HEALTH SCIENCES AUTHORITY

FOR CONSULTATION

Regulatory Guidelines for Laboratory Developed Tests (LDTs)

HSA Health Sciences Authority

CONTENTS

1. INTRODUCTION

1.1. Purpose

This document provides guidance and clarity in assisting clinical laboratories on understanding the regulatory requirements applicable to Laboratory Developed Tests (LDTs) under the Health Products Act 2007 (HPA) and Health Products (Medical Devices) Regulations 2010 (HP (MD) Regulations).

1.2. Background

LDTs are *in vitro* diagnostic tests (IVDs) developed in-house within the Ministry of Health (MOH) licensed clinical laboratories for clinical diagnostic use solely within their laboratories. While commercial IVDs have been subject to regulatory controls under the HPA, LDTs have not been regulated by HSA. Regulating LDTs under the HPA is necessary to ensure that these diagnostic tests (i.e. products) meet the essential standards of manufacturing quality and efficacy and provide accurate results for patients.

The regulatory approach for LDTs is titrated based on the current regulatory requirements applicable to commercial IVDs taking into consideration the existing regulatory requirements that are applicable to clinical laboratories under the Healthcare Services Act (HCSA).

Clinical laboratories are currently regulated and licensed by MOH under the HCSA. Under the HCSA, the licensees and management of clinical laboratories are required to comply with specific standards and requirements as prescribed under the Healthcare Services (General) Regulations 2021 and Healthcare Services (Clinical Laboratory Service and Radiological Service) Regulations 2021 and its Licence Conditions. These include specific requirements related to the provision of clinical testing service comprising licensing, governance, personnel, facilities and equipment, clinical service provision and laboratory specific safety and quality procedures. In relation to LDTs, licensed clinical laboratories are required to submit an annual notification of the list of LDTs manufactured, implemented and/or used in its laboratories. These

requirements will remain applicable to all local clinical laboratories and to the testing services offered therein. However, clinical laboratories that develop and use LDTs within their facilities will also be subject to certain product specific requirements under the HPA that will focus on ensuring the manufacturing quality, safety and continued efficacy of the LDTs on an on-going basis.

1.3. Scope

LDTs are *in vitro* diagnostics (IVD) that fall within the scope of the definition of medical devices stipulated under the first schedule of the HPA.

This guideline is applicable to all LDTs (i.e. products including test reagents, and kits) developed within a licensed clinical laboratory solely for use within the same laboratory. This does not include test reagents and kits developed within a licensed clinical laboratory and distributed outside of the laboratory where it was developed as these will be regulated as commercial IVD products by HSA.

1.4. Definitions

Definitions in this section are meant to aid in understanding of the contents in this document and should not be used in any legal context. These definitions are provided in layman terms.

ADVERSE EFFECT *(as set out in the HPA)*: means any debilitating, harmful, toxic or detrimental effect that the medical device has been found to have or to be likely to have on the body or health of humans when such a medical device is used by or administered to humans.

ADVERSE EVENT (AE): any event or other occurrence, that reveals any defect in any medical device or that concerns any adverse effect arising from the use thereof.

FIELD SAFETY CORRECTIVE ACTION (FSCA) *(as set out in the HP (MD) Regulations)*: any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device, including

a) the return of the medical device to its product owner;
b) replacement or destruction of the medical device;
c) any action regarding the use of the medical device that is taken in accordance with the advice of its product owner;
d) the clinical management of any patient who has used the medical device;
e) the modification of the medical device;
f) the retrofitting of the medical device in accordance with any modification to it or any change to its design by its product owner;
g) the making of any permanent or temporary change to the labelling or instructions for use of the medical device; or
h) any upgrade to any software used with the medical device, including any such upgrade carried out by remote access.

INSTRUCTIONS FOR USE (IFU): Information provided by the product owner to inform the device user of the medical device's intended purpose and proper use and of any precautions to be taken.

INTENDED PURPOSE/INTENDED USE *(as set out in the HP (MD) Regulations)*: in relation to a medical device or its process or service, means the objective intended use or purpose, as reflected in the specifications, instructions and information provided by the product owner of the medical device.

