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Regulatory Landscape of Laboratory Developed Tests (LDT) in APAC

APACMed White Paper

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Executive Summary

The APACMed white paper on Laboratory-Developed Tests (LDTs) presents an analysis of the current regulatory landscape across the Asia Pacific (APAC) region, emphasising the need for harmonised, risk-based regulatory frameworks. As LDTs continue to play a critical role in addressing unmet medical needs, this paper underscores the importance of ensuring patient safety while fostering innovation and accessibility.

The primary objectives of this white paper are to:

- Outline existing regulatory frameworks for LDTs across various APAC markets, based on a member survey
- Present case studies on LDT regulations from mature markets such as the United States, Europe, and Australia
- Summarise key observations and discuss critical considerations for the development of LDT regulations in the region

The paper highlights a diverse regulatory environment across the region. While some markets have established regulatory frameworks for LDTs, others still lack clear definition and regulatory oversight. This inconsistency not only complicates market entry for innovative LDTs but also raises concerns about patient safety and diagnostic reliability. The lack of clear regulatory definitions and regulatory oversight for LDTs in many markets highlights the urgent need for regulatory harmonisation to ensure consistent quality and safety standards across APAC.

APACMed has identified several elements to support the effective regulation of LDTs. These include the development and implementation of harmonised, risk-based regulatory frameworks across APAC markets, promoting collaboration with regulatory authorities, and establishing capacity-building initiatives. Training programs for regulators and industry stakeholders will ensure a shared understanding of risk-based regulation principles and the trending or best practices for LDT oversight. In addition, APACMed will continue to facilitate information sharing through workshops, roundtable discussions, and case studies of worldwide regulatory practices. These steps are essential to ensuring patient safety, supporting innovation, and enabling the timely market entry of innovative LDTs in the APAC region.

By pursuing these actions, APACMed aims to enhance patient care, foster innovation, and contribute meaningfully to the evolving regulatory landscape for LDTs in the medtech industry.

Introduction

Various Types of Diagnostic Testing in Healthcare

Diagnostic testing is integral to the global healthcare system, facilitating effective, efficient, and comprehensive patient care. These tests provide critical information used by healthcare providers for diagnosing diseases and making treatment decisions.

In the healthcare diagnostics landscape, In Vitro Diagnostic (IVD) devices, Laboratory Developed Tests (LDTs), and Research Use Only (RUO) products each play distinct roles. IVDs are commercially available tests that are rigorously regulated and used for diagnosing diseases, monitoring health conditions, and guiding treatment decisions based on the analysis of human specimens such as blood or tissue. LDTs, on the other hand, are developed, manufactured, and used within a single laboratory, particularly in response to emerging health needs or when standardised or commercial IVD tests are unavailable. RUO products are intended solely for research purposes and are not intended for clinical diagnostic use. RUO products provide researchers with the tools to advance scientific understanding and potentially develop new diagnostic assays, but they are commonly exempt from regulatory approval for use in patient care. Each of these categories serves a unique purpose, contributing to the advancement of medical science and the delivery of healthcare.

Below is a table with a summary of key differences among these tests. As the definition varies across jurisdictions, for the purposes of this paper, we adopt the International Medical Device Regulators Forum (IMDRF) definition for IVDs, Singapore Health Science Authority (HSA)'s definition for LDTs, and ASEAN Medical Device Directive (AMDD)'s definition for RUOs (reference links embedded in the table below).

Table 1: Summary of key differences among IVD, LDT and RUO

	IVD	LDT	RUO
Defination	IMDRF definition of IVDs IVD is a medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.	Singapore HSA definition of LDTs LDTs 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.	AMDD definition of RUOs RUO is where the medical device is made available to institutions/laboratories to be subject to studies intended for collation of data only. The product is not intended for any medical purpose or objective.
Development	Developed for commercial sale for clinical diagnosis	Designed, manufactured, and used within a single laboratory	Developed for commercial sale but exclusively for laboratory research purpose
Intended Use	Clinical diagnostics	In-house clinical use	Research purposes only
Regulatory Oversight	Mostly regulated by the Healthcare Products Authority	Mostly co-regulated by the Lab Authority and the Healthcare Products Authority. Unregulated in some markets	Regulatory oversight mostly focuses on labelling and distribution with pre-market requirements waived
Distribution	Commercially distributed	Used within a single laboratory	Research settings only under specific research agreement
Labelling	According to specific country IVD regulation	According to specific country LDT regulations (including labelling requirements on product packaging and/or test report)	Labelled as "Research Use Only"

Background of LDTs

LDTs are often developed to address unmet medical needs. This occurs in most part because of the challenges of developing commercially distributable IVDs for rare diseases due to the logistical challenges of obtaining the necessary number of samples to get regulatory approval, and the economic viability of such tests due to the relatively small number in sales may not allow companies to recoup their development and regulatory costs.

Historically, LDTs were commonly used and developed as local tests to treat patients within a medical practice or a geographic area, which was considered a lower risk practice by regulators because of the limited and significantly simpler technology used and the fact that labs would only be treating small, local patient populations. However, over time, technology evolved significantly, leading to a revolution towards personalised medicine. These scientific and medical advances, in conjunction with the ability to easily ship samples across the world, led to the rapid expansion in the development of LDTs.

The lack of medical device requirements for LDTs enabled a proliferation of tests because it was easier for clinical laboratories to develop their own tests and modify approved/cleared IVDs rather than purchasing IVDs. LDTs have flourished in a time of quickly evolving technologies, such as Next Generation Sequencing (NGS), because labs are able to develop and modify tests without regulatory review of their tests. While this has enabled technological advancements, it does not necessarily produce accurate and reliable tests that patients and providers can rely on. This does not mean that all LDTs are not accurate or reliable, but there is a real concern about variability in the quality of LDTs being provided.

Growth and Market Trends of LDTs

Given these efficiency advantages, the availability and use of LDTs have increased significantly over time, and is expected to grow exponentially in the coming years. Various industry reports have focused on the anticipated growth of both the global and regional LDT markets in years to come. One such report found that the global LDT market size was valued at USD 10.04 billion in 2022 and is expected to continue growing at a compound annual growth rate (CAGR) of 6.58% from 2023 to 2030[1] . The Asia Pacific region is anticipated to be one of the fastest growing regions regarding LDT market share, with the market value expected to increase from about USD 2.37 billion in 2021 to about USD 4.03 billion in 2028, representing a 7.9% CAGR over that period. This expanded development and use of LDTs in recent years—and the expected continued expansion - has been driven by various factors, including the pace of technological innovation, the time- and resource-intensity of many global regulatory frameworks, and significant gaps in the range of tests that have been approved by regulatory authorities.

