GOVERNMENT OF SAMOA

NATIONAL MEDICAL LABORATORY POLICY & ACTION PLAN FY 2024/25 – FY 2028/29

MINISTRY OF HEALTH

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Foreword

Hon. Valasi Luapitofanua T. Selesele
MINISTER OF HEALTH

The implementation of International Health Regulations (IHR) 2005 is an important concern for the Government of Samoa, and we are all aware laboratory services is one of the core public health capacity in this regulation. Therefore, a comprehensive approach to strengthening health laboratory system in Samoa is required to harmonize health sector's collaborative efforts to implement communicable disease prevention and control strategies within Samoa as we had implemented during measles epidemic in 2019 and COVID-19 global pandemic from 2020 till 2022.

Realizing the importance of laboratory services, the Ministry of Health in collaboration with World Health Organisation spearheaded the development of this National Medical Laboratory Policy and Action Plan FY2024/25-FY2028/29 to assist Samoa's health sector with strengthening and enhancing of strategic and operational planning of Samoa's health laboratory system. All relevant stakeholders and partners were widely consulted to ensure the national ownership of this policy document as well as the commitment of all relevant partners in health.

I believe that this important policy document will lay the foundation for building a sound health laboratory system for Samoa.

It is the responsibility of the Ministry of Health as the leading agency for Samoa's health sector to provide leadership through regulation, policy and collaboration as well as direct service provision to assure that within resource constraints the most appropriate mix of laboratory services – diagnostic, surveillance and outbreak response is developed to achieve the best outcomes in health for all in order to achieve the health priority of the Pathway for the Development of Samoa (PDS) FY2021/22-FY2025/26) to **promote health and wellbeing** and the vision of Samoa's health sector for **A Healthy Samoa** as articulated in the Health Sector Plan FY2019/20-FY2029/30.

Ma le fa'aaloalo lava.

Hon. Valasi Luapitofanua To'ogamaga T Selesele
MINISTER OF HEALTH

Key Message

Aiono Dr. Alec Ekeroma
DIRECTOR GENERAL OF HEALTH

I am pleased to present the Samoa National Medical Laboratory Policy and Action Plan FY2024/25-FY2028/29, a crucial milestone in our commitment to advancing laboratory services in Samoa. This policy has been meticulously developed to align with Samoa national health priorities articulated in the Pathway for the Development of Samoa FY2021/22-FY2025/26, Health Sector Plan FY2019/2020 - FY2029/2030 and the MOH Interim Corporate Plan FY2023/24 - FY2024/25, marking a significant step forward in our efforts to enhance the quality and accessibility of laboratory services for the people of Samoa.

Samoa's healthcare landscape is dynamic and ever evolving, and the role of laboratories in ensuring the highest standards of diagnosis, treatment, and prevention cannot be overstated. In this era of healthcare challenges, it is imperative that our laboratory systems are robust, efficient, and well-coordinated. The Health Sector Plan 2019/20-2029/30 sets the course for **'A Healthy Samoa'**, emphasising equity, accessibility, and quality in healthcare services. The Samoa National Medical Laboratory Policy FY2024/25-FY2028/29 is a significant stride towards realising the objectives outlined in this long-term strategy. It underpins our commitment to enhancing the quality of healthcare service, and most importantly, ensuring the health and well-being of our people. Our Ministry's Interim Corporate Plan FY2023/24- FY2024/25 provides the necessary operational framework to implement the policies and strategies outlined in the Health Sector Plan FY2019/20-FY2029/30 in order to achieve national health indicators indicated in the Pathway for the Development of Samoa FY2021/22-FY2025/26. The laboratory services are an integral part of this framework, and the National Health Laboratory Policy will be instrumental in guiding our actions and investments.

The Samoa National Medical Laboratory Policy FY2024/25-FY2028/29 is a result of extensive collaboration between laboratory personnel, healthcare professionals, stakeholders, and international experts, with the primary focus on strengthening laboratory systems. It reflects the aspirations of our people for a healthcare system that is responsive, efficient, and resilient. It sets clear objectives and strategies to strengthen laboratory services, encompassing, diagnostics, surveillance, and research, in years to come.

The key objectives of this policy include:

1. **Enhancing Laboratory Infrastructure:** We are committed to investing in state-of-the-art laboratory equipment and facilities to ensure accurate and timely diagnostic services.
2. **Laboratory Quality Management System:** Ensuring the highest standards of quality systems including international accreditation to provide reliable test results.
3. **Workforce Development:** We recognise the importance of a skilled and motivated laboratory workforce and will support training and capacity-building initiatives.
4. **Effective Data Management:** Implementing robust digital data management systems to streamline information sharing and decision-making.
5. **Collaboration:** Fostering partnerships with international organisations, strengthening regional networks, and building relationships with stakeholders to leverage resources and expertise.
6. **Community Engagement:** Educating the public about the significance of laboratory services and encouraging proactive health-seeking behaviours.

This policy is not just a document; it represents our unwavering commitment to improving the health and well-being of Samoa's citizens. It aligns with the overarching goals of Samoa's Health Sector Plan 2019/20- 2029/30 and the MOH Interim Corporate Plan FY2023/24- FY2024/25, emphasising the

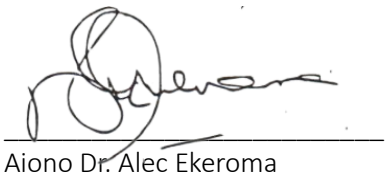
importance of evidence-based decision making, accessible health laboratory services, and **'A Healthy Samoa'** for all. One Health will be effectively supported through this policy by recognising the interconnectedness of human, animal, and environmental health and emphasising the need for stronger collaboration and coordination across the three sectors.

In conclusion, I would like to express my gratitude to all those who have contributed to the development of this policy, from the dedicated laboratory personnel, healthcare professionals and our valued partners, who have provided not only technical but also financial support. Special thanks to the World Health Organization for providing technical support, financial commitment and guidance on global best practices and insights. This collaboration reflects the commitment and dedication of many which has enabled and enriched the development of the National Health Laboratory Policy FY2024/25-FY2028/29 for Samoa.

The Samoa National Medical Laboratory Policy FY2024/25-FY2028/29 is a testament to our collective dedication to enhancing laboratory services within our country. It sets the course for a healthier and more prosperous future for our nation, and I am confident that its implementation will yield tangible benefits for our citizens. I encourage all stakeholders to embrace this policy and work together to realise its goals.

We look forward to its successful implementation and the positive impact it will have on healthcare in Samoa and its contributions to a 'Healthy Samoa'.

Ma le fa'aaloalo lava.



Aiono Dr. Alec Ekeroma
DIRECTOR GENERAL OF HEALTH

Executive Summary

Laboratory services, both clinical and public health functions are a critical component in building a strong national health system, through providing evidence-based diagnosis for the detection, management and prevention of diseases. Reliable, accessible and affordable laboratory services that produce quality assured results in a timely manner play a central role in supporting health decisions, guiding patient management, providing health data for national planning and mobilising resources. Lack of adequate infrastructure and system processes are obstacles to providing access to quality laboratory services. Limitations in proper resources, both financial and human, can result in a deficiency or delay in laboratory diagnostic results, and consequently providing less effective patient management and poorer health outcomes. Weaknesses in reporting systems causing delays in providing timely results and responding to disease outbreaks, can consequently lead to increased morbidity and mortality, especially in diseases of public health concern.

The National Medical Laboratory Policy (NMLP) FY2024/25-FY2028/29 provides the framework for strengthening the medical laboratory services in Samoa and supports the priority goals as defined by the Ministry of Health (MOH). The recognition of the necessity to formulate a NMLP and create a mandatory framework for comprehensive standards is a pivotal development. Medical laboratory is any facility that follows ISO15189 standards to conduct testing of human biological samples to aid in diagnosis, treatment, and prevention of diseases. In Samoa's context, there are two existing types of medical laboratories based on core functions; Clinical and Public Health. Each of these two disciplines focuses on different subspecialties of medical testing though they follow the same principles. This policy will play a critical role in standardising and enhancing quality healthcare services, providing a solid foundation for effective and efficient laboratory operations and service delivery.

The formulation of this NMLP was through extensive consultations across multiple sectors of the MOH, partners, healthcare professionals and other stakeholders. The collaborative and inclusive inputs from a wide range of perspectives and expertise, has contributed to a comprehensive and valuable policy. This policy will provide the framework for the coordinated development in strengthening the delivery of quality and accessible laboratory services in Samoa. The NMLP will be implemented through the National Medical Laboratory Strategic Plan (NMLSP) FY2024/25-FY2028/29 and Annual Operational Plans (AOPs) and supported through available resources, both domestic and international. Through the implementation of this policy the Tupua Tamasese Meaole (TTM) Hospital Laboratory will endeavour to achieve international accreditation and deliver international standards of best practice.

This policy defines the laboratory governance, coordination and collaboration structures and provides the foundation and guidance that will assure the delivery of quality medical laboratory services to all and support the priority health initiatives of the MOH. The Samoa NMLP 2024 has been designed to align with Samoa’s Health Sector Plan 2019/20 - 2029/30 and the MOH Interim Corporate Plan FY2023/24 - FY2024/25, and has been approved through the appropriate government channels, receiving full endorsement from the MOH.

The National Medical Laboratory Policy outlines a comprehensive and forward-thinking strategy to strengthen the laboratory services throughout Samoa by defining a clear Vision and Mission. The policy envisages safe, affordable and accessible quality laboratory services for ‘A Healthy Samoa’ with a mission to provide equitable and accessible quality laboratory services at all levels of healthcare in a timely manner. To carry out its mission, the laboratory service has defined the major policy objectives: (i) To enhance the capacity of the national health laboratories in providing accurate and timely diagnostic services to support clinical decision-making. (ii) To ensure adequate financial and human resources to meet the requirements of the health laboratory services. (iii) To contribute to public health surveillance by conducting testing and providing data and valuable information for the early detection, disease confirmation, and monitoring of disease outbreaks. (iv) To comply with national and

international standards and, regulations governing medical laboratories to ensure safety and quality. (v) To establish and maintain a robust quality assurance system to ensure the accuracy and reliability of laboratory test results. The laboratories shall adhere to a number of values in to fulfill their mission: quality, integrity, professionalism, patient-centred, innovation, and accountability. The laboratories are also guided by a number of principles: government commitment, equity, ethical values, stakeholder engagement, transparency and accountability, sustainability, integration, technology and innovation, partnerships, and community engagement. Fourteen policy objectives, for the key elements of the laboratory system, were developed and elaborated into policy statements by aligning them with the core values, guiding principles, and desired attributes of the laboratory services to achieve the vision and mission.

Abbreviations and Acronyms

ACEO	Assistant Chief Executive Officer
AMR	Antimicrobial resistance
AOP/s	Annual Operational Plan/s
APSED III	Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies III
BSC	Biosafety Cabinet
CD/s	Communicable Disease/s
CE	Conformité Européenne
COVID-19	Coronavirus disease 2019. An illness caused by the SARS-CoV-2 virus that was first identified in December 2019. Formerly known as 2019-nCoV
Epidemic	An outbreak or unusually high occurrence of a disease or illness in a population or area
EQA	External Quality Assurance
ESR	Environmental Science and Research
EUL	Emergency Use Listing
FDA	U.S. Food and Drug Administration
GOS	Government of Samoa
HCW	Health Care Worker (defined as doctors, nurses, community healthcare workers and other front line health personnel etc.)
HIS	Health Information System
HR	Human Resources
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
IATA	International Air Transport Association
IHR	International Health Regulations
ISO	International Organisation for Standardisation
LAT	Laboratory Assessment Tool
LIMS	Laboratory Information Management System
LQMS	Laboratory Quality Management System
M&E	Monitoring and Evaluation
MLS	Medical Laboratory Scientist
MLT	Medical Laboratory Technician
MOH	Ministry of Health
MOU	Memorandum of Understanding
MT II	Malietoa Tanumafili II Hospital
NCDs	Non-Communicable Diseases
NMLP	National Medical Laboratory Policy
NMLSP	National Medical Laboratory Strategic Plan
Pandemic	An epidemic on a global scale
POC	Point-of-care. The place where three elements come together: the patient, the HCW, and the care or treatment
PPE	Personal Protective Equipment (gowns, gloves, masks etc.)
PPTC	Pacific Pathology Training Centre
SARS-CoV-2	Severe acute respiratory syndrome coronavirus 2. The virus that causes COVID-19.
SAT	Samoan Tala
SOP/s	Standard Operating Procedure/s
SROS	Scientific Research Organization of Samoa
STI/s	Sexually Transmitted Infection/s
SWOT	Strengths, Weaknesses, Opportunities, Threats
TB	Tuberculosis
TGA	Therapeutic Goods Administration
TTM	Tupua Tamesese Meaole Hospital
TWG	Technical Working Group
UNDP	United Nations Development Programme
WHO	World Health Organization

Introduction

In the Asia Pacific region, health security is continually threatened by outbreaks of emerging infectious diseases, the impact of natural disasters and conflicts, and concerns related to food and water safety.[1] These unpredictable public health events necessitate constant vigilance and the development of core capacities to manage these threats, as mandated by the *International Health Regulations (2005)*, IHR (2005), which serves as the legal framework for Member States to detect, prepare and respond to public health emergences. The *Asia Pacific Strategy for Emerging Diseases (APSED)* provides a unified framework for action in the region, aimed at strengthening the core capacities required under IHR (2005). These capacities include the establishment of laboratory diagnostic capabilities for priority diseases and the implementation of biosafety and biosecurity practices.[2] Within the context of *Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies (APSED III),* the third focus area underscores the pivotal role laboratories play in ensuring health security. Laboratories contribution to disease surveillance, outbreak response, patient management, research and development, and policy formation.[1]

Reliable and timely results from laboratory investigations are critical elements for decision-making across the spectrum of healthcare. They also play a crucial role in disease surveillance, public health control, and addressing health security concerns. It is also essential for the surveillance and control of diseases of public health importance. Such results extend their influence beyond healthcare, impacting national economies and supporting the fulfilment of obligations under the IHR (2005). Furthermore, at the individual level, timely laboratory results are indispensable for ensuring the health and well-being of people. Enhanced disease recognition not only drives more effective public health planning it also increases the accuracy of health-related information.[3] In an era where evidence-based medical and public health practices are paramount, strengthening health laboratories becomes a compelling imperative. These laboratories serve as vital contributors, providing essential data in healthcare and public health.[4]

A well-functioning medical laboratory system comprises of essential elements that are fundamental to its effectiveness. Each of these elements plays a critical role in ensuring the efficiency and effectiveness of the laboratory system. Addressing these elements serves as the blueprint for establishing, strengthening, and sustaining national medical laboratory services. The cornerstone of this framework is the establishment of a national medical laboratory policy. This policy serves as the guiding document for the coordinated development and delivery of accessible, affordable, and high-quality national laboratory services. It systematically addresses critical issues essential for the efficient functioning of laboratory services, including, organisational and management structure, human resources, infrastructure, equipment procurement and maintenance, provision of laboratory supplies, establishment of a functional information management system, implementation of a quality management system and ensuring adequate financial support. This comprehensive approach reflects a steadfast commitment to creating a robust and sustainable healthcare laboratory system. The presence of a national medical laboratory policy demonstrates the government's dedication to providing quality

[1] Asia Pacific Strategy for Emerging Diseases and Public Health Emergencies. Advancing implementation of the International Health Regulations (2005). World Health Organization, 2017. Available from: https://apps.who.int/iris/handle/10665/259094

[2] International Health Regulations (2005), 3rd ed. World Health Organization, 2016. Available from: https://www.who.int/publications/i/item/9789241580496

[3] Development of national health laboratory policy and plan. World Health Organization. Regional Office for the Western Pacific, 2011. https://apps.who.int/iris/handle/10665/206926

[4] Guidance for Establishing a National Health Laboratory System. World Health Organization. World Health Organization. Regional Office for Africa, 2014. https://apps.who.int/iris/handle/10665/148351

healthcare services to its citizens. It ensures that systems are in place for the management and operation of laboratory services, and that sustainable financing is available.

