

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

TECHNICAL STANDARD AND CHECKLIST FOR LICENSING OF A HAEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) SUPPORT MEDICAL LABORATORY

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

KMLTTB QUALITY ASSURANCE SERVICES

 KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD <i>Make Testing a Safe Reality</i>	TECHNICAL STANDARD AND CHECKLIST FOR LICENSING OF A HAEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) SUPPORT MEDICAL LABORATORY		DOCUMENT CONTROL Serial: KMLTTB/TEC/STD/BTM/01 Revision No. 001 Revision Date: 15ST SEPTEMBER, 2026
	OWNERSHIP	REGISTRAR	

LIST OF ABBREVIATION

ASHI PT	American Society for Histocompatibility and Immunogenetics Proficiency Testing (PT) Program
BK	Polyomavirus
CBC	Complete Blood Count
CDC	Complement-Dependent Cytotoxicity
CMP	Cryopreservation Medical Laboratory
CMV	Cytomegalovirus
DSA	Donor-Specific Antibody
EBV	Epstein-Barr Virus
EQAS	External Quality Assessment Scheme
GMP	Good Manufacturing Practice
H and I	Histocompatibility and Immunogenetics
HLA	Human Leukocyte Antigen
HSCT	Haematopoietic Stem Cell Transplantation
ISHAGE	International Society of Hematotherapy and Graft Engineering
KIR	Killer-cell Immunoglobulin-like Receptor
KMLTTB	Kenya Medical Laboratory Technicians and Technologists Board
MPHO	Medical Products of Human Origin
NGS	Next-Generation Sequencing
PCR	Polymerase Chain Reaction
PRA	Panel Reactive Antibody
TNC	Total Nucleated Cells
QC	Quality Control
qPCR	Quantitative real-time PCR
RBC	Red Blood Cell
SOP	Standard Operating Procedures
STR-PCR	Short Tandem Repeat-Polymerase Chain Reaction
UHC	Universal Health Coverage

LIST OF STANDARDS

15189:2022	Medical laboratories — Requirements for quality and competence
ISBT 128	Coding and Labeling of Medical Devices Containing MPHO



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TECHNICAL STANDARD AND CHECKLIST FOR LICENSING OF A HAEMATOPOIETIC STEM CELL TRANSPLANTATION (HSCT) SUPPORT MEDICAL LABORATORY

CLASSIFICATION: CLASS F/G – BONE MARROW TRANSPLANT 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).

The implementation of this checklist will no doubt contribute to achievement of the right to the highest attainable standard of health as outlined in the constitution of Kenya 2010 as well as achievement of Vision 2030.

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

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 Hematopoietic Stem Cell Transplantation (HSCT).

No facility shall provide HLA typing, Stem Cell Processing, Chimerism or related testing for clinical transplantation without a KMLTTB Class F/G license.



Applies to all sections required for HSCT:

Histocompatibility and Immunogenetics (H and I), Hematology, Flow Cytometry, Molecular Biology, Transfusion Medicine, Microbiology/Virology, and Stem Cell Processing / CMP Laboratory.

2.0 MANDATORY PERSONNEL REQUIREMENTS

No	Cadre Minimum Qualification	KMLTTB Registration and licensure	Experience
1	Medical Laboratory Director	MSc or PhD in MLS Clinical Immunology or Hematology, Molecular Diagnostics or Transfusion Medicine	Specialist Medical Laboratory Technologist/Officer with 5 Years in transplant immunology
2	Quality Manager	BSc. MLS and QMS training	ISO 15189 Internal Auditor
3	H and I Specialist	BSc. MLS or Higher Diploma in Immunology/Molecular	Luminex and NGS competency
4	Flow Cytometry Specialist	BSc. or Higher Diploma Hematology	CD34 ISHAGE certified
5	Stem Cell Medical Laboratory Technologist	BSc. MLS or Higher Diploma Blood Transfusion	GMP/Aseptic processing

3.0 SCORING GUIDE

Score	
If YES	2
If NO	0



4.0 MEDICAL LABORATORY PROFILE

Name of the Facility	
Type (standalone, or integrated)	
KMLTTB Registration number	
County	
Sub-County	
Constituency	
Ward	
Geo-location – latitude and longitude.	
Affiliation (Private, Public, FBO, NGO, others)	
Email address	
Postal Address	
Contact	
KMLTTB Classification (if any)	

Head of Facility					
Name		ID No	Mobile Number		
Medical Laboratory Superintendent (persons whose documents was used/is to be used to register the laboratory)					
Name	ID No	Contact	Email	Reg. No	Renewal status
Date of application					
Date of inspection					



5.0 CHECKLIST

Section A: Human Resource			
Designation	Yes	No	KMLTTB Registration Number
1. Medical Laboratory Director			
2. Quality Manager			
3. H and I Specialist			
4. Flow Cytometry Specialist			
5. Stem Cell Medical Laboratory Technologist			
Section B: Histocompatibility and Immunogenetics Medical Laboratory (H and I)			
MANDATORY Requirement/Compliance	Yes	No	Evidence/Serial No. Inspector Remarks
High Resolution HLA typing by NGS (A, B, C, DRB1, DQB1, DPB1)			
Luminex Single Antigen Bead for PRA / DSA			
Flow Crossmatch and CDC Crossmatch capability			
Participation in EQAS for H and I/ASHI PT			
KIR genotyping platform (for haploidentical)			
Section C: Stem Cell Collection, Processing and Cryopreservation Medical Laboratory (CML)			
MANDATORY Requirement/Compliance	Yes	No	Evidence / Serial No. Inspector Remarks
Class II Biosafety Cabinet/Closed System (Sepax/CliniMACS)			
Controlled Rate Freezer with printout			
Vapor Phase LN2 Storage with 24/7 alarm and auto-fill			
ISBT 128 labeling system			