IN VITRO DIAGNOSTIC (IVD) PRODUCT (*as set out in the HP (MD) Regulations*): means any reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination with any other reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its product owner to be used in vitro for the examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information —

- concerning a physiological or pathological state or a congenital abnormality;

- to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or
- to monitor therapeutic measures; and

includes a specimen receptacle;

LABORATORY DEVELOPED TEST (LDT): are *in vitro* diagnostic tests (IVDs) for clinical diagnostic use that are developed and manufactured within a licensed clinical laboratory and solely for use within the same laboratory where it was developed.

MEDICAL DEVICE (*as set out in the HPA*): means

(a) any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article that is intended by its manufacturer to be used, whether alone or in combination, for humans for one or more of the specific purposes of:

(i) diagnosis, prevention, monitoring, treatment or alleviation of disease;

(ii) diagnosis, monitoring, treatment or alleviation of, or compensation for, an injury;

(iii) investigation, replacement, modification or support of the anatomy or of a physiological process, mainly for medical purposes;

(iv) supporting or sustaining life;

(v) control of conception;

(vi) disinfection of medical devices; or

(vii) providing information by means of in vitro examination of specimens derived from the human body, for medical or diagnostic purposes, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means; and

(b) the following articles:

(i) any implant for the modification or fixation of any body part;

(ii) any injectable dermal filler or mucous membrane filler;

(iii) any instrument, apparatus, implement, machine or appliance intended to be used for the removal or degradation of fat by invasive means.

PRODUCT OWNER *(as set out in the HP (MD) Regulations)*: in relation to a health product, means a person who —

- supplies the health product under his own name, or under any trade mark, design, trade name or other name or mark owned or controlled by him; and
- is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the health product, or for assigning to it a purpose, whether those tasks are performed by him or on his behalf.

1.5. Other guidance documents for additional information

- GN-04: Guidance on Medical Device Recall
- GN-05: Guidance on the Reporting of Adverse Events for Medical Devices for more information on the reportable AEs
- GN-10: Guidance on Medical Device Field Safety Corrective Action
- TR-02: Contents of a Product Registration Submission for In Vitro Diagnostic Medical Devices using the ASEAN CSDT

The above guidance documents can be accessed online at https://www.hsa.gov.sg/medical-devices/guidance-documents under the Product registration and Safety monitoring sections.

2. UNDERSTANDING THE SCOPE OF LDT

LDTs are *in vitro* diagnostic tests (IVDs) that are:

- developed and manufactured within a licensed clinical laboratory and solely for use within the same laboratory where it was developed, and
- intended for specific clinical diagnostic use

The following is an illustration of an LDT:

A licenced laboratory uses general reagents (i.e. antibodies, primers, probes, buffers etc.) that can either be developed/made within the laboratory or commercially purchased and instrument(s) to develop a test system (referred to as test). This test is intended for a specific clinical diagnostic purpose and has been verified and validated within the laboratory. Once validated, the test will be implemented for use solely by this laboratory to provide clinical diagnostic tests.

NOTE: *Once the test system developed in the licenced laboratory is supplied to other facilities outside of the laboratory (where it was developed), the test will no longer be considered an LDT. This test system will be a commercial IVD and subject to regulatory requirements under the HPA.*

The following are not considered LDTs:

- Use of commercial IVDs for purposes other than the intended use/indications for use specified by the manufacturer (i.e. off label use) or making modifications to procedures beyond manufacturer's protocols in the IFU or product insert (refer to Table 1 point 2)
- Use of "Research Use Only (RUO)" tests or assays by licenced clinical laboratories for clinical diagnostic purposes (refer to Table 1 point 5)

Table 1: Understanding LDTs based on various scenarios

(non-exhaustive list for illustration purposes only)

