LICENCE CONDITIONS FOR

CLINICAL LABORATORY SERVICE LICENSEES PROVIDING OR INTENDING TO PROVIDE ACID-FAST BACILLI (SMEAR) TESTING

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

1 Application

1.1 These licence conditions ("**LCs**") apply to all persons that have been licensed under the Healthcare Services Act 2020 (the "**HCSA**") to provide a clinical laboratory service and provide, or intend to provide, as part of that service, acid-fast Bacilli (smear) testing ("**AFB (Smear) 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 Acid-Fast Bacilli (Smear) 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 National Proficiency Testing for AFB (Smear) testing conducted by the Singapore General Hospital's Central Tuberculosis Laboratory.

2.2 The Licensee shall ensure that its Laboratory checks new lots or batches of AFB stains with positive and negative quality control organisms and have an acceptable performance before placing them on routine use.

2.3 The Licensee shall ensure that its Laboratory checks the positive and negative quality control organisms before each day of use.

2.4 The Licensee shall ensure that its Laboratory does not read patient smears, and does not proceed with testing if the results of the positive and negative control slides referred to in paragraphs 2.2 and 2.3 are unacceptable.

3 Safety Measures

3.1 The Licensee shall ensure that its Laboratory has written procedures in place, that include safety measures to minimise infection hazards (especially by way of infectious aerosols) to laboratory personnel involved in AFB (Smear) testing.

3.2 The Licensee shall ensure that its Laboratory informs all laboratory personnel of the written procedures referred to in paragraph 3.1, and that its Laboratory requires all laboratory personnel to comply with the measures set out therein.

3.3 The Licensee shall ensure that its Laboratory performs all manipulations in a biological safety cabinet, including but not limited to opening of specimens from patients suspected of having tuberculosis. Microscopy slides containing specimens from patients suspected of tuberculosis should be handled carefully and discarded in a biohazard container following examination.

3.4 The Licensee shall ensure that its Laboratory carries out specimen centrifugation in aerosol-proof safety carriers. Centrifuge cups should only be opened in a biological safety cabinet.

3.5 The Licensee shall ensure that its Laboratory uses a biological safety cabinet that meets minimum requirements for mycobacterial work and is certified at least annually to ensure that filters are functioning properly and that airflow rates meet the manufacturer's specifications.

4 Collection of Specimens

4.1 The Licensee shall ensure that its Laboratory collects specimens in sterile, leak-proof and disposable containers.

5 Records

5.1 The Licensee shall ensure that its Laboratory keeps all records associated with AFB (Smear) testing for a period of not less than three years.

6 Notification

6.1 The Licensee shall ensure that its Laboratory notifies all cases of AFB (Smear) testing with a positive result immediately to the requesting medical practitioner.

6.2 The Licensee shall also ensure that the Laboratory notifies Director-General of Health in writing of any person who is diagnosed with tuberculosis infection as a result of the AFB (Smear) testing conducted by its Laboratory, in accordance with the requirements set out under section 6 of the Infectious Diseases Act 1976 and any other applicable laws, regulations or requirements.