In the pursuit of a healthier and more resilient Samoa, the development of a robust and forward-thinking healthcare system is of paramount importance. The Government of Samoa (GOS) recognises the pivotal role that medical laboratory services play in bolstering healthcare delivery, disease surveillance, and public health initiatives. Working through the MOH the GOS is unwavering in its commitment to establishing a robust laboratory system that underpins healthcare services. The NMLP has been developed to define the essential standards for laboratory services at each level of care in Samoa. This policy acts as a prelude to the development of the long-term NMLSP and AOPs. The NMLP's progress will be closely monitored and evaluated through a Monitoring and Evaluation (M&E) framework that sets clear targets, indicators, responsibilities and financial requirements.

Background Information:

The *Health Sector Plan 2019/20 – 2029/30 "A Healthy Samoa"* details the priorities chosen by the MOH to drive its strategic direction for health care in Samoa over a ten-year period. The *Health Sector Plan 2019/20 – 2029/30 "A Healthy Samoa"* has seven key outcomes, with key outcome two, "Improved prevention control, and management of communicable and neglected tropical diseases" with the strategic goal "to end the epidemic of Neglected Tropical Diseases and combat Communicable Diseases" and key outcome seven "Improved Risk Management and Response to Disasters, Public Health Emergencies (Health Security) and Climate Change".[5] Strengthening health security will particularly focus on the *endemic* with existing burdens in Samoa (for example STIs and TB, as well as rapidly scaling up immunisation against measles) rather than the *exotic* (including Ebola).[5]

A broad scope of laboratory services in Biochemistry, Haematology, Serology (including Molecular Diagnostics), Blood Transfusion, Microbiology and Anatomical pathology (histology and cytology) are provided at TTM Hospital. A reduce capacity laboratory testing service is provided at Malietoa Tanumafili II (MT II) Hospital. The selections of specialized tests are referred to New Zealand, Australia and French Polynesia. The Public Health Laboratory was established to support the Samoa Typhoid Control Program and was strengthened during the COVID-19 pandemic to support the response. In October 2023, the Samoa Diagnostic Medical Laboratory was launched. This is a private laboratory established to provide timely screening, early diagnosis, and treatment for the population of Samoa, with a focus on women and underserved communities.

The delivery of medical laboratory services in Samoa is conducted in an organized structure based on different testing diversities, service scopes and availability of specialized personnel. This structure is recognized as the Laboratory Tier System. The purpose of having a tiered system in place is to categorize the defined ranges of tests that can be carried out at each level, from basic analysis that are available in a no-admission medical center, up to a complex investigation in a national hospital laboratory. The following outlines four different tiers of medical laboratory testing in Samoa with their associated standardized packages of services.

Tier Levels & Standard Packages of Service

Tier 1:

Tier 1 in Samoa refers to Health Centres that primarily serve rural district communities by performing point-of-care tests using disposable rapid diagnostic tests; and referring other tests to a higher tiered laboratory based on availability of referral test(s) in ascending order of tiered facilities.

Point of care tests are performed by clinical staff (registered nurses and doctors) in health centres and monitored by the Quality Assurance unit of the MOH Clinical laboratory.

[5] Health Sector Plan FY2019/20 – 2029/30, Ministry of Health, Samoa

Basic tests in tier 1 laboratories include qualitative troponin, blood sugar levels, haemoglobin, urinalysis dipstick, pregnancy test, hepatitis B, syphilis and dengue.

Tier 2:

Tier 2 in Samoa refers to remote laboratories in district hospitals testing specimens from their own patients and receiving referrals from tier 1 facilities. These laboratories serve rural district communities by performing point-of-care tests using mini devices, bench-top analysers and disposable rapid diagnostic tests; and referring all other work to a tier 3 or 4 laboratory.

Services in tier 2 laboratories include:

- phlebotomy and specimen collection
- sample centrifugation
- blood smear preparation.

Tests in tier 2 laboratories are:

qualitative troponin, blood sugar levels, Haemoglobin A1C, pregnancy test, electrolytes, blood grouping, haemoglobin, haematocrit, white blood cells, platelets, ESR, INR, urinalysis, HIV screening test, hepatitis B, syphilis, dengue and CRP.

Point of care tests in tier 2 facilities are performed by laboratory technician(s) who must be registered by the Samoa Allied Heath Council with continuous renewal of their Annual Practicing Certification.

Testing processes are monitored by the Quality Assurance unit of the MOH Clinical laboratory.
It is a must that tier 2 laboratories participate in an internal Quality Control Programme, as well as the Comparison Testing Programme by the MOH Clinical Lab QA unit.

Tier 3:

Tier 3 refers to remote laboratories in second-level hospitals such as MTII hospital in Tuasivi that receive specimens from their own patients, private clinics, as well as referrals from tier 1 and 2 facilities.

These laboratories have significant numbers of laboratory staff and testing processes are supervised by a Principal Technician/ Scientist, with a senior technician and at least two junior technicians to cover all routine testing in the major pathology disciplines.

All staff performing tests in tier 3 laboratories must be registered by the Samoa Allied Heath Council with continuous renewal of their Annual Practicing Certification.

Testing processes are supervised and monitored by the Principal staff of the respective laboratory.
It is a must that tier 3 laboratories participate in an External Quality Assurance Programme by a WHO-Collaborating Centre for EQAP.

Services in tier 3 laboratories include:

- phlebotomy and specimen collection
- donor recruitment and collection
- sample centrifugation
- Blood smear/film preparation
- media preparation
- Screening tests for Food Handlers
- Immigration Clearance

Tests in tier 3 laboratories are as follows:

Biochemistry	Haematology	Blood Bank	Serology	Microbiology	Anatomic Pathology
1. qualitative troponin 2. general chemistry (RFTs/LFTs/ Cardiac enzymes/Lipids/ Uric Acid/ Minerals), 3. HbA1C, 4. Microalbumin/ Creatinine ratio 5. pregnancy test 6. paraquat test 7. blood gas	1. Full Blood Count 2. Cell Morphology 3. ESR 4. INR	1. Blood grouping 2. Cross-match 3. preparation of whole blood and red blood cell packed units	1. HIV-Determine 2. Hepatitis A, B and C 3. Syphilis 4. Dengue and Leptospirosis 5. CRP 6. Rh Factor 7. ASOT 8. SARS-CoV-2 genexpert	1. Urine analysis 2. Microscopy-Culture-Sensitivity of all samples 3. Gram staining 4. Tb ZN Stain 5. Tb genexpert	1. Formalin fixing of tissues for referral to Tier 4 laboratory

Tier 4:

Tier 4 refers to main laboratories in national and teaching hospitals such as TTM hospital in Motootua that receive specimens from their own patients, private clinics and referrals from other lab facilities.

These laboratories have at least thirty (30) laboratory staff and each discipline is supervised by its own Principal Technician/ Scientist, with at least one senior and two permanent technicians to perform all routine testing in their respective section/department.

Testing processes are generally managed at ACEO level, with an independent Principal Quality Assurance Officer and at least one Procurement Officer.

All staff performing tests in tier 4 laboratories must be registered by the Samoa Allied Heath Council with continuous renewal of their Annual Practicing Certification.

It is a must that tier 4 laboratories participate in an External Quality Assurance Programme by a WHO-Collaborating Centre for EQAP.

There should be at least one in-house Clinical Pathologist otherwise the facility must have uninterrupted access to a remote Clinical Pathologist.

Services in tier 4 laboratories include:

- ALL services in tier 3 facilities
- Overseas Referral of pre-approved tests by Clinical Pathologist

Tests in tier 4 laboratories are as follows:

Biochemistry	Haematology	Blood Bank	Serology	Microbiology	Anatomic Pathology
1. *All respective tests in tier 3 facilities* 2. Quantitative troponin 3. Iron studies 4. TFTs 5. Tumour markers 6. Vit B12 7. Folate 8. Vancomycin levels	1. *All respective tests in tier 3 facilities* 2. D-dimer	1. *All respective tests in tier 3 facilities* 2. preparation of all products including frozen plasma and platelets for transfusion	1. *All respective tests in tier 3 facilities*	1. *All respective tests in tier 3 facilities* 2. Automated identification of bacterial species 3. Basic Parasitology	1. *All respective tests in tier 3 facilities* 2. Full processing of all histology and cytology specimens

Strengthening laboratory systems is crucial to ensure the timely, accurate and reliable diagnosis of emerging and other infectious diseases in Samoa. The dangers of emerging and re-emerging communicable diseases including dengue, chikungunya and Zika, highlight an ongoing vulnerability to outbreaks.[6] Lymphatic filariasis remains endemic, with management through mass drug administration campaigns.[6] Prevention and management of sexually transmitted infections (STIs) remain a challenge due to poor commodity distribution and low uptake of voluntary counselling and testing. [6] Vaccine-preventable diseases have rarely been reported, and Samoa maintains its polio-fee status. Although, there has been some progress made on improving laboratory core capacities as part of the IHR (2005) and the APSED III, the COVID-19 pandemic highlighted existing inequities and unmasked the fragility of systems on the laboratory network in Samoa. Therefore, having a sustainable and strengthened laboratory system will ensure the management of future pandemics and other health emergencies.

Purpose:

The main aim of developing this policy document is to strengthen medical laboratory services to execute the mandated core functions of health laboratories articulated in the Ministry of Health Act 2006 (amended in 2019), and to raise the quality of medical laboratory services to acceptable national and international standards through certification and accreditation.

These mandated functions include:

(i) Routine, reference, and specialized testing to confirm etiology of health events
(ii) Disease diagnosis, prevention, control and surveillance
(iii) Emergency response to public health events
(iv) Environmental health monitoring
(v) Food safety monitoring
(vi) Development of laboratory policy, guidelines and standards and
(vii) Strengthening public health and clinical related operational research.

[6] Samoa – WHO Country Cooperation Strategy 2018-2022. World Health Organization, 2017. Available from: https://www.who.int/publications/i/item/WPR-2017-DPM-020

Scope

This policy covers medical laboratory services provided by the MOH at all levels of care in Samoa. The purpose of this policy is to formulate the shared vision, mission and objectives for the laboratory services to successfully support healthcare delivery to the population of Samoa. This policy will set forth the basis for advocacy, resource mobilisation and laboratory system strengthening for the NMLSP FY2024/25-FY2028/29 and subsequent AOPs.

Process of the National Medical Laboratory Policy development

This policy has been developed by the MOH through a participatory and consultative process. A workshop was conducted in country, engaging representatives from various departments. The full list of workshop participants is provided in Annex 4. The MOH Technical Working Group (TWG) members have reviewed and approved the final version and were responsible for submitting the final draft to the MOH for endorsement.

Situational Analysis of the Laboratory System

The Situational Analysis of Samoa medical laboratory services was conducted as part of this policy document development in order to identify highlight strengths, weaknesses, opportunities and challenges associated with provision of health laboratory services within Samoa's health system. The findings and recommendations from this assessment are outlined in **Annex 1**.

Independent Evaluation and Laboratory Assessment Tool of Laboratory System

An independent evaluation of the medical laboratory system in Samoa was conducted in November 2022. The findings and recommendations from this assessment are outlined in **Annex 2**. For the collection of broader information on the laboratory system, the Laboratory Assessment Tool (LAT) developed by WHO was also completed.[7] The outcomes and the gap analysis from the LAT is provided in **Annex 2.**

Analysis of Laboratory Services Provision

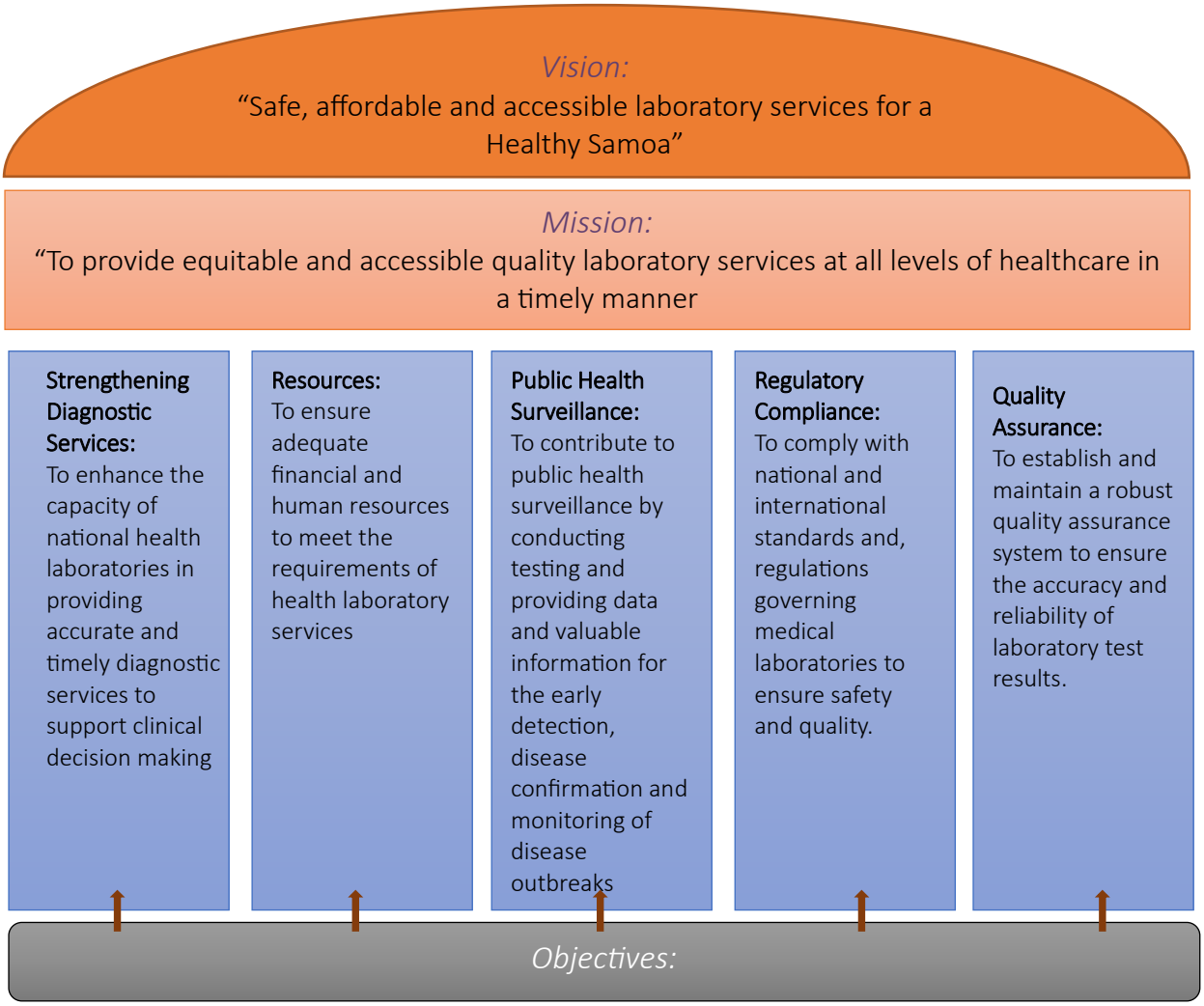
A detailed situational analysis of the laboratory system was conducted during the first consultative workshop in October 2023. This was undertaken to determine the status of the health laboratory services in Samoa.

