



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
KMLTTB REGULATORY STANDARDS FOR ONCOLOGY MEDICAL LABORATORY SERVICES

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

KMLTTB QUALITY ASSURANCE SERVICES

	KMLTTB REGULATORY STANDARDS FOR ONCOLOGY MEDICAL LABORATORY SERVICES		DOCUMENT CONTROL
	OWNERSHIP	REGISTRAR	SERIAL: KMLTTB/SP/ONCOLOGY/LAB/01 Version: 001 Revision Date: 16 TH , OCTOBER, 2026



KMLTTB REGULATORY STANDARDS FOR ONCOLOGY MEDICAL LABORATORY SERVICES

These standards establishes the minimum requirements for medical laboratory services to support the screening, diagnosis, treatment selection, monitoring, and prevention of neoplastic diseases. It is designed to ensure accuracy, clinical utility, and safety across all phases of laboratory testing.

CLASSIFICATION: CLASS E/F/G – SPECIALIZED ONCOLOGY MEDICAL LABORATORY

1.0 PREAMBLE AND LEGAL BASIS

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a statutory body mandated to oversee the training, practice, business, and employment of medical laboratory technicians and technologists and advises government on related matters as stipulated under Cap 253A of the Laws of Kenya. The Board also undertakes validation of in vitro diagnostics through Legal Notice No. 113 of 2011.

The Act gives the Board the responsibility of ensuring that all Medical Laboratories undertaking analysis and investigations meets the desired standards necessary for the delivery of quality Medical Laboratory services. These standards shall ensure the development of a robust Medical Laboratory services necessary to meet national and international health obligations that include sustainable development goals and Universal Health Coverage (UHC).

It is anticipated that compliance with the standards will enable Medical Laboratory run and sustain their analysis and investigations through ensuring the safety of the professionals, the patient and the environment are guaranteed.

1.1 VISION, MISSION AND CORE VALUES

Our Vision: “That the Health of every Kenyan will be fully protected through effective regulation of the practice of laboratory medicine.”

Our Mission: “To Exercise General Control and Supervision over training, business, employment and practice of Laboratory Medicine and Advise the Government on all related matters.”

Our Core Values: Integrity; Selfless service; Innovation and open-mindedness; Sense of belonging; Pride in what we do.



1.2 SCOPE

This standard sets the minimum requirements for any Medical Laboratory seeking to provide services in support of screening, diagnosis, treatment selection, monitoring, and prevention of neoplastic diseases.

No person or Health facility/institution shall provide oncology investigations and analysis or related specialized testing without a KMLTTB Class E/F/G license

These are comprehensive standards for medical laboratory services to support diagnosis, treatment and prevention of various types of cancers.

1. QUALITY MANAGEMENT SYSTEM (QMS) AND REGULATORY COMPLIANCE

Accreditation and General Requirements

- A. **Standard Compliance:** All oncology testing laboratories must be accredited under ISO 15189 (Medical laboratories requirements for quality and competence as certified by KMLTTB).
- B. **Proficiency Testing (PT):** Laboratories must participate in external quality assessment (EQA) or PT programs specifically designed for oncology biomarkers, immunohistochemistry (IHC), and molecular pathology.
- C. **Document Control:** Standard Operating Procedures (SOPs) must be maintained and reviewed annually for all diagnostic algorithms, assay validations, and critical value reporting workflows.

Personnel Qualifications and Competency

- A. **Pathologists/ Clinical Cytologists:** Histopathology and cytopathology reports must be signed out by a KMPDC-certified pathologist While Cytology reports may be reported by A KMLTTB certified Clinical cytologist specialist with documented competency in oncology.
- B. **Molecular Diagnostics:** Molecular assays (e.g., Next-Generation Sequencing) must be supervised by a clinical molecular geneticist or a pathologist specialized in molecular pathology.
- C. **Technical Staff:** Medical laboratory Sciences professionals must undergo documented, assay-specific competency assessments every 12 months.

2. PRE-ANALYTICAL PHASE: SPECIMEN INTEGRITY AND HANDLING

Specimen Collection and Identification

- A. **Unique Identification:** Specimen containers must feature at least two independent patient identifiers (e.g., full name and date of birth/unique medical record number).



