Malaysia National Laboratory Strategic Plan (MyNLSP) 2025-2029

Prepared by :
National Public Health Laboratory,
Malaysia

MINISTRY OF HEALTH MALAYSIA

RPHL
Regional Public Health Laboratory Network

MALAYSIA NATIONAL LABORATORY STRATEGIC PLAN

(MyNLSP)

2025-2029

With sincere appreciation to:

REGIONAL PUBLIC HEALTH LABORATORY NETWORK

MALAYSIAN ASSOCIATION OF PRIVATE MEDICAL LABORATORIES (MAPML)

DEPARTMENT OF PRIME MINISTER

MINISTRY OF AGRICULTURE AND FOOD SECURITY (MAFS)

MINISTRY OF SCIENCE, TECHNOLOGY AND INNOVATION (MOSTI)

MINISTRY OF DEFENCE (MINDEF)

MINISTRY OF NATURAL RESOURCES AND ENVIRONMENTAL SUSTAINABILITY (NRES)

MINISTRY OF HIGHER EDUCATION (MOHE)

MINISTRY OF INVESTMENT, TRADE AND INDUSTRY (MITI)

MINISTRY OF ENERGY TRANSITION AND WATER TRANSFORMATION (PETRA)

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Foreword by Deputy Director General of Health (Public Health), Malaysia

The Malaysia National Laboratory Strategic Plan (MyNLSP) has been developed using a consultative approach involving all key stakeholders and recognizing the multi-tiered structure of the national laboratory system within the One Health framework. This strategic initiative is guided primarily by the WHO Joint External Evaluation (JEE) Report 2019 and the Regional Public Health Laboratory Network (RPHL) Situational Analysis Report 2023, addressing the need for a comprehensive policy framework to govern laboratory services in Malaysia.

MyNLSP aims to enhance national laboratory capabilities by providing a structured focus on short-term, medium-term, and long-term priorities. These priorities are based on extensive assessments of selected laboratories across Malaysia's tiered laboratory system, with evidence-based recommendations guiding intervention strategies. The plan supports early detection and control measures for priority diseases and public health events while strengthening pandemic preparedness and response capacity.

As part of Malaysia's broader public health strategy, MyNLSP complements the National Health White Paper and aligns with the development of the National Centre for Disease Control (NCDC) in Enstek, Negeri Sembilan. The Ministry of Health, in collaboration with seven other ministries and private laboratories, is committed to the full implementation of this plan over the next five years. Through collective efforts, stakeholders will work together to ensure the successful execution of MyNLSP 2025-2029, guided by five strategic pillars and 12 thematic areas.

The Ministry of Health remains dedicated to providing quality and efficient laboratory services that support national health security and safeguard the well-being of the Malaysian population. Engagement and collaboration among all stakeholders will be crucial in achieving MyNLSP's strategic goals and reinforcing Malaysia's laboratory system as a cornerstone of public health resilience.

Dr. Ismuni bin Bohari

Deputy Director General of Health (Public Health)
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Foreword by Director of National Public Health Laboratory, Malaysia

The Malaysia National Laboratory Strategic Plan (MyNLSP) represents a significant milestone in strengthening laboratory services across the country. The plan aims to provide high-quality, accessible, and cost-effective laboratory services to support public health, including diagnostic testing, disease outbreak preparedness, surveillance, and laboratory system enhancements.

Initiated in 2024 under the leadership of the National Public Health Laboratory (NPHL) and its Secretariat, MyNLSP addresses critical areas such as laboratory quality management, biosafety, biosecurity, and surveillance. The plan is developed with the support of the Regional Public Health (RPHL) Network and involves collaboration among eight ministries and private laboratories, reflecting a multi-sectoral approach in line with the One Health concept—which integrates human, animal, food, and environmental health.

NPHL is committed to ensuring effective laboratory services and calls on stakeholders and partners to collaborate in implementing five key strategies and 12 thematic areas outlined in MyNLSP from 2025 to 2029. This initiative will play a vital role in enhancing laboratory infrastructure, data quality management, and trained personnel to support the country's public health and disease response efforts.

Dr. Nik Jasmin binti Nik Mahir

Director of National Public Health Laboratory
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Foreword by MyNLSP Secretariat

The development of the Malaysia National Laboratory Strategic Plan (MyNLSP) 2025-2029 represents an important continuation of efforts to enhance the functions of the Ministry of Health (MOH) in Malaysia. This strategic plan underscores the collaborative commitment of the MOH alongside other ministries to effectively plan and implement laboratory activities that will support public health initiatives.

The National Public Health Laboratory (NPHL) of Malaysia, under the Ministry of Health (MOH), plays a pivotal role in disease prevention, control, and monitoring. Its laboratory services extend to outbreak investigations, food safety assessments, and environmental health monitoring, contributing to a comprehensive public health framework.

MyNLSP 2025-2029 aims to enhance laboratory infrastructure, strengthen surveillance systems, and improve biosafety and biosecurity measures. Developed in 2024, under the leadership of NPHL and supported by the Regional Public Health (RPHL) Network, the plan focuses on expanding laboratory capabilities to address emerging public health challenges. This multi-sectoral approach aligns with the One Health concept, integrating human, animal, food, and environmental health.

Stakeholder engagement, involving eight ministries and private laboratories, is central to ensuring effective implementation of five strategies and 12 thematic areas outlined in the plan. Continuous updates and improvements will maintain relevance and adaptability in addressing evolving public health concerns.

Appreciation is extended to the editorial committee and reviewers for their dedication in the preparation of this document. The MyNLSP 2025-2029 is a testament to Malaysia's commitment to strengthening laboratory services for a resilient and responsive healthcare system. Collaborative efforts will be crucial in achieving national public health goals and safeguarding the well-being of communities.

MyNLSP Secretariat

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LIST OF ABBREVIATIONS

AMR	Antimicrobial Resistance
AQI	Air Quality Index
BRM	Biorisk management
BSL	Biosafety Laboratory
CAP	College of American Pathologists
CSF	Cerebrospinal fluid
DCD	Disease Control Division
DG	Director General
DHO	District Health Office
DVS	Department of Veterinary Services
EBS	Event-Based Surveillance
EIP	Epidemiology Intelligence Program
EQA	External Quality Assessment
e-SPAR	Electronic IHR States Parties Self-Assessment Annual Reporting Tool
FSQL	Food Safety and Quality Laboratory
FSQP	Food Safety and Quality Programme
GLLP	Global Leadership Laboratory Program
HAT	Hospital Angkatan Tentera Tuanku Mizan
HR	Human Resources
ICT	Information and Communication Technology
IHR	International Health Regulations
ILC	Inter-Laboratory Comparison
IMR	Institute for Medical Research
IQC	Internal Quality Control
ISO	International Organization for Standardization
JAKIM	Department of Islamic Development Malaysia (Jabatan Kemajuan Islam Malaysia)
JEE	Joint External Evaluation
LIMS	Laboratory Information Management System
NHLTAC	National Health Laboratory Technical Advisory Committee
LQA	Laboratory Quality Assurance
M&E	Monitoring and Evaluation
MOF	Ministry of Finance
MOH	Ministry of Health
MOU	Memorandum of Understanding
myOHAR	Malaysia One Health Antimicrobial Resistance
MyOHUN	Malaysia One Health University Network
MyNLSP	National Laboratory Strategic Plan Malaysia
MyCKAPS	Private Medical Practice Control Section
MyHAC	Malaysian Halal Analysis Centre
NBC	National Blood Center
NCDC	National Centre for Disease Control
NADMA	National Disaster Management Agency
NAHRIM	National Water Research Institute of Malaysia
NIH	National Institutes of Health
NLSP	National Laboratory Strategic Plan

NPHL	National Public Health Laboratory
NWFL	National Wildlife Forensic Laboratory
OH-FETP	One Health Epidemiology Training Program
PHL	Public Health Laboratory
POCT	Point-of-Care Testing
PPM	Plan Preventive Maintenance
PPP	Public-Private Partnership
PRET	Preparedness and Resilience for Emerging Threat Initiative
PT	Proficiency Testing
QMS	Quality Management System
RPHLN	Regional Public Health Laboratory Network
RTK	Rapid Test Kit
SEAOHUN	Southeast Asia One Health University Network
SG	Secretary General
SMART	Specific, Measurable, Achievable, Realistic and Time-Bound
SMEs	Subject Matter Expert
SWOT	Strength, Weaknesses, Opportunities, and Threats
TOR	Term of Reference
TWG	Technical Working Group
WGS	Whole Genome Sequencing
WHO	World Health Organization

Background

Laboratory services are an integral component of the health system in Malaysia. Its role in clinical and public health functions is critical for efficient and effective services, especially for disease surveillance, pandemic preparedness, diagnostics, treatment, research and health promotions. While laboratory pathology services in both public and private facilities are comprised of many disciplines, including pathology, specifically Anatomic Pathology, Chemical Pathology, Genetic Pathology, Haematology, and Medical Microbiology, other important services include animal health, environment and fisheries health. This is part of the One Health initiative, where public health is not limited to human health alone but transverses into animal, food and environmental health. Because of this and in keeping up with newer challenges such as the outbreak of novel and emerging pathogens in a borderless world and limitation in resources, laboratory services also need to undergo transformation for the continuation of effective and reliable services.

Past experiences of disease outbreaks such as the COVID-19 pandemic in 2019, pandemic H1N1 in 2009 and the current monkeypox outbreaks have provided valuable lessons on the importance of highly effective and efficient laboratory services as part of pandemic preparedness. Laboratory responses to the outbreak were satisfactory where guidelines including case definition, sample collection, transportation and referral, as well as various SOPs, were developed and shared with all laboratories, including private laboratories and laboratories outside of the Ministry of Health. Moving forward, one of the challenges faced during outbreaks, especially when involving One Health, is inter-agency cooperation and data sharing. There are also limitations of resources and manpower in smaller laboratories especially those located in other agencies.

The National Public Health Laboratory (NPHL) Malaysia recently reviewed laboratory services in Malaysia. The review is needed based on several country reports on laboratory capacity, including the WHO Joint External Evaluation of IHR Core Capacities of Malaysia, 2019 and the Situational Assessment Report for RPHL Network Capacity Building, 2023.

Figure 1. Examples of laboratories in Malaysia that provide routine and reference laboratory services in Malaysia

1.0 The Malaysia National Laboratory Strategic Plan (MyNLSP)

The Malaysia National Laboratory Strategic Plan (MyNLSP) encompasses the overall vision and roadmap for transforming and strengthening national laboratory services, aiming to improve public health outcomes by ensuring reliable and accessible laboratory services nationwide. It focuses on the following twelve thematic areas:

1. Leadership and Legal Considerations
2. Human Resources and Capacity Building
3. Financial Implications
4. Monitoring and Evaluation and Quality Assurance Programme
5. Supply Chain Management
6. Infrastructure Requirements & Equipment and Maintenance
7. One Health Plan and Policies
8. AMR and Genome Surveillance and Research
9. Emergencies and Pandemic Preparedness
10. Diagnostics Testing and Sample Referral System
11. Laboratory Data Management System
12. Biosafety and Biosecurity and Waste Management

The MyNLSP aligns with Malaysia's 2023 Health White Paper (HWP), which aims to reform the nation's health system towards realising better health and well-being for the people. It is also part of regional efforts to enhance national laboratory services across member countries.

1.1 Purpose of the strategic plan

This 5-year National Laboratory Strategic Plan (2025-2029) provides the guidance framework for transforming and developing the national laboratory services by the Ministry of Health Malaysia and other stakeholders.

1.2 The National Laboratory System in Malaysia

The National laboratory system in Malaysia involves various stakeholders. The main stakeholders are the Ministry of Health laboratories, other ministry laboratories (including the Ministry of Agriculture and Food Security, Ministry of Science, Technology and Innovations, Ministry of Higher Education, Ministry of Natural Resources and Environmental Sustainability, Ministry of Defence, Ministry of Investments, Trade and Industry, Ministry of Energy Transition and Water Transformation, and Malaysian Association of Private Medical Laboratories. Based on past responses, especially during the COVID-19 pandemic, most of these laboratories came

together to provide collective laboratory testing for COVID-19 to ensure adequate laboratory testing and responses.