The major findings of this analysis are outlined in **Annex 3.** The Policy key strategic areas were conducted during the first consultative workshop in October 2023. The analysis of health laboratory services provision in Samoa is categorized under the following Key Strategic Areas. These include:

1. Financing
2. Regulatory and Legal Framework
3. Organisation and Management of the Laboratory System
4. Laboratory Standards
5. Workforce
6. Quality Management System (LQMS)
7. Infrastructure
8. Equipment Management and Maintenance
9. Supply Chain Management
10. Bio Safety and Waste Management
11. Information Management System (LIMS)
12. Research and Development
13. Public and Private Partnerships

[7] Laboratory Assessment Tool. WHO Lyon Office for National Epidemic Preparedness and Response, 2012. https://apps.who.int/iris/handle/10665/70874

Strategic Agenda of the National Medical Laboratory Policy FY2024/25-FY2028/2029



Guiding Principles

The development and implementation of this policy will be guided by the following principles:

 Government Commitment	To affirm the government's commitment and support for the organization and management of an efficient, cost-effective and sustainable health laboratory services.
 Equity	Ensuring that laboratory services are accessible and available to all, irrespective of socio-economic status or geographical location.
 Ethical Values	The commitment in upholding ethical values in laboratory practice including patient confidentiality, adherence to professional codes and ethical research practices.

 Stakeholders Engagement	All relevant stakeholders including government authorities, healthcare providers, laboratory personnel, international partners and donors shall be included in all stages of the process.
 Transparency and Accountability	Decision making processes and resource allocation will be transparent. Clear lines of accountability will be established to track progress and ensure responsible use of resources.
 Sustainability	Ensuring the long-term viability of laboratory services through efficient resource management and planning
 Integration	Promoting seamless integration of laboratory services within the broader healthcare system to enhance patient care.
 Technology and Innovation	Embracing technology advancements and innovative practices to improve the efficiency and effectiveness of laboratory operations.
 Partnership	Collaborating with healthcare providers, government agencies and international organizations to strengthen laboratory services.
 Community Engagement	To engage and educate the community, healthcare providers, and other stakeholders to raise awareness about the importance of laboratory services in healthcare and promote health education.

These guiding principles serve as a foundation for this policy, facilitating its objectives and commitment to ensure a successful implementation, promoting high-quality healthcare service delivery and improving the overall health outcomes in Samoa.

Values

The development and implementation of this policy are based on the following core values:

i. **Quality:** Ensuring the highest standards of accuracy and reliability in laboratory testing to support patient care and public health.
ii. **Integrity:** Conducting all laboratory activities with honesty, transparency, and adherence to ethical principles.
iii. **Professionalism:** Maintaining a highly skilled and trained workforce dedicated to delivering quality laboratory services.
iv. **Patient-Centred:** Focusing on the needs of patients and healthcare providers by providing timely and accurate diagnostic information.

v. **Innovation:** Embracing new technologies and practices to improve laboratory services and advance diagnostic capabilities.
vi. **Accountability:** Taking responsibility for the accuracy of laboratory test results and the effective use of resources.

Policy Statements

This policy will build on the existing laboratory structure to support the laboratory services in Samoa. The laboratory services will support provisions for the following:

- Quality clinical diagnostics to provide evidence-based diagnosis, determine appropriate treatment strategies, early detection of diseases, monitoring chronic diseases.
- Quality diagnostics to support public health, including surveillance and monitoring of emerging diseases and emergency response to disease outbreaks.
- Blood transfusion services
- Research and development

Key Strategic Areas

The NMLP provides the direction for establishing and strengthening the medical laboratory system under the following Key Strategic Areas:

i. Organisation and Management of the Laboratory System
ii. Financing
iii. Regulatory and Legal Framework
iv. Laboratory Standards
v. Workforce
vi. Quality Management System
vii. Infrastructure
viii. Equipment and Equipment Maintenance
ix. Supply Chain Management
x. Bio Safety and Waste Management
xi. Information Management System
xii. Research and Development
xiii. Public and Private Partnerships

These Key Strategic Areas set the standards in providing quality laboratory services in Samoa and strengthening the laboratory systems at all levels of care, with a strong focus on TTM Hospital Laboratory in providing an international accredited standard of laboratory testing.

1. Organisation and Management of the Laboratory System

Objective

To establish and strengthen functional laboratory network system with well defined, harmonized package of services and effective communication, collaboration and coordination.

Statements

- A Medical Laboratory Technical Working Group (TWG) comprising of representatives from all laboratories and stake holders shall provide overarching coordination of laboratory services in the country.
- The TWG shall elect/nominate the National Medical Laboratory Focal Point.
- The National Medical Laboratory Focal Point shall provide overall management and coordination of health laboratory services country-wide.

- The National Medical Laboratory Services of Samoa shall have a well-defined organisational/divisional structure, with clearly identified management and technical roles and responsibilities.
- Operation of the Medical Laboratory Services shall be guided by this NHLP, NHLSPs and AOPs.
- There shall be a standardised package of Clinical Laboratory services, in accordance with national and international standards, defined for each level of care to ensure complementary services and effective use of resources.
- A clearly defined memorandum of understanding (MoU) with the MOH shall be in place with all partners, organisations, and stakeholders of the medical laboratory services.
- There shall be comprehensive guidelines to ensure appropriate referral and communication between the different levels of care.
- Sustainable and efficient sample collection and transportation systems shall be designed to ensure accessibility to laboratory services.
- A functional specimen referral system utilising accredited referral health laboratories (national, regional and/or international) shall be in place for all tests not carried out in any of the hospital laboratories in Samoa and include tests for disease monitoring and response system.

2. Financing

Objective

Effective, evidence-based and sustainable financing mechanisms shall be in place to ensure uninterrupted provision of adequate resources for health laboratory services.

Statements

- The financing of health laboratory services shall be part of the overall health financing plan and the national budgeting process of the Ministry of Health.
- There shall be dedicated and adequate budget lines that reflect the annual requirements to sustain and maintain health laboratory services.
- Budgets for the health laboratory services shall take into consideration all sources of funding, including the government, cost sharing, global health initiatives, partners, investors, and donors.
- Budgets for health laboratory services shall cover and be based on minimum essential standards for laboratory tests, techniques, major equipment and personnel (including upskilling, remuneration and recruitment), operational, management and development costs.
- Developing, reviewing and negotiating budget allocations for the health laboratory services shall be the responsibility of the National Laboratory Focal Point or the ACEO Laboratory, through the AOP process.
- Planning and financing for health laboratory services shall be based on cost analysis and laboratory needs assessment.
- An efficient, effective, user-friendly and transparent system of financial record-keeping and reporting, with clear lines of accountability, shall be in place.
- Health laboratory managerial personnel shall be equipped with knowledge and skills in operational planning and budgeting, advocacy and resource mobilisation for laboratory services.
- Financial support from donors and partners shall be in line with the national laboratory policy and its implementation plans.
- There shall be a coordination mechanism between the government and donors to ensure efficient and effective use of financial resources.
- Pricing schedules of paid services conducted and provided by health laboratories shall reflect actual costs which are reviewed and updated annually.

- The overall costs to finance health laboratory services in emergencies, including public health events of international concern according to International Health Regulations (IHR), shall be calculated and clearly documented and accounted for in annual and financial reports.

3. Regulatory and Legal Framework

Objective

An effective legal and regulatory framework shall be in place to support the sustainable implementation of the National Medical Laboratory Policy.

Statements

- All medical laboratories in Samoa including facilities that conduct testing of any human sample must be licenced as a MEDICAL TESTING PROVIDER.
- Licencing for MEDICAL TESTING PROVIDER in Samoa must only be granted when the Key Strategic Areas (iv)-(xi) defined in the Implementation Plan of this policy are satisfied.
- All medical laboratory personnel shall be registered with the appropriate national professional body relevant to human diagnostics.
- Recruitment and registration of personnel (including international personnel) shall comply with the national competency requirements for health laboratory personnel, as indicated under the Professional Registration and Standard Act 2007.
- International accreditation and/or certification of all medical laboratories under ISO15189:2022 standards shall be achieved and maintained.
- All medical laboratory operations shall be conducted in accordance with a professional code of ethics and must safeguard the health and safety of personnel.
- All relevant laboratory staff shall comply and protected, in accordance with the MOH Occupational Safety and Health Policy and Guideline 2021 and Occupational Safety and Health Act 2002
- All laboratory-related regulations, governance, surveillance, and technical standards shall be adhered.
- There shall be full compliance by all laboratories, with national and international standards and synergy with other relevant national policies.

4. Laboratory Standards

Objective

The laboratory system shall be organised, standardised and coordinated to promote sustainability and quality of results of all diagnostics services at each level of care throughout the health system.

Statements

- A minimum standard package for medical laboratory services, including laboratory infrastructure, tests, techniques, equipment, human resource capacity and biosafety, for each level of care, shall be established.
- Medical diagnostic and public health functions, including surveillance of emerging infections and diseases of public health importance, and seroprevalence studies shall be supported and strengthened through the implementation of complex and specialised testing procedures, as well as upskilling personnel.
- Rational use of laboratory services by health providers shall be promoted through development and implementation of provider awareness programs and tools.
- A system shall be set up to inform medical practitioners about the availability and interpretation of tests (results) of the laboratory services.
- Accessibility of laboratory services, including Telepathology, shall be sustained.
- Testing algorithms for principal diseases shall be defined for primary and confirmatory testing.

- New test methods for existing/new-or emerging infections and diseases shall be validated and approved by international mechanisms (WHO EUL, TGA, FDA, CE) and/or regulatory authorities before being donated or implemented in country.
- Advocacy and educational work shall be carried out among all stakeholders (at the level of the government, ministries and departments, local authorities, clinical staff and population in general) to promote the role of the medical laboratories in the protection of human health, namely, the importance of laboratory data for the diagnosis and prevention of diseases.

5. Workforce

Objective

To ensure well trained, competent and motivated staff are available in adequate numbers capable of providing quality laboratory services.

Statements

- Medical laboratory services shall be manned by personnel registered under the Samoa ALLIED HEALTH COUNCIL in the Ministry of Health.
- Each tier of the medical testing system shall be staffed by the recommended number of competent and appropriately trained personnel to ensure laboratory service is in line with well-defined terms. Staff workload ratio for each laboratory shall be determined and reviewed annually in an evidence-based way to ensure adequate staff is provided.
- All medical laboratories shall have an organizational chart clearly indicating the lines of authority.
- There shall be a protocol and system established to facilitate the secondment of personnel between medical laboratories and diagnostic testing health facilities (TTM, MTII, Public Health lab, district hospitals and remote health centers).
- All medical laboratories shall provide laboratory employees mandatory health and safety training and annual medical check-ups.
- Human resources management for the medical laboratory services shall be guided by a comprehensive national health laboratory workforce development plan that shall be in conformity with the overall health workforce plan and include pre- and in-service training, continuing education to maintain certification, motivation and incentives, retention, remuneration, and career development.
- The medical laboratory services workforce shall include the following personnel (in-house):
- Quality (Management) Coordinator
- Health and Safety officer
- Procurement and Logistics officer
- Equipment Maintenance officer
- Appropriate pre-service and in-service training opportunities shall be provided for all categories of medical laboratory staff through officially recognised local, regional and international training programs that may include distance learning and inter-country exchanges.
- A scheme of service for medical laboratory workers with clear structure and opportunities for career advancement shall be in place.
- Performance appraisal of medical laboratory staff by the immediate supervisor shall be conducted annually using a standard appraisal tool to provide feedback to individual staff and guide career development and shall include competency assessment to verify individual skills, knowledge and correct work practices.
- A Human Resource database shall be in place for each medical laboratory worker and will include training and employment records, evidence of current registration, authorised areas of testing, terms and conditions of employment, job description, continuing professional development, competency assessment records, disciplinary actions and work injury records.

- Medical laboratory managerial personnel shall be equipped with knowledge and skills in leadership and management, in addition to specialised skills in medical lab science.
- There shall be clear and relevant qualification standards and job descriptions available for each position in the national medical laboratory service.
- Remuneration (including overtime and allowances) of staff shall be based on the level and position of the staff and in accordance with the Public Service Act.
- There shall be procedures developed to account for employee attrition to ensure the availability of qualified staff to provide a sustainable laboratory service.
- There shall be regular participation in national and international training programs and workshops for all laboratory personnel to ensure experience exchange, up skilling and career development opportunities.

6. Quality Management System

Objective

Medical laboratory services shall provide accurate and reliable data in a timely manner for *'A Healthy Samoa'*.