[1] Grand Review Research, Laboratory Developed Tests Market Size, Share & Trends Analysis Report By Technology (Immunoassay, Molecular Diagnostics), By Application (Oncology, Nutritional & Metabolic Disease), By Region, And Segment Forecasts, 2023 - 2030, available at https://www.grandviewresearch.com/industry-analysis/laboratory-developed-tests-market-report

Regulatory Challenges and Opportunities

Often the medical device regulatory review processes are resource-intensive and challenging for developing products for small populations and rare diseases, in particular. The consequence of overly burdensome requirements for rare diseases results in many diseases, conditions, and patient populations that do not have any approved/cleared IVDs. In response, clinical laboratories may turn to internal development of LDTs to address these unmet medical needs. As a result, LDTs became the standard of care for identification or monitoring of certain diseases or conditions.

Despite LDTs often playing a role in patient diagnosis and care, the lack of regulatory oversight over these tests creates risk for patients, and the nebulous regulatory environment in many markets enables LDT development but discourages IVD development. The lack of clarity in many markets' regulatory frameworks concerning LDTs has only encouraged the growth and increased dependency on LDTs. This situation creates risks for patients and providers because often LDTs have not proven to be accurate and reliable in the same way that commercial IVDs are required to be prior to their placement on the market. Many markets lack a clear regulatory definition of LDTs and do not have clear requirements for LDTs. Because of this lack of clarity, it can be challenging for LDT providers to understand their regulatory obligations, and for various stakeholders to come to a mutual understanding on how the accuracy and reliability of such tests can be assured and monitored on an ongoing basis.

Additionally, LDTs' significant role during the COVID-19 pandemic, along with some highly publicised scandals related to LDTs in recent years[2] , has led some global regulators to reconsider how LDTs ought to be regulated. Acknowledging that the goal is to ensure the efficacy and safety of clinical laboratory tests and procedures for patients, regulators have been forced to consider how best to balance the need for oversight to protect patient safety against the practical realities of the modern medical world.

In developing regulations for LDTs, regulators must grapple with the fact that while it is vital to ensure that diagnostic tools and tests are both accurate and reliable, onerous regulatory frameworks disincentivise innovation or unnecessarily delay patient access to innovative tests. Therefore, it is important that regulatory frameworks seek to avoid creating cost, process, or timing obstacles that disincentivise commercial IVD manufacturers and LDT providers from investing the time and resources into developing and commercialising diagnostic tools needed for effective patient care.

[2] See, e.g., Kezie Parkins, "The Theranos saga: a wake-up call for the lab-developed test market," Medical Device Network. (Jan. 26, 2022). [Online]. Available: https://www.medicaldevice-network.com/features/theranos-ldt-regulation/?cf-view

Objectives of the White Paper

This white paper provides a comprehensive review of the regulatory landscape for Laboratory Developed Tests (LDTs) in the Asia-Pacific region. It analyses current trends, challenges, and opportunities within the APAC LDT regulatory environment. Specifically, the paper:

- Outlines existing regulatory frameworks for LDTs across various APAC markets, based on a member survey
- Presents case studies on LDT regulations from mature markets such as the United States, Europe, and Australia
- Summarises key observations and discusses critical considerations for the development of LDT regulations in the region

By examining both regional practices and global benchmarks, this paper aims to provide valuable insights for stakeholders involved in shaping LDT policies and practices across the Asia-Pacific region.

Regulatory Frameworks For LDTs In Key Asia Pacific Markets

The regulatory frameworks for Laboratory Developed Tests (LDTs) in 14 key Asia Pacific (APAC) markets - **Australia, China, India, Indonesia, Japan, Malaysia, Myanmar, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand, and Vietnam** - were reviewed to identify specific LDT requirements. Details of the findings can be found in the **Appendix**.

For each market, the analysis focused on several key aspects: the official definition of LDTs, when available, and their classification within the regulatory framework; the role and functions of the regulatory authority or authorities overseeing LDTs; the process for obtaining product market authorisation or registration for LDTs when applicable; requirements for post-market surveillance, including monitoring and reporting on the performance and safety of LDTs once in use; and the standards and requirements for Quality Management Systems (QMS) that ensure the quality and reliability of LDTs.

The data and information presented in the white paper reflect the regulatory frameworks and requirements as of the date of publication of this document. Regulatory environments are subject to change, and stakeholders are advised to consult local regulatory authorities for the most current information.

Gathering accurate and up-to-date information on the regulatory frameworks for LDTs presented numerous challenges, primarily due to the lack of harmonised definitions and the evolving nature of LDT oversight in many regions. In several markets, formal regulations specific to LDTs remain either absent or loosely defined, leading to variations in interpretation and enforcement. The data presented in this section is based on the collective knowledge and experience of APACMed Members, who provided insights into the existing regulatory practices concerning IVDs, RUO products, and laboratory standards across their respective regions.

The analysis of the data collected reveals significant variations in regulatory approaches, which can lead to inconsistencies in how LDTs are developed, validated, and monitored. This disparity not only complicates regulatory compliance for laboratories but also raises concerns about ensuring consistent patient safety and the reliability of diagnostic results across the region.

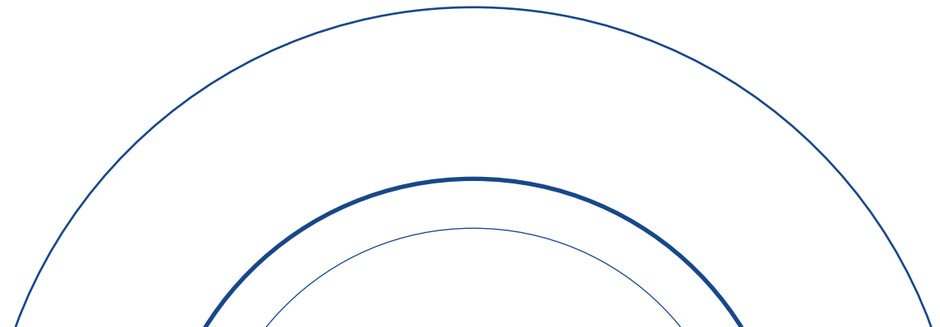
Regulatory Definitions

Some markets, such as Australia, have well-defined and specific definitions for LDTs. These definitions provide clarity on what constitutes a LDT and help guide their development, validation, and use within clinical laboratories. Having clear definitions ensures that LDTs are identified and managed appropriately within the healthcare system. However, in most APAC markets, official definitions for LDTs are still lacking. In these markets, LDTs are either loosely defined under broader categories or not explicitly defined at all, leading to inconsistencies and uncertainties in how they are perceived and managed. For example, in some markets, LDTs might be broadly categorised as research-use-only (RUO) products or simply fall under general medical device or IVD definitions, without a distinct classification of their own.

