("**CLS**") (such persons referred to as "**Licensees**").

1.2 These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Services' issued on 10 August 2022.

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

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

(a) suspension or revocation of the Licensee's CLS licence;

(b) shortening the term of the Licensee's CLS licence;

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

(d) a direction requiring 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 Requirements Relating to Personnel

<u>General Requirements</u>

2.1 The Licensee shall:

(a) document and define the minimum qualifications for each position that is relevant to the provision of its CLS, including the educational qualifications, skills and experience required of each position;

(b) document and define the job descriptions, roles and tasks for all positions in its CLS;

(c) implement a programme for training and development of the personnel in its CLS. This programme shall minimally cover the following aspects:
   (i) the frequency of the competency assessment(s) to be carried out by its CLS, and the programme(s) required to be implemented for continuing education of its CLS's personnel;
   (ii) the corrective actions to be taken against each personnel of its CLS who fails to attain a satisfactory work performance, such as retraining and competency assessment;
   (iii) laboratory safety programme(s) for all of its CLS's personnel; and
   (iv) assigning an experienced person (as defined under Regulation 10(2) of the Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 ("**CLSRS Regulations**")) to supervise, train and assess the competency of all of its CLS's personnel who are under training.

Section Leader

2.2 Save as provided under any other applicable licence conditions imposed under the HCSA, the Licensee shall ensure that the section leader of its CLS (as appointed under Regulation 8 of the CLSRS Regulations) ("**Section Leader**") shall have:

(a) any of the following minimum qualifications:
   (i) a pass in the Departmental Qualifying Examination of the Ministry of Health;
   (ii) a Diploma of Medical Laboratory Technology;
   (iii) a Bachelor of Biomedical Science;
   (iv) a Bachelor of Medical Laboratory Science/Technology; or
   (v) or an equivalent qualification that is acceptable to the Director-General of Health ("**DGH**")[1]; and

[1] Licensee shall ensure that as far as possible, to appoint a Section Leader who possess qualifications from (i) to (iv) or equivalent in any areas of pathology. The candidate may also possess post graduate certification or demonstrate training in specialised laboratory disciplines such as microbiology, biochemistry, and haematology.

(b) at least five years of clinical laboratory working experience that is acceptable to DGH[2].

3 Quality Management System

3.1 The Licensee shall ensure that as part of the quality management system required under Regulation 11 of the CLSRS Regulations, audits on its CLS's operations are carried out, and that corrective and preventive actions for all deficiencies identified are implemented. The following matters shall be documented by the Licensee:

(a) frequency of audits;

(b) the last audit review date; and

(c) the appropriate corrective and preventive measures taken by the Licensee for any deficiencies identified.

3.2 The Licensee shall ensure supervisory review is conducted on records relating to (i) instrument maintenance and functional checks and (ii) quality control. The Licensee shall ensure that corrective actions and troubleshooting actions are performed, where applicable, as part of the supervisory review.

3.3 The Licensee shall ensure that there is a written procedure for escalation of any issues related to its CLS operations to its Section Leader or its Clinical Governance Officer (as appointed under section 24(2) of the HCSA) ("**CGO**").

Quality Control Measures

3.4 The Licensee shall implement an internal quality control programme, comprising quality control measures, to validate the reliability of its CLS's test results. The Licensee shall ensure that the internal quality control programme shall:

(a) include: (i) the analytical test instrument or method, (ii) the selection of appropriate quality control materials, (iii) sample types, (iv) established acceptance criteria, (v) frequency of quality control and (vi) test volume; and

[2] Acceptable experience includes supervising technical staff in the conduct of testing, for example, setting up of test platform, validation/verification/optimization of work processes and quality assurance measures in accordance with the Quality Management System.

(b) be performed at least at the frequency stipulated by the manufacturer of the analytical test instrument or method.