Statements

- The National Medical Laboratory Quality Standards shall be developed and implemented, reviewed annually and updated to reflect international standards to improve quality of laboratory services. All medical laboratory services shall operate in compliance within the acceptable standards.
- A system of regulation and supervision ensuring compliance to the national quality standards shall be developed.
- There shall be a designated Quality (Management) Coordinator in each laboratory to oversee and coordinate all activities relating to the establishment and maintenance of the laboratory quality system in the country and ensure all laboratory staff are trained in all aspects of the quality management system.
- Appropriate quality system documentation shall be developed, maintained and updated. These will include a Quality Manual, Biosafety Manual, Standard Operating Procedures (SOPs) and documentation for all processes carried out in medical laboratories.
- All medical laboratories must participate in appropriate national, regional and/or international External Quality Assessment Programmes.
- All medical laboratories shall be internationally accredited, or certified or at least mandated to follow a lab quality system that encompasses policies in the international standards ISO15189:2022 (Medical laboratories — Requirements for quality and competence)
- Support to quality management system implementation shall be provided through trainings, technical guidelines and appropriate tools.
- There shall be an external auditing, quality indicators and a validation system in place to ensure compliance to quality standards for the different levels of care performing medical testing to objectively assess the quality of the work.

7. Infrastructure

Objective

Laboratory premises shall have a national and/or international standard laboratory infrastructure which provides the essential conditions for safe and effective delivery of services, including appropriate building space, design, utilities, and furniture.

Statements

- The laboratory building design, construction and physical infrastructure, must be in accordance with national and/or international standards, considering the requirements of the end-users. A mechanism shall be in place to ensure compliance by all laboratories to national standards and guidelines.

- Health facilities providing diagnostic testing shall be designed and constructed in a standardised and safe manner for different levels of care and comply with national and international standards and best practice suitable for the services that are being provided.
- The physical infrastructure of the laboratory facility shall ensure that there is adequate space available for the safe and secure storage of all laboratory supplies.
- Construction, upgrade, renovation and maintenance of the laboratory physical infrastructure shall be guided by the appropriate implementation plans and shall be closely coordinated with the laboratory focal point.
- All medical laboratories shall be provided with uninterrupted supply of water and electricity, appropriate ventilation, sanitation, heating, telecommunication and internet.
- There shall be safety guidelines developed to ensure compatibility of laboratory building design with safety levels requirements, based on services and testing being undertaken.
- A mechanism and financial plan shall be in place for preventive and corrective maintenance of laboratory infrastructure.

8. Equipment Management and Maintenance

Objective

National Medical Laboratories shall have appropriate, standardised, functional, fit-for-purpose, and well-maintained laboratory equipment to support uninterrupted provision of services.

Statements

- An Equipment Manual and register shall be developed and implemented.
- There shall be minimum essential standards and regulations for importation, registration, use, storage, repair, safe disposal and decommissioning of laboratory equipment to ensure high quality laboratory services and guide planning and procurement.
- All laboratory equipment must conform to national and/or international specifications and standards and procured through companies registered through an approved or recognised regulatory body.
- Equipment must be selected based on quality, value-for-money, suitability, ongoing service support and approved through the Medical Equipment Committee.
- An effective, efficient, evaluation procurement process and inventory management system shall be in place to select, quantify, procure, transport, store, distribute, implement, and maintain proper documentation of all equipment. The Laboratory Focal Point shall provide justification for the selection of laboratory equipment. The Medical Equipment committee shall ensure that any equipment purchased shall meet international specifications (ISO/CE/FDA) and standards.
- A sustainable equipment replacement program shall be in place.
- The equipment donation policy shall provide guidance, direction and established standards for all laboratory donations. All donations of equipment shall be needs-based and comply with appropriate international standards and guidelines.
- When new equipment is procured or donated, the manufacturer or agent will provide all the relevant training on the proper operation, care, preventative maintenance, troubleshooting, and repair of the equipment to the relevant personnel. Operation and service manuals, and adequate spare parts, will be provided with each item of equipment.
- Service contracts will be established for all major equipment, whether purchased or donated.
- For equipment not covered by a service contract, effective, efficient and sustainable mechanisms for equipment maintenance, annual servicing and calibration shall be in place. Including pipette and thermometer calibration.
- The Biomedical department shall provide high quality preventive maintenance (annually) and repair services.
- Each laboratory shall have an (in-house) Equipment Maintenance officer.

9. Supply Chain Management

Objective

The medical laboratory shall have access to an adequate quantity of all required supplies to support an uninterrupted provision of services.

Statements

- Minimum essential standards for health laboratory tests and techniques shall be established for all levels of the laboratory services to guide planning and procurement.
- A standardised system for inventory management and stock control shall be in place.
- A unified, standardised and effective procurement and supply management system shall be in place to select, plan, quantify, procure, transport, store, distribute, manage and dispose of all supplies with a laboratory focal point involved in all processes.
- All laboratory supplies shall conform to international specifications and standards and only procured from companies registered through an approved or recognised regulatory body.
- There shall be standards and regulations for importation, registration, use, storage and safe disposal of laboratory consumables to ensure high quality laboratory services.
- Laboratory staff will be equipped with knowledge and skills in procurement and supply management, including planning, quantification, costing, budgeting, storage, stock-keeping, inventory control and rational use of supplies.
- A national plan for emergency and long-term operations expansion and deployment of laboratory supplies for surge capacity shall be developed and implemented as required.
- There shall be a mechanism in place to regularly monitor and evaluate the supply system.

10. Bio Safety and Waste Management

Objective

All laboratory services operations shall be carried out in a way that ensures safety of all personnel, healthcare workers, patients, customers, community, and the environment.

Statements

- All laboratory services shall comply with the National Occupational Health and Safety guidelines on health emergency and hazardous substances and the National Health Care Waste Management Strategy 2020 – 2025.
- Adequate PPE shall be provided, and trainings conducted in accordance with the National Infection Control Policy.
- Mandatory first-aid induction (bi-annual) trainings for all personnel of laboratory services shall be conducted.
- Mandatory medical screening for laboratory services personnel, vaccinations and annual check-ups shall be provided.
- All laboratories shall be equipped with adequate and appropriate safety equipment for staff and premises.
- There shall be a universally enforced waste management system that ensures the segregation, containment, storage, collection, transportation and safe disposal of all waste including obsolete equipment, separated domestic, medical, chemical and radiological waste.
- Laboratory waste management shall comply with all national environmental protection regulations.
- A staff safety training programme shall be available and implemented.
- All laboratory personnel shall be provided with adequate protection to prevent occupationally acquired diseases and management in case of exposure, including appropriate immunisation and post-exposure prophylaxis.
- Referred biological materials shall be packed and shipped in compliance with appropriate regulatory requirements, including IATA regulations.
- All personnel involved in the packing and shipping of biological materials for overseas referrals by air shall be certified IATA shippers.

- Each laboratory shall nominate a Safety Officer to oversee and coordinate all activities relating to laboratory safety.
- There shall be regulations, standardised manuals and Standard Operating Procedures (SOPs) that comply with the national occupational health and safety guidelines, to protect, minimise hazardous exposure and ensure safety to laboratory personnel, healthcare workers, the community and the environment against all types of laboratory hazards.
- All laboratories must adhere to national laws that regulate the use and safe disposal of hazardous waste (radiological, chemical and biological materials etc.) in compliance with international regulations and signed treaties.
- A risk assessment shall be conducted annually in each laboratory to implement appropriate risk detection and mitigation measures.

11. Information Management System (LIMS)

Objective

To have an effective and user friendly digital laboratory information management system (LIMS) in place to provide relevant and timely data for patient care, laboratory management, disease surveillance, evidence-based planning, policy formulation, and research.

Statements

- Samoa laboratory services shall have a digital LIMS that is user friendly, interface capability with automated analysers, and able to integrate with other Health Information Systems (HISs).
- Selection and implementation of digital LIMS shall be coordinated through MOH TWG
- Digital LIMS shall have tools for easy analysis and generation of results.
- Digital LIMS must align or comply with International Standards such as HL7, ISO15189:2022 and/or ISO/IEC27001:2023.
- All levels of care providing diagnostic services will have a functional, standardised and comprehensive digital LIMS that manages, stores, uses, reports and disseminates data for all relevant stakeholders.
- Reported laboratory data shall be analysed at the central level to guide health services planning and resource mobilization.
- Storage, use, reporting and dissemination of laboratory information shall comply with the national guidelines for proper archiving and protection of confidentiality of patient information.
- Laboratory personnel shall be equipped with the knowledge and skills in the operation and use of the digital LIMS to enable effective data collection, transmission, processing, information analysis and reporting to decision-makers to improve planning and communication.

12. Research and Development

Objective

For Samoa medical laboratory services to be actively involved in health research and development for evidence-based advancements in technology and innovations to directly improve quality care of patients and general public health.

Epidemiological and seroprevalence studies shall be encouraged through the Public Health Laboratory in the aim to better inform the MOH Public Health with the dynamics of communicable diseases and ill-health conditions; as well as provision of solid scientific basis for public health measures. To promote the development of research that is relevant to the health priorities for Samoa.

Statements

- All laboratory research shall meet Health Research Committee ethical standards and guidelines.
- Data shall be utilised to inform operations and improvements all laboratory related research.

- There shall be a continuous research training and education for medical laboratory personnel to improve their health research skills.
- Medical Research forums shall be established to enhance communication with stakeholders.
- There shall be budget allocated for medical research and development activities, particularly for centralised medical lab research through the MOH PH Laboratory.
- There shall be collaborations and partnerships with national, regional and international laboratories for conducting research.
- All medical laboratory related researches, through the Health Research Committee shall work in collaboration with partners and relevant stakeholders to mobilise and coordinate national, regional and international resources for research.
- A national health research database shall be developed in collaboration with stakeholders to ensure overview of research activities and prevent duplication.

13. Public and Private Partnerships

Objective

To ensure efficient and effective coordination between all stakeholders within the medical laboratory sphere.

Statements

- Networking and communication mechanisms shall be in place to provide awareness and improve public and private partnership coordination.
- Knowledge expertise and capacity mechanisms shall be in place to ensure efficient use of resources, information and data sharing.
- There shall be MOUs established between the MOH and relevant partner organisations (to support HR, diagnostic services, provision of commodities, capacity building, and infrastructure).
- A national medical laboratory referral and reporting system shall be designed and implemented to ensure standardized and traceable sample referrals.
- All public and private partnerships relating to laboratory services shall first seek approval through the National Medical Laboratory Technical Working Group.
- There shall be a regulatory framework for medical laboratory services facilitating with public and private partnerships.
- Effective linkages shall be established between the public and private sector with respect to national surveillance, notification and statistics systems.
- The collaboration with international (accredited) laboratories and laboratory networks shall be promoted and an effective mechanism for data and information sharing established.

Implementation Plan

The Implementation Plan of this Policy as shown below is categorized under the 13 Key Strategic Areas as mentioned earlier. These include:

i. Financing
ii. Regulatory and Legal Framework
iii. Organisation and Management of the Laboratory System
iv. Laboratory Standards
v. Workforce
vi. Laboratory Quality Management System
vii. Infrastructure
viii. Equipment Management and Maintenance
ix. Supply Chain Management
x. Bio Safety and Waste Management
xi. Information Management System
xii. Research and Development
xiii. Public and Private Partnerships

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
KEY STRATEGIC AREA 1	Organization and Management System					
OBJECTIVE/S:	*To establish and strengthen functional laboratory network system with well-defined 35 harmonized package of services and effective communication, collaboration and coordination.*					
STRATEGIES	INIDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
1.1 Establish national medical laboratory organizational structure with clearly defined roles and responsibilities	Organizational Structure for Health Laboratory Services modified	Modified Organizational Structure for TTM and MTII Laboratories approved by PSC	By June 2024	MOH PSC	Not required	GoS
1.2 Establish a National Medical Lab technical Working Group	National Laboratory Technical Working Group established	National Laboratory Technical Working Group ToR developed	By April 2024	MOH Laboratory	Not required	GoS
		National Laboratory Technical Working Group meet frequently	Quarterly basis	MOH Laboratory	SAT5,000 per financial year	GoS/WHO
1.3 Strengthen laboratory-based surveillance of AMR, vaccine preventable diseases, foodborne diseases, etc, to support One Health initiative	National Public Health Laboratory designed and developed	National Public Health Laboratory completed and operated	June 2029	MOH	SAT2.5 million	GoS/DPs
1.4 Strengthen relationships with regional and international medical laboratories	National health laboratories relationship and network with international and regional laboratories strengthened	Evidence of networking with international and regional laboratories	Ongoing	MOH Laboratory	SAT50,000.00	GoS/DPs

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
1.5 Strengthen blood donor and transfusion services	Number of dispatches to referral laboratory a month	2 dispatchers a months	Ongoing	MOH Laboratory	SAT100,000.00	GoS/DPs
	Mobile Blood Unit established	Mobile Blood Unit in place and operated	By 2028	MOH	SAT500,000.00	GoS/DPs
KEY STRATEGIC AREA 2	Regulatory and Legal Framework					
OBJECTIVE/S:	*An effective legal and regulatory framework shall be in place to support the sustainable implementation of the National Health Laboratory Policy.*					
STRATEGIES	INIDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
2.1 Strengthen and monitor the implementation of the National Medical Laboratory Policy and Action Plan FY2024/25-FY2028/29	National Laboratory Policy and Action Plan FY2024/25-FY2028/29 implemented and monitored	National Laboratory Policy and Action Plan FY2024/25-FY2028/29 approved by NPCC and Cabinet	By April 2024	MOH Laboratory/SPPRD	SAT100,000.00	GoS/DPs
2.2 Strengthen registration process for laboratory personnel to include all cadre of professionals	Laboratory personnel registration is processed	Inclusion of all cadre of professionals in laboratory personnel registration	Ongoing	MOH Laboratory/Health Professional Development	Not required	GoS
KEY STRATEGIC AREA 3	Financing					
OBJECTIVE/S:	*Effective, evidence-based and sustainable financing mechanisms shall be in place to ensure uninterrupted provision of adequate resources for health laboratory services.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
3.1 Ensure a dedicated budget for laboratory services in the Ministry of Health financial yearly budget	Specific budget output allocated for laboratory services within MOH budget	Existence of budget output specific for laboratory services	Financial yearly	MOH Laboratory/ Finance & Procurement MOF	Not required	GoS