	Materials used in Test system	Test Protocol/ Procedure	Clinical diagnostic purpose	LDT/ Not LDT
1	Reagents and materials obtained from commercially available IVD test kits / systems indicated for clinical use	Protocols as recommended by the commercial manufacturer's IFU	As indicated by the commercial manufacturer in their IFU	**Not LDT** Regulated as IVD by HSA. Manufacturer is responsible for the safety, quality, and efficacy of the IVD
2	Reagents and materials obtained from commercially available IVD test kits / systems indicated for clinical use	The laboratory varies the protocols/ method of use of the commercial manufacturer's IFU	Use of the test system/ materials for a **different** diagnostic purpose from what is indicated by the commercial manufacturer in their IFU	**Not LDT** Off-label use of an IVD. Licensed laboratory is responsible for the safety and efficacy of the test.
3	Reagents and materials developed, manufactured and validated in-house by Laboratory A	Protocols developed and standardised in-house by Laboratory A	Clinical indications defined by Laboratory A	**LDT** *(when used within the Laboratory A)* Laboratory A as the manufacturer is responsible for the safety, quality and efficacy of the LDT **Not LDT** *(when distributed outside Laboratory A)* - Regulated as IVD by HSA
4	Some reagents and materials developed and manufactured in-house by Laboratory A and used in combination with other reagents and materials obtained from commercially available IVD test kits / systems indicated for clinical use. All reagents are validated in-house by Laboratory B	Protocols developed and standardised in-house by Laboratory B OR Modifications/ variations made to the protocols of the commercial manufacturer's IFU for some of the reagents	Clinical indications defined by Laboratory B	**LDT** *(when used within the Laboratory B)* Laboratory B as the manufacturer of the final test is responsible for the safety, quality and efficacy of the LDT **Not LDT** *(when distributed outside Laboratory B)* - Regulated as IVD by HSA

5	Reagents and materials obtained from commercially available Research Use Only (RUO) test kits/ systems only	Protocols as recommended by the commercial manufacturer for research use in their IFU OR Modifications/ variations made to the protocols of the commercial manufacturer for research use in their IFU	As indicated by the commercial manufacturer in their IFU	**Not LDT** This is off-label use of a RUO test. Licensed laboratory is responsible for the safety, quality and efficacy of the test.

3. OVERVIEW OF REGULATORY CONTROLS FOR LDTS

The regulatory controls for LDTs can be divided into three broad categories:

1. Product Controls
2. Manufacturing Quality Controls
3. Post-market Controls

3.1 Product controls

LDTs, unlike commercial IVDs, are developed and used by laboratory professionals with relevant expertise and experience within their own facility. Therefore, LDTs are not subject to product evaluation and registration by HSA.

3.1.1 Notification of LDTs

Clinical laboratories are able to notify the list of LDTs they implement and use in their laboratory at MOH's licensing portal, Healthcare Application and Licensing Portal (HALP) (https://halp.moh.gov.sg).

Note: *Upon successful login to HALP, select "Laboratory Developed Test" under "eServices" from the top navigation bar.*

3.1.2 Maintaining an objective checklist

Clinical laboratories are responsible for the validation and implementation of these tests in their facilities and are required to ensure that their LDT continues to be safe and effective for clinical use. In doing so, laboratories are required to systematically document specific prescribed information regarding their LDT in an Objective Checklist, update this periodically and maintain on file within their facility.

Decision to develop and use the LDT is at the discretion of the clinical laboratory and the professionals. However, the laboratory should document the rationale for developing and using the LDT instead of commercial IVDs (e.g. superior performance, lack of commercial alternatives) in the Objective Checklist.

The checklist should also include the performance evaluation results or equivalent for the LDT based on the clinical purpose assigned to it. This includes information on design of the LDT (e.g. choice of biomarker, biomarker-disease information) and relevant scientific literature supporting the clinical utility of the LDT. Information on evaluation of the analytical and clinical validity of the LDT, as applicable, based on the clinical purpose assigned to the test (e.g. Linearity or Measuring range of the LDT, Limit of detection, stability of reagents, clinical sensitivity, clinical specificity) should also be included. Other relevant and essential information such as use of appropriate controls to verify the clinical accuracy of the results (e.g. for rare mutations, use of patient samples pre-determined as carrying specific mutations as positive controls) and traceability of controls and calibrators used should also be documented.