3.5 The Licensee shall ensure that as far as reasonably possible, the quality control measures performed by its CLS in relation to a test is conducted in accordance with the procedures used for the testing of that patient specimen ("**test procedures**"), and at the appropriate intervals defined in the test procedures.

3.6 The Licensee shall ensure that for all quality control results which are assessed to be unacceptable based on its established acceptance criteria in paragraph 3.4(a)(iv):

(a) the results are investigated by the appropriate personnel;

(b) the possible ramifications for patient specimen testing are considered by the Licensee; and

(c) the appropriate corrective and preventive actions are taken to address and rectify the underlying cause for the unacceptable quality control results.

3.7 The Licensee shall ensure that the potency and reliability of reagents shall be tested for acceptable reactivity on each day of use, or as specified by the manufacturer's instruction for use, whichever is applicable, prior to the reporting of any patient results.

3.8 The Licensee shall ensure that all errors or issues detected prior to the conduct of any testing of patient specimens are resolved in a timely manner.

External Quality Assessment ("EQA") Programme

3.9 The Licensee shall ensure that samples of a test used for EQA:

(a) are not treated differently from patient samples; and

(b) are processed and tested in accordance with the established standard operating procedures ("**SOPs**") and by the same personnel who performs that test.

3.10 Where commercial EQA programmes for a test method are unavailable, the Licensee shall ensure that its CLS's performance is evaluated by other appropriate and equivalent methods of EQA[3].

3.11 The Licensee shall review all EQA programme results, and in the event that unacceptable results are disclosed (including results not graded by an EQA provider), the Licensee shall:

(a) ensure that the unacceptable results are investigated to identify all possible causal factors;

(b) implement the appropriate and effective corrective and preventive actions; and

(c) review the impact of any causal factors identified in paragraph 3.11(a) on the reliability of patients' results reported during the affected period.

3.12 The Licensee shall ensure that all EQA programme reports and, where applicable, investigation reports shall be reviewed by its CGO or any other suitably qualified personnel designated by the CGO.

Participation in National Proficiency Test Scheme for Certain Tests

3.13 The Licensee shall, for each of the following tests specified in the table below, participate in the relevant national proficiency test schemes stipulated in the table below[4]:

Tests	**Name of National Proficiency Test Scheme**
(a) Human immunodeficiency virus screening	Singapore General Hospital's National HIV Reference Laboratory Proficiency Testing for HIV screening
(b) Acid-fast bacilli smear testing ("**AFB (Smear)**")	Singapore General Hospital's Central Tuberculosis Laboratory National Proficiency Testing for AFB (Smear)
(c) Glycated haemoglobin (haemoglobin A1c) ("**HbA1c**") testing	Health Sciences Authority's Chemical Metrology Laboratory for HbA1c testing
(d) Malaria parasite testing (Morphology-based)	National Public Health Laboratory's Malaria Parasite Proficiency Test

[3] Examples of other appropriate and equivalent methods of EQA include but are not limited to inter-laboratory comparison, method comparison or split sample testing.

[4] For avoidance of doubt, the licensee must provide demonstrate competency in NPTs (one cycle) for all tests before they can be approved, **except** for HbA1c and AFB (smear) testing.

(e)	Molecular SARS-CoV-2 testing for Coronavirus Disease 2019 (COVID-19)	National Public Health Laboratory's inter-laboratory comparison for SARS-CoV-2 before patient testing

4 Premises, Equipment and Reagents

Premises

4.1 The Licensee shall ensure that for its approved permanent premises, approved conveyance and temporary premises where its CLS is provided ("**Premises**"):

(a) there is adequate space in the Premises such that the quality of work and safety of the personnel will not be compromised;

(b) there is adequate space for the movement of its CLS's personnel;

(c) there is adequate lighting and proper ventilation;

(d) there are adequate environmental controls (such as temperature, humidity, and where applicable, pressure) for its CLS's personnel to carry out the CLS without compromising the quality of work and the optimal functioning of laboratory equipment;

(e) the floorings and laboratory benches are constructed of materials that permit cleaning and disinfection, and are non-absorbent (e.g. non-permeable materials for laboratory furniture);

(f) there is adequate emergency power supply for the proper provision of its CLS; and

(g) safety facilities and equipment, including but not limited to emergency showers and eye wash, are adequate, accessible, in working order and regularly maintained.