1.2.1 National Public Health Laboratory (NPHL), Ministry of Health

The Public Health Laboratory (PHL) was established under the Ministry of Health Malaysia (MOH) to support the Public Health program in the prevention, control, and monitoring of communicable (emerging and re-emerging) and non-communicable diseases, outbreak investigations, food and environmental safety. It also aims to strengthen the existing laboratory services under the MOH with a broader scope, which includes laboratory analytical-diagnostic in public health crises, identification of potential bioagents of terrorism, chemical crisis, disasters, congenital disease screening, as well as other public health threats.

Prior to the establishment of the PHL, these services were supported by the Institute for Medical Research (IMR), Kuala Lumpur. The establishment of the PHL was initially proposed in 1966 by the 16th Director of IMR, Dr. Ungku Omar Ahmad, as part of the initiative to refocus the IMR on high-end research programs. Following his passing in 1969, this effort was continued by the former Director-General of Health, Tan Sri Abu Bakar Suleiman, in 1992. The proposal was approved under the Sixth Malaysia Plan (6MP), with three Regional PHLs successfully established in 1999: Regional PHL Sungai Buloh for the central region of Malaysia, which was later mandated as the National Public Health Laboratory (NPHL); the Regional PHL Johor Bahru, Johor for the southern region; the Regional PHL Ipoh, Perak for the northern region of Malaysia. The establishment of the NPHL was co-funded by the World Bank with an allocation of RM 27.7 million. The Regional PHL Kota Kinabalu, Sabah (for Sabah & Sarawak) and Regional PHL Kota Bharu, Kelantan (for the East Coast region) were later built in 2015 and 2011, respectively.

The NPHL was officially inaugurated on July 3, 2003, by Dato' Dr. Chua Jui Meng, Malaysia's former Minister of Health. The initial scope of services included analytical-diagnostic services for Food Safety under the Food Act 1983, Biochemistry Testing (screening for congenital hypothyroidism) and Tropical Diseases. Towards more integrated disease control activities, the NPHL was placed under the jurisdiction of the Disease Control Division (DCD), Public Health Program, Ministry of Health Malaysia. Meanwhile, all the Regional PHLs were placed under the respective State Health Department. As part of future planning, the PHLs services will be further strengthened with the establishment of a Public Health Reference Laboratory under the National Centre for Disease Control (NCDC) scheduled to be completed in 2026,

delivering an extensive scope of services supporting the 'all-hazard approach'. The governance aspect of PHLs will also be streamlined to improve overall technical capacity and better delivery of quality services.

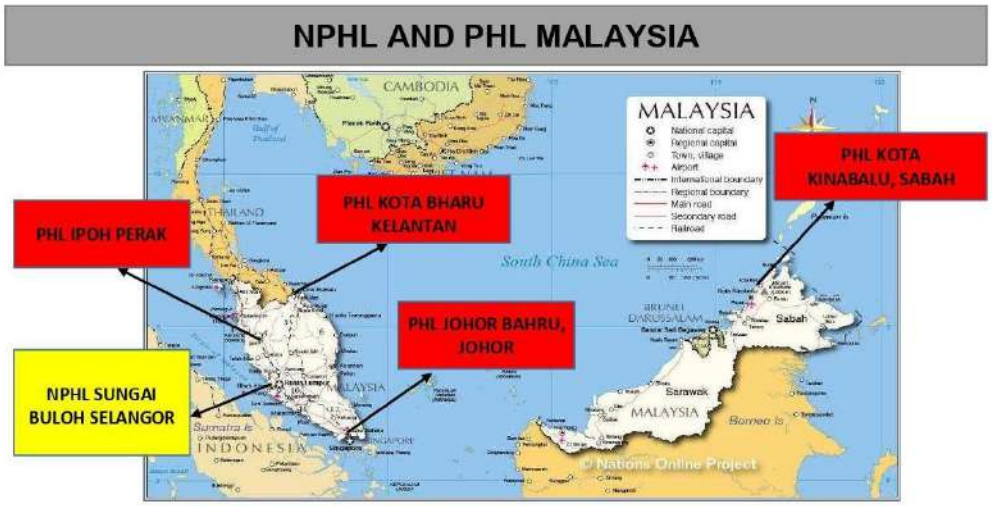

Figure 2: Location of NPHL and the PHL Malaysia Network.

MyNLSP CONNECTION TO PHLS AND OTHER HEALTH LABORATORY SERVICES

MyNLSP shall be designed to ensure the following:

1. Support the development and expansion of public health laboratories and other health laboratory services, and to align with the nation's goals towards becoming a safe,
2. developed country
3. Enhance core public health laboratory and other health laboratory functions to meet the nation's public health and health security requirements
4. Strengthen partnerships with stakeholders and strategic partners to enhance the delivery of quality services in a more comprehensive and sustainable manner.

OUR STRATEGIC PARTNERS

The following are our main strategic partners, national and international level but not limited to the following:

STRATEGIC PARTNERS – NATIONAL LEVEL

1. All health agencies at national, state and district levels under MOH
2. All health institutions under MOH
3. National Blood Centre

4. National Anti-Drug Agency
5. National Poison Centre
6. Agency Nuclear Malaysia
7. University Laboratories / Public & Private Higher Education Institutions
8. National Pharmaceutical Services Bureau
9. Health Facility Laboratories (Private & non-MOH)

STRATEGIC PARTNERS- INTERNATIONAL LEVEL

1. World Health Organisation, WHO
2. ASEAN Plus 3 Laboratory Partnership
3. Global Health Security Agenda, USA
4. Global Affairs Canada
5. UNITEDengue
6. ASEAN member states
7. Japan International Cooperation Agency (JICA)
8. International Atomic Energy Association (IAEA)

1.2.2 Pathology Service, Ministry of Health

The Pathology Services under Malaysia's Ministry of Health (MOH) play a crucial role in supporting clinical and public health functions. These services are essential for disease diagnosis, prognosis, and management. The MOH has established comprehensive policies to ensure the efficiency and effectiveness of pathology services across the country.

Key aspects of the pathology services include:

1. Disciplines: Covering areas such as anatomical pathology, chemical pathology, medical microbiology, hematology, and genetic pathology.
2. Quality Assurance: Ensuring laboratory accreditation and adherence to international standards.
3. Infrastructure: Providing state-of-the-art facilities and equipment to support diagnostic and research activities.
4. Training: Developing skilled personnel through continuous education and training.

Several hospitals are stakeholders of the MyNLSP including Hospital Queen Elizabeth, Hospital Selayang, Hospital Melaka and Hospital Sultan Idris Shah Serdang

1.2.3 Food Safety and Quality Programme (FSQP), Ministry of Health

The Food Safety and Quality Programme (FSQP) is an initiative under Malaysia's Ministry of Health (MOH) aimed at ensuring food safety and protecting public health. It operates under the Food Act 1983 and Food Regulations 1985, focusing on preventing health hazards and fraud in food preparation, sale, and consumption.

The FSQP oversees various activities, including:

1. Inspection and registration of food premises.
2. Food sampling and analysis to ensure compliance with safety standards.
3. Import and export food control to meet regulatory requirements.
4. Enforcement actions, such as closing insanitary food premises or recalling non-compliant products.

1.2.4 Disease Control Division, Ministry of Health

The Disease Control Division under Malaysia's Ministry of Health is responsible for managing and preventing the spread of infectious diseases and other health threats. It plays a vital role in safeguarding public health through various initiatives and programs.
Key functions include:

1. Surveillance and Monitoring: Tracking disease outbreaks and trends to implement timely interventions.
2. Policy Development: Establishing guidelines for disease prevention and control.
3. Vaccination Programs: Promoting immunization to prevent vaccine-preventable diseases.
4. Public Awareness Campaigns: Educating the public on health risks and preventive measures.
5. Emergency Response: Coordinating efforts during health crises, such as epidemics or pandemics.

1.2.5 Institute for Medical Research (IMR), Ministry of Health

The Institute for Medical Research (IMR) in Malaysia was established in 1900 as the Pathological Institute for the country. Initially founded to address the pressing health concerns of the time, particularly tropical and nutritional diseases, the IMR has since evolved into a leading centre for biomedical research and public health initiatives.

In the 124 years since its inception, IMR has contributed significantly to the knowledge, understanding, treatment, and control of some major tropical diseases in the country and region, including beriberi, malaria, cholera, typhoid, smallpox, leprosy, tuberculosis, filariasis, dengue, scrub typhus, and nutrient deficiencies. Over the years, the scope and function of IMR have expanded to include non-communicable diseases, cancers, herbal medicine, and preclinical drug discoveries.

Today, the core functions of the IMR are research, specialised diagnostic services, training, and technical consultancies. Its vision is to be a world-renowned biomedical research institution recognised for its ability in science, technological production of services, innovations, and education. Its mission is to protect and improve the population's health by conducting biomedical research to address health needs, providing specialised diagnostic services, and building national capacity through technology transfer and consultative services.

The IMR is dedicated to advancing scientific knowledge that contributes to the prevention and control of diseases and improves the health and well-being of the Malaysian population. It plays a pivotal role in Malaysia's healthcare landscape, influencing national and international health strategies.

1.2.6 Division of Family Health Development, Ministry of Health

The Division of Family Health Development under Malaysia's Ministry of Health focuses on improving the health and well-being of families, women, children, and vulnerable groups. It plays a pivotal role in implementing policies and programs that address public health concerns related to family health.

Key areas of focus include:

1. Maternal and Child Health: Ensuring safe pregnancies, deliveries, and child development.
2. Reproductive Health: Promoting family planning and addressing reproductive health issues.
3. Nutrition: Tackling malnutrition and promoting healthy eating habits.
4. Adolescent Health: Addressing the unique health needs of teenagers.
5. Elderly Care: Supporting the health and well-being of older adults

1.2.7 Medical Device Authority, Ministry of Health

The Medical Device Authority (MDA) Malaysia is a regulatory body under the Ministry of Health Malaysia that is responsible for ensuring the safety, quality, and effectiveness of medical devices in the country. Established under the Medical Device Act 2012 (Act 737), the MDA oversees the registration, licensing, and post-market surveillance of medical devices. Companies involved in manufacturing, importing, exporting, or distributing medical devices must obtain an Establishment License and register their products through the Medical Device Centralized Online Application System (MeDC@St). Devices are classified into four risk categories (Class A–D), with higher-risk devices requiring more rigorous conformity assessments before approval.

MDA also plays a crucial role in monitoring compliance, enforcing regulations, and conducting post-market surveillance to ensure continuous safety. It has the authority to inspect premises, investigate violations, and recall unsafe medical devices. Additionally, MDA aligns its regulations with international standards (ISO, IMDRF, WHO) to facilitate global trade and ensure Malaysian medical devices meet worldwide benchmarks. Beyond regulation, MDA supports innovation and industry development, providing guidance for AI-powered medical devices, cybersecurity measures, and digital health technologies to keep up with global advancements.

Looking ahead, MDA aims to strengthen its regulatory framework, focusing on digital health regulations, ASEAN harmonization, and enhanced market surveillance. Challenges include keeping up with evolving medical technologies, ensuring data security, and monitoring imported devices. By enforcing stringent policies and supporting industry innovation, MDA helps protect patients, healthcare professionals, and the overall medical device ecosystem in Malaysia.

1.2.8 National Blood Centre, Ministry of Health

The National Blood Centre (Pusat Darah Negara) in Malaysia is a key institution under the Ministry of Health, responsible for ensuring a safe and sufficient blood supply for the nation. It plays a vital role in blood donation, processing, storage, and distribution to hospitals and healthcare facilities.

Key functions of the National Blood Centre include:

1. Blood Donation Drives: Organizing campaigns to encourage voluntary blood donation.
2. Blood Screening: Ensuring all donated blood is thoroughly tested for safety.
3. Research and Development: Conducting studies to improve transfusion medicine and blood safety.
4. Training and Education: Providing training for healthcare professionals in blood transfusion practices.

1.2.9 National Cancer Institute (IKN), Ministry of Health

The National Cancer Institute (Institut Kanser Negara, IKN) in Malaysia is a specialized center under the Ministry of Health dedicated to cancer care, research, and prevention. Located in Putrajaya, it serves as a hub for comprehensive cancer treatment and education.

Key functions of the National Cancer Institute include:

1. Comprehensive Cancer Treatment: Offering services such as surgery, chemotherapy, and radiation therapy.
2. Research and Development: Conducting studies to advance cancer treatment and prevention strategies.
3. Public Education: Raising awareness about cancer prevention and early detection.
4. Collaboration: Partnering with other organizations to improve cancer care and outcomes.

