



**MINISTRY OF HEALTH**  
SINGAPORE

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Licensees of Clinical Laboratory Services

**REVISED REGULATORY GUIDELINES FOR LABORATORY DEVELOPED TESTS (LDTs) BY THE HEALTH SCIENCES AUTHORITY (HSA)**

The Ministry of Health (“**MOH**”) informs licensees of clinical laboratory services under the Healthcare Services Act 2020 (“**HCSA**”) of the revised Regulatory Guidelines for LDTs published by the HSA on 4 September 2025.

2. The revised guidelines are available on the HSA's website at <https://www.hsa.gov.sg/medical-devices/guidance-documents> under Product Registration > Product Specific Regulatory Guidelines. For convenience, the revised guidelines have also been appended at **Annex A** (under “MOH-MHC-0022-2026 12MAR26 Revised Regulatory Guidelines for Laboratory Developed Tests (LDTs) by the Health Sciences Authority (HSA) Annex A”).

3. The key revision in the updated guidelines is the addition of Section 3.3.1, which states that:

- (a) **LDTs must not be advertised to the general public**, as they are intended solely for clinical diagnosis under medical supervision and used only within the MOH-licensed clinical laboratory where they were developed.
- (b) **Any advertisements for LDTs are only permitted in publications intended for circulation among qualified practitioners.**
- (c) **Such advertisements for LDTs**, which should only be intended for circulation among qualified practitioners, **must not be false or misleading.**

4. Licensees which develop and use LDTs in the course of providing a clinical laboratory service are reminded to comply with the Health Products Act 2007.

5. Licensees are also reminded to ensure compliance with the HCSA and all applicable laws and regulations, including the Healthcare Services (Advertisement)

Regulations 2021, when publishing, disseminating or conveying any information that is related to the delivery of clinical laboratory service.

6. Should you require any further information or clarification on the revised Regulatory Guidelines for LDTs, please contact [HSA MD Info@hsa.gov.sg](mailto:HSA_MD_Info@hsa.gov.sg).

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## Annexes

<b>Annex A</b>	MOH-MHC-0022-2026 12MAR26 Revised Regulatory Guidelines for Laboratory Developed Tests (LDTs) by the Health Sciences Authority (HSA) Annex A
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