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
3.2 Coordinate funding activities for laboratory services	% of laboratory senior staff trained and involved in MOH budgeting processes	100% of senior laboratory staff trained and involved in MOH budgeting processes	Ongoing	MOH Laboratory/ Finance & Procurement	SAT10,000.00 per year	GoS
KEY STRATEGIC AREA 4	Laboratory Standards					
OBJECTIVE/S:	*The laboratory system shall be organised, standardised and coordinated to promote sustainability and quality of results of all diagnostics services at each level of care throughout the health system.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
4.1 Establish regulatory framework for medical laboratory standards and guidelines	Laboratory standards regulatory framework developed	Laboratory standards regulatory framework completed, approved and implemented	Completed and approved by December 2024 Implemented: Ongoing	MOH Laboratory/ SPPRD	SAT80,000.00	GoS/WHO Other DPs
4.2 Improve laboratory infrastructure to meet international standards of practice	Compliance rate of laboratory infrastructure to international laboratory standards of practice	At least 90% complied	Ongoing	MOH Laboratory	SAT20,000.00	GoS/WHO Other DPs
4.3 Review and update guidelines for specimen collection, packaging and transportation	Guidelines for specimen collection, packaging and transportation developed and reviewed	Guidelines for specimen collection packaging and transportation completed and implemented	By end of 2025	MOH Laboratory	SAT50,000.00	GoS/WHO Other DPs

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
KEY STRATEGIC AREA 5	Workforce					
OBJECTIVE/S:	*The laboratory system shall be organised, standardised and coordinated to promote sustainability and quality of results of all diagnostics services at each level of care throughout the health system.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
5.1 Review and update current scheme of laboratory workforce	Scheme of laboratory services available is reviewed and updated	Scheme of available laboratory services is in place	By Dec. 2024	MOH Laboratory SROS	SAT50,000.00	Gos DPs
5.2 Design and implement training program for healthcare providers to improve knowledge and promote rational use of laboratory services	Number of laboratory training program designed and implemented	Reports of laboratory trainings in place	Ongoing	MOH Laboratory	SAT200,500.00	GoS DPs
5.3 Engage with PSC and MOF to approve and operationalize the scheme of laboratory services	Laboratory scheme of services consulted and approved	Approves Laboratory scheme of services is in place	By Dec. 2024	MOH Laboratory/HR SROS, PSC MOF	SAT50,000.00	GoS DPs
5.4 Recruit adequate laboratory staff to fill vacant and new positions at all levels in line with the revised scheme of laboratory services	Laboratory vacant and new positions filled	Percentage of vacant and new positions filled	Ongoing	MOH Laboratory/HR PSC MOF	SAT500,000.00	GoS
5.5 Retain adequate laboratory staff at all levels in line with the revised scheme of service	All laboratory vacant positions filled	Percentage of laboratory vacancies filled	Ongoing	MOH Laboratory/HR PSC MOF	Not required	GoS

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
5.6 Review remuneration packages for overtime, allowances and incentives for laboratory staff	Remuneration packages for laboratory staff reviewed and updated	Reviewed and updated remuneration packages is in place and executed	Ongoing	MOH Laboratory/HR PSC MOF	SAT25,000.00	GoS
KEY STRATEGIC AREA 6	Quality Management System					
OBJECTIVE/S:	*Health laboratory services shall provide accurate and precise data in a timely manner for 'A Healthy Samoa'*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S		SOURCES OF FUND
6.1 Strengthen laboratory services for surveillance, public health emergency investigations and management at all laboratory levels including private sector	Number of notifiable diseases reported by laboratory to public health	All notifiable diseases laboratory reports are disseminated on time.	Ongoing	MOH Laboratory/ National Health Surveillance	SAT30,000.00	GoS
6.2 Strengthen safe and secure specimen collection, packaging and transportation within the medical laboratory network	% of laboratories with appropriate specimen packaging materials	Appropriate packaging materials provided for specimen collection.	Ongoing	MOH Laboratory/ National Health Surveillance	SAT100,000.00	GoS
6.3 Develop and implement a database for Laboratory Quality Management System with respect to MLIMS	Laboratory Quality Management System developed	A functional Laboratory Quality Management System is available	By 2026/27	MOH Laboratory/HICT	SAT250,000.00	Gos/WHO Other DPs
6.4 Develop National Medical Laboratory Standards	National health laboratory standards developed and implemented	National health laboratory standards in place	By 2025	MOH Laboratory	SAT50,000.00	GoS/WHO Other DPs

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
KEY STRATEGIC AREA 7	Infrastructure					
OBJECTIVE/S:	*Laboratory premises shall have a national and/or international standard laboratory infrastructure which provides the essential conditions for safe and effective delivery of services, including appropriate building space, design, utilities, and furniture.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
7.1 Upgrade national reference laboratories to have capacity and control systems to handle highly infectious organisms and meeting nationally acceptable containment standards	National reference laboratories renovated and upgraded	Evidence of national reference laboratories renovation and upgrade	By 2025	MOH	SAT500,000.00	DPs
7.2 Establish a Blood Donor Centre	Blood Donor Centre established	Blood Donor Centre in place	By 2028	MOH	SAT500,000.00	GoS/DPs
7.3 Establish a Mobile Blood Unit	Mobile Blood Unit established and operated	Mobile Blood Unit in place	By 2026	MOH	SAT250,000.00	GoS/DPs
KEY STRATEGIC AREA 8	Equipment Management and Maintenance					
OBJECTIVE/S:	*Laboratory premises shall have a national and/or international standard laboratory infrastructure which provides the essential conditions for safe and effective delivery of services, including appropriate building space, design, utilities, and furniture.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
8.1 Strengthen the coordination of laboratory supply chain management system	Procurement position developed to specifically focus on coordination of laboratory supply chain procurement and management	Procurement position specific for laboratory supply chain established	Asap	MOH PSC	SAT70,000.00	GoS

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
8.2 Procure spare parts for preventative maintenance and repair of laboratory equipment	At least 90% of identified needed spare parts are procurements	% of spare parts procured	Ongoing	MOH Laboratory/Finance and Procurement	SAT1 million	Gos/DPs
KEY STRATEGIC AREA 9	Supply Chain Management					
OBJECTIVE/S:	*The health laboratory shall have access to an adequate quantity of all required supplies to support an uninterrupted provision of services.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
9.1 Establish and strengthen equipment management (procurement, corrective and preventative maintenance, replacement) for all levels of care	Laboratory equipment register established, reviewed and update	Laboratory equipment register in place	By 2024	MOH Laboratory/Assets Registration Unit	SAT25,000.00	GoS
9.2 Establish a system for standardized collection, analysis and reporting of patient data including data on drug resistance, laboratory-based disease surveillance, notifiable diseases and outbreak investigation to improve data use	Number of laboratories with quality data for decision making	Accurate quality laboratory data generated for decision making at all levels	Ongoing	MOH ICT/Laboratory	Not required	Gos/WHO
KEY STRATEGIC AREA 10	Bio Safety and Waste Management					

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
OBJECTIVE/S:	*The health laboratory shall have access to an adequate quantity of all required supplies to support an uninterrupted provision of services.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
10.1 Develop and implement essential integrated laboratory packages to define laboratory services at every level of healthcare delivery in line with MOH approved standards	Number of additional tests implemented at TTM and MTII Hospital laboratories	Essential Integrated Laboratory packages in place and utilized	By end of 2025	MOH Laboratory	SAT10,000.00	GoS
10.2 Improve strengthen compliance of laboratories with laboratory biosafety, biosecurity and waste management standards to contribute to safeguarding laboratory personnel, community and the environment	Compliance rate of laboratories with laboratory biosafety, biosecurity and waste management standards	At least 95% compliance	Ongoing	All national reference laboratories in Samoa	Not required	GoS/DPs
KEY STRATEGIC AREA 11	Information Management System					

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
OBJECTIVE/S:	*To have an effective and user friendly digital laboratory information management system (LIMS) in place to provide relevant and timely data for patient care, laboratory management, disease surveillance, evidence-based planning, policy formulation, and research.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
11.1 Develop and implement an electronic integrated Health Laboratory Information Management System to improve laboratory data and information management.	Integrated electronic Health Laboratory Information Management System developed and implemented	A functional Integrated Health Laboratory Information Management System available and accessible	FY2026/2027	MOH ICT/Laboratory	SAT1 million	GoS/WHO/Other DPs
11.2 Develop and conduct training on guidelines for laboratory data management.	Numbers of laboratory staff receiving trainings per year	Trainings on laboratory data management guidelines conducted for laboratory staff	Ongoing	MOH ICT/Laboratory	SAT50,000.00	GoS/WHO/Other DPs
11.3 Conduct quarterly reviews/analysis of laboratory data.	Number of laboratory data reviews/analysis conducted	Quarterly review reports of laboratory data management	Quarterly	MOH ICT/Laboratory	SAT20,000.00 per financial year	GoS/WHO/Other DPs
KEY STRATEGIC AREA 12	Research and Development					

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
OBJECTIVE/S:	*For Samoa laboratory services to be actively involved in research and development for evidence- based advancements in technology and innovations to directly improve quality care of patients. To promote the development of research that is relevant to the health priorities of Samoa.*					
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
12.1 Develop operational framework for research on laboratory services to guide medical laboratory research efforts	MedicalLaboratory Research Operational Framework to be developed	Medical Laboratory Research Operational Framework in place	FY2026/27	MOH Laboratory	SAT80,000.00	GoS/WHO Other DPs
12.2 Establish a medical laboratory research database to track and disseminate research findings on medical laboratory services	Functional laboratory research database for tracking and disseminating research efforts on laboratory services	Laboratory research database tracks and disseminates all research findings by laboratory services	Ongoing	MOH Laboratory	SAT20,000.00	Gos/WHO
12.3 Promote the utilization of research findings to information decision making at all levels, policy revision and improve medical laboratory practices.	Number of laboratory research findings utilized to inform decision making at all levels, policy revisions and improve practice	Research results from laboratory researches are shared	Ongoing	MOH Laboratory/HRC	Not required	GoS
KEY STRATEGIC AREA 13		Public and Private Partnership				
OBJECTIVE/S:		*To ensure efficient and effective coordination between all stakeholders within the laboratory sphere.*				

NATIONAL MEDICAL LABORATORY POLICY FY2024/25-FY2028/29 IMPLEMENTATION PLAN						
STRATEGIES	INDICATORS	TARGETS	TIMEFRAME	IMPLEMENTER/S	COSTING (SAT)	SOURCES OF FUND
13.1 Establish a medical laboratory multi-sectoral Technical Working Group to oversee the implementation of the National Medical Laboratory Policy and Action Plan FY2024/25-FY2028/29	ToR of Laboratory Multi-Sectoral Technical Working Group developed and approved	Approved ToR for Laboratory Multi-Sectoral Technical Working Group	Asap	MOH Laboratory	Not required	No fund required
	Multi-sectoral Laboratory Technical Working Group constituted	Number of multi-sectoral Laboratory Technical Working Group conducted	Quarterly	MOH Laboratory	SAT20,000.00 per financial year	GoS/WHO
13.2 Establish mechanisms to outsource specialized medical laboratory services to increase efficiency and effectiveness in service delivery	Public-Private-Partnership promote. Development & signing of MOU for national & international specialized laboratories commit to perform identified outsourced tests	MOUs signed	Ongoing	MOH Laboratory National and International laboratories	Not required	GoS/Other DPs
13.3 Develop information, education and communication (IEC) materials on laboratory services	Laboratory IEC materials developed and distributed	IEC materials for awareness program on laboratory services developed and distributed for community awareness	Ongoing	MOH Laboratory/Health Promotion Unit	SAT100,000.00 per financial year	GoS/Other DPs

Monitoring and Evaluation

To effectively monitor and evaluate the provision of medical laboratory services and the implementation of this policy's implementation plan it is very important to:

i. Have a set of measurable quality indicators shall be developed and implemented to continuously monitor performance of laboratory services.
ii. Carry out annual internal audits for laboratory staff performance against the National Health Laboratory Standards.
iii. Conduct external assessments to evaluate overall performance of laboratory services.
iv. Equip laboratory managerial personnel with knowledge and skills in monitoring progress and
v. Analyse and use data generated by the monitoring and evaluation activities to continuously improve the quality of laboratory services.

Results of the monitoring and evaluation activities shall be readily available to all users of laboratory services.

Laboratory services shall provide an annual progress report and submit through Strategic Planning Policy and Research Division and Health Information Services and Monitoring and Evaluation Division, to be included in the MOH Annual Report.

Annexes

Annex 1: Situational Analysis of the Laboratory System

The Situational Analysis of Samoa health laboratory services identify highlight strengths, weaknesses, opportunities and challenges associated with provision of health laboratory services within Samoa's health system.

Existing Laboratory Services

The laboratory services in Samoa play a critical role in supporting healthcare delivery, disease surveillance, and public health initiatives. There is a need to strengthen and expand diagnostic capacity throughout Samoa to respond rapidly and effectively to public health threats and emerging infectious diseases. Point-of-care testing should be reviewed for decentralising to the peripheral district hospitals and utilised during community outreach and outbreak investigations. Despite the progress and resources made available through the COVID-19 response, some clinical laboratory services have been heavily affected and neglected.

MOH Tupua Tamasese Meaole (TTM) Hospital Clinical Laboratory

Is one of only two laboratories in Samoa, supporting a population of approximately 200,000 people. Specimens and/or patients are referred from other district hospitals on Upolu and MT II. Based on the laboratory organisational structure, there are approximately 40 staff, a ACEO managing the laboratory and the remaining officers working across the six main disciplines (Biochemistry, Haematology, Serology, Blood Transfusion, Microbiology, Anatomical Pathology), including phlebotomists performing blood and donor collection and mortuary assistants supporting Anatomical Pathology. However, the actual number is approximately 30 due to vacant positions. The laboratory has its own operational budget, for domestic and international procurement.[8]

The National Medical Laboratory Policy was initially drafted in 2018 and was never being shared and consulted with Samoa's health sector. There are standard operating procedures (SOPs) for all laboratory procedures, Quality, Health and Safety, and Equipment manuals that are also available. The laboratory is working towards ISO15189:2022 accreditation with support from Pacific Pathology Training Centre (PPTC), with plans to be internationally assessed. In addition to PPTC, the laboratory receives strong support, both technical and financial, from World Health Organization (WHO), Institute of Environmental Science and Research Limited (ESR), South Pacific Community (SPC), New Zealand Foreign Affairs and Trade (MFAT), Australia Department of Foreign Affairs and Trade (DFAT), United Nations Development Programme (UNDP). Inventory is managed manually using stock cards and an excel spreadsheet. Data is managed through paper—based reporting and using excel spreadsheets, which are located on a shared drive and accessible to clinicians to review results. [7]

Serology testing is mostly by point-of-care (POC) testing for infectious/public health diseases (HIV, HAV, HBV, HCV, Syphilis, Influenza, Dengue, Leptospira etc.). Molecular testing is performed on the GeneXpert (TB, SARS-CoV-2). Chlamydia and Gonorrhoea testing was available using GeneXpert, however cartridges were supplied through UNDP and have since run out or expired. Automated techniques (identification and drug susceptibility testing) are available for Microbiology testing. COVID-19 Rapid Antigen Tests (RATs) were performed at the district hospitals. There are two new Biochemistry

[8] Independent Evaluation of the Laboratory System in Samoa. Prepared by World Health Organization for the Ministry of Health, Samoa. 7-11 November 2022.

analysers (Roche Cobas c311). [7] There is also a Roche Cobas e411 Biochemistry analyser that has been operational since 2018.