1.2.10 Private Medical Practice Control Section (MyCKAPS)

The Private Medical Practice Control Section (MyCKAPS) is a division under Malaysia's Ministry of Health responsible for regulating and monitoring private healthcare facilities and services. It ensures compliance with the Private Healthcare Facilities and Services Act 1998 (Act 586) and its related regulations.

Key functions of MyCKAPS include:

1. Licensing and Registration: Overseeing the approval process for private healthcare facilities, such as clinics, hospitals, and dialysis centres.
2. Monitoring and Enforcement: Ensuring private healthcare providers adhere to legal and professional standards.
3. Policy Implementation: Developing and enforcing policies to maintain the quality and safety of private medical practices.

4. Public Complaints Management: Addressing complaints related to private healthcare services.

1.2.11 Department of Legal Affairs Division, Ministry of Health

The Department of Legal Affairs Division in Malaysia plays a crucial role in overseeing legal matters and ensuring compliance with laws and regulations. It often focuses on areas such as:

1. Policy Development: Drafting and implementing legal frameworks to support national governance.
2. Advisory Services: Providing legal advice to government agencies and departments.
3. Legislative Review: Evaluating existing laws and proposing amendments to address current challenges.
4. Public Engagement: Facilitating transparency and public access to legal information.

1.2.12 Department of Chemistry Malaysia, Ministry of Science, Technology and Innovations (MOSTI)

The Department of Chemistry is at the forefront of scientific innovation, operating a cutting-edge network of laboratories across the nation. These state-of-the-art facilities are dedicated to providing top-notch scientific analysis, investigation, and consultancy. Their pivotal role extends to supporting law enforcement and advancing critical programs in forensic science, water safety, food quality, environmental protection, and industrial standards. With a mission to safeguard public health and ensure consumer and workplace safety, these labs are essential to enhancing overall well-being.

From its central hub in Petaling Jaya, the department extends its reach through 8 strategically located branches in Peninsular Malaysia and 5 in East Malaysia. Each location is outfitted with the latest technology and staffed by experts dedicated to protecting and improving the quality of life for communities nationwide.

The department houses three main centres, each specializing in critical areas of scientific service:

1. The Forensic Science Analysis Centre: Offers impartial and independent forensic science services to both government and private sectors.
2. The Drinking Water, Food, and Environmental Safety Analysis Centre: Ensures public health through rigorous testing of food and drinking water safety while championing environmental protection and conservation.

3. The Industry and Custom Tariff Analysis Centre: Provides vital analysis and advisory services to government agencies to bolster law enforcement, safeguard government revenue, and promote consumer interests and workplace health and safety.

In addition to these core functions, the department offers expert opinions, lectures, and training to further support and educate various stakeholders.

1.2.13 Hospital Angkatan Tentera (HAT) Tuanku Mizan, Ministry of Defence

Established in 2008, the Pathology Department of Hospital Angkatan Tentera (HAT) Tuanku Mizan offers comprehensive laboratory test services for the Malaysian Armed Forces. This department supports the Royal Medical Corps in its mission to preserve the health and fighting strength of the Malaysian Armed Forces.

The Pathology Department of HAT Tuanku Mizan is located at Section 2, Wangsa Maju, Kuala Lumpur. It acts as the central lab providing a wide range of quality diagnostics and analytical laboratory testing services for over 100 medical facilities in military camps and bases nationwide.

The facility primarily conducts scheduled mandatory screening laboratory tests for military personnel, in addition to offering routine and specialised diagnostic services.

1.2.14 Malaysia One Health University Network (MyOHUN)

The Malaysia One Health University Network (MyOHUN) is a collaborative initiative established in 2012 as part of the Southeast Asia One Health University Network (SEAOHUN). It is hosted at Universiti Putra Malaysia (UPM) and focuses on promoting the One Health approach, which recognizes the interconnectedness of human, animal, and environmental health.

Key highlights of MyOHUN include:

1. Capacity Building: Providing training, workshops, and professional development for students and professionals across disciplines.
2. Research and Collaboration: Encouraging multidisciplinary research to address zoonotic diseases, antimicrobial resistance, and other health challenges.
3. Education and Outreach: Developing curricula and conducting public awareness campaigns to strengthen the One Health concept.

4. National and Regional Impact: Collaborating with universities, government agencies, and international organizations to enhance health systems.

1.2.15 The National Wildlife Forensic Laboratory, Ministry of Natural Resources and Environmental Sustainability

The National Wildlife Forensic Laboratory (NWFL) in Malaysia was established in 2015. It was set up to support the country's efforts in combating wildlife crime through the application of forensic science.

The laboratory plays a crucial role in supporting law enforcement by using various forensic methods, such as DNA analysis, to identify species from biological samples, thereby providing vital scientific evidence in the investigation of illegal wildlife trade and other wildlife crimes.

In addition, NWFL assists in the conservation initiatives of endangered species and their habitats by providing accurate data to conservationists and law enforcement agencies.

1.2.16 Resources and Environment Department of Fisheries Malaysia, Ministry of Agriculture and Food Security

The Resources and Environment Department under the Department of Fisheries Malaysia focuses on managing and conserving aquatic resources and their ecosystems. Its primary goal is to ensure sustainable fisheries and environmental protection for future generations.

Key responsibilities include:

1. Resource Management: Developing policies and strategies for the sustainable use of marine and freshwater resources.
2. Environmental Conservation: Protecting aquatic habitats and biodiversity through conservation programs.
3. Research and Development: Conducting studies on fisheries and aquatic ecosystems to support evidence-based decision-making.
4. Monitoring and Enforcement: Ensuring compliance with laws and regulations related to fisheries and environmental protection.

1.2.17 Department of Veterinary Services (DVS), Ministry of Agriculture and Food Security

The Department of Veterinary Services (DVS) Malaysia, under the governance of the Ministry of Agriculture and Food Security (MAFS), envisions being a competent veterinary authority serving the animal industry for the benefit of human welfare. Its mission is to provide quality veterinary services that ensure public health and support a sustainable livestock industry for the sake of human welfare. Initially formed in the early 1900s, DVS was established to strengthen and maintain animal health to support a thriving animal industry, ensure public health through controlling zoonotic diseases and promoting the production of safe animal-based products, encourage sustainable livestock production and value-added industries, explore and develop the use of technology for optimising resources in the animal industry, and promote animal welfare practices across all aspects of rearing and production systems.

The Department of Veterinary Services (DVS) is committed to safeguarding public health through its extensive network of laboratory services. The Veterinary Laboratory Services Section, under the Disease Control and Veterinary Biosecurity Division, is responsible for overseeing the operation of diagnostic veterinary laboratories across Peninsular Malaysia. This includes five regional diagnostic veterinary laboratories: Makmal Veterinar Zon Selatan (Johor), Makmal Veterinar Zon Timur (Pahang), Makmal Veterinar Zon Timur (Kelantan), Makmal Veterinar Zon Utara (Pulau Pinang), and Makmal Veterinar Zon Tengah (Selangor). Additionally, the Veterinary Research Institute (VRI) in Ipoh, Perak, serves as the reference laboratory for advanced diagnostic services under the Research Division. Meanwhile, Makmal Kesihatan Awam Veterinary Kebangsaan, located in Salak Tinggi, Selangor, under the Veterinary Public Health Division, is responsible for ensuring the safety of livestock-based food and livestock-derived products.

1.2.18 National Water Research Institute of Malaysia (NAHRIM), Ministry of Energy Transition and Water Transformation

The National Water Research Institute of Malaysia (NAHRIM) is a key organization under the Ministry of Energy Transition and Water Transformation (PETRA). NAHRIM acts as a national focal point on water research and development, offering expertise in areas such as hydrology, climate change adaptation, water resources management, water quality and disaster risk reduction.

They also provide consultancy and technical advisory services both locally and internationally.

Water Quality Laboratory, offers services for water quality testing accredited under MS ISO 17025 for chemical and microbiology analysis. Apart from that, the Water Quality Laboratory focuses on research on emerging pollutants in the environment that may pose a risk to the public health system. These include Endocrine Disrupting Chemicals (EDC), antimicrobial resistance (AMR) and microplastics.

1.2.19 Malaysia Halal Analysis Centre (MyHAC), Department of Islamic Development Malaysia

The development of the Halal Research Center, Malaysian Islamic Development Department for the first phase in Enstek, Nilai, Negeri Sembilan has been approved in the Tenth Malaysia Plan (RMK-10) with a focus on the construction of a halal laboratory which is currently named as the Pusat Analisis Halal Malaysia / Malaysia Halal Analysis Center (MyHAC).

MyHAC is the first halal analysis laboratory fully owned by the government that aims to provide halal analysis services to empower Malaysian Halal Certification under the management of the Halal Management Division, Department of Islamic Development Malaysia.

Sample analysis offers for the purpose of halal certification and research were received from JAKIM, the State Department of Islamic Religion (JAIN) and the State Islamic Religious Council (MAIN) beginning in 2020. While internal sample analysis is for the purpose of method development, validation, skill testing and research.

MyHAC obtained accreditation recognition under the Malaysian Laboratory Accreditation Scheme (SAMM) from the Malaysian Standards Department based on the requirements of MS ISO/IEC 17025:2017: General Requirements for the Competence of Testing and Calibration Laboratories in 2022.

JAKIM towards developing MyHAC as a Halal Research Center, not just a halal laboratory with recognition as the first Halal Laboratory in the world with a combination of sharia and science elements that lead to Halal Forensic methods. In addition, MyHAC also intends to offer cooperation with the Halal Certification Body to establish cooperation at the global level.

1.2.20 Department of Standard Malaysia (DSM), Ministry of Investment, Trade and Industry (MITI)

The Department of Standard Malaysia (DSM) is a National Standards Body and the National Accreditation Body under Ministry of Investment, Trade and Industry (MITI). DSM provides standardisation and accreditation services for global competitiveness. It plays a vital role in ensuring the development, implementation, and promotion of standards to enhance Malaysia's competitiveness and quality of life.

Key functions include:

1. Standard Development: Establishing national standards across various industries to ensure consistency and quality.
2. Accreditation: Providing accreditation services to certify organizations and systems meet international standards.
3. International Collaboration: Representing Malaysia in global standardization bodies like ISO and IEC.
4. Capacity Building: Offering training and resources to improve understanding and application of standards.

1.2.21 Malaysian Association of Private Medical Laboratories (MAPML)

A private laboratory is a facility that is being set up for the purpose of performing tests on its own patients or from clinics and hospitals (either private or government).

The main aim for the services includes a comprehensive range of diagnostic services, including clinical chemistry, haematology, immunology, microbiology, histopathology, cytopathology, cytogenetics and molecular diagnostics, for the purpose of providing information for the diagnosis, prevention or treatment of a disease or assessment of a medical condition. Some of the private laboratories are equipped with advanced and specialised high-end technology and are staffed by highly qualified professionals, including pathologists, medical laboratory scientists, medical laboratory technologists, and support staff. It also supports medical research and provides accessibility testing services to the public with shorter waiting times.

During the COVID-19 pandemic, private laboratories were also actively involved in the diagnosis and surveillance of SARS-CoV-2 infections, providing great assistance in curtailing the pandemic.

These private laboratories are represented by the Malaysian Association of Private Medical Laboratories (MAPML).

1.2.22 Ministry of Higher Education

The Ministry of Higher Education (MOHE) plays a pivotal role in shaping and maintaining a robust higher education ecosystem, which includes Public Universities (UA), Private Higher Educational Institutions (PHEIs), Polytechnics, and Community Colleges. These institutions collectively form the backbone of the national education system, each contributing uniquely to the development of human capital.

To ensure the success of its role, the Ministry of Higher Education (MOHE) typically has two (2) key departments that manage institutions of higher learning. These departments are:

1. The Department of Higher Education (JPT) – UA and IPTS;
2. Department of Polytechnic Education and Community College Education (JPPKK) – Community Colleges

Efforts to achieve the Ministry of Higher Education's (MOHE) goals are further supported by several key agencies that play vital roles in the higher education ecosystem. These agencies include:

1. Akademi Kepimpinan Pengajian Tinggi (AKEPT) - Human capital development transformation centre.
2. Perbadanan Tabung Pendidikan Tinggi Nasional (PTPTN)- Coordinating the financing of higher education.
3. The Malaysian Qualifications Agency (MQA)- Supervising and coordinating quality assurance as well as accreditation of national higher education; and
4. Education Malaysia Global Services (EMGS) - Promotes educational diplomacy and internationalization of the Malaysian education sector.