A template of an Objective Checklist with information that should be considered for inclusion is presented in **Annex 1**. This template is meant for reference purposes only and all sections are applicable to LDTs. The laboratory should determine the specific information that is to be included in each section based on the design and clinical purpose assigned to their LDT.

It is the responsibility of the laboratory to ensure that there is appropriate governance on the development, implementation and use of the LDTs in their facility. The completed Objective Checklist for all LDTs shall be duly signed by the Laboratory Quality Assurance Manager and the Clinical Governance Officer (CGO) or equivalent. This document shall be updated periodically, kept on file by the laboratory and shall be submitted for review when required by HSA.

When there is a change to the clinical purpose assigned to the LDT (e.g. expansion of clinical purpose) the laboratory should ensure that all relevant information is updated and documented in the relevant sections of the Objective Checklist including the analytical and clinical validity and clinical utility.

3.2 Manufacturing Quality Controls

3.2.1 Implementing a quality management system

Clinical laboratories that develop and use LDTs for clinical diagnostic purposes are manufacturers. Considering that they are already licensed under the HCSA by MOH, they will not be required to hold a manufacturer's licence from HSA. However, clinical laboratories that are also manufacturing facilities, are required to implement and maintain an appropriate quality management system in their facilities in relation to their manufacturing activities. This is essential to ensure that all batches of LDTs (i.e. products) they manufacture continue to meet consistent quality and performance specifications (e.g. accuracy, reproducibility).

Quality management systems (QMS) based on the *ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* is the standard requirement for manufacturers of commercial IVDs and medical devices. While ISO 13485 certification from Singapore Accreditation Council (SAC) accredited certification bodies is the standard requirement, clinical laboratories manufacturing LDTs for their own use could also leverage relevant laboratory accreditation programs (e.g. SAC laboratory accreditation, *ISO 15189: Medical Laboratories – Requirements for quality and competence*) for an appropriate QMS, where available.

Clinical laboratories manufacturing LDTs should comply with one of the following to demonstrate appropriate standards of manufacturing quality in their facilities:

- Certification by SAC accredited certification bodies to the international standard *ISO 13485: Medical devices — Quality management systems — Requirements for regulatory purposes*; OR
- SAC laboratory accreditation based on the *ISO 15189: Medical laboratories — Requirements for quality and competence*; OR
- Any other relevant and equivalent laboratory accreditation program for the LDT (e.g. College of American Pathologists Laboratory Accreditation Program – CAP-LAP).

3.2.2 Ensuring quality/performance of the LDT on an on-going basis

The entire design and manufacturing process of the LDT should be carried out under the quality management system (e.g. ISO 13485, ISO 15189) implemented in the facility. The development and manufacturing process of the LDT should be documented including the quality control steps and measures implemented during the various steps (i.e. design, manufacturing, processing, packaging, labelling, storage).

The equipment and machines used in the manufacturing process should be calibrated and maintained. The specifications of all raw materials (e.g. buffers, chemicals, solvents) used in the manufacturing process should be documented and verified (e.g. certificate of analysis) prior to use. Any changes to the machines, materials or methods of manufacture should be carefully verified and validated to ensure that the performance of the LDT is not negatively impacted by these changes.

Appropriate records of each batch of the LDT manufactured within the facility must be maintained in order to ensure traceability. Batch testing reports including the release criteria and results of each batch must be maintained. Revalidation of the LDT's performance should be conducted on an on-going

basis to prevent any batch to batch or lot to lot variations. The laboratory should ensure that the newly manufactured batches continue to meet the appropriate standards of quality and efficacy.

Staff involved in the manufacturing and validation of the LDT must be appropriately trained and should be familiar with the standard operating procedures and processes. Laboratory professionals performing these LDTs should also be trained in the protocols and familiarised with the LDT reagents and equipment. The laboratory should implement appropriate clinical governance and oversight to ensure maintenance and compliance with the quality systems implemented within their facility.