Regulatory Authority and Market Authorisation Processes

In markets with established LDT regulations, oversight is typically divided among multiple regulatory authorities, each responsible for different aspects of LDT management. For example, in Australia, the National Association of Testing Authorities (NATA) handles the laboratory's quality management system (QMS) accreditation and the review of LDTs, while the Therapeutic Goods Administration (TGA) manages the inclusion of higher-class LDTs in the Australian Register of Therapeutic Goods (ARTG). Similarly, in Singapore, the Ministry of Health (MOH) and the Health Sciences Authority (HSA) jointly oversee various facets of LDT regulations. These markets generally have defined processes for LDT market authorisation, including validation of performance characteristics, safety, and efficacy, followed by notification or registration with relevant authorities. For instance, in Australia, Class 1-3 in-house LDTs require notification, whereas Class 4 in-house LDTs must be included in the ARTG. However, it is worth noting most markets in APAC do not apply risk-based classification rules for LDTs.

In contrast, markets without specific LDT regulations often rely on broader regulatory frameworks that govern medical devices or IVDs, without dedicated oversight for LDTs. This can lead to ambiguities in how LDTs are regulated and monitored, potentially impacting the patient access or losing the control of their quality and safety. In such markets, LDTs may be treated as general medical devices or IVDs, or they might be exempt from formal registration altogether. In these cases, there is often more reliance on clinical laboratory management during the development and use of LDTs, which is drastically different from the regulatory oversight for IVDs, although both products share the same intended purpose. Some markets may require LDTs to be listed in a health authority database to ensure they fall under the regulatory framework and are subject to appropriate surveillance, but the lack of specific regulations can result in inconsistent practices across different regions.



Post-Market Surveillance

Markets with established LDT regulations require laboratories to adhere to post-market surveillance practices, including reporting adverse events (AEs) and field safety corrective actions (FSCAs). This ensures ongoing monitoring of LDT performance and safety after they are in use.

For markets lacking specific LDT regulations, there may be limited or unclear requirements for post-market surveillance. This can result in insufficient monitoring of LDT performance, which may compromise patient safety and regulatory oversight.

Quality Management System (QMS) Requirements

In some markets there are stringent QMS requirements for laboratories developing LDTs. These laboratories must comply with national or harmonised standards such as ISO 15189, ISO 17025, or ISO 13485. This ensures that LDTs are developed and maintained under high-quality standards.

In other APAC markets, while general quality standards may be applicable to the clinical laboratories, mandatory or voluntary accreditation of the clinical laboratories may be requested, but specific QMS requirements for LDTs might not be well-defined. This could lead to variability in quality practices and potentially affect the reliability of LDTs.

In summary, the regulatory landscape for LDTs in the APAC region shows a dichotomy between markets with established frameworks and those lacking specific regulations. Markets with defined LDT regulations provide clearer guidance and oversight, ensuring better safety and efficacy of LDTs. In contrast, the absence of dedicated LDT regulations in other markets can create uncertainties and challenges in maintaining high standards for LDTs. This inconsistency underscores the need for harmonised regulations and clearer guidelines to ensure patients have access to safe and effective LDTs across the APAC region.

Discussion and Key Elements For A Risk-Based LDT Regulatory Framework

In recent years, the complexity and scope of LDTs have expanded significantly. LDTs are increasingly used in high-stakes areas such as oncology, rare diseases, or infectious diseases, where accurate results are critical for determining treatment plans. A false result, whether positive or negative, can have serious implications, potentially leading to inappropriate treatments that could cause significant harm to the patient or public health.

However, LDTs are often developed to address unmet patient needs. Overly onerous, time-consuming, or expensive regulatory frameworks may disincentivise laboratories from developing or continuing to provide LDTs, decreasing the volume and diversity of LDTs on the market and leaving patients without access to the diagnostic tests they need. This may be of particular concern in instances where patients or healthcare providers have made decisions in reliance on access to, or the continued manufacturing of, currently offered LDTs.

The COVID-19 pandemic highlighted both the critical role, and the challenges associated with LDTs. During the pandemic, LDTs were essential for rapid testing and managing public health. However, the urgency and variability in testing standards also exposed gaps in regulatory oversight and the need for more robust frameworks to ensure test accuracy and reliability. Given the increasingly significant role that LDTs have come to play in the health care system, regulators must carefully consider how to structure regulatory frameworks in a way that balances the need to ensure product safety and effectiveness against the potential risk to patients of increasing regulatory burdens on LDT manufacturers.

Based on our review of LDT regulations across the APAC region and insights from the US and EU, several key elements **constituting a risk-based LDT regulatory framework** emerge as below:

- **Definition**
  Regulatory authorities should consider establishing clear and harmonised definitions for LDTs (to differentiate from IVDs and RUOs) in their regulations. This lays the foundation for appropriate regulatory pathways based on risk-benefit profiles and local clinical needs. APACMed member companies have observed that the lack of LDT definitions in some markets has created an uneven playing field with higher risks for patients.

- **Transparency & Accountability**
  It is critical to clearly assign roles and responsibilities in the regulations to different stakeholders involved in the lifecycle management of LDTs, including manufacturers/developers, distributors, medical institutions/laboratories, and healthcare professionals. Due to the complex stakeholder mapping in the LDT lifecycle, it is equally important to implement regulatory measures ensuring transparency for all stakeholders, including providers and patients (such as labelling considerations for products and/or testing reports).

- **Regulatory agencies with authorities**
  Due to the unique nature of LDTs, it may be reasonable to establish a co-regulation mechanism between healthcare product authorities and laboratory authorities, with complementary but not duplicative responsibilities for LDTs across their product lifecycle.

- **Scope & Criteria**
  Regulatory authorities are recommended to consider which types of LDTs would offer the best benefit-risk profile for patients in their markets, aiming to balance product availability and patient safety. Domestic clinical needs and local market dynamics should be taken into consideration, such as testing needs for rare diseases and other life-threatening conditions, commercial supply of IVDs, and public health emergency circumstances.

- **Pre-market Pathway**
  Establishing risk-based regulatory pathways for LDTs is recommended. Regulatory agencies may consider leveraging the risk-based classification rules of similar medical products that are consistent with international best practices.

- **Product Quality**
  Ensuring quality control throughout the development, manufacturing, and testing processes is essential for reliable and effective LDTs. Institutions involved in LDT development and manufacture are encouraged to follow internationally recognised standards, such as ISO 15189 for medical laboratories and ISO 13485 for medical devices.