- B. **Clinical Annotation:** Requisitions must explicitly note the primary anatomic site, specimen type (e.g., core needle biopsy, resection, liquid biopsy), tumor stage (if known), and current targeted therapies.

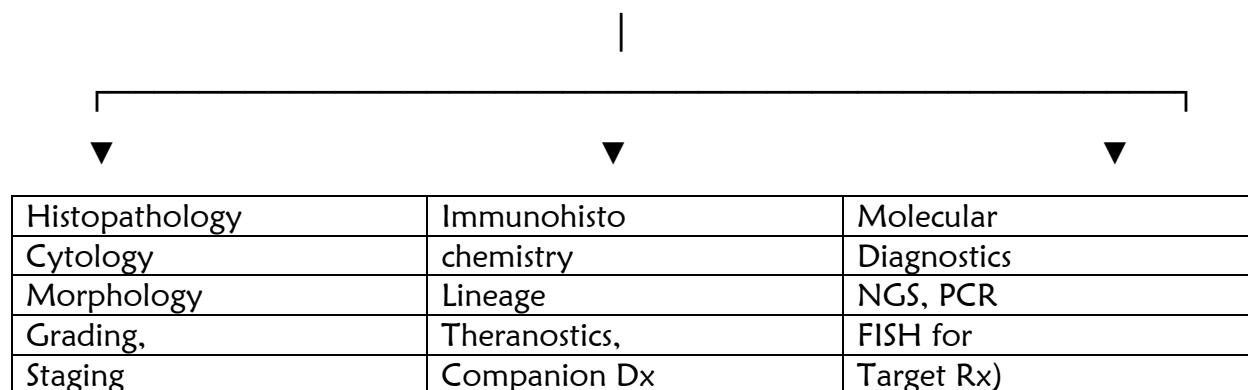
Tissue Handling and Fixation (Solid Tumors)

- A. **Cold Ischemia Time:** The time from tissue excision to immersion in fixative must be less than 60 minutes to preserve morphological features, RNA, and phosphoproteins (e.g., HER2/neu, breast biomarkers).
- B. **Fixative Standard:** Specimen fixation must utilize 10% neutral buffered formalin (NBF).
- C. **Fixation Duration:**
Biopsy specimens: 6 to 24 hours.
- D. **Large surgical resections:** 12 to 72 hours.
- E. **Decalcification:** For bone metastases, non-acid or EDTA-based decalcification agents are required to preserve nucleic acids for subsequent molecular testing.

3. ANALYTICAL PHASE: TESTING MODALITIES AND FRAMEWORKS

Oncology laboratory services must provide a tiered diagnostic framework integrating multiple disciplines.

INTEGRATED ONCOLOGY DIAGNOSIS



Histopathology and Cytopathology

- A. **Gross Examination:** Standardized macroscopical evaluation must record specimen dimensions, tumor size, margins, and lymph node yields using structured checklists (e.g., College of American Pathologists [CAP] Cancer Protocols).
- B. **Reporting Metrics:** Every diagnostic report must definitively include:
 1. Histological type (WHO classification).
 2. Histological grade (e.g., Nottingham score for breast cancer, Gleason score for prostate cancer).
 3. Lymphovascular and perineural invasion status.
 4. Surgical margin status (distance in millimeters to the closest ink margin).

Immunohistochemistry (IHC)

- A. **Controls:** Every IHC run must contain verified on-slide positive and negative external tissue controls.
- B. **Companion Diagnostics:** Specific scoring criteria must follow validated guidelines:
 1. **Breast Cancer:** ASCO/CAP guidelines for HER2/neu (0, 1+, 2+, 3+), Estrogen Receptor (ER), and Progesterone Receptor (PR).
 2. **Immunotherapy Selection:** PD-L1 scoring systems (CPS or TPS) specified by the corresponding companion diagnostic kit (e.g., 22C3, SP263).

