REPUBLIC OF KENYA
MINISTRY OF HEALTH

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
Make Testing a Safe Reality

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

MEDICAL LABORATORY DIAGNOSTICS AS FOUNDATION FOR SAFE, EFFECTIVE AND QUALITY HEALTHCARE.

Pursuant to the Medical Laboratory Technicians and Technologists Act CAP 253 A Laws of Kenya.

KMLTTB QUALITY ASSURANCE SERVICES

	MEDICAL LABORATORY DIAGNOSTICS AS FOUNDATION FOR SAFE, EFFECTIVE AND QUALITY HEALTHCARE.		DOCUMENT CONTROL Serial: KMLTTB/ML/DIAG/QA/HC/01 Revision No. 001 Revision Date: 2ND, JAN,2026
KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD Make Testing a Safe Reality	OWNER THE FORM	REGISTRAR	

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MEDICAL LABORATORY DIAGNOSTICS AS FOUNDATION FOR SAFE, EFFECTIVE AND QUALITY HEALTHCARE.

Medical Laboratory Diagnostics are not a peripheral support service in healthcare, they are the foundation upon which safe, effective and quality care is built. In modern health systems, Medical Laboratory diagnostics are treated as a core pillar of Universal Health Coverage (UHC), patient safety, disease surveillance, outbreak control, rational prescribing, and health financing efficiency.

A. **The World Health Organization states that diagnostics are "the most important tools that empower the health workforce in the identification of diseases or health conditions."**

In practical terms, without Medical Laboratory diagnostics:-

1. Diseases are misdiagnosed;
2. Treatment becomes guesswork;
3. Antibiotics are overused;
4. Cancers are detected late;
5. Maternal complications are missed;
6. Health insurance schemes pay for inappropriate care;
7. Public health surveillance collapses.
8. Studies frequently estimate that nearly 70% of clinical decisions depend on diagnostic information.

B. Why Medical Laboratory diagnostics are central to quality healthcare

Quality healthcare requires:-

1. Correct Medical Laboratory diagnosis;
2. Appropriate treatment;
3. Monitoring of response;
4. Prevention of complications;
5. Early detection of deterioration.

C. Medical Laboratory Diagnostics sit at the centre of all five.

C. Examples:

1. A patient with chest pain cannot safely be treated without ECGs, cardiac enzymes and imaging.
2. A diabetic patient requires glucose and HbA1c monitoring.
3. Cancer treatment depends on pathology and molecular diagnostics.
4. Maternal mortality reduction depends on ultrasound, haemoglobin testing and infection screening.
5. ICU care is impossible without medical laboratory and imaging support.

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D. WHO now treats Medical Laboratory diagnostics similarly to medicines as "essential health products".

The major global shift occurred in 2018 when WHO introduced a landmark policy intervention placing Medical Laboratory diagnostics at the same strategic level as essential medicines.

The WHO Essential Medical Laboratory Diagnostics List:-

1. Identifies Medical Laboratory tests every country should guarantee;
2. categorizes Medical Laboratory diagnostics by level of care;
3. Links Medical Laboratory diagnostics to disease burden;
4. guides Medical Laboratory procurement and reimbursement;
5. standardizes Medical Laboratory quality expectations;
6. Supports medical laboratory accreditation and regulation.

E. WHO defines essential Medical Laboratory diagnostics as Medical Laboratory tests that:

"Satisfy the priority of the health care needs of the population."

F.The EDL framework protects diagnostics through:-

1. Medical Laboratory Mandatory prioritization;
2. Medical Laboratory Integration into national health plans;
3. Medical Laboratory Tiered referral systems;
4. Medical Laboratory Quality assurance requirements;
5. Medical laboratory governance systems;
6. Medical Laboratory Regulatory oversight;
7. Medical Laboratory Public financing inclusion.

G. WHO also urges countries to:-

1. Develop national Medical Laboratory diagnostics strategies;
2. Establish national essential Medical Laboratory diagnostics lists;
3. Strengthen laboratory systems;
4. Ensure equitable access to Medical Laboratory diagnostics;
5. Embed Medical Laboratory diagnostics into UHC frameworks.

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H. Countries with advanced quality-of-care legislation or frameworks generally protect Medical Laboratory diagnostics in six major ways:

1. Legal recognition of Medical Laboratory diagnostics as an essential service
2. Countries increasingly embed Medical Laboratory diagnostics into:-
i. national health laws;
iii. Patient rights laws;
iii. UHC statutes;
iv. Insurance reimbursement frameworks.