Several public universities are stakeholders of the MyNLSP including Universiti Kebangsaan Malaysia (UKM), Universiti Putra Malaysia (UPM) and Universiti Malaya (UM).

The main contributions of the stakeholders from Universities include research, genome surveillance and biosafety & biosecurity and waste management

1.2.23 Forensic Service, Ministry of Health

The Forensic Service under Malaysia's Ministry of Health plays a critical role in supporting the justice system and public health through forensic investigations. It provides expertise in the examination of evidence, post-mortem investigations, and other medico-legal services.

Key functions include:

1. Post-Mortem Examinations: Conducting autopsies to determine causes of death, especially in cases of unnatural or suspicious deaths.
2. Forensic Analysis: Examining physical evidence to assist in criminal investigations.
3. Training and Education: Providing training for healthcare professionals and law enforcement in forensic practices.
4. Collaboration: Working closely with law enforcement agencies, legal entities, and other stakeholders to ensure justice and public safety.

Several hospitals are stakeholders of the MyNLSP including Hospital Queen Elizabeth, Hospital Sultanah Bahiyah and Hospital Sultan Idris Shah Serdang.

2.0 Review of Current Laboratory System

A desk review on the national plan for laboratory services revealed the absence of a National Laboratory Plan that is encompassing all laboratory services in Malaysia including outside of the Ministry of Health and Private Laboratories. There is also no policy that can be used to govern laboratory services. Nevertheless, there are guidelines and ad-hoc directives from the Director General of Health Malaysia that are widely used by the Ministry of Health Laboratories to operate as well as respond responses to outbreaks. These guidelines can also be used to get assistance from laboratories outside of the Ministry of Health. In addition, private laboratory services come under the preview of 586 Act (Private Healthcare Facilities and Services Act 1998). The Act is applicable to all private laboratories (stand alone or hospital based) and laboratories in statutory bodies (Universities, foundations) only. It is not applicable to public laboratories (established and operated by the government). Hence, there is absence of an Act that governs all laboratories in Malaysia.

In Malaysia, several Acts regulate laboratory health and safety, ensuring public health and safety standards in medical and research laboratories. The primary legislation governing laboratory health in Malaysia includes but not limited to:

1. Fisheries Act 1985 (Act 317)
2. Standards Malaysia Act 1996 (Act 549)
3. Medical Device Act 2012 (Act 737)
4. Allied Health Professions Act 2016 (Act 774)
5. Private Healthcare Facilities and Services Act 1998 (Act 586)
6. Food Analysts Act 2011 (Act 727)
7. Chemist Act 1975 (Act 158)
8. Occupational Safety and Health Act 1994 (Act 514OSHA)
9. Factories and Machinery Act 1967 (Act 139FMA)
10. Food Act 1983 (Act 218) & Malaysia Food Regulations 1985
11. Poisons Act 1952 (Act 366)
12. Atomic Energy Licensing Act 1984 (Act 304)
13. National Environmental Quality Act 1974 (Act 127)
14. Public Health (Control of Disease) Prevention and Control of Infectious Diseases Act 1988 (Act 1988 Act 342)
15. Animals Act 1953 (Act 647)
16. Medical Act 1971 (Act 50)

These laws, along with guidelines and regulations set by relevant authorities such as Ministry of Health Malaysia (MOH) and the Department of Occupational Safety and Health (DOSH), govern laboratory operations, health, and safety in Malaysia.

2.1 Generic Data Flow for Laboratory Investigations during Outbreaks

2.1.1 Data Sources for Event Based Surveillance (EBS)

Most data are primarily received by DHO and may come from different sources:

1. Syndromic notification
2. Event based Surveillance
3. Mandatory notification
4. Surveillance data monitoring

2.1.2 Laboratory Networking (Specimen Management)

Provision of laboratory investigations are offered by different level of facilities according to the type of data sources:

1. Community (Health Clinics/ GPs)
2. District Health Office
3. Hospital (Public / Private)
4. Public Health Laboratory (National/ Regional)
5.

Tertiary level - usually for case requiring advance lab test referred either from hospital /DHO/ PHL

1. Institute for Medical Research (IMR), National Institutes of Health (NIH)
2. Public Health Lab (National/ Regional)
3. National Poison Centre
4. Another private laboratory (outsource)

2.1.3 Capacity of Laboratory Services at Each Level/Tier

1. Community (Health Clinics/ GPs)
   i. RTK
   ii. POCT

2. District Health Office
   i. Clinical sample
   ii. Environment sample
   iii. Entomology sample

3. Hospital (Public / Private)
   i. RTK
   ii. Molecular
   iii. Serology

iv. Culture & Sensitivity

4. Tertiary level: i.e. NPHL, PHL, IKN, IMR, NBC
   i. Advanced laboratory tests for cases referred either from the hospital or DHO i.e. WGS, Histopathology, Forensic DNA, Electron Microscopy

Terms of Reference for the Laboratory

Laboratory systems in Malaysia are diverse and encompass a wide range of fields, from research and development to healthcare and industrial applications. These systems are integral to various industries, including education, healthcare, manufacturing, and biotechnology. Here's an overview of key aspects of laboratory systems in Malaysia:

1. **Healthcare Laboratories**
   i. **Clinical Labs:** Hospitals and healthcare facilities across Malaysia have diagnostic laboratories for medical testing, including blood work, microbiology, and pathology. These labs are crucial for diagnosing diseases and providing accurate results for patient care.
   ii. **Public and Private Sectors:** Public healthcare labs are managed by the Ministry of Health (MOH), while private healthcare labs are operated by private companies, offering specialized services.

2. **Research & Development Laboratories**
   i. **Universities and Research Institutions:** Malaysia has many research institutions like the Fisheries Research Institute (DOF), Malaysian Palm Oil Board (MPOB), Malaysian Nuclear Agency (MNA), and universities such as Universiti Malaya (UM), Universiti Kebangsaan Malaysia (UKM), and Universiti Putra Malaysia (UPM), which conduct cutting-edge research in fields like agriculture, biotechnology, and environmental science.
   ii. **Biotechnology and Life Sciences:** Malaysia's government has invested in biotech parks and labs as part of its Bioeconomy Transformation Program to position Malaysia as a leading biotechnology hub in Asia.

3. **Industrial and Manufacturing Laboratories**
   i. **Quality Control and Testing:** Laboratories in industries such as manufacturing, construction, food processing, and chemicals are used to test raw materials, finished

products, and ensure compliance with safety and environmental standards.

ii. **Product Development:** Many companies in Malaysia maintain laboratories for research and development purposes, ensuring innovation in product design and material performance.

iii. **Environmental and Agricultural Laboratories**

iv. **Soil, Water, and Air Quality Testing:** Malaysia's tropical environment and the agricultural industry necessitate laboratories that focus on environmental testing, soil testing, water quality analysis, and monitoring pollutants.

v. **Agriculture:** Laboratories specializing in agricultural research support Malaysia's dominant industries such as palm oil, rubber, and timber.

4. **Technology and Innovation in Laboratory Systems**

i. **Automation and AI:** Malaysian labs increasingly incorporate automation and AI-driven technology for data analysis and testing, improving accuracy and efficiency.

ii. **Digitalization:** Labs are adopting software systems for data management, inventory tracking, and result reporting to ensure smooth operations and real-time data sharing.

2.1.4 List of Event-Based Surveillance

List of Event-Based Surveillance Initiatives in Malaysia as of the development of MyNLSP.

1. National Dengue Virus Serotype Surveillance Program (Director-General of Health Circular No. 14/2011)

2. Malaysia Influenza Surveillance Protocol (MISP)

3. Laboratory Report on Measles & Rubella (Measles Elimination Programme)

4. Laboratory Report on Japanese Encephalitis

5. Laboratory Report on Bordetella Pertussis

6. Hand, Foot, and Mouth Disease (HFMD)

7. Environmental Surveillance Program for Poliovirus

8. Laboratory Surveillance for Salmonella spp.

9. Laboratory Surveillance for Brucellosis & Q Fever

3.0 Rational of NLSP Development

The National Public Health Laboratory (NPHL) Malaysia had recently reviewed the laboratory services in Malaysia. The review is needed based on several country reports on laboratory capacity, including the WHO Joint External Evaluation of IHR Core Capacities of Malaysia, 2019, and the Situational Assessment Report for RPHL Network Capacity Building, 2023. During the WHO JEE assessment, the team visited several laboratories, which include a reference laboratory, state hospitals, primary clinic and veterinary laboratory. The summary of the report is described below:

3.1 WHO JEE of IHR Core Capacity (2019)

Malaysia has demonstrated a high level of achievement in fulfilling IHR requirements. It has a well-developed security system and National Surveillance System (NHS) that synthesizes data across various reporting systems with various real-time entries at the district, state and national level. These systems are monitored daily with continuous improvement through the conduct of simulation exercises, after-action reviews and other assessments. Nevertheless, there are areas for improvement, including strengthening of the National Laboratory Systems, Inter-agency cooperation in AMR surveillance and improving Biosafety and Biosecurity.

3.2 Situational Assessment Report for RPHLN Capacity Building, 2023

Malaysia has scored high average capacity based on the WHO JEE Report 2019 and eSPAR scores of 80-100% for most of laboratory capacities. The Malaysian Laboratory Network builds on several strengths including laboratory testing for priority disease, responding to workforce surge during public health events and surveillance for public health emergencies. However, certain fields can be strengthened, including laboratory quality systems, biosafety and biosecurity and electronic reporting tools. Therefore, this MyNLSP document is needed for further enhancement of Malaysia's laboratory services.

4.0 Development of MyNLSP 2025-2029

Following RPHL Network technical report on situational analysis report on Malaysia laboratory services 2023, several gaps have been identified, which warrant the development of MyNLSP by adopting a One Health approach through collaboration between health and other relevant sectors. This Strategic Plan provides a framework to guide development of public health laboratory services in Malaysia with involvement of all relevant authorities including Ministry of Health, Ministry of Agriculture and Food Security, Ministry of Defence, Ministry of Science, Technology and Innovation, Ministry of Natural Resources and Environmental Sustainability, Ministry of Higher Education, Ministry of Investment, Trade and Industry, Ministry of Energy Transition and Water Transformation, Department of Prime Minister and Malaysian Association of Private Medical Laboratories (MAPML) who are also major stakeholders.

The development process included several key engagement activities such as a three-day workshop in May 2024 for document review and SWOT analysis, followed by a series of exercises including key informant questionnaires, laboratory facility assessments, and virtual meetings in June and July 2024. A situational analysis workshop was conducted in late July 2024 to refine the SWOT analysis and identify strategies and activities. Ad-hoc virtual meetings ensured continuous input and buy-in from all involved parties. A Monitoring and Evaluation (M&E) workshop held in November 2024 finalized sub-strategies and activities, focusing on strengthening laboratory capacity in critical areas as highlighted by situational analysis reports and international assessments.

4.1 Strategy for Development of MyNLSP 2025-2029

General Strategy

To develop a robust and sustainable National Laboratory Strategic Plan that enhances leadership, strengthens quality management systems (QMS), and establishes comprehensive biosafety and biosecurity frameworks, thereby improving the operational capacity, credibility, and safety of national laboratories. This will ensure that laboratories can effectively support national health, environmental, and scientific priorities while aligning with international standards and best practices. The plan aims to foster collaboration, increase capacity building, and enhance safety protocols to create a globally competitive and resilient laboratory system.

Sub Strategies

1. Support country to map existing laboratory systems to defined requirements of national laboratory system (specifically quality, standards and biosafety) and networks (with specific linkages to disease surveillance and clinical care for both health laboratory and other relevant sectors).
2. Strengthen the leadership capabilities within Malaysia's national laboratories through specialized training programs on strategic management, scientific leadership and advanced laboratory operations.
3. Enhancing QMS activities for Malaysian national laboratories, with alignment to National and International Standards Requirements which includes Good Laboratory Practices (GLP).
4. Enhancing existing national biosafety and biosecurity management for Malaysia’s laboratories including waste management.
5. To explore opportunities and optimize laboratory services on One Health Laboratory Network.
6. Digitalization

4.2 Scope, Vision and Mission of the Malaysian NLSP

Policy Statement: Public Health Laboratory Services are an essential component for an integrated and comprehensive healthcare system. The MyNLSP aims to strengthen efforts for all laboratories involved in human, animal, agricultural, food safety and environmental care under the concept of “One Health” and to ensure the development of a sustainable system of laboratory services in-line with national and international standards and able to meet the needs and security of the population.