Equipment

4.2 The Licensee shall ensure that the functionality and performance of all its CLS's analytical test instruments are verified:

(a) prior to their use in the CLS's tests or after any major maintenance, major servicing or relocation; and

(b) to meet the manufacturer's specifications, after having been installed in accordance with the manufacturer's specifications.

4.3 The Licensee shall ensure that for all of its CLS's analytical test instruments and equipment:

(a) the appropriate maintenance and functional checks are performed in accordance with the manufacturers' specifications;

(b) equipment failures are investigated and resolved prior to resumption of the use of that equipment; and

(c) there is adequate documentation of all equipment calibration, maintenance, repairs and troubleshoots.

4.4 The Licensee shall ensure that for all of its CLS's temperature-dependent equipment:

(a) temperatures of each of such equipment are measured, checked and recorded on each day of use;

(b) the temperatures recorded are traceable to each of such equipment; and

(c) all temperature measurements that fall outside of the acceptable limits shall be investigated and rectified in a timely manner.

4.5 The Licensee shall ensure that all temperature-monitoring devices used in its provision of CLS are verified against a reference standard or, in the case of reference thermometers, calibrated to a reference standard at least once every 12 months or as stated on the certificate of calibration.

Reagents and Materials

4.6 The Licensee shall ensure that there are effective measures to quarantine and prevent any inadvertent use of test reagents and critical materials in its provision of CLS where:

(a) the reagents and/or critical materials have been received by the Licensee or any of its personnel from the supplier but are not released from quarantine;

(b) the Licensee or any of its personnel have been notified of any issues with the reagents and/or critical materials which may affect their potency, sterility, quality or performance; and/or

(c) suboptimal quality or performance of the reagents and/or critical materials is suspected.

4.7 The Licensee shall ensure that there are appropriate checks on any reagents and critical materials received by the Licensee or any of its personnel from the supplier, and that such checks are done in accordance with its CLS's established criteria for acceptance prior to the release of the reagents and critical materials for use. The Licensee shall also ensure that its personnel who have received and checked the reagents and/or critical materials are identifiable and traceable.

4.8 The Licensee shall ensure that all reagents and critical materials used in its provision of CLS:

(a) are stored under the conditions specified by the manufacturer of the reagents or critical materials (as applicable); and

(b) that are used off-label are validated to demonstrate acceptable performance prior to routine use.

Laboratory Information System and Equipment Data

4.9 Where the Licensee implements a laboratory information system for its CLS, the Licensee shall implement a policy that covers the following:

(a) the various levels of access control and privilege rights in its laboratory information system as may be necessary for each of its personnel's job function;

(b) user authentication (i.e. the process of verifying the identity of the user of the laboratory information system); and

(c) audit trail(s) of access to the laboratory information system and amendments made to the laboratory information system.

4.10 The Licensee shall ensure that its laboratory information system is qualified for proper performance prior to its implementation and after any significant modifications to the system.

4.11 The Licensee shall ensure that its laboratory information system is evaluated for accurate, timely and secure data transmission from its CLS's interfaced analytical instruments or systems to its CLS's test reports.

5 Laboratory Practices

General Requirements for all Licensees

5.1 The Licensee shall ensure that SOPs are properly documented, and are made available and readily accessible to all of its CLS's personnel.

5.2 The Licensee shall ensure that the SOPs are approved by its CGO or any other suitably qualified personnel designated by the CGO prior to their implementation and are reviewed regularly and updated periodically as required in its CLS's quality management system.

5.3 The Licensee shall ensure that there are clear and effective processes for the storage of all of its CLS's specimens to prevent unauthorised access and use.