I. Examples include:-

(a). UK NHS Medical Laboratory diagnostic waiting-time guarantees;
(b). India's National Essential Medical Laboratory Diagnostics List;
(c). Thailand's UHC Medical Laboratory diagnostics package;
(d). Rwanda's tiered Medical laboratory policy;
(e). South Africa's National Health medical Laboratory Service framework.
These systems recognize that denying diagnostics is effectively denying treatment.
3. Mandatory quality standards and accreditation
Strong systems legally require:-
(a). Medical laboratory licensing;
(b). accreditation standards;
(c). quality assessment;
(d). calibration protocols;
(e). proficiency testing;
(f). biosafety standards.

J. Common accreditation systems include:-

1. ISO 15189 for medical laboratories;
2. KMLTTB medical laboratory services standards.

K. This protects patients from:-

1. False Medical Laboratory results;
2. Inaccurate testing;
3. Poor Medical Laboratory specimen handling;
4. Fraudulent Medical laboratories.
3. Public financing and reimbursement protection

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L. High-performing systems protect Medical Laboratory diagnostics financially by:-

1. Reimbursing diagnostic tests through insurance;
2. Making core tests free or subsidized;
3. Ring-fencing medical laboratory budgets including diagnostics in benefits packages.

M. WHO now strongly emphasizes that diagnostics must be included in UHC financing packages.

Paying for treatment without Medical Laboratory diagnostics leads to:

Waste;

1. overtreatment;
2. insurance fraud;
3. irrational prescribing;
4. Poorer outcomes.

N. Tiered national diagnostic networks

WHO recommends diagnostics be distributed according to level of care:

1. Community;
2. Primary care;
3. County/regional hospitals Medical Laboratories;
4. Tertiary referral Medical laboratories.

O. The EDL specifically categorizes tests based on facility level.

This protects:-

1. Referral integrity;
2. Turnaround times;
3. Equity in rural access;
4. Outbreak detection capacity.
5. Integration into disease surveillance and public health law

P. COVID-19 demonstrated that diagnostics are national security infrastructure.

Modern health systems therefore legally integrate diagnostics into:

1. epidemic preparedness;
2. antimicrobial resistance surveillance;
3. cancer registries;
4. mortality surveillance;
5. Vaccine monitoring systems.
6. WHO explicitly describes diagnostics as:
7. “The first line of defence against emerging pathogens.”
8. World Health Organization
9. Regulation against commercial abuse and low-quality diagnostics

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Q. Advanced systems regulate:

1. counterfeit Medical Laboratory tests;
2. un validated Medical Laboratory kits;
3. predatory over Medical Laboratory testing;
4. unnecessary radiology;
5. Conflict of interest in Medical laboratories.

R. In the Republic of Kenya we have separate:

1. prescribing;
2. Medical Laboratory ownership;
3. Medical Laboratory Referral incentives.

This is intended to prevent profit-driven Medical Laboratory diagnostics abuse.

S. The emerging global consensus

The global health community increasingly recognizes:

1. Medicines without Medical Laboratory diagnostics are unsafe;
2. Insurance without Medical Laboratory diagnostics is inefficient;
3. UHC without Medical Laboratory diagnostics is incomplete.

T. WHO and recent global health literature now treat diagnostics as:

1. Human-rights issue;
2. Health-system building block;
3. Prerequisite for quality care;
4. Strategic national asset.

U. Implications for the Republic of Kenya

For Kenya's evolving SHA/UHC framework, Medical Laboratory diagnostics become critical in:

1. Claims verification;
2. Fraud control;
3. Rational referral systems;
4. Reducing unnecessary admissions;
5. Improving primary healthcare;
6. Chronic disease management;
7. Cancer detection;
8. Maternal and child survival;

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9. Epidemic preparedness.

V. A health financing model that under funds diagnostics risks:

1. Massive claims inflation;-
2. Poor outcomes;
3. Denial of care;
4. Irrational treatment;
5. System distrust.

W. This is why Republic of Kenya must move towards:-

1. National essential Medical Laboratory diagnostics lists;
2. Legally protected Medical laboratory systems;
3. Digital diagnostic integration;
4. Accreditation mandates;
5. Diagnostics reimbursement guarantees;
6. Medical Laboratory workforce strengthening.

.....THE END.....

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