There are Biosafety Cabinets Class II (BSC II) installed for processing specimens, however, they are overdue for servicing/decontamination. There is an additional BSC II, which is non-functioning and waiting to be repaired. Laboratory working and storage space is extremely limited. Corridors and main thoroughfares are blocked with equipment and consumables. The eye wash station is inaccessible; there is no emergency shower or first-aid kit located within easy access in the main laboratory. The flooring of the laboratory is high gloss tiles, which are extremely slippery when wet. [7]

MOH Malietoa Tanumafili II Hospital Clinical Laboratory (MT II)

Is the second of only two laboratories in Samoa, supporting a population of approximately 10,000. Specimens and/or patients are referred from other district hospitals on Savai'i. Based on the laboratory organisational structure, there are approximately 6 staff, a principal officer managing the laboratory and the remaining officers working across Biochemistry, Haematology, Serology, Blood Transfusion, Microbiology and the Mortuary supported by two mortuary assistants. The scope of testing is a reduced service provided by TTM. Laboratory officers perform blood and donor collection. The laboratory receives reagents and consumables through TTM. Specimens are referred to TTM, 2-3 times weekly, for tests not available onsite. The hospital vehicle or laboratory staff will transport the specimens. The laboratory has a fume hood for processing specimens. Data is managed through paper—based reporting and using excel spreadsheets, which are located on a shared drive and accessible to clinicians to review results. [7]

Serology screening is by POC testing for infectious/public health diseases. Molecular testing is performed on the GeneXpert (TB, SARS-CoV-2). There is one IV-Module GeneXpert instrument, however one module is faulty, and another module is missing. Chlamydia and Gonorrhoea testing was available using GeneXpert, however cartridges were supplied through UNDP and have since runout or expired. [7]

MOH Typhoid (Public Health) Laboratory

MOH Typhoid Laboratory was established with support from the University of Maryland and funded through the Bill & Melinda Gates Foundation, to implement the Samoa Typhoid Control Program and provide Typhoid testing on contacts of confirmed cases. This project is nearing completion in early 2024. It also performs water testing using the Collilert-18 test kit, which detects total coliforms and E coli or faecal coliforms in water samples. It provided support for SARS-CoV-2 testing for immigration screening on the IV-Module GeneXpert instrument. World Bank are supporting with the development and construction of a new laboratory. UNOPS have supported with the procurement of laboratory equipment, including BSCs II, thermal cycler, refrigerators and freezers. [7]

Annex 2: Independent Evaluation and Laboratory Assessment Tool of Laboratory System

The independent evaluation was undertaken between 7 – 11 November 2022 and included visits to the Tupua Tamasese Meaole (TTM) Hospital Medical Laboratory, the MOH Typhoid Laboratory, Malietoa Tanumafili II (MT II) Hospital Medical Laboratory, inspection of the pharmacy warehouse, and meetings with key personnel from the Procurement Branch, Pharmacy Warehouse and Biomedical Department. This review focused on the capacity of the laboratory services in Samoa as they play a crucial role in monitoring the COVID-19 pandemic and responding to other public health threats throughout the country.

The main areas that require significant improvement are coordination and management, regulations, infrastructure and human resources. There has not been a Laboratory Policy or Strategic Plan to guide and strengthen the laboratory services in Samoa. Currently there are only two clinical laboratories providing laboratory services in Samoa, both laboratories have been working towards accreditation with support through partners. Coordination and collaborations between the laboratory services, other Ministries and the Public Health Division is limited. The organisational structure at TTM has recently been reviewed and updated to include a total of 51 MLS/MLTs. The current organisational structure at TTM has 39 core positions, 30 of which are currently filled. There is an operational budget (~5million SAT) for the procurement of laboratory consumables, however this budget does not cover replacement or new equipment, service contracts, training or development. No formal or standardised inventory management system has been implemented at TTM or MT II. There is no digital LIMS implemented at TTM or MTII Hospital Laboratories, however TTM are currently using a shared drive to manage, and report results to clinicians. PPTC have been conducting annual reviews and assessments of the Samoa Medical Laboratories based on the Stepwise Laboratory Improvement Process towards Accreditation and the WHO minimum standard assessment checklist, to assess the progress. Infrastructure is inadequate (flooring, ventilation, space) at both TTM and MT II. There is funding available through World Bank to develop design plans for a Public Health Laboratory, currently there are no existing national standards for the design and layout for laboratory facilities. The Equipment Manual at TTM has been recently updated. The Biomedical team conducts annual preventative maintenance on the laboratory equipment; however, they are unable to service the Biosafety Cabinets or install major laboratory equipment. There are no service contracts established for major equipment.

An 'Overview of the findings from the mission is as follows:

Strengths and Challenges to Laboratory Services Delivery

The delivery of high-quality and efficient laboratory services holds paramount importance in supporting the healthcare system in Samoa. These services form the foundation for clinical decisions and offer an objective means to measure and monitor biological and environmental indicators. Accurate and timely laboratory results play a critical role in the identification, tracking, and containment of public health threats, emerging diseases, or outbreaks. Medical laboratory services also provide essential diagnostic information, to guiding healthcare professionals in making informed and accurate clinical decisions for patient care and management.

Strengths

- Financial support through MOH for laboratory consumables (~5M SAT, FY23/24)
- Samoa National Health Laboratory Policy 2024 revised and updated from 2018 Edition.
- Samoa National Health Laboratory Policy revised and updated (30 November 2018) from 2013 Edition.
- Samoa Health Sector Plan 2019/2 – 2029/30
- Strong government support and commitment
- Knowledgeable, multi-skilled, and strong workforce.

- Laboratory Quality management system developed and laboratory working towards accreditation ISO15189:2022 (Quality Manual, SOPs, Health and Safety Manual, Equipment Manual). PPTC providing support to align with international standards as a stepwise approach to achieving accreditation.
- TTM Clinical Laboratory Handbook developed in 2021.
- TTM Clinical Laboratory Organisational structure updated (51 positions)
- Expansion of molecular based testing on GeneXpert instrument (SARS-CoV-2).
- New Biochemistry analyser (Cobas e 411) capable of performing testing for infectious diseases.
- Strong partnerships and donor support (PPTC, ESR, WHO, SPC, MFAT etc.).
- Enrolled in External Quality Assurance Programmes.
- Training and capacity building opportunities
- Commitment to develop National Public Health Laboratory

Challenges and Impact

Laboratory Framework and Services

- Samoa National Medical Laboratory Policy 2018, yet to be approved by MoH Policy Division.
- No National Medical Laboratory Strategic Plan
- Only two hospitals performing laboratory services. Specimens or patients referred.
- Establishment of Public Health Laboratory.

Impact: Policy and Plan guide the development of the laboratory services and standards which are aligned with MoH strategic priorities and the MoHs commitment to provide quality health services. Longer TAT of results (specimen referral) or additional out-of-pocket expenses (patient referral).

Data Management

- No Laboratory Information System (LIMS). Excel spreadsheet (shared drive) and paper based.

Impact: Data security and patient confidentiality concerns. Long TAT of results, delays in evidence based clinical decisions.

Public Health screening and disease outbreak response

- Under utilisation of molecular diagnostics (GeneXpert). Signification reduction in Xpert SARS-CoV-2 testing (October 2022: 10 tests).

Impact: Expensive equipment under utilised (1x16-Module, 4x4-Module) and costly to maintain.

- HPV, RSV, Rubella, Measles, Chikungunya testing not available in country.

Impact: Longer TAT for results as specimens referred overseas. Increased costs (transportation). Compromises patient management, delay in diagnosis and treatment.

Inventory Management

- Excel spreadsheet and stock-cards used to manage inventory.
- Limited space in laboratory for bulk storage of laboratory commodities.
- Donations provided by partners not captured in MoH procurement. (Xpert, Serology RDTs)

Impact: Unable to track/monitor batch number and expiration information easily. Overcrowding of laboratory space compromises safety.

Equipment Management

- Some equipment is old, outdated or not functioning.
- No specific budget line for replacement laboratory equipment.
- BSCs require servicing/certification/decontamination by qualified technician.

Impact: Newer and advanced equipment improves quality, performance and TAT of testing. Compromises health and safety of laboratory personnel.

Occupational Health and Safety

- Essential safety equipment not available, not accessible, outdated (eye wash station, emergency shower, fire extinguishers).
- Corridors/thoroughfares are crowded with equipment and consumables.
- Floors tiled (slippery, permeable surface, prone to breakages).
- Laboratory personnel must undertake safety training and procedures regularly (annually).

Impact: Compromises health and safety of laboratory personnel.

Recommendations

1. Address recommendations and action items identified during site assessment

- To improve service delivery and patient management by reducing delays in testing and reporting results.

2. Review and revise Samoa National Medical Laboratory Policy and Regulatory Framework

- Develop national laboratory regulatory mechanisms.
- To provide the framework for the strengthened delivery of quality, sustainable and accessible national laboratory diagnostics. Clearly outlining the structure and function of laboratory services and standards.
- Ensure policy is consistent with the Health Sector Plan FY2019/20– FY2029/30 and Implementation Plan and receives full endorsement from the MoH and financial commitment.

3. Develop long-term (5 years) National Laboratory Strategic Plan.

- Conduct situational (SWOT) analysis.
- Systematically outline objectives to be achieved, human resource development (quantity, positions), laboratory infrastructure, strengthening diagnostic services (STI, AMR), equipment (replacement, service, maintenance), procurement (reagents, consumables), inventory management, accreditation (ISO15189:2022), and adequate financial investment (budget).
- Provides guidance for coordinated and directed partner/donor support and investments.

4. Strengthen response to public health emergencies and disease outbreaks, including antimicrobial resistance.

- Review national standards for tests, techniques and/or equipment. Undertake feasibility (cost, shelf-life, sensitivity) to expand testing and transition to automated and/or molecular diagnostics (integrate diseases/duo assays).
- Expand molecular diagnostic capacity to include STIs (routine Chlamydia/Gonorrhea and HPV) and Respiratory (Flu, RSV) panels.
- Strengthen surveillance and monitoring for Influenza/SARS-CoV-2 and AMR.
- Pilot decentralizing (selection of POC testing) to health facilities on Upolu (6) and Savai'i (4). Provide training to HCWs in performing, recording and reporting.

5. Review equipment, inventory and data management systems

- Review service contracts and ensure sustainability (BD, Roche, GeneXpert, Sysmex etc.).
- Support in-country capacity building of biomedical team to certify, decontaminate and service BSCs.

- Assess feasibility for the implementation of an established inventory management system (mSupply implemented in pharmacy/warehouse/EPI) to manage laboratory stock.
- Relocate bulk stock to declutter laboratory.
- Support the implementation of a Laboratory Information Management System (LIMS) and interface with existing automated instruments.

6. Strengthen workplace health and safety (including biosafety)

- Conduct a risk assessment to ensure minimal standards and requirements (WHO Biosafety Manual 4th Ed) are implemented.
- Procure and install BSC II at MT II.
- Implement control measures and essential safety equipment (non-slip floor, accessible eye wash station, emergency shower, check/replace fire extinguishers etc.)
- Clear main thoroughfares for access to emergency equipment and exits.
- Provide necessary training to staff as indicated (use of safety equipment, emergency procedures, evacuation etc.).

LAT assessment

The summary outcomes of the LAT assessment and the gap analysis are provided in Figures 1 and 2. The outcomes and findings were discussed during the first consultative workshop and formed the basis of the subsequent situational and SWOT analysis.

Outcomes of the LAT assessment

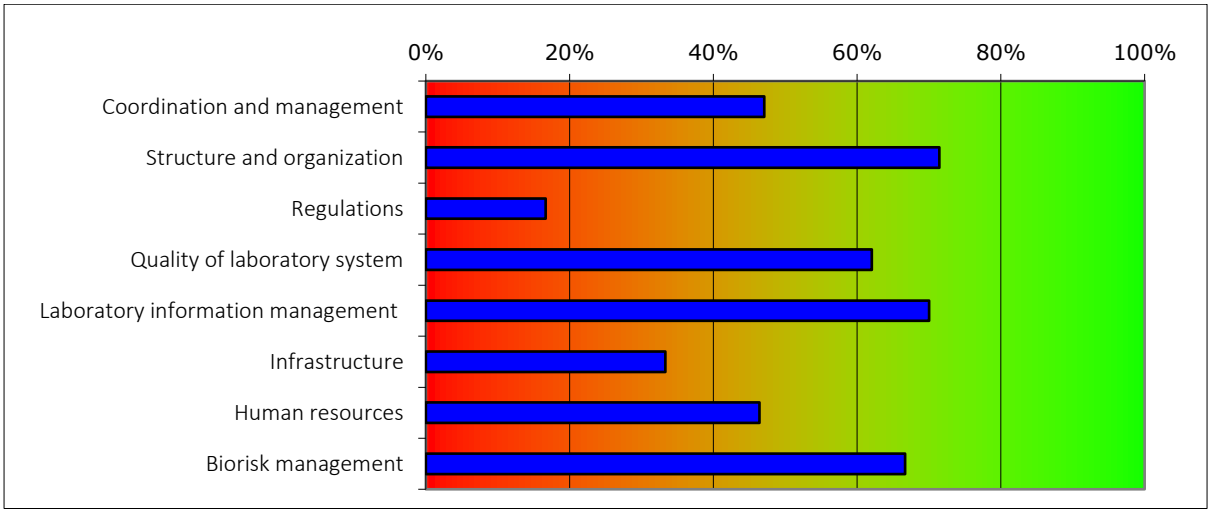


Figure 1: *Summary of outcomes from the LAT assessment of the laboratory system in Samoa*

The analysis of the Laboratory System in Samoa is provided in Figure 1. The average score was 52%, indicating some improvements are necessary. A brief overview of the findings and scores are provided below:

Coordination and management (47%)

Requires significant improvement: The low score for this area was the absence of a Laboratory Policy and Strategic Plan, and limitations with the collaboration between other Ministries and the Public Health Division.

Structure and organization (71%)

Some improvement is necessary: Currently there are only two clinical laboratories providing laboratory services in Samoa.

Regulations (17%)
Requires significant improvement: There is no existence of a regulatory framework for laboratory services in Samoa.

Quality of laboratory system (62%)
Some improvement is necessary: The weakness in this area is the absence of laboratory certification and accreditation.

Laboratory information management (70%)
Some improvement necessary: There is no digital LIMS implemented at TTM or MTII Hospital Laboratories, however TTM are currently using a shared drive to manage, and report results to clinicians.