Scope: A National Laboratory Strategic Plan in Malaysia encompass the overall vision and roadmap for enhancing the quality, capacity, and effectiveness of laboratory services across the country, focusing on areas like disease surveillance, diagnostic testing, research capabilities, workforce development, quality assurance, and preparedness for emerging health threats, all aimed at improving public health outcomes by ensuring reliable and accessible laboratory services nationwide involving all the stakeholders.

Vision: Malaysia shall have a well-organized, sustainable system of quality laboratory services for public health under the One Health concept that are accessible and affordable to all.

Mission: Implementing strong governance to ensure the long-term sustainability and effectiveness of national laboratories, providing integrated, high-quality, and comprehensive public health laboratory services that support laboratory testing, public health responses, and disease surveillance.

4.3 Situational Analysis

In early 2024, a laboratory technical working group was established to conduct situational analysis for development of MyNLSP. This analysis is needed to identify current strengths (S), weaknesses (W), opportunities (O) and threats (T) in the Malaysian laboratory systems.

This National Laboratory Working Group, includes experts from the National Public Health Laboratory (NPHL), public and private laboratories, and stakeholders from various ministries such as Ministry of Agriculture and Food Security, Ministry of Science, Technology and Innovations, Ministry of Higher Education, Ministry of Natural Resources and Environmental Sustainability, Ministry of Defence, Ministry of Investments, Trade and Industry, Ministry of Energy Transition and Water Transformation.

4.3.1 Methodology for Situational Analysis

The methodology used for data collection for the development of MyNLSP includes the followings:

1. Desk Review- A total of 33 documents were reviewed by expert stakeholders from various agencies.
2. Key Informant Questionnaire (TO2)
3. Laboratory Facility Assessment (TO3)
4. Laboratory Systems Questionnaire (TO4)

There were several ways used to collect the data from stakeholders. This includes physical visit to the facilities as well as virtual engagement.

All data collected was scrutinized by the MyNLSP Secretariat with the local MyNLSP consultant. The data were then aligned based on four key areas i.e. Strengths, Weakness, Opportunities and Threats.

Figure 4: Desk Review Workshop to review 33 documents for the development of MyNLSP that was carried out in May 2024.

Figure 5: Situational analysis of MyNLSP with RPHL Network Members and stakeholders

Figure 6: Monitoring and Evaluation Workshop for MyNLSP involving all stakeholders

4.3.2 Findings of Situational Analysis

Based on the SWOT analysis and situational assessment, stakeholders reached a consensus on five key strategic plans, twelve (12) thematic areas, forty-three (43) sub-strategies, and seventy (70) corresponding activities.

Main Strategies

1. Strategy 1: Fostering Multi-Sectoral Leadership to ensure the availability and accessibility of functional laboratory services.
2. Strategy 2: Ensuring Attainability of Efficient and Excellent Laboratory Testing Services for All Public Health Laboratories.
3. Strategy 3: Strengthening Multi-Sector Coordination Among Public Health Laboratories, Ensuring Effective Routine and Pandemic Preparedness Responses.
4. Strategy 4: Leveraging National, Regional, and International Partnerships and Collaboration.
5. Strategy 5: Strengthening Regulations and Legislations for Smooth Operations of Laboratory Services.

Thematic Areas

1. Leadership & Legal Considerations
2. Human Resources & Capacity Building
3. Financial Implications
4. Quality Assurance Programme and Monitoring & Evaluation
5. Supply Chain Management
6. Infrastructure Requirement and Equipment & Maintenance.
7. One Health Plan & Policies
8. Anti-Microbial Resistance (AMR) and Genomic Surveillance & Research
9. Emergencies and Pandemic Preparedness
10. Diagnostic Testing and Sample Referral System
11. Laboratory Data Management System
12. Biosafety & Biosecurity and Waste Management

5.0 Thematic Areas for MyNLSP

5.1 Leadership & Legal Consideration

Showcasing excellent leadership qualities, especially during a crisis, projects good governance of institutional bodies. It is also very important to have multi-sector agencies' cooperation and sharing of responsibilities, as well as sharing data for the management of outbreaks of infectious diseases of public health concerns. This is very important as part of pandemic preparedness. In addition, organisations must ensure their responses comply with legal requirements to avoid potential lawsuits and regulatory penalties. Effective crisis management integrates both legal and ethical considerations, not only complying with the law but also reflecting societal values and expectations.

5.2 Human Resources & Capacity Building

Human resources and capacity building can be defined as the development of knowledge, skills, and attitudes among individuals or groups of people. Capacity building also involves providing training and empowerment of individual employees in order to improve their job performance. Job skills should also reflect the current requirements, as there has been vast development of knowledge and skills, and the workforce should be trained according to the present needs. There is also a need to review the availability of resources to reflect market directions.

5.3 Financial Implication

Financial implications are critical for the implementation of strategies and activities under the MyNLSP. Many factors are involved in financing, including managing, planning, implementing and monitoring the activities. Based on the feedback from various stakeholders, the needs of agencies are different according to their priorities, strategies and activities. Thus, it is important for stakeholders to use MyNLSP for funding justification.

5.4 Quality Assurance Programme and Monitoring & Evaluation

The Quality Assurance Programme is one of the key indicators to monitor and evaluate the success of the MyNLSP program. In addition, it is critical for the recognition of the services provided by facilities under the MyNLSP. The M&E framework can be used to identify potential problems, provide remedies to overcome glitches, and progress towards

desired outcomes. It can assist leaders and staff to learn from experiences, allowing informed decisions and accountability.

5.5 Supply Chain Management

The supply chain of goods, reagents, equipment, and other essentials for the operation of a laboratory system is a complex network involving manufacturers, wholesalers, distributors, retailers, suppliers, and customers. Effective supply chain management is about optimizing the network to ensure all goods are delivered accurately, timely, and with maximum efficiency at all times.

5.6 Infrastructure Requirement and Equipment & Maintenance

All facilities providing laboratory services should have infrastructure and equipment, including maintenance, that comply with various regulations and/or standards. Maintenance and Calibration of equipment should comply with the manufacturer's recommendations. It includes standardization of apparatus and devices for personnel safety, health, environmental protection, and energy saving, which are an integral part of the laboratory.

5.7 One Health Plan & Policies

One Health Plan & Policies are an important aspect of routine and pandemic preparedness. Multi-agency collaboration involving human health, animal health and environmental health has transformed during pandemic preparedness to mitigate the impact of current and future health challenges at the human-animal-plant-environment interface at global, regional, and country levels. One Health aims to create a framework to integrate systems and capacities so that agencies can collectively prevent, predict, detect, and respond to health threats. The One Health Joint Plan of Action, developed through a participatory process, provides a set of activities that aim to strengthen collaboration, communication, capacity building, and coordination equally across all sectors responsible for addressing health concerns at the human-animal-plant-environment interface (refer to One Health policies).

5.8 AMR and Genomic Surveillance & Research

Through whole-genome sequencing (WGS) and metagenomics, we can articulate the complex dynamics of genetic changes and disease patterns, as well as the development of resistance of microbes. Genomic sequencing provides a high-resolution picture of AMR evolution and

transmission, as well as being pertinent in other pathogen surveillance, including viral agents of public health concern. Research into the development of newer tools based on bioinformatics is an important approach for scientists to be ahead of microbes, in terms of disease surveillance and the prediction of the next pandemic. There is a need to build capacity for genome sequencing and analysis among stakeholders in the country as well as in the region. This will go a long way for harmonisation and standardisation of surveillance systems, developing equitable data sharing and governance frameworks, and strengthening interactions and relationships among stakeholders at multiple levels.

5.9 Emergencies and Pandemic Preparedness

WHO has launched an initiative called Preparedness and Resilience for Emerging Threats (PRET) as a platform or opportunity for countries to be operationally ready to respond to infectious disease threats and showcase better coordination among relevant stakeholders. Thus, it is important to have a platform that enhances multi-agency cooperation through the sharing of data as well as promoting, strengthening integrated preparedness and responses.

5.10 Diagnostic Testing and Sample Referral System

The National Laboratory Strategic Plan efforts recognize the importance of strengthening laboratory systems, including competent personnel, infrastructure development, quality management, supply chain management, specimen referral system and results-reporting and laboratory quality management system. These are important and are prerequisites for providing efficient and quality diagnostic testing, for both routine and outbreak laboratory investigations. An efficient sample referral system is important, especially in resource-limited settings where samples need to be referred quickly to reference laboratories as part of good management of patients.

5.11 Laboratory Data Management System

A laboratory data management system is critical for the processing, organisation, and storage of scientific data. Effective laboratory data management in life sciences and healthcare is important for the laboratory as it ensures that the data collection is accurate, reliable, and accessible. There are many platforms that can be used, such as LIMS or LIS, but more importantly, there should be sufficient funding to sustain

the laboratory data management system, and the application should be extended to all laboratory levels.

5.12 Biosafety & Biosecurity and Waste Management

The increasing threats of emerging infectious diseases and the possibility of bioterrorism have led many countries to strengthen biosafety and biosecurity measures in the handling of infectious agents. All staff dealing with infectious agents must be trained in biorisk management (BRM) to minimise the risk of accidental exposure (biosafety issues) and intentional exposure (biosecurity issues). Regular training in BRM should be provided to all staff and include clinical waste management. In addition, the laboratory design and specification should comply with the requirements of international standards, according to the risk group of the biological agents.

6.0 Implementation, Monitoring and Evaluation

6.1 Implementation Framework

The strategic activities to be implemented in the 2025-2029 timeline of this strategic plan are captured (refer to Supplementary Edition). Responsibilities for the various activities, costing and implementation indicators were included.

The relevant stakeholders will spearhead the coordination of these activities based on strategies and thematic areas identified. Priority strategic activities were identified in line with the country's needs, and stakeholders were encouraged to align their support to these prioritized areas.

6.1.1 Review Meetings

The implementation of this strategic plan will be incorporated into the agenda of the Laboratory Technical Working Group (TWG). This will allow for regular tracking of progress on the planned activities, enable review of implementation plans, and facilitate necessary adjustments during these meetings.

6.1.2 Funding and Resources Mobilization

A national strategic plan is a significant initiative that requires substantial financial investment. While government budget allocations will provide foundational support, they may represent only a portion of the total funding needed. Therefore, it is essential to approach costing with diligence, considering factors such as annual inflation, fluctuations in workload, and potential public health developments. With a carefully prepared budget, additional funding opportunities can be proactively pursued. The following considerations will help guide this process:

1. Based on the costing, advocate for special funds to be specifically allocated for implementing the strategic plan by the government.
2. Standardize operations to bring the costs of reagents and supplies down through bundling and bulk purchases.
3. Consider setting up Public-Private Partnerships in selected laboratories to improve efficiency and generate income.
4. Seek support from international partners.

6.2 Monitoring and Evaluation

Monitoring and Evaluation (M&E) play a vital role in the successful implementation of this strategic plan, as they provide the means to assess both progress and the overall impact of achieving the strategic objectives.

Each strategic activity is accompanied by clearly defined performance indicators, outlined in the M&E plan matrix. These indicators serve as essential tools for regularly tracking activities, managing resources effectively, and enabling stakeholders to review data, measure progress in key areas, and make informed adjustments to goals, implementation strategies, and funding as needed.

The National Laboratory Strategic Plan, spanning from 2025 to 2029, will provide a comprehensive framework for strengthening and advancing laboratory services throughout Malaysia. It will be implemented in collaboration with government agencies and other key stakeholders.

7.0 Strategic Framework of the MyNLSP

The National Laboratory Strategic Plan pursues a shared vision and goals for expected laboratory services for the period 2025-2029, prioritizing 12 thematic areas. The pursued strategies, sub-strategies and strategic activities for each thematic area are described in the following implementation plan. As agreed, the responsibility of implementing each strategy and activity in the MyNLSP is shared by all stakeholders. In addition, information on the responsible agencies, resources needed, indicators of achievements and timeline are also captured and provided in Supplementary Edition Implementation of Activities: Monitoring and Evaluation.

