



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD
SPECIALISED BLOOD TRANSFUSION UNIT MEDICAL LABORATORY OPERATIONAL
FRAMEWORK.

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

KMLTTB QUALITY ASSURANCE SERVICES

	SPECIALISED BLOOD TRANSFUSION UNIT MEDICAL LABORATORY OPERATIONAL FRAMEWORK		DOCUMENT CONTROL SERIAL: KMLTTB/SP/BTU/LAB/01 Version: 001
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TECHNICAL STANDARD FOR SPECIALISED BLOOD TRANSFUSION UNIT MEDICAL LABORATORY OPERATIONAL FRAMEWORK.

CLASSIFICATION: CLASS D/E/F/G – SPECIALIZED RENAL 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 are ensuring the safety of the professionals, the patient and the environment.

1.1 Vision, Mission and Core Values

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

1.1.2 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.”

1.1.3 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 as a Blood Transfusion Unit.

No facility shall provide Blood transfusion Unit services or related specialized testing without a KMLTTB Class D/E/F/G license.



SPECIALISED BLOOD TRANSFUSION UNIT MEDICAL LABORATORY OPERATIONAL FRAMEWORK.

KMLTTB has prescribed Blood Transfusion Unit Medical Laboratory benchmark. The benchmarks includes ISO 15189:2022 (Medical Laboratories, Requirements for Quality and Competence) and AABB (Association for the Advancement of Blood and Biotherapies) Standards.

The Blood transfusion unit Medical Laboratories are meant to support organ transplantation, open-heart surgeries, oncological therapeutics, and specialized hematology investigations.

2.0 ORGANIZATIONAL GOVERNANCE AND LEADERSHIP

Specialised Blood Transfusion Unit Medical Laboratory must maintain a highly formalized leadership structure to ensure full legal, ethical, and clinical accountability.

2.1 Medical Direction

The unit must operate under a licensed, full-time Medical Laboratory Director specializing in Medical laboratory sciences (Blood Transfusion Science) or Haematology. The position carry final accountability for donor/recipient safety, medical protocols, and legal compliance.

2.2 Hospital Transfusion Committee (HTC)

An independent, multidisciplinary HTC must meet at least quarterly. It must include representatives from surgery, anesthesia, hematology, nursing, oncology, and the Medical Laboratory to review Blood utilization, audit waste, and enforce evidence-based clinical guidelines.

2.3 Medical Laboratory Quality Manager

A dedicated Quality Management Officer independent of daily testing workflows must be appointed to supervise the Quality Management System (QMS), document deviations, and lead accreditation efforts.

3.0 ADVANCED IMMUNOHEMATOLOGY AND INVESTIGATIONAL SCOPE

To serve as a regional referral nexus, the testing portfolio must bypass routine grouping and encompass state-of-the-art Medical Laboratory analysis and investigational capabilities:

3.1 Red Cell Serology and Phenotyping

3.1.1 Extended Phenotyping

Routine electronic or manual gel-card phenotyping for Rh (C, c, E, e) and Kell (K) antigens for all chronically transfused patients (e.g., Sickle Cell Disease, Thalassemia) to mitigate alloimmunization.

3.1.2 Rare Blood Group Registry



Maintenance of a mapped repository and reference samples for high-frequency antigen-negative rare blood types.

3.1.3 Complex Antibody Identification

Multi-panel (11- or 14-cell) antibody identification assays, including auto-adsorption, alloadsorption, and elution techniques for resolving multi-specific or warm/cold autoantibodies.

3.2 Molecular and Specialized Diagnostics

3.2.1 High-Resolution HLA Typing

Next-Generation Sequencing (NGS) or Polymerase Chain Reaction (PCR) based HLA-A, B, C, DR, DQ matching to support solid organ and bone marrow transplant units.

3.2.2 Platelet Serology

Human Platelet Antigen (HPA) genotyping and antibody screening to resolve Refractory Platelet States and Neonatal Alloimmune Thrombocytopenia (NAIT).

3.3.3 Hemolytic Disease of the Fetus and Newborn (HDFN) Workup

Regular titration of maternal alloantibodies, fetal RhD genotyping via cell-free fetal DNA (cffDNA), and quantitative Kleihauer-Betke (KB) testing or flow cytometry for fetomaternal hemorrhage quantification.

3.0 QUALITY MANAGEMENT SYSTEM (QMS) AND REGULATORY COMPLIANCE

The Medical laboratory must institute a zero-tolerance framework for diagnostic errors, governed by strict internal and external validation cycles

QMS Pillar	Core Standard Requirement	Verification Method
Document Control	Mandatory creation, biannual review, and archiving of all Standard Operating Procedures (SOPs) via automated Document Control software.	Full digital audit logs; signature verification by the Medical Director.
Internal Quality Control (IQC)	Daily testing of positive and negative controls for all blood grouping, antibody screening, and infectious disease assays prior to clinical testing.	Levy-Jennings charts with automated blockages if Westgard rules are breached.
External Quality Assessment (EQA)	Compulsory enrollment in an international, accredited Proficiency Testing program (e.g., UK NEQAS, CAP, or WHO-recognized reference schemes).	Blinded panel analysis three times annually with >99% performance score required.



