LICENCE CONDITIONS FOR

LICENSEES PROVIDING OR INTENDING TO PROVIDE SIMPLE IN VITRO DIAGNOSTIC TESTS

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

1. Application

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

(a) all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a licensable healthcare service other than clinical laboratory service; and

(b) that provide or intend to provide, as part of that licensable healthcare service, simple in vitro diagnostic ("**simple IVD**") tests without a licence to provide clinical laboratory service.

(such persons referred to as "**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 A breach of these LCs may result in regulatory action(s) being taken against Licensees under section 20 of the HCSA, including but not limited to:

(a) suspension or revocation of the Licensee's HCSA licence;
(b) shortening the term of the Licensee's HCSA 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.

1.4 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, codes of practice made thereunder.

2. Definitions

2.1 The following definitions shall apply to these LCs:

(a) "**Health Sciences Authority**" or "HSA" means the Health Sciences Authority established under section 3 of the Health Sciences Authority Act 2001; and

(b) "**test material**" means test kits, reagents, quality control materials, calibrators and any material used in the conduct of simple IVD tests.

3. Restrictions

3.1 The Licensee shall ensure that every simple IVD test conducted is incidental to the provision of the licensable healthcare service that the Licensee is licensed to provide.

3.2 The Licensee shall ensure that every simple IVD test conducted is part of its delivery of care to its patients. The Licensee shall not (1) sell any test material and/or test instrument to its patients; or (2) conduct any sale of simple IVD tests which is not part of its delivery of care to its patients.

4. Facilities, test instrument and test material

4.1 The Licensee shall ensure that every test instrument which is used in the conduct of a simple IVD test, is operated in an environment which permit safe and optimal operation as specified by the manufacturer of that test instrument.

4.2 The Licensee shall ensure that, where applicable, every test instrument and test material used in the conduct of simple IVD tests are registered with HSA or are approved for use in Singapore by HSA.

4.3 The Licensee shall monitor and ensure that every test instrument and test material used in the conduct of simple IVD tests are stored and used under the conditions as specified by the relevant manufacturers of the test instrument and test material.

4.4 The Licensee shall ensure that regular routine reviews are conducted on every test instrument and test material, in accordance with the operator's manual or instructions for use.

4.5 Where temperature measurements for any test instrument or test material falls outside of acceptable limits under the operator's manual or instructions for use, the Licensee shall ensure that any underlying causes of such deviations are investigated and rectified in a timely manner.

4.6 The Licensee shall ensure that the operator's manual or instructions for use of every test instrument and test material used in the conduct of simple IVD tests are available at all times at the site where simple IVD tests are conducted.

5. Quality measures

Test evaluation

5.1 Where the conduct of a simple IVD test requires the use of a test instrument for analysis, the Licensee shall ensure that the test performance of that test instrument is verified in accordance with the manufacturer's specifications before use:

(a) upon the installation of that test instrument; and

(b) where required under the manufacturer's specifications, after each relocation of that test instrument.

5.2 The Licensee shall ensure that every test material is subject to functional checks in accordance with the manufacturer's specifications prior to the use of that test material in:

(a) conducting a simple IVD test; or

(b) reporting the result of the simple IVD test conducted.

Quality control measures

5.3 Where required under the manufacturer's specifications for a test instrument or test material, the Licensee shall perform internal quality control ("QC") checks on that test instrument or test material in accordance with the manufacturer's specifications.

5.4 In performing internal QC checks as required for a test instrument or test material, the Licensee shall:

(a) put in place an internal process for identifying, reporting and investigating any results of such QC checks ("QC results") which are unacceptable under the relevant manufacturer's specifications;

(b) take appropriate corrective and preventive actions to rectify any underlying causes of such QC results which are unacceptable; and

(c) ensure that all QC results are reviewed and verified by a suitably trained person.

6. Test procedure

6.1 The Licensee shall ensure that every simple IVD test carried out is accurate.

6.2 The Licensee shall ensure that every simple IVD test carried out shall only be performed within the scope of its intended purpose.

6.3 The Licensee shall ensure that in carrying out a simple IVD test, all testing procedures are undertaken in accordance with the manufacturer's instructions for use for that simple IVD test.

6.4 Where there is reason to suspect that the result of a simple IVD test is inaccurate, including having a test result for a patient deviating substantially from those earlier reported in respect of the patient or having reason to suspect that a test result is inaccurate given the patient's clinical presentation, the Licensee shall, before it resumes performing that simple IVD test, ensure that investigations are performed and remedial actions are taken to ensure the accuracy of that test.

7. Test results

7.1 The Licensee shall ensure that the results of every simple IVD test conducted are traceable to:

(a) the patient; and
(b) the test material used in the conduct of that simple IVD test.

8. Records

8.1 The Licensee shall ensure that the results of every simple IVD test conducted are properly documented. For avoidance of doubt, Patient Health Records (as defined in the Licence Conditions on the Retention Periods of Patient Health Records) include simple IVD test results, and shall be retained in accordance with the requirements under the Licence Conditions on the Retention Periods of Patient Health Records.

8.2 The Licensee shall ensure that the following records are retained for such period as may be required under any applicable laws, and made available for inspection by the Ministry of Health from time to time:

(a) records of every test instrument used by the Licensee in the conduct of simple IVD tests, including maintenance and servicing and temperature measurements;
(b) records of every test material used by the Licensee in the conduct of simple IVD tests, including storage temperature, lot number and expiration dates and quality measures undertaken; and
(c) personnel training records, which shall be retained for at least two (2) years after each relevant personnel has ceased employment or engagement with the Licensee.

9. Specific requirements for the use of glycated haemoglobin (haemoglobin A1c) test as a screening modality for diabetes mellitus

9.1 Licensees who offer or intend to offer glycated haemoglobin (haemoglobin A1c) test ("HbA1c") as a screening modality for diabetes mellitus shall meet the following requirements:

(a) the Licensee shall ensure that the conduct of every HbA1c test is performed using a method which is certified by the National Glycohemoglobin Standardisation Programme ("NGSP");

(b) for avoidance of doubt, the Licensee is not required to undergo certification under NGSP, but shall ensure and verify that all manufacturers and suppliers of the Licensee's HbA1c test kits maintain NGSP certification. Where any manufacturer or supplier of the Licensee's HbA1c test kits fails to maintain NGSP certification, the Licensee shall cease using such test kits supplied by that manufacturer or supplier; and

(c) the Licensee shall participate in the External Quality Assessment Programme administered by HSA's Chemical Metrology Laboratory for HbA1c test.