The following are the five strategies that have been mentioned in para 4.3.2:

1. Strategy 1: Fostering Multi-Sectoral Leadership to ensure the availability and accessibility of functional laboratory services.
2. Strategy 2: Ensuring Attainability of Efficient and Excellent Laboratory Testing Services for All Public Health Laboratories.
3. Strategy 3: Strengthening Multi Sector Coordination Among Public Health Laboratories, Ensuring Effective Routine and Pandemic Preparedness Responses.
4. Strategy 4: Leveraging National, Regional and International Partnerships and Collaboration.
5. Strategy 5: Strengthening Regulations and Legislations for Smooth Operations of Laboratory Services.

Note: Certain thematic areas may not encompass all identified strategies; however, modifications and realignments can be considered during the mid-term review process.

7.1 Implementation Plan of MyNLSP 2025-2029

7.1.1 Thematic 1: Leadership and Legal Considerations

Strategy 1: Fostering multi-sectoral leadership to ensure the availability and accessibility of functional laboratory services

Sub-strategy 1: Strengthen the framework for leadership succession to ensure the operational stability of public health laboratory services in the country.

Activities:

i. Create a structured mentor-mentee program to support succession planning and enhance leadership development across all levels within public health laboratories (i.e. Global Laboratory Leadership Programme).

ii. Implement a regular Training of Trainers (ToT) program to support succession planning and enhance leadership development across all levels within public health laboratories (i.e. Global Laboratory Leadership Programme).
iii. Implement a structured mentor-mentee program across all levels within public health laboratories (i.e. Global Laboratory Leadership Programme).

Strategy 5: Strengthening regulations and legislations for smooth operations of laboratory services

Sub-strategy 1: Improve the existing legal and regulatory frameworks to enhance the uniformity and quality of services across public health laboratories.

Activities:

i. Revise existing legal frameworks on mandatory laboratory licensing for medical laboratories by drawing on the experiences of regional and international networks (i.e. Act 674, Act 586).

7.1.2 Thematic 2: Human Resources & Capacity Building

Strategy 1: Fostering multi-sectoral leadership to ensure availability and accessibility of functional laboratory services

Sub-strategy 1: Strengthen the laboratory HR capacity to keep pace with the rapidly evolving technologies.

Activities:

i. Conduct regular needs analysis and planning to address the growing HR demands driven by rapidly evolving technologies.
ii. Implement short, targeted training sessions (micro-learning) focusing on specific skills or knowledge areas.
iii. Incorporate training and capacity building in automation and AI use into the KPIs for various health professional schemes.
iv. Conduct regular training on rapidly evolving technologies via virtual or physical platforms.

Strategy 3: Strengthening multi-sector coordination among public health laboratories, ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Enhance laboratory workforce surge capacity through multisectoral coordination.

Activities:

i. Identify gaps in the surge capacity at all public health laboratories

ii. Formalize surge capacity agreements within public health laboratories for shared workforce and resources during surges.
iii. Organize regular training sessions to equip laboratory staff within public health laboratories with skills for surge situations.
iv. Conduct frequent multisectoral simulation exercises to test the coordinated response during surge situations.

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Build HR capacity and competency by securing training opportunities through external partners.

Activities:

i. Collaborate with external partners to expand quotas and scholarships for further study.
ii. Collaborate with external partners to increase the training opportunities for subject matter experts (SMEs).

7.1.3 Thematic 3: Financial Implications

Strategy 1: Fostering multi-sectoral leadership to ensure availability and accessibility of functional laboratory services.

Sub-strategy 1: Leverage strong government commitment and detailed financial planning to create a diversified funding allocation model that can withstand economic fluctuations.

Activities:

i. Review funding allocation model to adjust for rising healthcare costs and ensure the maintenance of service quality.
ii. Provide training on leveraging automated cost analysis tools and price forecasting models to improve budgeting accuracy amid global economic fluctuations.
iii. Establish Trust Funds for supporting public health laboratories at ministries other than the Ministry of Health (MOH).

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories

Sub-strategy 1: Develop cost-cutting strategies through cost analysis, strategic procurement, cost-effective technologies, and waste management.

Activities:

i. Conduct cost-benefit studies on the consolidation of public health laboratory services.
ii. Identify opportunities for implementing cost-effective technologies across all levels of laboratory activities within public health laboratories.

Strategy 3: Strengthening multi-sector coordination among public health laboratories ensuring effective routine and pandemic preparedness and responses.

Sub-strategic 1: Enhance existing financial tracking systems to ensure efficient fund usage during economic downturns and unpredictable disease outbreaks.

Activities:

i. Conduct awareness training on contingency fund usage during surge situations and unpredictable events.
ii. Develop a guideline on robust financial planning to enhance preparedness and resilience for future pandemics and surge situations.

7.1.4 Thematic 4: Monitoring & Evaluation and Quality Assurance Programme

Strategy 1: Fostering Multi Sectoral Leadership to ensure availability and accessibility of functional laboratory services

Strategy 4: Leveraging national, regional and international partnerships and collaboration

Sub-strategy 1: Encourage collaboration between national, regional and international associations, academia, organizations and standards bodies to attain minimal Laboratory Quality Assurance standards across sectors, ministries and departments for continuous monitoring and surveillance through Laboratory QA/QMS/Key Performance Indicators /National Indicator Approach /Quality Indicator programs.

Activities:

Establish a Steering Committee and Technical Working Group

Form a dedicated technical team focused on capacity building to monitor and enhance laboratory quality services. This team will provide education and training on essential aspects such as method verification/validation, lot-to-lot assessments, measurement of uncertainty, monitoring IQC/quality indicator and

ensuring metrological traceability- referring to DG of Health Special Meeting

i. Identify opportunities for implementing cost-effective technologies across all levels of laboratory activities within public health laboratories.
ii. Promote participation in Laboratory Quality Assurance (LQA) programs (EQA/ILC) at the national, regional level through these international bodies.
iii. Promote staff training applications in Quality Assurance via national, regional and international training centres/bodies to support quality assurance programs.
iv. Establish a National PT/EQA Provider. Develop a national Proficiency Testing (PT) and External Quality Assessment (EQA) provider to support laboratory quality.
v. Leverage on the regionally and internationally recognized pool of trainers for mitigating the high cost for implementation and maintenance of quality services according to national/regional/international practice.

Strategy 2: Ensuring the attainability of efficient and excellent laboratory testing services for all public health laboratories

Sub-strategy 1: Establish a registry of laboratories in Malaysia through the usage of available digital tools for monitoring and evaluation for Quality Assurance programs.

Activities:

i. Leverage on available digital tools for the development of the registry for capacity building by creating a survey or e-form for the initiation of the registry of laboratories and its services within the country.

7.1.5 Thematic 5: Supply Chain Management

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Improve details on laboratory supply chain management by leveraging regional collaboration for better laboratory services, diagnostic access and therapeutics, in order to sustain and diversify the supply chain for managing price inflation and economic irregularities.

Activities:

i. Develop and implement an integrated supply chain management electronic database, incorporating digital systems and data analytics for effective stockpile management, real-time inventory visibility, efficient procurement processes and enhanced supply distribution.

Sub-strategy 2: Enhance inter-agency and inter-ministerial coordination to facilitate effective networking in procurement, storage, and distribution processes to ensure safety, compliance, and efficiency.

Activities:

i. Designate a primary agency or ministry to launch and spearhead the partnership utilizing established documentation processes.
ii. Secure additional resources for deployment and distribution by diversifying suppliers through local and international platforms for mitigation management during natural disasters and geopolitical events.

7.1.6 Thematic 6: Infrastructure Requirements, Equipment and Maintenance

Strategy 1: Fostering multi-sectoral leadership to ensure availability and accessibility of functional laboratory services.

Sub-strategy 1: Advocate for the development and enforcement of legislation and policies that address laboratory infrastructure needs, considering geographic and logistical challenges to ensure equitable distribution and access.

Activities:

i. Develop a strong policy framework to enhance resilience against natural disasters and aging infrastructure by defining inter-ministerial responsibilities, improving coordination, and securing funding for technological upgrades that ensure safe, hygienic infrastructure to manage pandemic and disaster risks.

Strategy 1: Fostering multi sectoral leadership to ensure availability and accessibility of functional laboratory services

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Address disparities in national laboratory infrastructure by exploring alternative financing mechanisms and public-private partnerships to secure adequate financial support for upgrading aging infrastructure, purchasing and maintenance of equipment to ensure high-quality and reliable services.

Activities:

i. Close financial support gaps by fostering public-private partnerships to secure funding, mitigate the effects of natural disasters, and address aging infrastructure.
ii. Implement preventive maintenance programs in collaboration with qualified external partners to enhance the sustainability and efficiency of laboratory services.
iii. Invest strategically in modernizing outdated equipment to ensure laboratories remain aligned with technological advancements.
iv. Expand the use of mobile labs to address geographic and logistical challenges, ensuring equitable access to laboratory services across diverse regions.

Strategy 5: Strengthening regulations and legislations for smooth operations of laboratory services.

Sub-strategy 1: Advocate for the development and enforcement of legislation and policies that address laboratory infrastructure needs, considering geographic and logistical challenges to ensure equitable distribution and access.

Activities:

i. Promoting and ensuring laboratory compliance with applicable laws, regulations, and ISO management system standards by addressing infrastructure, equipment, and maintenance requirements. Pursue accreditation from recognized authorities to enhance service reliability and build confidence in the laboratory's quality management system, supporting sustained improvement and global recognition.

7.1.7 Thematic 7: One Health Plan & Policies

Strategy 1: Fostering multi sectoral leadership to ensure availability and accessibility of functional laboratory services.

Sub-strategy 1: Strengthening laboratory skilled workforce and capacity building in multi sectors at all levels through national, regional and international funding, technical assistance, and technological advancements, to minimize the impact of emerging zoonotic infectious diseases and AMR, and climate change.

Activities:

i. To conduct Interagency meetings for capacity building and workforce.
ii. To conduct inter sectoral laboratory technical meeting for coordination and consideration.

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Optimizing mechanisms for standardization of laboratory SOPs and guidelines for human and zoonotic disease, food, environment, and surveillance systems..

Activities:

i. Review and update policies/guidelines /laboratory SOP by incorporating technological advancements when necessary.

Sub-strategy 2: Fostering and enhancing policy and guidelines to outbreak response and emergencies through national, regional and international collaboration, technical assistance and technology.

Activities:

i. Review and update policies/guidelines /laboratory SOP by incorporating technological advancements when necessary.

Strategy 3: Strengthening multi-sector coordination among public health laboratories ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Leveraging technological advancements for rapid detection, genomic analysis and data sharing in One Health.

Activities:

i. To strengthen the data sharing (events, surveillance, publications) on the Malaysia One Health AMR (MyOHAR) platform.

Sub-strategy 2: Strengthening timely systematic monitoring and surveillance system including data sharing among multi-sectors to minimize the impact of emerging zoonotic infectious diseases and AMR, and climate change.

Activities:

i. To execute and improve the Integrated One Health AMR surveillance.

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Enhancing collaborative research through national and international partners funding on One Health integrated surveillance and emerging diseases.

Activities:

i. Enhancing collaborative research through national and international partners funding on One Health integrated surveillance and emerging diseases.
ii. Whole genome sequencing (WGS) one health surveillance on selected pathogens.

Sub-strategy 2: Fostering resources for One Health Initiatives through international technical assistance and funding bodies.

Activities:

i. Engagement with potential funding bodies to secure resources and funding for One Health activities.

7.1.8 Thematic 8: AMR and Genome Surveillance & Research

Strategy 1: Fostering multi sectoral leadership to ensure availability and accessibility of functional laboratory services.

Sub-strategy 1: Enhancing coordination and communication among public-private partnerships, while simultaneously investing in laboratory workforce development through funding, technical support, and technological innovation, will strengthen expertise across all level. Together this efforts will drive effective

responses to emerging infectious disease, AMR, and climate change, fostering more resilient health system.

Activities:

i. To conduct meetings among stakeholders on coordination and communication for comprehensive AMR and genomic surveillance programs.

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Strengthening the genomics and bioinformatics workforce through career growth, global partnerships, and modern technology.

Activities:

i. Conduct joint training program for genomic testing for rapid detection and response among public and private sectors.

Strategy 3: Strengthening multi-sector coordination among public health laboratories ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Enhancing multisectoral collaboration and communication for AMR and genomic surveillance by securing international funding, expertise support.