Traceability	Absolute "Vein-to-Vein" electronic tracking matching every unique donation ISBT 128 barcode directly to the specific recipient.	Bi-annual simulation audits tracking random units from collection to final destination.
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4.0 BLOOD PROCESSING, COMPONENT PREPARATION, AND PATHOGEN REDUCTION

Advanced therapeutics require tailored Blood components to optimize patient outcomes and minimize post-transfusion complications.

4.1 Automated Apheresis

Capabilities for real-time collection of single-donor platelets (SDP), therapeutic plasma exchange (TPE), and leukapheresis.

4.2 Leukoreduction

Universal pre-storage leukoreduction (residual White Blood Cell Count (WBC) count $< 1 \times 10^6$ per unit) to dramatically lower febrile non-hemolytic transfusion reactions (FNHTR) and Cytomegalovirus (CMV) transmission.

4.3 Irradiation Unit

On-site Gamma or X-ray irradiator (25–50 Gy) targeting cellular components for severely immunocompromised patients, neonates, and bone marrow transplant recipients to prevent Transfusion-Associated Graft-Versus-Host Disease (TA-GvHD).

4.4 Pathogen Reduction Technology (PRT)

Utilization of Riboflavin/Amotosalen combined with UV light systems on platelet and plasma units to chemically inactivate broad-spectrum viruses, bacteria, and parasites.

5.0 Infrastructure, Cold Chain Management, and Biosecurity

The physical plant must be engineered to mitigate cross-contamination, guarantee structural stability, and secure biological assets.

5.1 Zonality

Strict architectural segregation dividing the space into a Specimen Receipt Zone, Diagnostic Immunohematology Zone, Component Processing Cleanroom (ISO Class 7/Class 10,000 for open systems), and a Restricted Issue Vault.

Specimen and Request Receipt (Unclean Zone)



Immuno-hematology and Testing Area (Clean Zone)



Component Storage and Issue Vault (Controlled/Clean Zone)



5.2 Validated Storage Matrix

- Packed Red Blood Cells (PRBCs)
Controlled refrigeration at +2°C to +6°C with continuous electronic spatial monitoring.
- Fresh Frozen Plasma (FFP) / Cryoprecipitate
Deep-freeze storage at $\leq -30^{\circ}\text{C}$.
- Platelets

Continuous agitation incubators maintained at +20°C to +24°C.

5.3 Continuous Redundancy Protocol

All cold storage units must link to an automated Central Environmental Monitoring System that broadcasts real-time telemetry and triggers immediate SMS/telephonic alerts upon any deviation exceeding 15 minutes.

Back-up power must include automated local uninterrupted power supply (UPS) systems paired with dual-redundant emergency hospital generators.

6.0 HEMOVIGILANCE AND ADVERSE EVENT MANAGEMENT

A comprehensive national referral framework mandates an aggressive, multi-tiered tracking system monitoring the clinical side of the transfusion chain.

6.1 Bedside Verification Protocol

Implementation of an unalterable Double Independent Verification process at the patient's bedside.

Two qualified healthcare professionals must verify the patient's identity, the matching Blood unit crossmatch tag, and the ISBT 128 barcode directly against the patient's electronic health record (EHR) before initiating infusion.

6.2 Immediate Reaction Algorithm

Immediate termination of any transfusion exhibiting signs of an adverse event (e.g., fever spike, dyspnea, hypotension, back pain). The Medical Laboratory must immediately initiate an acute hemolysis workup (Clerical check, Direct Antiglobulin Test (DAT), visual plasma hemoglobin inspection, and repeat crossmatching).

6.3 National Registry Reporting

Mandatory legal reporting of all Serious Adverse Reactions (SAR) and Serious Adverse Events (SAE) (such as Transfusion-Associated Circulatory Overload (TACO), Transfusion-Related Acute Lung Injury (TRALI), or hemolytic reactions) to the national hemovigilance database within 24 hours of clinical occurrence.

7.0 INFORMATION TECHNOLOGY AND BUSINESS CONTINUITY

Modern, error-free Blood Banking at scale requires specialized digital infrastructure to oversee highly complex inventories.



7.1 Validated Blood Bank Information System (BBIS)

A dedicated, standalone BBIS that seamlessly interfaces with the hospital-wide Electronic Health Record (EHR) and Laboratory Information Management System (LIMS).

The BBIS must possess built-in hard logic gates that prevent the physical electronic printing of an issue voucher if there is any mismatch in the patient's historical ABO grouping or crossmatching profile.

7.2 Disaster Recovery Strategy

Real-time data mirroring onto secure, offsite servers. The Medical Laboratory must conduct unannounced biannual operational drills to test physical recovery workflows using manual paper-based tracking systems to ensure complete continuity during sudden cyber-security threats or prolonged network blackouts.

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