Validated DMSO cryopreservation protocol (10% DMSO)			
Independent viability testing (7-AAD Flow)			
Sterility, Endotoxin, Mycoplasma testing SOP			
Section D: Flow Cytometry and Hematology			
MANDATORY Requirement/Compliance	Yes	No	Evidence / Serial No. Inspector Remarks
8-10 Colour Flow Cytometer with CD34 enumeration (ISHAGE)			
CBC 5-part diff analyzer with QC			
Bone Marrow morphology reporting by Pathologist			
TNC, CD34 ⁺ dose calculation worksheet			
Section E: Molecular and Chimerism Medical Laboratory			
MANDATORY Requirement/Compliance	Yes	No	Evidence / Serial No. Inspector Remarks
Three-room PCR principle (Pre-PCR, PCR, Post-PCR)			
qPCR for CMV, EBV, BK, Adenovirus quantitative			
STR-PCR or NGS chimerism assay (sensitivity 1-5%)			
MRD assay - Flow MRD 0.01% and Molecular (BCR-ABL qPCR)			
Section F: Transfusion and Infectious Disease Monitoring			
MANDATORY Requirement/Compliance	Yes	No	Evidence / Serial No. Inspector Remarks
Irradiator for blood products			
NAT Testing / CMV-safe provision			
Tacrolimus/Cyclosporine TDM by LC-MS/MS or CLIA			



BACTEC blood culture, Galactomannan, Beta-D-Glucan					
Section G: QMS and Safety (ISO 15189:2022)					
MANDATORY Requirement/Compliance	Yes	No	Evidence / Serial No. Inspector Remarks		
ISO 15189:2022 Certificate / In-process					
Documented QMS Manual, IQC, L-J charts					
Chain of Custody from vein-to-vein					
Adverse event and Biovigilance reporting to KMLTTB					
Data backup and LN2 temperature monitoring logs					
Section H: Mandatory Standard Operating Procedures (SOP) List A laboratory must submit the following 25 SOPs. Each SOP must have Document No, Version, Author, Approver and Review Date.					
HSCT SOP	Document No.	Version	Author	Approver	Review Date
High Resolution HLA Typing by NGS					
KMLTTB-HSCT-002: HLA Antibody Screening and DSA Identification by Luminex SAB					
Complement Dependent Cytotoxicity and Flow Crossmatch					
ABO/Rh Grouping, Antibody Screen and Titration for ABO Incompatible HSCT					
KMLTTB-HSCT-005: Donor and Recipient Infectious Disease Screening Algorithm					



Peripheral Blood CD34+ Enumeration by ISHAGE Protocol					
Apheresis Product - TNC Count, CD34 Dose and Viability Calculation					
ABO Incompatible Product Processing - RBC/Plasma Depletion					
Cryopreservation, Controlled-Rate Freezing and Thawing of HSC Product					
Sterility, Endotoxin and Potency (CFU-GM) Testing of Product					
Vapor Phase LN2 Storage, Alarm Management and Inventory					
Chimerism Analysis by STR-PCR - Pre/Post Transplant					
Minimal Residual Disease Monitoring - Flow and Molecular					
Quantitative PCR Monitoring for CMV, EBV, BK, Adenovirus					
Therapeutic Drug Monitoring for Calcineurin Inhibitors					
Blood Product Selection, Irradiation and Issue for HSCT Recipients					



Daily Engraftment Monitoring and Reporting					
Graft Failure and Poor Graft Function Workup					
Fungal Biomarker Testing (Galactomannan and Beta-D-Glucan)					
Immunoglobulin and Lymphocyte Subset Monitoring Post-HSCT					
ISBT 128 Labeling and Chain of Custody / Traceability					
Handling DMSO Toxicity and Adverse Infusion Reactions					
Equipment Calibration and Preventive Maintenance for HSCT					
Internal Audit and Management Review per ISO 15189					
Biovigilance, Deviation and Corrective and Preventive Action (CAPA)					



6.0 FINDING AND RECOMMENDATIONS

FINDINGS		
AREAS CHECKED	MINIMUM SCORE (%)	SCORE ACHIEVED
A. Human Resource	100	
B. Histocompatibility and Immunogenetics Medical Laboratory (H and I)	100	
C. Stem Cell Collection, Processing and Cryopreservation Medical Laboratory (CML)	100	
D. Flow Cytometry and Hematology	100	
E. Molecular and Chimerism Medical Laboratory	100	
F. Transfusion and Infectious Disease Monitoring	100	
G. QMS and Safety (ISO 15189:2022)	100	
H. Mandatory Standard Operating Procedures (SOP) List	100	
I. Medical Laboratory Classification	100	

SCORE	RECOMMENDATION
<75% FAILED	Re-inspection after 6 months
75-89%	Provisional License with CAPA within 90 days
≥90% ISO 15189 accredited, successful Proficiency Testing and Full Class F/G	License for HSCT support valid 1 Year



7.0 ATTESTATION

A. AUDIT /INSPECTION VISIT TYPE			
AUDIT / INSPECTION		REINSPECTION	
DATE OF INSPECTION VISIT			

B. KMLTTB INSPECTION AUDIT TEAM				
NO.	NAME	DESIGNATION	MOBILE NUMBER	SIGNATURE
i.				
ii.				
iii.				
iv.				

C. INSTITUTIONAL TEAM:				
NO	NAME	DESIGNATION	MOBILE NUMBER	SIGNATURE
i.				
ii.				
iii.				
iv.				
v.				
vi.				
vii.				
viii.				