Activities:

i. Develop public-private partnership proposals by organizing AMR and genomic surveillance workshops.
ii. To establish a pathogen genomic surveillance strategy.

Sub-strategy 2: Develop the mapping of genomic facilities and expertise to strengthen the response to climate change-related AMR risks.

Activities:

i. Create a database of genomic facilities and expertise
ii. To establish a pathogen genomic surveillance strategy.

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Enhancing national, regional & international partnerships and collaborations on technological advancement of AMR and genomic testing.

Activities:

i. Joint training among stakeholders on AMR and genomic testing.

Strategy 5: Strengthening regulations and legislations for smooth operations of laboratory services.

Sub-strategy 1: Enhancing national, regional & international partnerships and collaborations on technological advancement of AMR and genomic testing.

Activities:

i. To revise policies on the use of antimicrobial agents and strengthen enforcement activities on a regular basis.

7.1.9 Thematic 9: Emergencies & Pandemic Preparedness

Strategy 1: Fostering multi sectoral leadership to ensure availability and accessibility of functional laboratory services.

Sub-strategy 1: Strengthening Laboratory Network at national and regional level.

Activities:

i. Regular inter sectoral laboratory technical meeting for coordination and consideration.

Sub-strategy 2: Laboratory simulation exercise for all hazards.

Activities:

i. Top stakeholders table top exercise.

Sub-strategy 3: Multi sectoral and multi agencies laboratory leadership training using Laboratory Leadership Curriculum Modules developed.

Activities:

i. Training workshop (i.e. Global Laboratory Leadership Programme module)

Sub-strategy 4: Multi sectoral and multi agencies laboratory leadership training using Laboratory Leadership Curriculum Modules developed.

Activities:

i. Yearly Training workshop (i.e. Global Laboratory Leadership Programme module)

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Strengthening timely and quality laboratory detection.

Activities:

i. Training for laboratory based- testing molecular protocol for priority pathogens and parameters for food and environment samples.
ii. Training for development for in-house protocol development for multiplex panel and design and synthesizing primer probe for priority testing.

Sub-strategy 2: Enhancing national essential diagnostic lists at all tiered levels.

Activities:

i. Review and update national essential diagnostics list including diagnostic lists for national and global priority diseases and hazards.

Strategy 3: Strengthening multi-sector coordination among public health laboratories ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Strengthening coordination of the National Disaster Management Plan including One Health Approach to minimize resource disruption and reduce risk of zoonotic disease transmission (taken from Strategy 1).

Activities:

i. Review policy/guideline/manual -update the *Pelan Pengurusan Bencana* KKM (National Disaster Management Plan) regularly as and when necessary

Sub-strategy 2: Enhancing information resources and systems to inform public health actions through partnership and collaboration during an emergency situation.

Activities:

i. Enhancement of public health network websites for example https://myohar.moh.gov.my/.

Sub-strategy 3: Strengthening inter-agency coordination and engagement to ensure timely responses and surge capacity during pandemics.

Activities:

i. Strengthen comprehensive laboratory emergency plans for pandemic preparedness.

Sub-strategy 4: Enhancing resources mobilization and standardizing procedures for emergency preparedness, response and recovery during pandemics and health threats.

Activities:

i. Strengthen partnerships between governments, international organizations, the private sector (i.e. pharmaceutical companies, manufacturers of personal protective equipment) to ensure rapid mobilization of human, financial and material resources during health emergencies.

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Strengthening communication and engagement with internal and external partners at an early phase of threat.

Activities:

i. Develop communication channel with regional and international partners to strengthen coordination and responsiveness in emergency preparedness efforts (i.e. video conferencing, conferences network)

7.1.10 Thematic 10: Diagnostic Testing & Sample Referral System

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Leveraging advanced diagnostic techniques and skilled laboratory personnel by investing in new technologies and automation and Addressing limited testing locations and equipment maintenance capabilities.

Activities: Procurement in Cutting-Edge Equipment, automated systems and Digital Technologies. This will improve workflow efficiency, increase longer lab operation hours and increase testing capacity without the need for multiple locations.

i. Training and Professional Development.
ii. Secure funding for equipment maintenance.

Strategy 3: Strengthening multi-sector coordination among public health laboratories, ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Enhancing comprehensive laboratory network, well-defined SOPs and framework for mobilizing mobile/field lab to quickly scale up testing capacities during unpredictable outbreaks or pandemics.

Activities:

i. Develop a Comprehensive Emergency Response SOP for Labs and establish a central authority to oversee the entire laboratory network with details on how to activate mobile/field labs, rapid deployment, mobilize personnel, and prioritize testing during outbreaks.

Sub-strategy 2: Optimizing the comprehensive laboratory network and establishing sample referral and transportation systems to mitigate the impact of disruptions in logistics during natural disasters.

Activities:

i. Develop SOP for sample transportation during Disaster, and to review existing Guideline (i.e. Guideline for the safe transport of clinical specimens and infectious substances in Malaysia)
ii. Formulate Partnerships for Resource Sharing with relevant agencies

7.1.11 Thematic 11: Laboratory Data Management System

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Enhancing seamless data management between the public and private sectors by implementing an integrated LIMS in all health facilities, including POCT.

Activities:

i. Develop integrated LIMS systems and Digital Technologies.

Strategy 3: Strengthening multi-sector coordination among public health laboratories ensuring effective routine and pandemic preparedness and responses.

Sub-strategy 1: Utilizing the existing comprehensive system and effective interagency data sharing platform to integrate information systems across various tiers, thereby improving data flow and communication.

Activities:

i. Harmonise MOUs /agreements between agencies. Create common data-sharing agreements that facilitate the exchange of information while ensuring data privacy and security.

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Integrating the established LIMS with open-source bioinformatics workflows and cloud computing to boost data processing, improve data access and enhance collaboration.

Activities:

i. Upgrading ICT equipment with cost-effective cloud-based solutions.
ii. Providing training and support to fully harness the capabilities of existing IT systems
iii. Mitigate the risks for breach of data security and transmission through the capacity building.

7.1.12 Thematic 12: Biosafety & Biosecurity and Waste Management

Strategy 2: Ensuring attainability of efficient and excellent laboratory testing services for all public health laboratories.

Sub-strategy 1: Enhancing biosafety practices, especially for handling unknown or novel pathogens, by addressing the shortage of skilled laboratory personnel.

Activities:

i. Training and Capacity Building.
ii. Appointment of Biosafety Committee in relevant agencies

Strategy 4: Leveraging national, regional and international partnerships and collaboration.

Sub-strategy 1: Utilizing the established Institutional Biosafety and Biosecurity Committees along with international partnerships with reliable equipment suppliers to ensure compliance with protocols and standards.

Activities:

i. Review existing national guidelines for BSL facilities, including maintenance and backup plans

7.2 Supplementary Edition Implementation of Activities: Monitoring and Evaluation (Please refer website NPHL *www.mkak.moh.my*)

8.0 Conclusion and Recommendation

The development of MyNLSP 2025–2029 represents a significant milestone in strengthening the laboratory services across the country. This comprehensive plan, rooted in the One Health approach, underscores the importance of integrated efforts between multiple sectors—including human health, veterinary, environmental, and food safety laboratories—to enhance disease surveillance, emergency preparedness, and laboratory capabilities. The strategic plan builds on past experiences from public health crises like COVID-19 and reflects the urgent need for coordinated action, improved data sharing, and sustainable capacity building. The situational analysis has identified both strengths and gaps, highlighting the necessity for systemic reforms in leadership, quality management, infrastructure, legal frameworks, and human resource development to support a resilient and responsive laboratory network.

To ensure successful implementation, it is recommended that all stakeholders commit to the strategies outlined in the MyNLSP, particularly those focusing on multi-sectoral collaboration and legislative harmonization. Establishing a robust governance and monitoring system will be crucial for tracking progress and making necessary adjustments. Additionally, it is imperative to secure diversified funding sources, enhance training and knowledge exchange across sectors, and leverage technological advancements such as genomic surveillance and digital laboratory management systems. These efforts will not only improve national health security but also position Malaysia as a regional leader in laboratory excellence and public health response.

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10.0 Appendices

Appendix 1: Summary of total sub-strategies and activities according to thematic areas

There are a total of 43 Sub-strategies and 73 Activities under 12 Thematic Areas, as shown below: -

Thematic area	Sub-strategies/ Activities	Total
1. Leadership & Legal Considerations	Sub-strategies	**2**
	Activities	**4**
2. Human Resources & Capacity Building	Sub-strategies	**3**
	Activities	**10**
3. Financial Implications	Sub-strategies	**3**
	Activities	**7**
4: Monitoring & Evaluation and Quality Assurance Programme	Sub-strategies	**2**
	Activities	**6**
5: Supply Chain Management	Sub-strategies	**2**
	Activities	**3**
6: Infrastructure Requirements & Equipment and Maintenance	Sub-strategies	**3**
	Activities	**6**
7. One Health Plan & Policies	Sub-strategies	**7**
	Activities	**6**
8. **AMR and Genome Surveillance & Research**	Sub-strategies	**6**
	Activities	**7**
9. **Emergencies & Pandemic Preparedness**	Sub-strategies	**6**
	Activities	**8**

10. **Diagnostics Testing and Sample Referral System**	Sub-strategies	**4**
	Activities	**8**
11. **Laboratory Data Management System**	Sub-strategies	**3**
	Activities	**5**
12. **Biosafety & Biosecurity, Waste Management**	Sub-strategies	**2**
	Activities	**3**
Total (**Sub-strategies**)		43
Total (**Activities**)		73

Appendix 2: Example data collection form for TO2 (Key Informant Questionnaire)

Questionnaire to Key Informants : NLSP Malaysia

Description:

Based on the RPHL situational analysis report 2023 has identified several gaps in the National Laboratory System in Malaysia, which warrant for the need to establish National Laboratory Strategic Plan (NLSP). Thus, Malaysia has proposed for development of NLSP as stated in the RPHL workplan 2024-2028. An approval has also been granted in the National Laboratory Technical Advisory Committee (NLTAC) Meeting conducted on 9 December 2023. There are 20 thematic areas relevant to diagnostics and laboratory that NLSP Malaysia team would like to assess to determine the strength and needs of the country with regard to capacity building.The primary goal of this initiative is to develop a NLSP for Malaysia that considers the current national situation and requirements by adopting integrated and One Health Approach, adheres to global standards and best practices, and encourages robust country leadership and stakeholder involvement for effective execution.

Instruction:

Most questions below are answerable by Yes or No or Not Applicable. Kindly choose the answer and provide the document, comment or any appropriate explaination.This will take approximately 45-60 minutes of your time.