- **Post-market Surveillance**
  Risk-based post-market requirements should be in place for various stakeholders involved in LDT lifecycle management, including mechanisms for reporting adverse events or other quality, performance, or safety issues to ensure ongoing monitoring of LDT performance and safety after they are in use.

- **Pilot Programs**
  For markets currently without clear LDT regulations, it is recommended to start with pilot programs to evaluate the types of LDTs available and being used in the local market. Such information could further guide regulatory authorities in establishing right-sized regulations for LDTs that would improve patient lives and public health in the market.

- **Collaboration and Communication**
  APACMed encourages collaboration between government agencies, healthcare institutions, laboratories, and manufacturers to foster innovation, address regulatory challenges, and ensure patient access to safe and effective LDTs.

Conclusion and Next Steps

Laboratory-developed tests (LDTs) play a crucial role in modern healthcare, addressing unmet medical needs. However, the increased complexity and usage of LDTs have also brought attention to regulatory challenges and the need for a balanced and risk-based approach to oversight.

As this white paper primarily explores the current LDT regulatory landscape in Asia Pacific, the APACMed project team aims to share its observations and considerations with key stakeholders in the region. Our goal is to contribute meaningfully to the development of LDT regulations in key markets. Additionally, APACMed will continue to monitor LDT regulatory developments in significant markets outside our region, such as the US and EU. Building on this foundation, our next project will be a position paper that further elaborates on our recommendations, incorporating insights from global regulatory trends and their potential impact on the Asia Pacific region.

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Appendix

Data Collected About LDT Regulatory Mechanism in Asia Pacific Markets

The information presented in this appendix is based on publicly available sources, our own analysis, and the collective experience of our members. However, due to the lack of clear and consistent definitions for Laboratory-Developed Tests (LDTs) across many APAC markets, the data may not always be harmonised. In some markets, regulatory frameworks are still evolving, and there are significant variations in how LDTs are defined and regulated. As a result, the content in the appendix reflects our best efforts to compile and interpret the available information, but there are inherent challenges and limitations in this analysis, **especially in markets where official definitions or regulations for LDTs are absent or unclear**. When 'N/A' is indicated, it means that the relevant data was either unavailable on the national regulatory authority's website, unclear, or could not be found by our members at the time of the survey.

Market	Definition of LDTs	Regulatory Authority and Role	Product Market Authorisation	Post-market Surveillance	Quality Management System
Australia	**LDTs are regulated by the Therapeutic Goods Administration (TGA) under the framework for IVDs.** LDTs are named as "In-house IVDs" in Australia, which refer to pathology tests that have been developed (or modified) and validated within a laboratory (or laboratory network) to carry out testing on human samples, where the results are intended to assist in clinical diagnosis or be used in making decisions concerning clinical management.	The National Association of Testing Authorities (NATA) performs the laboratory's QMS accreditation and the LDT review. Laboratories manufacturing Class 1-3 in-house IVDs must comply with the essential principles and conformity assessment procedures. However, only Class 4 in-house IVDs require inclusion on the Australian Register of Therapeutic Goods (ARTG) after NATA's review.	The TGA employs a risk-based classification system for LDTs. This means the level of regulatory rigor depends on the potential risk the test poses to individual and public health. All LDT tests must meet the NPAAC standard: Requirements for the Development and Use of In-house IVD. **Class 1-3 in-house IVDs - Notification** • Laboratories that commence manufacturing Class 1-3 in-house IVDs must submit an initial notification to the TGA by the 1st of July of the next financial year (or within 20 working days of this date). • The inclusion in ARTG is not required, but the TGA maintains a notifications database that is not publicly available. • Laboratories must be accredited by NATA either to ISO 15189 (Medical laboratories - Particular requirements for quality and competence) or ISO 17025 (General requirements for the competence of testing and calibration laboratories). **Class 4 in-house IVDs** • Requires application for inclusion in the ARTG. • Must be accredited by NATA to ISO 15189 or obtain a TGA manufacturing license.	Laboratories must implement a post-market system for the ongoing monitoring of the performance of their in-house IVDs (e.g., via quality assurance programs and internal quality control) and notify the TGA of any AE and FSCAs.	**Class 1-3 in-house IVDs** • Be accredited by the NATA • Meet the NPAAC standard • Establish QMS in accordance with ISO 15189 or 17025 **Class 4 in-house IVDs** • Obtaining the TGA conformity assessment certificates prior to applying for inclusion of their Class 4 in-house IVDs in the ARTG OR • Using their existing NATA accreditation to ISO 15189, or their TGA Manufacturing licence, to apply directly for inclusion of their Class 4 in-house IVD in the ARTG

Appendix

Data Collected About LDT Regulatory Mechanism in Asia Pacific Markets

Market	Definition of LDTs	Regulatory Authority and Role	Product Market Authorisation	Post-market Surveillance	Quality Management System
China	In China, the information is only available about the LDT pilot program, according to which an LDT could only be developed on the condition there is no equivalent commercial IVD reagent launched on the domestic market. Additionally, the LDT product must demonstrate technical maturity with clear clinical significance.	The National Medical Products Administration (NMPA) owns the supervision of products, including the filing of pilot products and quality management. The National Health Commission (NHC) owns the supervision of medical institutions, including the management of the use of pilot products by pilot hospitals.	**Filing process** • Pilot medical institution list is defined by both NMPA & NHC. • Pilot medical institutions need to file the type of LDT product to local/province NMPA, after getting approval from joint review by NMPA and NPC, the pilot medical institution can start the LDT process. • The label of the LDT must clearly indicate "This product is an in vitro diagnostic reagent developed by our medical institution and is only for use within our institution. This institution does not include other medical institutions of the same medical consortia or medical groups".	Post-filing inspection by the NMPA: check whether the filing product meets the requirements, whether the product matches the filing documents, and whether the development and preparation/production process comply with GMP. On-site inspection shall be conducted within 3 months after filing, no less than one on-site inspection shall be conducted in the 6th and 12th months respectively, after filing. Post-filing inspection by the NHC: check whether the medical institution meets the qualification requirements and whether it uses LDT according to the requirements. On-site inspection in the 6th and 12th months respectively post-filing.	• The development and production process shall follow GMP requirements. • If the production is outsourced to a contracted manufacturer (this is a unique and new model that is currently being explored in the pilot), the contracted manufacturer shall hold a medical device manufacturing license that covers Class II and Class III IVD products and have experience in manufacturing the same kind of IVD products.
India	Not defined in law or regulation	The Indian Council of Medical Research (ICMR) is the technical advisor to the India Ministry of Health (MOH). Laboratories are controlled by ICMR (but not the reagents).	N/A	N/A	National Accreditation Board of Laboratories (NABL) is a voluntary certification for laboratories for Quality Management System. NABL Certificate is a prerequisite.
Indonesia	Not defined in law or regulation	N/A	N/A	N/A	N/A
Japan	Not defined in law or regulation	Registered Clinical Laboratories (RCL) – Controlled by the Ministry of Health, Labour and Welfare of Japan (MHLW)	Some site-specific assays located in Japan and other region could be registered as software as a medical device by PMDA and reimbursed in Japan	N/A	The responsibility for ensuring the quality and accuracy of LDTs falls on the individual laboratories developing and performing them. However, laboratories are expected to have a robust QMS in place. This ensures the tests are performed accurately and reliably. Lab accreditation adopts ISO 15189 for medical laboratories.