5.4 The Licensee shall ensure that the specimen retention and storage conditions are defined in its SOPs for each type of specimen tested in its CLS.

5.5 The Licensee shall ensure that there is no mix-up of specimens in its provision of CLS.

5.6 The Licensee shall ensure that effective measures are implemented to prevent transcriptional or typographical errors in any documentation created or produced by its CLS.

Requirements for Anatomic Pathology Laboratory Discipline

5.7 A Licensee that provides a testing service in anatomic pathology shall, for its CLS:

(a) establish a policy for the specimen acceptance and rejection that sets out the process for the handling of sub-optimal specimens. Such sub-optimal specimens include, but are not limited to those specimens with:
  (i) insufficient information;
  (ii) incorrect site; or
  (iii) no or incorrect preservative, transport medium or anticoagulant used;

(b) ensure that specimens are accepted in accordance with its CLS's specimen acceptance and rejection policies referred to in paragraph 5.7(a);

(c) ensure that specimens which do not meet the criteria for acceptance in accordance with the policies referred to in paragraph 5.7(a) are either (i)

rejected and disposed or (ii) retained in accordance with the specimen retention policy;

(d) ensure that specimens which are re-collectable are not returned to the requestor[5] unless (i) there are applicable exceptional circumstances defined in the specimen acceptance and rejection policies referred to in paragraph 5.7(a), and (ii) the return is documented;

(e) ensure that any rejection of specimens is communicated to the requestor and documented;

(f) ensure that microscopic slides and/or paraffin blocks are permanently identified; and

(g) ensure that all stains are tested for intended reactivity.

5.8 A Licensee that performs immunohistochemistry (IHC) and/or in-situ hybridisation (ISH) for estrogen receptor (ER) and human epidermal growth factor-2 (HER2) as part of breast cancer predictive marker testing shall evaluate, on a yearly basis, the annual positivity rate of its CLS's results against established benchmarks and intradepartmental concordance rates amongst pathologists interpreting IHC and ISH tests for ER and HER2.

Requirements for Cytology Laboratory Discipline

5.9 A Licensee that provides a testing service in cytology shall, for its CLS:

(a) ensure that microscopic slides and/or paraffin blocks are permanently identified;

(b) ensure that all stains are tested for intended reactivity; and

(c) for gynaecological specimens, to ensure that a system of re-screening of smears is in place to ensure that:
  (i) there is selected full screen of 10% negative and benign reactive smears; and
  (ii) rapid re-screen of all negative and benign reactive smears will be conducted by a senior or supervisory cytotechnologist, and that the cytotechnologist documents the method of re-screening employed.

Requirements for Medical Microbiology Laboratory Discipline

[5] As defined under Regulation 2 of the CLSRS Regulation.

5.10 A Licensee that provides a testing service in medical microbiology shall, for its CLS, ensure that:

(a) all stains are tested for intended reactivity;

(b) all chemical and biological solutions, reagents and antisera are tested to ensure proper reactivity; and

(c) every batch of media is tested for sterility and with selected organisms to confirm the required growth characteristics.

6 Reporting of Results

General Requirements for all Licensees

6.1 The Licensee shall ensure that there are effective processes for clear, secure and timely communication of its CLS's results to the requestor.

6.2 The Licensee shall not provide reports of its CLS's results to any requestor verbally as far as reasonably possible. Where it is necessary for the Licensee to provide its CLS's results to a requestor verbally, the Licensee shall ensure that:

(a) there are policies in place relating to the provision of verbal reports to the requestor (including procedures of verification of results received by the requestor receiving the verbal report ("**Recipient**") and that such policies are properly documented and made available to the relevant personnel in its CLS;

(b) such verbal reports are given in accordance with its documented policies on verbal reports;

(c) any verbal reports which are provided by its personnel are documented in writing, and such documentation shall include (i) the name of the person providing the verbal report, (ii) the name of the Recipient, (iii) contents of the communications and (iv) the date and time of the communication; and

(d) it provides the Recipient with an electronic or hard copy of the report of the results as soon as possible.