3.2.3 Other duties and obligations

Clinical laboratories, as manufacturers of LDTs are required to comply with the relevant duties and obligations as applicable to the manufacturers under the HP(MD) Regulations. These includes the following:

- Monitoring the safety and performance of their LDTs on an on-going basis and implement additional measures (e.g. additional control procedures) to improve the accuracy of the tests - Ensures that the LDT meets the essential requirements of safety and performance
- Maintaining records of manufacture and clinical use of the LDTs in their facility – Enables traceability to identify affected patients efficiently when necessary (e.g. when certain batches of the LDTs are reported to provide inaccurate test results)
- Maintaining records of any complaints or feedback from the laboratory users on the LDT performance and implement corrective and/or preventive actions to improve the LDT performance, where necessary.

When testing samples from external/other HCIs, clinical laboratories or external entities using the licensed laboratory's own LDTs, the laboratory must inform the requesting entities that in-house developed LDTs have been used to perform the tests.

3.3 Post-market Controls

Post-market requirements as prescribed under the HPA and HP (MD) Regulations are applicable to clinical laboratories that manufacture LDTs. This includes reporting of Adverse Events (AEs) and Field Safety Corrective Actions (FSCAs), including recalls, associated with the use of the LDT to HSA. When AEs and FSCAs are reported, HSA will monitor the progress of the investigations conducted by the laboratory (i.e. manufacturer of the LDT) on the issue identified (e.g. defective reagent or inaccurate results). HSA will review the proposed follow-up measures and corrective/preventive actions, including the corresponding validation studies conducted to ensure that these are adequate and appropriate to ensure the quality, safety and efficacy of the LDT by the laboratory.

3.3.1 Adverse Events

Adverse event (AE) in the context of LDT refers to any event or occurrence, that reveals a defect in the LDT (e.g. inaccurate results, quality issues) or that concerns any adverse effect (e.g. incorrect diagnosis, inappropriate treatment) arising from the use LDT.

Reportable AEs for LDTs are similar to those for IVDs and it would be sufficient that:-

- an AE associated with an LDT occurred, and
- the AE might lead to death or serious deterioration in health if it happens again;

for the AE to become reportable.

For example, when there is an error (false positive/false negative) in the reported result using the LDT, which results in an inappropriate treatment given to the patient or a patient left untreated, due to which the patient suffers a decline in health status, this is a reportable AE. If the impacted patient does not suffer a decline in health status, since any recurrence of the incorrect result from the LDT might potentially lead to decline in health status in other patients, this is still a reportable AE.

In general, any incorrect results, discrepant results and/or errors (instrument, reagent) detected should be reported as an AE. There should always be a predisposition to report when in doubt.

Timelines for AE reporting as prescribed in the HP (MD) Regulations is presented below:

AEs should be reported immediately and

- not later than 48 hours for events that represents a serious threat to public health;
- not later than 10 days for events that has led to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person;
- not later than 30 days for events where a recurrence of which might lead to the death, or a serious deterioration in the state of health, of a patient, a user of the medical device or any other person

Clinical laboratories can submit their AE reports online at: https://www.hsa.gov.sg/adverse-events/healthcare-professionals'-guide-to-adverse-events-reporting

Laboratories may refer to GN-05: Guidance on the Reporting of Adverse Events for Medical Devices for more information on the reportable AEs

3.3.2 Field Safety Corrective Action (FSCA) (including Recalls):

LDTs are developed, manufactured and used within the same clinical laboratory. Therefore, FSCAs including recalls are likely to be rare as compared to commercial IVDs that are widely used.

In general, for commercial IVDs, FSCA may be triggered when information from the post-market surveillance (e.g. product complaints, product defects, adverse events) indicates an unacceptable increase in risk associated with the use of

the IVD. FSCA actions for IVDs could range from a simple update to the IFU accompanying the IVD to a physical recall of specific lots or batches of IVD reagents. Under the HP (MD) Regulations, FSCAs, including recalls, are required to be reported to HSA prior to initiation of the field action.

Clinical laboratories as the manufacturers of the LDTs are responsible to determine the need for a post-market action i.e. FSCA for their LDTs. Clinical laboratories must monitor the quality, safety and performance of their LDTs on an on-going basis (e.g. reviewing user feedback or complaints, manufacturing data such as batch testing results). When there is any potential quality or performance related issue noted or suspected for the LDT, laboratories should consider the need for initiating an FSCA especially if the risk is assessed to be high (e.g. multiple LDT reagents are affected or the manufacturing process may be potentially impacted).