Infrastructure (33%)
Requires significant improvement: Working and storage space is limited at both TTM and MT II. There is funding available through World Bank to develop design plans for a Public Health Laboratory.

Human resources (46%)
Requires significant improvement: The organisational structure at TTM has recently been reviewed and updated to include a total of 51 MLS/MLTs. The current organisational structure at TTM has 39 core positions, 30 of which are currently filled.

Bio-risk management (67%)
Some improvement is necessary: The areas that require the most strengthening to improve biosafety/biosecurity are improvements to infrastructure and developing legislation. There is no local body able to certify Biosafety Cabinets.

Gap analysis of the Laboratory system

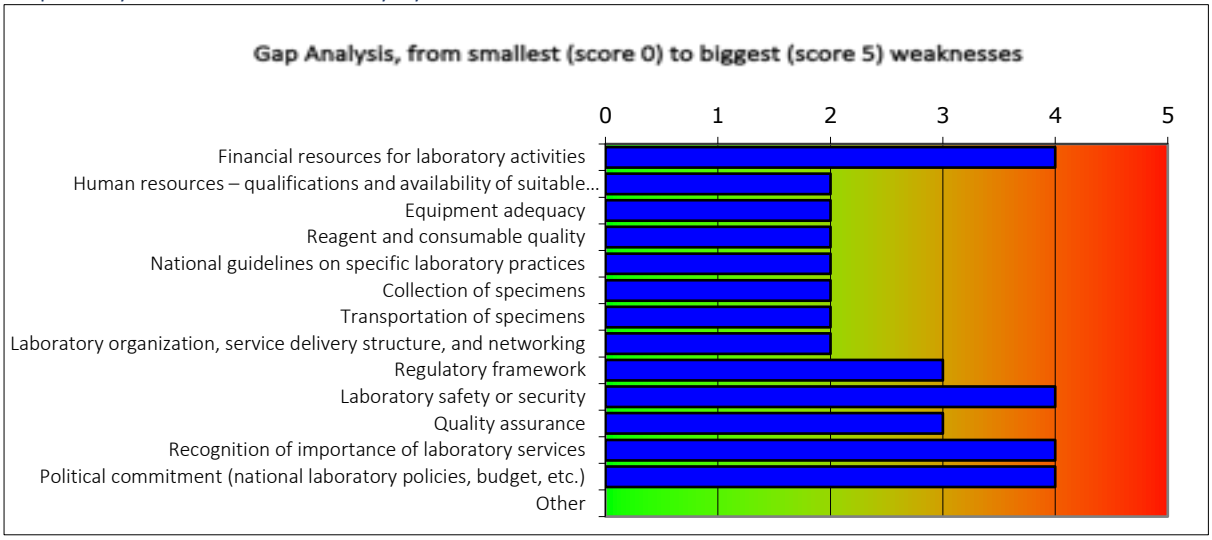


Figure 2: *Gap analysis scores from the LAT assessment of the laboratory system in Samoa*

The overall findings from the gap analysis in all areas of the laboratory system are depicted in Figure 2. The majority of weaknesses (score 4) are inadequate financial resources, laboratory safety risks, the absence of international certification and accreditation, and limited political commitment.

Annex 3: Situational Analysis of the Medical Laboratory System

1. Financing

The operational budget for the laboratory is approximately 5 million Samoa Tala (FY2023/24). There is no existing Strategic Plan to direct investments. The operational budget does not capture funding for equipment procurement or service and maintenance. Donor investments are not captured in the operational budget or laboratory expenditure.

Areas to be strengthened: Financing Laboratory Services

- Improve participation and knowledge sharing on the budget allocation decision-making.
- Provide capacity building for Laboratory Management in operational planning and budgeting.
- Strengthen budget allocation based on needs assessment.
- Allocate separate budget for laboratory equipment (procurement, service, maintenance).

2. Regulatory and Legal Framework

There is no existing regulatory framework for the laboratory services. The National Health Laboratory Policy drafted in 2018 was never endorsed and there was no Laboratory Strategic Plan developed to set the standards and guiding principles of the laboratory services. The Health Sector Plan 2019/20 - 2029/30 and the MOH Interim Corporate Plan FY2023/24-FY2024/25 sets out the priorities to strengthen laboratory services and the Annual Operational Plans outline the activities to be implemented and conducted.

Areas to be strengthened: Regulatory and Legal Framework

- Endorse Samoa National Medical Laboratory Policy and Action Plan FY2024/25 – FY2028/29
- Establish regulatory framework for laboratory standards and guidelines (commodities, equipment, infrastructure).
- Strengthen registration process for laboratory personnel to include all cadre of professionals.

3. Organisation and Management of the Laboratory System

The TTM and MTII Hospital laboratories have strong partnerships (PPTC, SPC, WHO) with organisations that provide technical expertise and resources. The organisation structure for TTM Hospital laboratory has been recently updated and pending approval. The laboratory services is supported by a regional laboratory (LABPLUS) to provide referral testing for a service.

Areas to be strengthened: Organisation and Management of the Laboratory System

- Approve the updated laboratory organisational structure for MOH.
- Fill vacant positions.
- Establish a National Laboratory Technical Working Group (NLTWG) and appoint national laboratory focal point.
- Define TOR for NLTWG
- Review and update laboratory organisational structure and workforce, defining and establishing systems, roles, and responsibilities.
- Strengthen relationships with regional and international laboratories.

4. Laboratory Standards

There is a standardised list of laboratory services provided in the Laboratory Handbook 2021. Serology based POC testing is being used for infectious/communicable diseases (COVID-19, HIV, HAV, HBV, HCV, Syphilis, Flu A/B, Leptospira, Rota/Adeno viruses). Microbiology culture, ID and DST is used to monitor AMR. Rapid molecular based assays have been established for the diagnosis of COVID-19, TB and some STIs. GeneXpert instruments were first introduced for TB diagnosis and previously used for Chlamydia and Gonorrhoea screening.

Areas to be strengthened: Laboratory Standards

- Establish standards and guidelines for laboratory consumables and equipment.
- Improve laboratory infrastructure to meet international standards of practice.
- Decentralise a selection of POC testing to TTM and MT II Hospitals (Emergency, OPD, ANC) District Hospitals, Health Centres, and community (during outbreak response).

5. Workforce

The Health Sector Plan FY2019/20-FY2029/30, Samoa Human Resources for Health Strategy 2021-2026 and Samoa Health Workforce Development Plan 2021-2026 noted that health workforce is still a key bottleneck for the appropriate provision of health services, with challenges in adequacy of numbers and skills, retention, motivation and performance challenges.

The laboratory workforce is knowledgeable, multi-skilled and competent. The organisational structure of TTM Hospital Laboratory has been recently updated, although yet to be approved. Under the new structure, there is a total of 51 positions proposed. Currently there are 30 personnel at TTM Hospital Laboratory. Further capacity building and mentoring, for technical and managerial strengthening would be beneficial. The organizational structure should be updated to include all and proposed laboratory services and workload capacity being provided to support a tiered level of service, this will ensure there are adequate and qualified personnel to meet the demands in delivering a quality service.

Areas to be Strengthened: Laboratory Workforce

- Fill vacant positions.
- Appoint a permanent Pathologist.
- Develop a Quality Management officer position.
- Implement a workforce development program for training and capacity building.
- Review remuneration packages for overtime, allowances, and incentives.
- Strengthen in country Bio-medical team skill set.

6. Quality Management System (LQMS)

A laboratory quality management system has been established and implemented (SOPs, Quality, Equipment and Biosafety manuals), with support from PPTC to align with international standards. Each discipline is enrolled and actively participates in the external quality assurance program facilitated by PPTC. PPTC conducts annual audits of the progress of the implementation of the LQMS.

Areas to be strengthened: Laboratory Standards

- Appoint a Quality Management officer at all laboratories.
- Review and update manuals, SOPs, documentation as required.
- Strengthen audit programme.
- Provide training to all laboratory personnel in LQMS.
- Strengthen capacity at all laboratories to achieve ISO15189:2022 accreditation.
- Implement Monitoring and Evaluation framework and system to track progress.
- Strengthen the capacity of the laboratory workforce at a facility level to implement the LQMS.

7. Infrastructure

The laboratory design and layout at TTM and MTII laboratories are inadequate, as there is minimal space to expand services and store commodities. The flooring is improper, and the ventilation is inadequate. Equipment and consumables are restricting the main corridors and thoroughfares and blocking access to safety equipment.

Areas to be strengthened: Laboratory Infrastructure

- Laboratory infrastructure to meet International Standards.
- Additional storage space for laboratory commodities
- Blood donor collection area/Blood donor centre
- Provide input into design and layout of National Public Health Laboratory.
- Ensure national reference laboratories have capacity and control systems to handle highly infectious pathogens and meet acceptable containment standards.

8. Equipment Management and Maintenance

Laboratory equipment is provided entirely through development partners. There is no/inadequate budget through the MOH to procure equipment. There is an Equipment Donation Policy. Sustainability for maintaining all laboratory equipment should be established. The service contracts for all major equipment are established at the time of procurement. Most of the service contracts for the major equipment have expired and overdue for renewal. The BSCs II require annual servicing by a qualified technician, in which this capacity is not available in country.

Areas to be strengthened: Equipment and Equipment Maintenance

- Establish a service and maintenance schedule with biomedical team.
- Establish service contracts for all major laboratory equipment.
- Establish pipette and thermometer calibration in country.
- Implement a life cycle policy and plan for laboratory equipment.
- Allocate adequate budget for procurement and replacement of laboratory equipment.
- Provide support to strengthen the capacity of the biomedical team and end-users for all major equipment.
- Appoint an Equipment Maintenance officer at all laboratories.

9. Supply Chain Management

There is no formal system established for managing laboratory reagents and consumables. To prevent wastage and manage budget allocations, orders are submitted ~6 monthly or ad-hoc if required urgently. The ACEO Laboratory submits the requisitions through the Procurement and Logistic officer. Donations provided through partners/donors are not captured in the budget allocation or expenditure for laboratory services. Therefore, when support is ceased, sustainability is often not maintained, as in the case for the Xpert cartridges, which causes challenges for the laboratory to justify and advocate for increasing the budget allocation to continue testing. The hospital pharmacy and warehouse have installed mSupply to manage inventory.

Areas to be strengthened: Supply Chain Management

- Implement a standardised inventory management system (mSupply)
- Improve and increase storage of laboratory commodities.
- Strengthen knowledge and skills of laboratory personnel in procurement and supply management.
- Appoint a Procurement and Logistics officer at all laboratories.
- Establish regular, reliable and sustainable procurement processes of quality assured reagents and consumables.

10. Bio Safety and Waste Management

Laboratory waste is separated into general and infectious waste and collected by the hospital cleaners to incinerate and dispose. Hospital cleaners and/or laboratory personnel are responsible for cleaning the laboratory floors and benches. Key essential safety equipment is not available, not accessible, or outdated (eye wash station, emergency shower, fire extinguishers), compromising the safety of the laboratory personnel. Infrastructure is inadequate (floors, ventilation, space).

Areas to be Strengthened: Laboratory (Bio) Safety) and Waste Management

- Appoint a Safety Officer in all laboratories.
- Implement staff safety training for all laboratory personnel.
- Establish vaccination program, including immunisation status for all laboratory personnel.
- Ensure all safety equipment is available and accessible.
- Conduct a bio-risk assessment at all laboratories.

11. Information Management System (LIMS)

There is no standardised LIMS, excel spreadsheets and a shared drive are used to manage laboratory data and information. There are ongoing discussion to implement a digital LIMS (SENAITE) at TTM and MTII Hospital Laboratories.

Areas to be Strengthened: Laboratory Information Management System

- Implement a digital Laboratory Information system, that is reliable, sustainable, fit-for-purpose. Ensure laboratory personnel are regularly consulted and provide ongoing input.
- Provide staff training on recording and reporting laboratory results, including for disease surveillance and monitoring.
- Develop and implement a mechanism for collecting, analysing, and reporting laboratory data for notifiable and vaccine preventable diseases and AMR.

12. Research and Development

No research or development activities are currently being conducted by clinical laboratories. The laboratory personnel are eligible to apply for research grants. A Health Research Committee has been established.

Areas to be Strengthened: Research and Development

- Strengthen relationships with regional and international laboratories to coordinate and collaborate on research opportunities.
- Clinical and public health to collaborate on research activities.
- Allocate budget to conduct research.
- Support operational research. Pilot expanding molecular diagnostics and decentralising POC testing. Transition POC testing from serum to whole blood.

13. Public and Private Partnerships

LABPLUS is providing fee-for-service referral testing. National Reference Laboratories in New Zealand, Australia, French Polynesia, and New Caledonia provide support as required, during outbreaks and for confirmatory testing. There is strong partnerships support from PPTC, SPC and WHO. The Public Health Laboratory was established to support the Samoa Typhoid Control Program and was strengthened during the COVID-19 pandemic to support with the response. The Scientific Research Organisation of Samoa (SROS) was established in 2006 by the Government of Samoa, to implement and support the Government's strategy for the development of Samoa by providing the research, training, and analysis required for competitive research, and market opportunities and to provide a foundation for scientific research in Samoa. In October 2023, the Samoa Diagnostic Medical Laboratory was launched. This is a private laboratory established to provide timely screening, early diagnosis, and treatment for the population of Samoa, with a strong focus on women and underserved communities.

Areas to be strengthened: Public and Private Partnerships

- Establish standardised Memorandum of Understanding for partnership arrangements.
- Strengthen relationships with the private sector.
- Utilise revenue generated from private services to provide training and capacity building opportunities for laboratory personnel.
- Strengthen PPPs

There is a need to strengthen and expand diagnostic capacity throughout Samoa to respond rapidly and effectively to public health threats and emerging infectious diseases. Point-of-care testing should be reviewed for decentralising to the peripheral district hospitals and utilised during community outreach and outbreak investigations. Despite the progress and resources made available through the COVID-19 response, some clinical laboratory services have been heavily affected and neglected. Laboratory infrastructure and some equipment is sub-optimal and human resource capacity needs to be assessed, both of which can compromise the quality of results and limit the ability to respond to the public health demands. Laboratory inventory must be managed effectively, and equipment must be replaced and maintained to ensure sustainability of services.

The allocation of adequate financial resources could address many of the deficiencies In the laboratory system, however capacity strengthening should be guided by a health laboratory policy and strategic

plan. Developing a national health laboratory policy will provide the framework for the coordinated development and strengthen the delivery of quality and accessible national laboratory services in Samoa.

Building on the progress made prior to and during the pandemic, the MOH is committed to strengthening the national capacity to detect, prepare for and respond to public health emergencies. Moreover, implementing a laboratory system that will ensure early detection, targeted response and encouraged diagnostic integration across all disease programs is critical.