Molecular Diagnostics and Cytogenetics

- A. **Tumor Fraction Enrichment:** A pathologist must evaluate and mark a corresponding H and E slide to ensure the specimen contains the minimum required tumor cell content (typically $\geq 10\text{-}20\%$ depending on the assay platform) prior to macrodissection and DNA/RNA extraction.
- B. **Next-Generation Sequencing (NGS):** Large panels or comprehensive genomic profiling (CGP) must be validated to detect Single Nucleotide Variants (SNVs), Small Indels, Copy Number Variations (CNVs), and Structural Variants (fusions).
- C. **Turnaround Times (TAT):** Molecular target results required for first-line therapeutic decisions (e.g., EGFR, ALK, ROS1 in advanced NSCLC) must have a clinical TAT of ≤ 10 calendar days from sample receipt in the molecular lab.

4. SPECIFIC DIAGNOSTIC AND MONITORING STANDARDS BY MAJOR CANCER CATEGORY

S.N o.	Cancer Category	Key Screening and Early Detection Tests	Diagnostic Confirmati on Standard	Companion Diagnostics and Theranostics	Long-term Monitoring and Recurrence
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	Breast	Mammography screening,	High-risk germline screening (BRCA1/2)	Core needle biopsy, H and E histology	ER, PR, HER2 (IHC/FISH), Ki-67, Oncotype DX/Mamma Print Serum CA 15-3 / CEA, Circulating Tumor DNA (ctDNA)
2.	Colorectal	FIT (Fecal Immunochemical Test)	Cologuard, Colonoscopy Tissue biopsy via endoscopy	H and E histology KRAS	NRAS, BRAF mutations; MSI/MMR status; HER2 amplification Serum CEA, ctDNA (molecular residual disease monitoring)
3.	Lung (NSCLC)	Low-dose CT screening (eligible populations)	Core/FNAB biopsy, Cytology (EBUS),	H and E EGFR, ALK, ROS1, BRAF, RET, MET, NTRK, KRAS, PD-L1	ctDNA liquid biopsy for resistance mutations (e.g., EGFR T790M/C797S)
4.	Hematologic	Complete Blood Count (CBC) with peripheral smear	Bone marrow aspirate and trephine biopsy	Flow cytometry (Immunophenotyping), BCR-ABL1 quantitation	Next-Generation Sequencing Flow cytometry or NGS for Measurable Residual Disease (MRD)



5. POST-ANALYTICAL PHASE: REPORTING, CRITICAL VALUES, AND DATA STEWARDSHIP

Synoptic Reporting

- A. **Standardized Templates:** Pathologists must use structured synoptic reporting formats for all definitive resection specimens. Narrative reporting is not acceptable for primary definitive diagnoses.
- B. **Integrated Reporting:** For complex cases, Medical laboratories should issue integrated reports combining morphological, IHC, and molecular findings into a single, cohesive clinical document.

Critical Values in Oncology

The laboratory must establish an immediate notification protocol (telephonic or secure electronic alert to the ordering clinician within 1 hour) for critical oncology findings, including:

- A. New, unexpected diagnosis of acute leukemia or hyperleucocytosis ($WBC > 100 \times 10^9/L$).
- B. Significant, unexpected cytopenia in a patient undergoing active chemotherapy (e.g., Absolute Neutrophil Count $< 0.5 \times 10^9/L$).
- C. Findings indicative of spinal cord compression or superior vena cava syndrome in a cytological/histological specimen.

6. BIOBANKING AND SPECIMEN RETENTION STANDARDS

- A. **Wet Tissue:** Formalin-fixed tissue remnants must be retained for at least 2 weeks after the final report is signed out.
- B. **Paraffin Blocks and Slides:** Formalin-Fixed Paraffin-Embedded (FFPE) blocks and diagnostic glass slides must be securely archived for a minimum of 10 years (or longer depending on regional statutory requirements) to facilitate retrospective review, clinical trials, or future biomarker testing.
- C. **Extracted Nucleic Acids:** DNA and RNA extracted for molecular testing should be stored at $-80^{\circ}C$ for a minimum of 1 to 3 years to allow for repeat or confirmatory testing if clinically indicated.

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