Appendix

Data Collected About LDT Regulatory Mechanism in Asia Pacific Markets

Market	Definition of LDTs	Regulatory Authority and Role	Product Market Authorisation	Post-market Surveillance	Quality Management System
Malaysia	Not defined in law or regulation	N/A	N/A	N/A	Although there are no LDT regulations, clinical labs are required to comply with the Pathology Laboratory Act (Act 674). One of the requirements is to be ISO15189 accredited.
Myanmar	Not defined in law or regulation	N/A	N/A	N/A	N/A
New Zealand	Not defined in law or regulation	N/A	N/A	N/A	N/A
Philippines	Not defined in law or regulation	N/A	N/A	N/A	N/A
Singapore	LDTs are 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.	The Ministry of Health (MOH) regulates the Clinical Laboratory The Health Science Authority (HSA) regulates health products and provide guidance on LDT regulation	Clinical laboratories are to notify the list of LDTs they implement and use in their laboratory at MOH's licensing portal, Healthcare Application and Licensing Portal (HALP)	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.	Clinical laboratories that develop and use LDTs for clinical diagnostic purposes are manufacturers. The lab has to be registered with MOH and maintain QMS. This is stipulated as part of regulatory requirement under the Healthcare Services (Clinical Laboratory Service and Radiological Service) From HSA's regulatory point of view, the clinical labs are required to document the rationale for developing and using the LDT instead of commercial IVDs in the Objective Checklist (GL-08 Section 3.1.2). 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.

Appendix

Data Collected About LDT Regulatory Mechanism in Asia Pacific Markets

Market	Definition of LDTs	Regulatory Authority and Role	Product Market Authorisation	Post-market Surveillance	Quality Management System
South Korea	Not defined in law or regulation	The Ministry of Environment (MoE) is the regulatory authority overseeing chemical substances and raw materials based on Chemical Control Act and the K-REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals), but the MoE does not regulate LDT	It is mostly based on the lab's own evaluation guidelines	N/A	N/A
Taiwan	LDT refers to tests established and used by certified laboratories for the purpose of medical examination, diagnosis or treatment for specific patients or diseases. Administrative Measures for the Implementation or Use of Specific Medical Technology Inspection and Inspection Medical Instruments - National Laws and Regulations Database (moj.gov.tw)	LDTs regulations particularly the Lab accreditation falls under the Taiwan - Food and Drug Administration (TFDA) of the Ministry of Health and Welfare (MOHW). The Joint commission of Taiwan (JCT), also under the Ministry of Health and Welfare (MOHW), performs the technical review. Overseas LDTS are also regulated under this LDTS Law in Taiwan.	Currently, MOHW only requires those tests listed below to be submitted as LDTs. There will be another a list of some low-risk tests that are exempted from submission (and those not mentioned in either list will not be allowed to develop as LDTs) 1. CDx anti-cancer 2. Genetic testing for cancer screening, diagnosis, treatment and prognosis 3. Chromosome/gene mutations test for prenatal care and newborns 4. Genetic test for adverse drug reactions or drug metabolism 5. Genetic test for genetic metabolism and rare diseases 6. Pathogen identification, virulence and drug resistance gene detection 7. Other CDx gene testing, which are mentioned in IFU need to test before medication. Need to register as a Precision Medical Molecular Testing Laboratory, which is like a GMP that the auditor will audit in lab. Analytical V&V (Accuracy, Precision/ Reproducibility, Reportable Range, Cut-off Value, Traceability, Sensitivity, Specificity, Interference Study, Stability.) is required which might need to include clinical specimen but clinical V&V isn't required. With plan, method, report, and result. If the medical institutions need to perform verification, labs should provide raw data/ record/ result.	Follows medical device Adverse Events notification action, lab should be with CAPA process.	Refer to CLIA/ISO15189

Appendix

Data Collected About LDT Regulatory Mechanism in Asia Pacific Markets

Market	Definition of LDTs	Regulatory Authority and Role	Product Market Authorisation	Post-market Surveillance	Quality Management System
Thailand	Not defined in law or regulation	Thai Food and Drug Administration (TFDA) regulates all medical devices including IVDs. Although LDT was not specifically mentioned in the regulation, if the "intended use" of an LDT product falls under the scope of IVD, it shall be defined and regulated as IVD. However, the Thai FDA exempts public hospitals and government labs from such requirements.	If the "intended use" of an LDT product falls under the scope of IVD, it shall follow IVD classification rules. However, the Thai FDA exempts public hospitals and government labs from such requirements.	If the "intended use" of an LDT product falls under the scope of IVD, it shall follow IVD PMS rules. However, the Thai FDA exempts public hospitals and government labs from such requirements.	ISO 13485 is to be followed if the "intended use" of an LDT product falls under the scope of IVD. However, the Thai FDA exempts public hospitals and government labs from such requirements. Lab Accreditation is not mandatory.
Vietnam	Not defined in law or regulation	N/A	N/A	N/A	N/A

Global Regulatory Frameworks Case Studies

To provide a comprehensive perspective on regulatory approaches, we examined major markets like the United States, Europe, and Australia, where there is a noticeable trend toward increasing oversight of LDTs (Lab Developed Tests). This trend reflects the recognition of the growing complexity of LDTs and their significant impact on treatment decisions. The rising level of scrutiny in these regions serves as an important signal for other regulators to consider adopting similar measures. By applying a risk-based approach - similar to how other medical devices are classified - regulators can better determine the necessary level of oversight for LDTs.

