LICENSING CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE HUMAN IMMUNODEFICIENCY VIRUS SCREENING

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

1. Application

1.1 These licensing conditions ("**LCs**") apply to all persons which have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service and provides, or intends to provide, as part of that service, the specified test of human immunodeficiency virus ("**HIV**") Screening (as defined at paragraph 2.1 below) ("**Licensees**").

1.2 These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Service Licensees Providing or Intending to Provide Human Immunodeficiency Virus Screening' issued on 10 August 2022.

1.3 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.

1.4 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 clinical laboratory service licence;

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

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

(d) directing 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. Definition of HIV Screening

2.1 For the purpose of these LCs, HIV screening ("**HIV Screening**") refers to the laboratory testing of Specimens of human blood ("**Blood Specimens**") to detect the presumptive presence of HIV using serology assays.

3. Practices

A. Acceptance of Specimens for HIV Screening

3.1 Licensees shall ensure that their clinical laboratory service ("**Laboratory**") only accepts Blood Specimens for HIV Screening if:

(a) the Blood Specimens are labelled with sufficient information to allow for it to be traced to the Patient; and

(b) the HIV Screening is requested by a Requestor (including those who are employed in-house by the Licensee to provide services at their Laboratory) provided that the request contains the relevant details of the registered medical practitioner who provided the pre-HIV Screening counselling to the Patient and who will be providing the post-HIV Screening counselling to the Patient (**"Counselling Doctor**") as set out in clause 3.3(b)(9) and clause 3.3(b)(10) below.

3.2 For the purposes of clause 3.1(a), a Blood Specimen is labelled with sufficient information if it contains at least two unique identifiers of the Patient.

3.3 Licensees shall ensure that their Laboratory's acceptance criteria for Blood Specimens (i.e., specimen acceptance criteria) includes the following:

(a) a minimum specimen volume to ensure that there is sufficient amount of the Blood Specimen (at least 1.5mL of serum/plasma) to be sent to the National HIV Reference Laboratory of the Division of Pathology, Singapore General Hospital (the "**NHRL**") for confirmatory testing should the HIV Screening provided produce reactive or equivocal results;

(b) the requirement for the following information to be collected for each Blood Specimen:

(1) Name of the Patient;
(2) Identification number or passport number of the Patient;

(3) Date of birth of the Patient;
(4) Gender of the Patient;
(5) Nationality of the Patient;
(6) Purpose of the HIV Screening;
(7) Name of the Requestor;
(8) Medical Council Registration ("**MCR**") number of the Requestor, if the Requestor is a Medical Practitioner;
(9) Contact details of the Requestor;
(10) Name of the Counselling Doctor (unless the Counselling Doctor is also the Requestor;
(11) MCR of the Counselling Doctor (unless the Counselling Doctor is also the Requestor; and
(12) Contact details of the Counselling Doctor (unless the Counselling Doctor is also the Requestor).

B. Conduct of HIV Screening

3.4 Licensees shall ensure that their Laboratory subjects Blood Specimens that have been determined to be reactive for HIV from the HIV Screening to a repeated HIV Screening ("**Repeated Test**").

3.5 Licensees shall ensure that their Laboratory refers and sends Blood Specimens that are (1) determined to be reactive for HIV following a Repeated Test, and (2) those with equivocal results to the NHRL for further testing to either confirm or determine the results, as the case may be.

3.6 Licensees shall ensure that all Blood Specimens sent by their Laboratory to the NHRL for confirmatory testing are accompanied with the relevant information described in clause 3.3(b) above and the test results from the HIV Screenings provided by the Laboratory.

3.7 Licensees shall ensure that their Laboratory does not release the test results of the HIV Screening or Repeated Test to the Requestor before they are confirmed or determined by the NHRL.

3.8 Licensees shall ensure that their Laboratory does not pool sera/plasmas for HIV Screening.

3.9 Licensees shall use 4th generation HIV assay kits that have been registered with the Health Sciences Authority for HIV Screening.

4. Quality Assurance

4.1 Licensees that shall ensure that their Laboratory:

(a) participates in and passes the HIV Proficiency Testing programme that is conducted by the NHRL ("**National Proficiency Test**") irrespective of the assay methods used by their Laboratory for HIV Screenings, before providing any HIV Screenings; and

(b) subject to clause 4.2, provides at least 100 HIV Screenings per quarter of each year in order to maintain continued competence.

4.2 Licensees that solely provide HIV Screenings for the purposes of clinical trials shall be regarded as having satisfied the requirements under clause 4.1(b) if their Laboratory participates in and passes an external quality assessment programme (EQA) (other than the National Proficiency Test) in relation to that Laboratory's proficiency in HIV Screening each year.

5. Notification

5.1 Licensees shall submit quarterly returns of the HIV Screenings provided by their Laboratory via the National Public Health Unit Registry System (NPHURS).

5.2 Licensees shall ensure that their Laboratory notifies the Director-General of Health of any person who is suffering from a HIV infection in accordance with the requirements set out under section 6 of the Infectious Diseases Act 1976 and any other applicable laws, regulations or requirements.