The detailed SWOT analysis of health laboratory services provision in Samoa is outlined below;

Situational Analysis Topic	Current Situation	Current Policies/Expectations/Standards	Main Weaknesses/Gaps	Potential Solutions
1. Financing Laboratory Services	• Operational budget for laboratory • International donor funding available	• Budget allocated on previous year (FY22/23) expenditure. • No existing Laboratory Policy or Strategic Plan to direct investments	• Operational budget does not cover replacement/new equipment. • Inadequate budget for service contracts • COVID-19 investments no captured in budget	• Develop costed National Laboratory Strategic Plan • Develop Laboratory Policy
2. Regulatory and Legal Framework	• SGD, SIDS, PDS, HSP, Corporate Plan, MOH Amendment Act 2019, Health Professionals registration Act 2007, HPAC, NPCC	• MOH Policy register (updated & distributed regularly) • Laboratory Handbook	• No Blood donor Policy • No desk review of Situational Analysis of the Laboratory System	• Newly endorsed Laboratory Policy
3. Organisation and Management of the Laboratory System	• Strong partnerships (PPTC, SPC)	• Organisational structure available	• Several positions vacant	• Approve updated laboratory organisation structure.
4. Laboratory Standards	• EQA QTRLY • SOP, Manuals, Manual Review Annually • Occupational Safety and Health (OSHA) Standards • EUCAST guidelines • ISO15189:2022	• QA testing • Positive feedback on results • Proper procedures/protocols are adhered. • Manuals to be monitored/reviewed for improvement. • Adapt according to resources available. • Adapt most of the standards towards achieving accreditation.	• Delay delivery/shipment to the laboratory • SOP/Manual outdated (new assays, discontinuation) • Storage • Documentation • No LIMS • CLSI	• Improve procurement system. • Communication courier services • Quality Officer to follow up. • Improve tracking system. • Continuous review of SOPs/Manuals • Mandated training of laboratory services

Situational Analysis Topic	Current Situation	Current Policies/Expectations/Standards	Main Weaknesses/Gaps	Potential Solutions
				• New storage facility • LIMS
5. Laboratory Workforce	• Knowledgeable and multi-skilled laboratory team • Several positions vacant	• Currently 30 personnel at TTM	• Workforce capacity (qualifications, technical skills) needs strengthening	• Fill vacant positions. • Develop training schedule. • Strengthen in country biomedical skill set
6. Quality Management System	• Internal and external EQA programmes & compliance with MOH QA	• Regular clinical laboratory audits (PPTC) and internal	• Low incidents management	• Newly endorsed policy & commitment/ committed and regularised corporate governance management system
7. Laboratory Infrastructure	• Inadequate laboratory infrastructure (flooring, ventilation, space)	• No existing standards for design and layout for laboratory facilities	• Laboratory design poor. • Inadequate space to store commodities • Equipment and consumables are restricting the main corridors and thoroughfares and blocking access to safety equipment	• Develop laboratory standards for all levels of healthcare
8. Equipment and Equipment Maintenance	• Supplies equipment needing specialist for installation and maintenance. • BioMed on ground not trained for servicing/installation. • Daily maintenance performed my laboratory staff. • Equipment problem/temperature logs	• Upskill/train staffs on installation, maintenance. • Certification of staff • SOP for training/services needs to be recorded accordingly. • Yearly maintenance (reagent/specimen/people)	• Staff turnover lack of knowledge transfer/operation • Sustaining reagent supplies • Lack of support on island e.g., spare parts/maintenance specialists • Breakdown due to environmental problems, power outages, air-condition failure, technical mishandling etc. • Communication breakdown • Specialist needed. • Spare parts not available in country, lengthy	• In-house training to be available for all staff. • Sending local BioMed/Engineers for overseas trainings • Availability/affordability of spare parts on island • Clear understanding of contract with suppliers e.g., hidden costs • New laboratory facility • Biomedical personnel • Biomedical engineer/Laboratory personnel

Situational Analysis Topic	Current Situation	Current Policies/Expectations/Standards	Main Weaknesses/Gaps	Potential Solutions
	• Yearly check by Biomedical team • Maintenance team • Equipment manual updated.		process and long wait	trainings during installation and operation of new equipment • Full understanding of the contract
9. Supply Chain Management	• No formal or standardised inventory management system implemented	• mSupply implemented in Hospital Pharmacy and warehouse	• No structured system to manage inventory. • Donations provided by partners/donors not captured in MOH procurement processes	• Implement mSupply
10. Laboratory (Bio)Safety and Waste Management	• Poor facility, storage, ventilation, safety measures • Poor segregation of waste/ clinical and general when disposing • Exposure to toxic/hazardous chemicals • OSHA guidelines	• HCW policy/strategy/MOH • OSH Manual by MCIC	• Poor ventilation • No storage space. • Poor waste management for toxic chemicals • Rubbish does not travel separately. • Hospital cleaners do use PPE properly. • Storage of commodities blocking eye wash, hallways, fire extinguishers access etc. • Facility issues (leaky ceilings etc.)	• Undertake a bio-risk assessment at TTM and MT II • Implement control measures and essential safety equipment. • New storage facility • Proper chemical cabinet storage • Hospital incinerator • Another waste transport vehicle
11. Laboratory Information Management System (LIMS)	• Shared drive, requirements gathering for LIMS.	• eHealth policy and strategy 2017 to be reviewed (2023)	• LIMS developer contract yet to be varied to commence the work	• Due diligence
12. Research and Development	• Can apply for research grants. • SROS conducting research.	• Health Research Committee established.	• No research or development activities being conducted by clinical laboratories	• Strengthen and coordinate R&D with regional and international reference laboratories. • Pilot expanding molecular diagnostic capacity to include STIs (Chlamydia/Gon

Situational Analysis Topic	Current Situation	Current Policies/Expectations/Standards	Main Weaknesses/Gaps	Potential Solutions
				orrhoea PCR, HPV PCR) and Respiratory panels, transition from SARS-CoV-2 only to multiplex (SARS-CoV-2, Flu, RSV) as routine testing. • Conduct operational research on POC testing to valid the use of whole blood
13. Public Private Partnership	• LABPLUS providing fee for service referral testing	• NRL support from New Zealand, Australia, French Polynesia and New Caledonia • Strong partnerships and donor support (PPTC, WHO, SPC, MFAT)	• Support not well coordinated.	• Strengthen PPPs • Standardise testing costs for private organisations.
14. Monitoring and Evaluation	• M&E section in the 2018 unendorsed policy • KPIs in HSP	• 2018 Lab Policy to review, revise, update, enhance and endorse. • AOPs	• Lack of staff	• Develop M&E framework with NHLSP 2024-2030 • Retain staff. Refer to 2018 Lab Policy (unendorsed)

Annex 4: SWOT Analysis for Policy development

1. Financing Laboratory Services	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Allocated budget • Fees for service	• Delay of procurement process • System – MOH to the MOF • Budget allocation
Opportunities (Prospects)	**Threats (Challenges)**
• Annual financial plan • Suppliers/Couriers • Standardised procurement process • Quarterly order of resources • Establish MOUs • Donor, Partner, Stakeholder funding	• Donor commitment/priorities • Private laboratory service competition

2. Regulatory and Legal Framework	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Very qualified staff • Registration with professional body	• No regulatory framework • No Laboratory Policy • No Laboratory Strategic Plan • Staff shortage • Unstainable funding sources • Not all laboratory personnel are registered. • Retaining qualified staff • Limited staff benefits • Not all laboratory staff are registered. Do not meet the minimum requirements.
Opportunities (Prospects)	**Threats (Challenges)**
• Working towards ISO accreditation. Aligning national regulations with international standards can facilitate international collaboration and data sharing. • Newly endorsed policy • Provide incentives. • Finalise and approve career pathway	• Political agendas (Government run institutions can be burdened by bureaucracy, which can hinder agile decision-making and responsiveness • Emergencies • Non-compensation of staff benefit • Public Service Commission • Unstainable funding. Changed priorities of funding sources.

3. Organisation and Management of the Laboratory System	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Existing organisational structure	• No documented MOU for the collaboration • No standards available of which services to offer at different levels of healthcare
Opportunities (Prospects)	**Threats (Challenges)**
• Collaboration in place with reference laboratories and other laboratories in the country	• Private laboratory • Limited number of free testing quota for referral testing

4. Laboratory Standards	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Existing standards, SOPs and manuals • Utilisation of standards • Auditing of standards • Internal quality control between users	• Limited and inadequate storage • Documentation • No LIMS
Opportunities (Prospects)	**Threats (Challenges)**
• Make use of available land on hospital premise. Build-up. • To implement standard to other laboratories • Capacity Building	• Trained staff moving or leaving. • SOP instructions not clear • SOP not reviewed. • New reagents not clearly labelled (foreign language)

5. Laboratory Workforce	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Qualified staff • Networking between the laboratory through continuous professional development • HRH strategy and Workforce Plan in place	• Not enough staff • Staff retention • HRH strategy not reviewed
Opportunities (Prospects)	**Threats (Challenges)**
• Recruitment of skilled staff from overseas can assist	• Competing salary packages offered from other laboratories

6. Quality Management System	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• LQMS in development • Documentation available (Quality and Biosafety Manual, SOPs) • Partnerships • Internal Quality Assurance Program • Low incidents management. Promotes best practice. • Biomedical staff • Quality of services. Improved reporting. Improves standards. • Quality Assurance staff	• Four Star rating on LQMS audit • Not accredited • Insufficient resources. Despite access to advanced equipment, budgets cab be limited, leading to resource constraints in maintaining and improving the QMS. • Poor ventilation (infrastructure) • Government run institutions can be burdened by bureaucracy, which can hinder agile decision-making and responsiveness.
Opportunities (Prospects)	**Threats (Challenges)**
• Newly endorsed Laboratory Policy • Trainings and professional development. Develop training programs for staff to continuously improve their understanding and adherence to QMS principles. • Develop maintenance plan for all analysers. • Support from partners (WHO, PPTC, SPC) • Partner support for laboratory accreditation • LIMS. Advancements in technology can improve data collection, analysis, and reporting capabilities. • Maintenance plan for all analysers • Promote international collaboration	• Retain Biomedical staff. • Emergencies • Budget cuts. Economic downturn or changes in government priorities can lead to reduced funding for quality management initiatives. • Data security. Increased reliance on digital systems poses risks to data security and integrity, which is crucial for QMS. • Competitive pressure. Other research institutions, both public and private may pose competition in terms of research and QMS effectiveness.

7. Laboratory Infrastructure	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Good location	• Limited storage space • Poor planning • No involvement of laboratory personnel during the design process • Not a standardised building
Opportunities (Prospects)	**Threats (Challenges)**
• Stakeholder engagement • Procurement process • Grants • Insurance companies	• Location of new laboratory

8. Equipment and Equipment Maintenance	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Quality control and calibration • Quality results • Increase volume of testing • Faster TAT • Quality standards of equipment (CE and FDA approved) • Sharing of resources between users	• Health facilities and Assets Management and Maintenance Policy not endorsed. • Sustainability • Manual test processes still exist
Opportunities (Prospects)	**Threats (Challenges)**
• Staff training • New office space • Back up support contract • WHO recommended	• Staff leaving • Breakdown of equipment • Expiry of quality controls and calibrations checks • Biomedical and users not trained for installation and servicing. • Affordability of reagents

9. Supply Chain Management	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Adequate stock for most commodities • Use of mSupply for procurement processes • Stock cards used to monitor inventory	• Lack of testing resources • No laboratory procurement personnel • Delay in procurement process
Opportunities (Prospects)	**Threats (Challenges)**
• Integrated procurement for all laboratory commodities • Strong donor/partner support • mSupply available in hospital pharmacy • Private laboratory and SROS (research and collaboration) • Insurance companies	• Inadequate budget • Procurement processes • Donors/partners priorities/agenda • Procurement supply connections

10. Laboratory (Bio)Safety and Waste Management	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• PPE Disinfection availability and usage • Segregated waste • Existing incinerator	• Inappropriate PPE use • Minimal training • Hazardous environment • Slippery/floor/tiles • Not enough waste bags (infectious and general) • Pests (mice, flies etc.)
Opportunities (Prospects)	**Threats (Challenges)**
• Better facility (makeover) • Training of staff • Strengthening polices and SOPs. • Autoclave of waste before disposal	• Transmission of diseases • Non-compliance of SOP and polices. • Poor developed chemical hygiene plan and exposure control plan. • Ineffective waste disposal strategies

11. Laboratory Information Management System	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Shared drive at TTM. To make processes more efficient and effective. More accountability. • Funding secured for LIMS. It is a costly system and no budget provision in the local budget. • Telehealth (Telepathology) integration • Interoperability and integrability with other related systems (e.g., Tamanu and mSupply)	• No accessibility to shared drive at District Hospital • Connectivity
Opportunities (Prospects)	**Threats (Challenges)**
• Fully functional and operational digital LIMS. More effective and efficient processes, accessibility to specialised personnel. • Training, Capacity building, enhance workforce capabilities and sustain changes to the system.	• Maintain patient confidentiality. Lose confidence in the system. • Data/cyber security. Loss of data. • Connectivity. Accessibility. • Power supply • Constant changes. Update and train staff on changes.

12. Research and Development	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Health Research Committee established. • Can apply for research grants	• Research not encouraged amongst MOH staff. • Research data collection disruptive with normal diagnostic routine testing
Opportunities (Prospects)	**Threats (Challenges)**
• Collaboration with research institutions/suppliers or distributors	• Data ownership

13. Public Private Partnerships	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• Sharing of workload and resources (overseas reference and local laboratories)	• Overlapping of responsibilities in the absence of an MOU

• Patient preference/choice • Improved waiting time and TAT of results	
Opportunities (Prospects)	**Threats (Challenges)**
• Establish further collaboration. Acquiring funds, human and asset resources, research.	• Data confidentiality • Competing costs

14. Monitoring and Evaluation	
Strengths (Assets, Resources)	**Weaknesses (Limitations, Restrictions)**
• AOPs • KPIs to measure performance. • Annual reports.	• Approved/endorsed organisational structure. Needs to be endorsed which was delayed due to the merge in 2019.
Opportunities (Prospects)	**Threats (Challenges)**
• Health Sector Plan M&E framework • Partner support to develop NHLSP and M&E framework. • Training. For sustainability to meet the needs of the workforce • Professional development (curriculum NUS). For sustainability to meet the needs of the workforce.	• Public Service Commission. Lack of alignment/communication.

Annex 5: List of Participants that participated in the consultative workshops.

On behalf of the Ministry of Health we wish to acknowledge our appreciation for the invaluable contributions and collaborative efforts provided by the below participants in the development and finalisation of this policy.

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