This paper will delve into the regulatory frameworks of the European Union (EU) and the US FDA (Food and Drug Administration), offering valuable insights and implications for the Asia-Pacific region. Additionally, a thorough examination of the LDT regulations in Australia, as outlined by the Therapeutic Goods Administration (TGA), will be included. Detailed case studies for these markets are provided further in the paper to support our analysis and recommendations.

EU Case Study

Definition of a LDT

In the EU, LDTs are governed by Regulation (EU) 2017/745 on medical devices (MDR) or Directive 98/79/EC (IVDD) replaced by Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) and MDCG 2023-1: Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 an LDT is defined as a device that is manufactured and used only within a health institution established in the Union and that meets all conditions set in Article 5(5) of the MDR or IVDR: amongst these, (a) there must be no marketed device with equivalent performance CE-marked device available to address specific needs of target patient groups; (b) no industrial-scale manufacture is involved; (c) the device is manufactured according to appropriate quality management systems and relevant standards; and (d) manufacture and use of the device must be within a health institution. A health institution is an organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.

Relevant Authorities

EU legislation allows for LDTs to be made available, without the involvement of Notified Bodies and without CE markings. This constitutes an exemption from the general requirements of the MDR and IVDR. Therefore, strict adherence with the specific conditions laid out in Article 5(5) are required to meet the overarching legislative objective of protecting public health and patient safety. The specific conditions set out in Article 5(5) are:

- The health institution must make a declaration on the compliance with General Safety and Performance Requirements provided in Annex I and particulars under Article 5(5)(f)
- The exempted device is not transferred to another legal entity
- Application of appropriate quality management system for the manufacture and use of the device
- Compliance with ISO 15189 regarding the requirements for quality and competence in medical laboratories
- Justification for the use of the exempted device (see above)
- For class D IVDs (the highest risk) according to rules set out in Annex VIII, documents drawn up on the manufacture, design and performance of the exempted device including its intended use (such documentation forms the basis for the manufacture and could be the subject of review by competent authorities; and health institution is required to respond to such regulatory inquiries)
- Review of the clinical use of the exempted device by health institution to inform decision on appropriate corrective actions

Research Use Only (RUO) products are (1) not regulated by the MDR or IVDR and (2) are not considered to be LDTs when used for research purposes only. However, if a health institution ascribes a RUO product an intended medical purpose in view of its use in the health institution, the requirements of Article 5(5) for LDTs will apply. The LDT can include research use only products as components, provided that the resulting LDT complies with the requirements of Article 5(5).

The transitional periods of the IVDR should also be noted. The IVDR repealed and replaced Directive 98/79/EC (which also contains health institution exemption) and became fully applicable since 26 May 2022. However, there are various transition periods for the requirements of the IVDR to be applied for LDTs:

- Since 26 May 2022, all provisions of Article 5(5), except points (b) to (i) have been in application
- From 26 May 2024, all provisions of article 5(5) except point (d) will be in application
- From 26 May 2028, the full Article 5(5) provision will be applicable

US Case Study

Definition of a LDT

In the United States, the US Food and Drug Administration (FDA) is responsible for the regulation of medical devices. The Food, Drug and Cosmetic Act (FDCA) defines a medical device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent…, which is…(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease…"[3] FDA defines LDTs as a subcategory of IVDs that are intended for clinical use[4] and are designed, manufactured, and used within a single clinical laboratory which meets certain laboratory requirements. Specifically, such laboratory must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meet the regulatory requirements under CLIA to perform high complexity testing.

By defining LDTs as a type of IVD, the FDA has maintained that LDTs are medical devices, and that regulation of LDTs therefore falls within FDA's statutory authority. This has long been a source of debate, as some representatives of clinical laboratories and manufacturers of LDTs, such as the American Clinical Laboratory Association (ACLA), have taken the position that LDTs are, in fact, clinical services and not medical products, and that FDA lacks authority to regulate them.[5] In part in response to this longstanding question of authority, FDA issued a final rule in April 2024 to "amend its regulations to make explicit that IVDs are devices under the [FDCA] including when the manufacturer of the IVD is a laboratory. This amendment reflects that the device definition in the [FDCA] does not differentiate between entities manufacturing the device."[6] Following FDA's issuance of this final rule, various industry groups including the ACLA[7] and the Association for Molecular Pathology[8] have filed suit against FDA challenging this interpretation of the FDCA and arguing that the regulation of LDTs is beyond FDA's statutorily granted scope of authority. How the courts will ultimately rule on this issue remains to be seen, though challenges to FDA's interpretation may have a higher likelihood of success than in the past due to recent Supreme Court jurisprudence. [9]

[3] 21 U.S.C. § 321(h)(1). https://www.law.cornell.edu/uscode/text/21/321#h_1

[4] FDA maintains investigational use requirements that must be complied with for research use only ("RUO") or investigational use only ("IUO") devices, including IVDs. FDA has made clear that mere placement of an RUO or IUO label on an LDT does not render it exempt from otherwise applicable requirements if FDA determines that the device is actually intended for clinical use based on other evidence.

[5] See, e.g., American Clinical Laboratory Association, "ACLA Statement on Changes to LDT Regulation and Review" 15 Nov. 2021. Available: https://www.acla.com/acla-statement-on-changes-to-ldt-regulation-and-review/.

[6] 89 Fed. Reg. 37,286 (May 6, 2024).

[7] Compl., Am. Clinical Lab. Ass'n, et al. v. U.S. Food and Drug Admin., No. 4:24-cv-479 (E.D. Tex.).

[8] Compl., Ass'n for Molecular Pathology, et al. v. U.S. Food and Drug Admin., No. 3:24-cv-00241 (S.D. Tex.).

[9] Namely, on June 28, 2024 the U.S. Supreme Court issued a decision in the matter of Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244 (June 28, 2024) formally overturning the historical judicial doctrine of Chevron deference. Under the doctrine of Chevron deference, courts were instructed to defer to an agency's reasonable interpretation of arguably ambiguous statutory language, rather than substituting the court's own interpretation of such statute. However, the Supreme Court in Loper Bright held that courts "must exercise their independent judgment in deciding whether an agency has acted within its statutory authority." Loper Bright, 144 S. Ct. at 2248. In the context of LDTs, this means that while courts may have historically been apt to defer to FDA's interpretation of the FDCA—assuming it was deemed "reasonable" --courts are now more likely to engage in independent statutory interpretation to assess whether the definition of "medical device" under the FDCA is intended to appropriately encompass LDTs.