Key Informant Information:

Name of key informant :	
Designation :	
Enail address:	
No Telephone :	
Laboratory : Human / Veterinar/ Food/ other (please specify)	
Institute :	
Affiliation: (Public/Private)	

	1. National Leadership/ Governance of Diagnostic systems/services including NLSP	Answer	Material	Comments
1	Is there a Laboratory Strategic Plan of your laboratory? If yes please provide the soft copy of the Laboratory Strategic Plan.	YES	UPLOAD https://shorturl.at/nB	
2	Is there a test registry or handbook of your laboratory? If yes, please provide the soft copy of the test registry /handbook. If not, are there any plans to develop one? Please provide answer in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
3	Do you have a functional national lab technical working group/s? If yes, please provide all the name of the technical working group/s. Please provide answer in **comments** column. If not, in your opinion, is there any need to develop one? Please provide answer in **comments** column.	YES		
	2. Laboratory Program Structure			**Comments**
1	Is there a Laboratory Program structure example based on discipline (ie anatomy, microbiology, biochemistry, genetic, drug residue, natural contaminant etc) of your laboratory? If yes, please provide the soft copy of the Laboratory Program Structure.	YES	UPLOAD https://shorturl.at/nB	
	3. Infrastructure Requirement			**Comments**
1	Is the current infrastructure capacity is appropriate with the laboratory service? If not, please give the suggestion in the **comments** column.	YES		
	4. Test Requirement at each tier			**Comments**
1	How many tier(s) level of national laboratory setting example primary, secondary, tertiary level. Please provide answer in number in **comments** column.	YES		
2	Is there a test requirement at each tier of laboratory? If yes, please provide the soft copy of test requirement.	YES	UPLOAD https://shorturl.at/nB	

5. Financial Support				**Comments**
1	Is there a good funding to improves laboratory service? If yes, please upload the list of source. Alternativey, please provide answer in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
2	Is the funding well distributed to the respective laboratory? If not, please give the suggestion in the **comments** column.	YES	UPLOAD https://shorturl.at/nB	
6. Human resources				**Comments**
1	Is there enough human resources in your laboratory? If not, please give the suggestion in the **comments** column.	YES		
2	Is the staff is qualified and competent in giving technical laboratory service? If yes, please provide soft copy of list of qualification of the education and training If not please give the reason in the **comments** column.	YES	UPLOAD https://shorturl.at/nB	
7. Training				**Comments**
1	Is there adequate training for the technical personnel in your laboratory? If not, please give the suggestion.Please provide answer in **comments** column.	YES		
2	Is there any area of laboratory expert can be assisted by other experts from other laboratory/instituation ?	YES		
8. Career path lineated				**Comments**
1	Is there good carreer path in the laboratory profesion? If not, please give the suggestion in the **comments** column.	YES		

9. Quality Assurance Program				**Comments**
1	Is your laboratory accredited? If yes, please provide the soft copy of name/list of certificate (s).Alternatively please provide answer in comments column. If not, are there any plan to have soon? Please provide answer in **comments** column.	YES	Name of certificate (UPLOAD)	
2	Does your laboratory have the capacity to develop QC and SOP ? If yes, please provide the soft copy of list and support document? If not, are there any plans to develop one? Please provide answer in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
3	Does your laboratory have the capacity to develop EQA/PT and SOP? If yes, please provide the soft copy of list and support document? If not, are there any plans to develop one? Please provide answer in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
10. Sample referral system				**Comments**
1	Is there good sample referral system (between different laboratory tiers during normal versus ourbreak /emergency) of the laboratory in the country? If yes please provide the soft copy of the document.	YES	UPLOAD https://shorturl.at/nB	
11. Laboratory data management system				**Comments**
1	Is there good laboratory data management system of your laboratory? If not, please give the suggestion in the **comments** column.	YES		
12. Supply chain Management				**Comments**
1	Is there good supply chain management system of the laboratory in the country? If yes, please provide soft copy of the document. If not, please give the suggestion in the **comments** column.	YES	UPLOAD https://shorturl.at/nB	

13. Laboratory Facility Assessment/Equipment maintenance				**Comments**
1	Is there good equipment maintenance management system of your laboratory? If yes, please provide sofy copy an example of the PPM schedule. If not, please give the suggestion in the **comments** column.	YES	UPLOAD https://shorturl.at/nB	
14. Anti Microbial Resistance				**Comments**
1	Is there antimicrobial resistance test activities in your laboratory? If yes, please provide soft copy the example of the result. If not, are there any plans to develop it.Please provide plan in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
2	Is there is international networking example WHO net in term of sharing of antimicrobial resistance data of your laboratory with others country? If yes, please provide name of networking. Alternatively please provide answer in **comments** column. If not, are there any plans to develop one?Please provide plan in **comments** column.	YES	Name of networking (UPLOAD	
15.One health approach plan and policies				**Comments**
1	Is there one health approach of any laboratory activities? if yes, please give the example. Please Provide example in **comments** column. If not, are there any plans to develop one?Please provide plan in **comments** column.	YES		
2	Are there needs to improve the One Health approach in your laboratory? If yes,please give suggestion.Please provide suggestion in **comments** column. If not,please state the reason.Please provide reason in **comments** column.	YES		

16. Emergency and pandemic preparedness				**Comments**
1	Is there any lab specific emergency plan in response to outbreaks/ threats/emerging bio-threats? If yes, please provide soft copy the document. If not, are there any plans to develop one? Please provide plan in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
2	Are there any guidelines for labs on disease notification covering all diseases of your laboratories.	YES		
17. Legal consideration, regulation and licensing				**Comments**
1	Did you working under any act example pathology act for your laboratory activities? If yes, please provide the soft copy of the Act. Alternatively please provide the list of act in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
2	Is there national laboratory registration in placed? If yes, .Please provide the soft copy of your national laboratory registration. If not, are there any plans to develop one? Please provide plan in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
18. Laboratory Genomic activities				**Comments**
1	Is there are genomic diagnostic activities run in your laboratory? If yes, give the example.Please provide example in **comments** column. If not, are there any plans to develop one? Please provide plan in **comments** column.	YES		
2	Is there are genomic surveillance activities run in your laboratory? If yes, give the example.Please provide example in **comments** column. If not, are there any plans to develop one? Please provide plan in **comments** column.	YES		

19. Biosecurity and Bio safety and waste mangement				**Comments**
1	Is there biosafety laboratory level 4 at your laboratory? If yes, how many? Please provide number in **comments** column.	NO		
2	Is there biosafety laboratory level 3 at your laboratory? If yes, how many? Please provide number in **comments** column.	YES		
3	Is there enough autoclave at your laboratory?	YES		
4	Is there a waste management system in place? If yes, please provide soft copy of the document. If not, are there any plans to develop one? Please provide plan in **comments** column.	YES	UPLOAD https://shorturl.at/nB	
20. Monitoring & Evaluation				**Comments**
1	Do you think you laboratory has good monitoring and evaluation system of your laboratory plan strategic? If yes, please provide soft copy of the the evidence If not, please give suggestion to improve. Please provide the the suggestion in **comments** column.	YES	UPLOAD https://shorturl.at/nB	

Appendix 3: Example data collection form for TO3 (Laboratory Facility Assessment)

USER INSTRUCTIONS:

Please read this user instruction thouroughly before filling in the questionnaires

The questionnaire is provided in Excel format using automatic calculations. The file includes 17 worksheets entitled in English. Majority of the worksheets are protected against any modification to avoid performing incorrect manipulations that may compromise calculation. Please do not modify or rename the worksheets as this may result in calculation error and possibly compromise interpretation of data. In case of modification/revision in the wording is needed, this in the should be done only in "Language" worksheet as the cells of other modules report to the "Language" worksheet.

To ensure correct interpretation, please also make sure to answer to all questions (using the "Non applicable" answer when needed) and to select the answer that best describes the current situation for each question.

The questionnaire is in English by default. To switch from English to Thai select the "Language" tab, toggle the cell number A3 from 1 (English) to 2 (Thai). Thai language translation is added to be Thailand specific context. You can choose the appropriate column number in cell A3 to change the language.

To start the assessment, go to the "Lab" worksheet and fill in all the requested cells in column B.

Afterwards, fill in all the requested cells (columns D and E) of the 11 specific module worksheets and the gap analysis module. A color formatting was added to ensure no questions are missed - in particular, the cells in column D will remain light orange if blank. For most of the questions, clicking the small arrow at the right side of the answer cells (generally in column D) opens a dropdown list with authorized values: 1.Yes; 2.Partial; 3.No; 4.Non applicable. An error message will appear when trying to enter values other than the ones listed in the dropdown list. Other values can be entered (generally in column E) when asking "Number of equipment", "Number of tests performed", "Please describe", etc. A cross in column C indicates that documents are required to validate the answer. Additional information can be given in column E or in the comment box at the bottom of each worksheet. When no answer is expected in column D (in the case of an open question for instance), the corresponding cell in column D is shaded out. All answers in grey or light blue color cells in Column D will be taken into account to calculate the capacities indicators.

A gap analysis worksheet has been added to determine the overall biggest need/weaknesses in the system. For most questions, clicking the small arrow at the right side of the answer cells (generally in column C) opens a box with allowed values: 0,1,2,3,4,5. These numbers represents a score from 0 (no gap) to 5 (high gap). In column D, please comment on the area/s showing the biggest weaknesses (score 4 and 5). Scores graphics are automatically generated.

Use the "Summary" worksheet to visualize the average indicator for the laboratory core competencies and capababilities. Indicators are automatically calculated and graphics are generated. Add pictures, additional comments and conclusions in the dedicated text boxes as needed.

1. Organization and management

83%

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

"Change this topic to "1. Leadership, Organization and Management (policies, legal and regulatory framework, technical and administrative management structures)"

		Documents required	Responses	Provide here the answer to the open question/s and/or any additional information		
	Service hours					
1.1	*What are the days and hours of operation of routine service?*					
1.2	*If relevant, how many shifts of operation available?*					
	External communication					
	Is the laboratory equipped with:					
1.3	Telephone (landline)?		1		100%	100%
1.4	Fax?		1		100%	
1.5	Computer/laptop with internet access?		1		100%	
1.6	Mobile phone with data connection?		1		100%	
	Internal communication and structure					
1.7	Is there an organizational structure defining the lines of authorities and responsibilities for key laboratory staff?		1	ddd	100%	100%
1.8	Are staff meetings organized at least once a month?		1		100%	100%
1.9	*Please describe the means by which information is internally communicated (notice board, e-mail, etc.).*					
1.10	Do laboratory representatives participate in hospital/institution board meetings as relevant?		1		100%	100%

	Budget		<-- *cross-cutting subtopic*			
1.11	Is the budget for staff salaries adequate for the need?		1		100%	100%
1.12	*Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)*		x			
1.13	Is there an adequate budget for laboratory (e.g. staff training/development, consumables, reagents, equipment purchase/maintenance, surveillance,etc.)? Please, specify		2		50%	50%
1.14	*Please indicate the source of funds (proper funds, relevant ministry, NGO, specific networks, etc.)*		x			
	Licensing/Supervision/Accreditation					
1.15	Has the laboratory been licensed (i.e. authorized to operate) by the authorities? If licensing is not required, please indicate "Non applicable".	X	2		50%	50%
1.16	Has the laboratory undergone an audit or assessment by a third party within the last two years and implemented recommendations where relevant? If yes or partial, please provide details.		2		50%	50%
1.17	Does the laboratory hold any form of accreditation (ISO 17025, ISO 15189, WHO polio or measles, etc.)?	X	1		100%	100%
1.18	*If yes, please detail the relevant standards and the names of the accreditation bodies.*		x			
	Comments					

Appendix 4: Example data collection form for TO4 (Laboratory Systems

1. Coordination and management — 100%

Possible answers (unless otherwise advised): 1.Yes; 2.Partial; 3.No; 4.Non applicable

		Documents required	Responses	Provide here the answer to the open question/s and/or insert any additional information
	Coordination			
1.1	Does the relevant Ministry have a dedicated unit in charge of health laboratory coordination? If yes, please provide name/s, terms of reference and contact details of the unit and responsible person/s	X	1	
1.2	Has this unit have a dedicated budget?		1	
1.3	Has this unit provide an oversight role of reference laboratory designation and operations?			
1.4	Does this unit participate in public health-related committees such as influenza preparedness committees, emergency committees, or			
1.5	Does the coordinating unit coordinate its activities with the Ministry of Agriculture or its relevant agencies?			
1.6	Does the coordinating unit coordinate its activities with the Ministry of Environment or its relevant agencies?			
1.7	Is there a national policy for health laboratory services defining the goals and objectives of the national laboratory system?	X		
1.8	Is there a strategic plan aiming at strengthening laboratory services or other strategic plan/s with a laboratory component?	X		
	Funding			
	How are the laboratory services funded (for each source, specify percentage of funding)?			
1.9	Government or public health insurance			
1.10	User's fees			
1.11	Donors			
1.12	Other (specify)			
1.13	Is there a specific budget assigned for public health laboratory activities (such as reference laboratories and networks operations)?			
1.14	Are testing prices regulated? If yes, specify if recommended by national, social security/public health insurance or private health insurance.			

Equipment and supply management

1.15	*Please describe the procurement system/s for public laboratories (centralized or decentralized purchasing and storage, bulk or small purchasing, quality of supplies, suppliers' location, etc.) and provide all necessary documents*	X	X	
1.16	*Please describe the procurement system/s for private laboratories (centralized or decentralized purchasing and storage, bulk or small purchasing, quality of supplies, suppliers' location, etc.) and provide all necessary documents*	X	X	
1.17	Do disease-specific control programmes (e.g. TB, malaria) use specific procurement systems?			
1.18	Are there national guidelines on laboratory equipment donations?			
1.19	Are coordination mechanisms established with donors for equipment and supply donation or procurement?			
1.20	Do the donors or partners (e.g. NGOs, international organizations, foundations) follow national regulations for equipment or supply procurement (e.g. distribution of qualified IVD devices only)?			

Comments

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