Certain AE reports may also lead to initiation of an FSCA in order to mitigate the risk identified. For instance, upon investigation of an AE for an LDT, the root cause of the issue may be identified to be a manufacturing quality issue that affects multiple batches of the LDT manufactured by the laboratory. This would warrant implementation of corrective actions that could include stop use or recall of specific batches. Under such situations, though not very common, the laboratory may be required to initiate an FSCA.

For example, during use, the LDT users noticed that there is cloudiness and particulate matter in one of the reagents. The laboratory, as the manufacturer of the reagent, identifies a drop in the reagent performance upon revalidation as compared to the original validation results during manufacture. This could potentially lead to inaccurate results from the LDT resulting in wrong diagnosis. Upon review of the manufacturing records, the laboratory decides to recall all affected batches of the LDT reagents. This is an FSCA (recall) that should be reported to HSA.

Timelines for reporting of FSCA (including recalls) are presented below:

The FSCA Notification Report should be submitted before the initiation of field action (e.g. recall). There shall not be any undue delay in the initiation of the FSCA. Some information (e.g. batch size and manufacturing records) may not be available immediately, but notification to HSA should be submitted with best available information.

- After initiating the FSCA, submit a Final Report within 21 days
- If the FSCA has not been completed, submit a follow-up report at the 21st day mark.

FSCAs involving LDTs are different from those involving commercial IVDs. Laboratories may refer to GN-10: Guidance on Medical Device Field Safety Corrective Action and GN-04: Guidance on Medical Device Recall for more detailed information on FSCA and recall requirements. These are specific to commercial medical devices and IVDs and not all steps and requirements will be applicable to LDTs. HSA will work with the clinical laboratories to advise on the investigation and specific follow-up actions on a case-by-case basis.

Clinical laboratories can report FSCAs including recalls with the best available information on hand via email to HSA_Medical_Device@hsa.gov.sg

3.3.3 Who should report?

The Laboratory Quality Assurance Manager or the Clinical Governance Officer (CGO) or equivalent or any person designated or appointed by them from the clinical laboratory can report AEs and FSCAs for the affected LDTs.

ANNEX 1: OBJECTIVE CHECKLIST TEMPLATE

1. LDT Description	
Name of the LDT	
Clinical purpose assigned/ Intended use of the LDT	
Clinical utility information (scientific literature, biomarker-disease association etc.)	*Name of reference documents/files*
List of items in the LDT (reagents, instruments, buffers, controls etc.) and their source (e.g. manufactured in house or commercially sourced)	*Name of reference documents/files (where applicable)*
Medical Specialty Area	
2. Rationale for using LDT	
3. Validation Records	
Analytical Validation data	*Name of reference documents/files*
Clinical Validation data	*Name of reference documents/files*
Revalidation data	*Name of reference documents/files*
4. Manufacturing Information	
ISO 13485/ ISO 15189 or equivalent lab accreditation record	*Name of reference documents/files*
Manufacturing records (e.g. batch numbers, batch size, date of manufacture)	*Name of reference documents/files*
Batch testing and batch release records	*Name of reference documents/files*
5. Post-market surveillance records	
Records of follow-up on user feedback/ complaints	*Name of reference documents/files*
Signed and dated by Lab Quality Assurance Manager and the Clinical Governance Officer (CGO) or equivalent	

The above checklist serves as a reference for clinical laboratories to develop and maintain the Objective Checklist for their LDTs. This checklist should be saved on file in the laboratory and should be submitted to HSA when required.

The five sections in the above checklist are the key information that the laboratory should keep on file. However, the content mentioned in each section is meant as examples. The laboratory may modify the specific contents depending on the nature and the clinical purpose of their LDTs. Some of the contents in the checklist could be applicable to multiple LDTs within the same clinical laboratory (eg: ISO 13485/ ISO 15189 or equivalent lab accreditation record) and the laboratory could maintain this as a common file and then refer this file in the checklist maintained for each LDT.

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