Relevant Authorities

Even with this change, the FDA's definition of LDT relies in part on certification under CLIA[10], which is overseen by the U.S. Centers for Medicare & Medicaid Services (CMS). However, both the FDA and CMS have asserted that their regulatory schemes are "different in focus, scope and purpose, but they are intended to be complementary,"[11] and "CLIA is not a substitute for FDA oversight."[12] CMS lacks the authority and expertise to regulate certain critical aspects of LDT development that are more appropriately overseen by FDA, including evaluating the performance of a test before it is offered to patients or providers; assessing clinical validity (i.e., the accuracy with which a test identifies, measures, or predicts the presence or absence of a clinical condition or predisposition in a patient); regulating certain manufacturing activities, such as design controls and acceptance activities; providing human subject protections for patients who interact with LDTs in clinical research trials; and monitoring adverse events through required reporting.

Regulatory Requirements

Under FDA's regulatory authority, all IVDs, including (under FDA's interpretation that is currently the subject of legal challenge) LDTs, are subject to various pre-market and post-market controls. FDA classifies medical devices into classes (Class I, II, or III) according to the level of regulatory control needed to reasonably assure safety and effectiveness, and this classification determines the appropriate pre-market clearance or approval process, as well as the relevant post-market controls. As a general matter, however, all classes of medical devices are subject to "general" post-market controls that include, but are not limited to, establishment registration and device listing requirements, compliance with current Good Manufacturing Practices (cGMPs) as laid out in FDA's Quality System Regulation ("QSR")[13], recordkeeping and reporting requirements, and requirements related to false and misleading labelling and promotion.

Higher risk devices, including Class II and Class III devices, may be subject to "special controls," which are device-specific but may include, among other things, performance standards, post-market surveillance requirements, patient registries, special labelling requirements, and pre-market data requirements.

Though the FDA has long maintained the position that LDTs are medical devices and are therefore legally subject to these regulatory requirements, the Agency has used an enforcement discretion policy in the past to exempt LDTs from medical device regulatory requirements. The FDA based its approach on the nature of LDTs and the environment in which they were offered at the time the CLIA regulations were implemented in 1988 (i.e. simple, manual test technology used in laboratories that were integral to a health care facility). The FDA stated that LDTS were historically "manufactured in small volumes by laboratories that served their local communities… were typically intended for use in diagnosing rare diseases or for other uses to meet the needs of a local patient population, or were generally similar to well-characterised, standard IVDs… [and] tended to employ manual techniques (and did not use automation) and were performed by laboratory personnel with specialised expertise."[14] In conjunction with issuing its final rule amending the definition of IVDs in April 2024, however, FDA stated its intention to phase out this enforcement discretion policy and to begin requiring compliance with applicable regulations by LDTs and LDT manufacturers, except where the LDT falls within a specific enumerated exemption.

[10] While a test may still be considered an IVD if the CLIA requirements are not met, an LDT by definition must be designed, manufactured, and used within a laboratory that is certified under CLIA and meets the regulatory requirements to perform high complexity testing.

[11] See, e.g., U.S. Centers for Medicare & Medicaid Services, "CLIA Overview," 22 Oct. 2023. Available: https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf; U.S. Food and Drug Administration, Laboratory Developed Tests Proposed Rule: Preliminary Regulatory Impact Analysis, Initial Regulatory Flexibility Analysis, Unfunded Mandates Reform Act Analysis, FDA-2023-N-2177 (citing CMS' prior statement). [Online]. Available: https://www.fda.gov/media/172557/download?attachment

[12] 89 Fed. Reg. at 37,292.

[13] 21 CFR Part 820. However, FDA published the Quality Management System Regulation (QMSR) Final Rule in February 2024 to amend the current good manufacturing practice requirements for medical devices by harmonising the existing requirements with ISO 13485:2016. See 89 FR 7496 (Feb. 2, 2024). The QMSR will become effective on February 2, 2026.

[14] 89 Fed. Reg. At 37,289.

The FDA's shift in stance is based in large part on what it views as the increased complexity and potential risk of LDT use over time. More specifically, FDA notes that: "Today, many LDTs increasingly rely on high-tech or complex instrumentation and software to generate results and clinical interpretations . . . [and] are often used in laboratories outside of the patient's healthcare setting and are often run in high volume for large and diverse populations . . . [and] are more commonly manufactured with instruments or other components not legally marketed for clinical use and are more often used to inform or direct critical treatment decisions, to widely screen for common diseases, to predict personal risk of developing certain diseases, and to diagnose serious medical conditions."

The rule outlines a five-stage phase-out over a period of four years, with each stage marking the end of the Agency's policy of enforcement discretion for certain pre- and post-market requirements. As it relates to compliance with quality system requirements, FDA has stated that FDA will only expect compliance with certain elements of the QSR for LDTs, including design controls, purchasing controls, acceptance activities, adverse event and medical device reporting requirements, corrective and preventive actions (CAPAs), and records requirements.

In identifying the types of LDTs for which FDA intends to continue engaging in enforcement discretion (i.e., exempt from requiring compliance with FDA requirements), the Agency focused on, among other thing, the risk level of the device; among the categories of LDTs for which FDA intends to continue engaging in enforcement discretion are "1976-Type LDTs" that use manual techniques (without automation) performed by laboratory personnel with specialised expertise, and use only components legally marketed for clinical use.[15] Additionally, FDA intends to exempt from certain specific requirements-including premarket review requirements and certain quality system requirements--LDTs for which the Agency believes the cost of compliance with such requirements outweighs the benefit to public health, including LDTs manufactured and performed by a laboratory integrated within a healthcare system to meet an unmet need of patients receiving care within the same healthcare system. FDA notes, however, that such LDTs will remain subject to other regulatory requirements that generally involve lower resource expenditure by the laboratory, including medical device reporting and labelling requirements, and that FDA intends to use these tools to actively monitor to ensure the safety and effectiveness of such LDTs.

[15] 89 Fed. Reg. At 37,408.

Australia Case Study

Definition of a LDT

Australia reformed its regulatory framework for IVDs extensively between 2010 and 2017. IVDs are now classified as medical devices and regulated under Chapter 4 of the Therapeutic Goods Act 1989 (Cth) (TG Act) along with all other forms of medical device.[16]

The Australian equivalents to LDTs are **in-house IVD medical devices**, which are a recognised subset of IVDs.

