LICENCE CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE GLYCATED HAEMOGLOBIN (HAEMOGLOBIN A1C) TESTING

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 and provides, or intends to provide, as part of that service, glycated haemoglobin (haemoglobin A1c testing) ("**HbA1c testing**") ("**Licensees**").

1.2 These LCs shall supersede and replace the LCs entitled 'Licence Conditions for Clinical Laboratory Service Licensees Providing or Intending to Provide Glycated Haemoglobin (Haemoglobin A1C) Testing' 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) 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 Quality Management System

2.1 The Licensee shall ensure that its clinical laboratory service ("**Laboratory**") participates in the External Quality Assessment Programme administered by Health Sciences Authority's Chemical Metrology Laboratory for HbA1c testing.

3 Practices

3.1 The Licensee shall ensure that its Laboratory conducts HbA1c testing by way of a method certified by National Glycohemoglobin Standardisation Programme ("**NGSP**"), as traceable to the Diabetes Control and Complications Trial reference. A list of the certified assay methods is available on the NGSP website (http://www.ngsp.org/certified.asp).

3.2 The Licensee shall ensure that its Laboratory only uses an assay method for HbA1c testing that has been certified by NGSP within the last 12 months or as stated in the certificate of traceability, which shall be valid.

3.3 The Licensee shall ensure that its Laboratory ceases the use of any assay method if that assay method is no longer certified by NGSP, and only makes use of an alternative assay method that is certified by NGSP.

3.4 For the avoidance of doubt, the Licensee is not required to undergo NGSP certification. However, the Licensee shall ensure that:

(a) its Laboratory only makes use of HbA1c test kits purchased from a manufacturer or a local supplier that maintain their NGSP certification; or

(b) If the manufacturer did not undergo NGSP certification for a method that the Laboratory chose to use, the Laboratory shall undertake NGSP certification specifically for the said method for use only in the Laboratory which conducts the test.