6.3 When errors are detected in patient test reports, the Licensee shall ensure that the personnel involved in the provision of its CLS promptly notifies all of the

Licensee's clinical personnel who are responsible for the patient test reports and/or the requestor, as applicable.

Requirements for Anatomic Pathology Laboratory Discipline

6.4 A Licensee that provides a testing service in anatomic pathology shall, for its CLS, ensure that:

(a) each section of a specimen is evaluated by a pathologist; and

(b) all abnormal or suspicious smears are evaluated by a pathologist or registered medical practitioner qualified in anatomic pathology.

Requirements for Cytology Laboratory Discipline

6.5 A Licensee that provides a testing service in cytology shall, for its CLS, ensure that:

(a) all abnormal or suspicious smears are evaluated by a pathologist;

(b) a periodic review of all previous cytology test results provided by it will be conducted (in particular, all cases of new high grade squamous intraepithelial lesion), and that the review is documented; and

(c) its CLS establishes a correlation between cytology results and subsequent histology results (or follow-up of abnormal smear results if subsequent histology results are not available).

Requirements for Cytogenetics Laboratory Discipline

6.6 A Licensee that provides a testing service in cytogenetics shall ensure that all abnormal or suspicious chromosomal preparations are evaluated by a pathologist or registered medical practitioner qualified in cytogenetics.

7 Outsourcing of test(s)

7.1 The Licensee shall be allowed to appoint a person who operates a clinical laboratory outside Singapore that is accredited by any of the accreditation bodies which are approved by DGH in **Annex A** to conduct a test on the Licensee's behalf.

7.2 The Licensee shall ensure that where it appoints or engages another person to conduct a test on its behalf under Regulation 41(1) of the CLSRS Regulations

("**Outsourced Laboratory**"), the reports of the Outsourced Laboratory for that test are not copied or reproduced except in their entirety.

8 Notification of Laboratory-Developed Test[6] ("LDTs")

8.1 The Licensee shall notify the Ministry of Health ("**MOH**") of the list of LDTs manufactured, implemented and/or used in its CLS on an annual basis, by submitting the list on MOH's licensing portal, currently known as the Healthcare Application and Licensing Portal (HALP) (accessible via https://halp.moh.gov.sg/), or any other equivalent portal or website used by MOH at the time of the notification.

[6] As defined under the Health Products (Medical Device) Regulations 2010.

Annex A

LIST OF APPROVED CLINICAL LABORATORY ACCREDITATION BODIES

The list of accreditation bodies approved by DGH is as follows:

(a) Accreditation Canada (Canada)

(b) American Society for Histocompatibility and Immunogenetics (USA)

(c) ANSI National Accreditation Board (ANAB) (USA)

(d) Association for the Advancement of Blood & Biotherapies (AABB) (USA)

(e) College of American Pathologists (USA)

(f) Danish Accreditation (DANAK) (Denmark)

(g) Deutsche Akkreditierungsstelle (DAkkS) (Germany)

(h) Dutch Accreditation Council (Raad voor Accreditatie) (The Netherlands)

(i) Foundation for the Accreditation of Cellular Therapy (USA)

(j) International Accreditation New Zealand (New Zealand)

(k) National Association of Medical Examiners (USA)

(l) National Association of Testing Authorities (Australia)

(m) National Pathology Accreditation Advisory Council (Australia)

(n) Singapore Accreditation Council-Singapore Laboratory Accreditation Scheme (Singapore)

(o) Swiss Accreditation Services (Switzerland)

(p) Taiwan Accreditation Foundation (Taiwan)

(q) The Joint Commission (USA) (formerly known as Joint Commission on Accreditation of Healthcare Organizations)

(r) United Kingdom Accreditation Service (formerly known as Clinical Pathology Accreditation) (UK)