An IVD medical device is defined as:

- a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in combination with another diagnostic product for in vitro use; and
- intended by the manufacturer to be used in vitro for the examination of a specimen derived from the human body, solely or principally for:
  - giving information about a physiological or pathological state or a congenital abnormality; or
  - determining safety and compatibility with a potential recipient; or
  - monitoring therapeutic measures; and
- not a product that is:
  - intended for general laboratory use; and
  - not manufactured, sold or presented for use as an IVD medical device.[17]
- **An in-house IVD medical device** must meet the definition of an IVD medical device, as well as fall within one of the following categories.
  - is developed from first principles (meaning, a laboratory has been responsible for its design and production); or
  - developed or modified from a published source; or
  - developed or modified from any other source; or
  - used for a purpose, other than the intended purpose assigned by the manufacturer.
- Further, this development or use must take place within the confines or scope of an Australian laboratory or Australian laboratory network.[18]
- An IVD device which is developed in a laboratory, but supplied outside of the laboratory or network, is **not** an in-house IVD medical device.[19] A device of this kind would become a commercially supplied IVD and would be regulated as such. Commercially supplied IVDs must be included on the Australian Register of Therapeutic Goods (**ARTG**), but most in-house IVDs are exempt from this requirement.

[16] Explanatory Statement, Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015
[17] Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (Medical Device Regulations), reg 1.3.
[18] Medical Device Regulations, reg 1.3. A laboratory network is a network of laboratory organisations which operate with a single QMS systems.
[19] Medical Device Regulations, reg 1.3.

Relevant Authorities

The Therapeutic Goods Administration (TGA) regulates the manufacture, marketing and supply of therapeutic goods, including medical devices under the TG Act and the Therapeutic Goods (Medical Devices) Regulations 2002 (Cth) (Medical Device Regulations). As such, the regulation of in-house IVD medical devices in Australia is the responsibility of the TGA.

In addition, the National Association of Testing Authorities (NATA) works with the TGA to ensure that regulatory requirements for in-house IVD devices are met. NATA is Australia's national authority for accreditation of laboratories conducting tests, calibrations and measurements, and the peak body for accrediting other providers and testing bodies.[20] As of September 2016, there has been a Memorandum of Understanding between the Commonwealth of Australia and NATA in relation to the regulation of In-House In Vitro Diagnostic Medical Devices (NATA MOU).

NATA also reviews technical documents for compliance with the National Pathology Accreditation Advisory Council's standard "Requirements for the Development and Use of In-house In Vitro Diagnostic Medical Devices" (NPAAC Standard).

The NATA MOU explains its role in the in-house IVD regulatory landscape: *With the need to minimise additional compliance costs and avoid duplication of effort, the regulatory requirements for in-house IVD medical devices utilise existing systems of laboratory oversight, so that laboratories are able to meet the applicable conformity assessment procedures for in-house IVD medical devices provided they maintain the required accreditation with NATA and comply with the NPAAC Standard.*

[20] Memorandum of Understanding between the Commonwealth of Australia and the National Association of Testing Authorities, Australia in relation to In-House In Vitro Diagnostic Medical Devices, 2 September 2016, Recitals B

Regulatory requirements

In-house IVD devices are subject to pre-market and post-market requirements.

Pre-market requirements

There are several differences between the regulation of in-house IVD medical devices and other medical devices. IVDs and in-house IVD medical devices have their own classification system, and, while they must, like all medical devices, comply with the Essential Principles, they are subject to some additional Essential Principles beyond those which apply to medical device generally. However, for in-house IVD medical devices compliance with the NPAAC Standard is taken as compliance with the relevant Essential Principles.[21]

In-house IVDs are classified according to a risk-based approach.[22] As such, there are two "buckets" of in-house IVD, with differing conformity requirements:

- Class 1-3 in-house IVDs: Conformity assessment requires manufacturers to meet specified benchmarks for safety and performance. Class 1-3 IVDs are required to meet the conformity requirements set out in Part 6A, Schedule 3 of the Medical Device Regulations. However, provided they comply with those conformity requirements, they are exempt from registration on the ARTG.[23]
- Class 4 in-house IVDs
  - Must be included on the ARTG.
  - In 2015, the TGA addressed concerns from the manufacturers of in-house IVDs that it was difficult to comply with the new regulatory framework, particularly in respect of conformity assessment requirements.[24] It was recognised that overly strict conformity assessment was required of Class 4 in-house IVD medical devices. The TGA also recognised that this posed a risk to the availability of important services provided by in-house IVD medical devices.[25] In explaining the changes, the TGA stated that: The changes provide appropriate flexibility for Class 4 in-house IVDs and ensure the continued availability of critical laboratory testing in Australia needed for a range of important services, such as donor screening.[26] Accordingly, manufacturers now have two alternative pathways to satisfy the conformity requirements:
  - relying on their existing NATA accreditation to ISO 15189, or a previously issued TGA Manufacturing licence, to apply directly for ARTG registration; or
  - for manufacturers without NATA accreditation or a TGA Manufacturing license, obtaining a TGA conformity assessment certificate before applying for ARTG registration.[27]

Post-market requirements

All manufacturers of in-house IVD medical devices must maintain evidence of compliance with conformity assessment and the Essential Principles. They are required to have in place post-market monitoring of the performance of in-house IVD medical devices and report any adverse events to the TGA.[28]

[21] Therapeutic Goods Administration, Regulatory requirements for in-house IVDs, (3 May 2024), p. 9
[22] Therapeutic Goods Administration, Regulatory requirements for in-house IVDs, (3 May 2024), p. 4
[23] Medical Device Regulations, Sch 4, Part 2, reg 2.10
[24] Explanatory Statement, Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015
[25] Explanatory Statement, Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015
[26] Explanatory Statement, Therapeutic Goods (Medical Devices) Amendment (In Vitro Diagnostic Medical Devices) Regulation 2015
[27] Therapeutic Goods Administration, Regulatory requirements for in-house IVDs, (3 May 2024), p. 13
[28] Medical Device Regulations, Sch 3, Part 6A, reg 6A.4; Sch 4, Part 2, reg 6B

Authors & Contributors

APACMed Secretariat

Cindy Pelou APACMed Regulatory Affairs Lead

Devya Barathi APACMed Regulatory Affairs Associate

Authors

Charles Lim Thermo Fisher Scientific

Chrissy Huang Ascensia Diabetes Care

Elizabeth Freitas Illumina Inc.

Fadzlon Yunos Becton Dickinson

Yasha Huang Roche Diagnostics

Contributors

Ai Lie Cheah Thermofisher

Bivash Chakraborty Biomerieux

Karthik G M Guardant health

Martini Hoan Thermofisher

Merrilyn Colussi Roche Diagnostics

Mita Rosalina Roche Diagnostics

Xiaofang Zhuo Johnson & Johnson

Yon Ju Kang Johnson & Johnson

Knowledge Partner

Katherine Wang Ropes & Gray LLP

Dr. Lincoln Tsang Ropes & Gray LLP

Michael Purcell Ropes & Gray LLP

Daisy Bray Ropes & Gray LLP

Greg Williams Clayton Utz

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