



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

MANDATORY MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS FOR SICKLE CELL DISEASE IN KENYA

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

KMLTTB QUALITY ASSURANCE SERVICES

	MANDATORY MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS FOR SICKLE CELL DISEASE IN KENYA		DOCUMENT CONTROL CODE: KMLTTB/LAB/SICLE/C/INV/01 Version: 002
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INTRODUCTION

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, as stipulated under Cap 253A of the Laws of Kenya. The Board also provides government advisories on related matters, including the validation of in vitro diagnostics through Legal Notice No. 113 of 2011.

The Act gives the Board the responsibility of ensuring that students undertaking medical laboratory science (MLS) training acquire the desired knowledge and skills that are necessary for the delivery of medical laboratory services.

These standards will ensure the development of a robust human resource for health necessary to meet national and international health obligations that include sustainable development goals and universal health coverage. The implementation of these guidelines 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 training institutions run and sustain their training programs thereby equipping medical laboratory scientists with the necessary skills and competencies to provide medical laboratory services in diverse settings.

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.

MANDATORY MEDICAL LABORATORY ANALYSIS AND INVESTIGATIONS FOR SICKLE CELL DISEASE IN KENYA

Medical Laboratory Sciences Regulatory Authority - Kenya Medical Laboratory Technicians and Technologists Board KMLTTB

Taking into account the MOH National Guidelines for Prevention and Management of Sickle Cell Disease 2021 and Policy Guidelines on Infant Screening for SCD 2023

This framework is proposed as a Minimum Mandatory Panel. No laboratory or Person should diagnose, treat or monitor SCD without these investigations. It applies to KMLTTB Class B to Class G Medical Laboratory facilities.



1. LEGAL AND CLINICAL BASIS

Under CAP 253A, KMLTTB regulates scope of practice, test validation and referral. Ministry of Health (MOH) estimates 14,000 children born with SCD annually in Kenya, with 90% under-5 mortality if undiagnosed. Government must now make screening mandatory during MCH visits and incorporating diagnostics into SHA.

Principle: **Screening test alone is NOT diagnosis.**

Any positive solubility, sickling test **MUST** be followed by hemoglobin separation.

2. CLASSIFICATION OF MANDATORY INVESTIGATIONS

A. PREVENTION AND SCREENING PANEL

Mandatory for all Medical Laboratories

PURPOSE	MANDATORY TEST	METHOD PRESCRIBED BY KMLTTB	SPECIMEN AND WHEN
Newborn , Infant Screening 6 weeks to 12 months	Point-of-Care Sickie SCAN Confirmatory	Sickle SCAN POCT is acceptable for initial. MUST confirm with HPLC, Capillary Electrophoresis or Isoelectric Focusing IEF. Sickling test is PROHIBITED for newborns due to high HbF causing false negatives	Heel-prick DBS or EDTA at 6-week immunization visit
Premarital , Preconception , Antenatal Carrier Screening	Hb Genotype Screening	1. Solubility , Sickling as triage 2. Mandatory Hb Electrophoresis Alkaline pH or HPLC quantification of HbA, HbS, HbF, HbA2, HbC	Adults, couples, pregnant women in high-burden regions



High-Risk Population Screening	Family Testing	Cascade	Same as above	First-degree relatives of index case
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All positive screens must be reported as: Phenotype, % fractions, Interpretation e.g., HbSS, HbAS, HbSC, HbS, and β -thalassemia.

B. DIAGNOSTIC CONFIRMATION PANEL Mandatory before labeling patient as SCD

Required at KMLTTB Class D-G Medical Laboratories compliant to ISO 15189:2022

1. Full Blood Count, RBC Indices: Hb low normocytic, macrocytic, raised WBC, platelets. Microcytic suggests co-existent thalassemia or iron deficiency
2. Reticulocyte Count Absolute, %: Raised due to hemolysis
3. Peripheral Blood Film: Irreversibly sickled RBCs, polychromatic, NRBCs, Howell-Jolly bodies indicating hyposplenism
4. Hemoglobin Separation - GOLD STANDARD: HPLC or Capillary Electrophoresis. Must quantify HbS 50%, HbF, and HbA2. Differentiates SS, SC, S β O, S β ,
5. DNA, Molecular Testing: For equivocal HPLC, prenatal diagnosis, or S β -thal differentiation. Beta-globin gene sequencing, GAP-PCR for deletions.

MLS must NOT issue final diagnosis on Solubility Test alone. It is positive in SS, SC, S β -thal AND Trait AS. 6ce3

C. BASELINE ASSESSMENT AT DIAGNOSIS Once, within 1 month of confirmation

Mandatory to establish steady-state:

- a) Hemolytic Profile: Total and Direct Bilirubin, LDH, Haptoglobin
- b) Renal: U, Creatinine, eGFR, Urinalysis, ACR, urine microscopy
- c) Hepatic: ALT, AST, ALP, GGT
- d) Infectious: Blood Group ABO and RhD, Extended RBC Phenotype - vital for chronically transfused to prevent alloimmunization, HIV, HBV, HCV serology, Malaria smear, RDT, HBV vaccination status
- e) Other: HbF % baseline, Ferritin, Vitamin D, Calcium, G6PD screening microalbuminuria



D. ROUTINE MONITORING FOR STABLE PATIENTS

Quarterly Every 3-4 months:

- a) CBC with differential, Reticulocyte count
- b) LFT, RFT, Bilirubin
- c) Malaria RDT if febrile

Annual Comprehensive Mandatory - KMLTTB Audit Item:

- a) CBC, Retic, PBF
- b) HbF quantification for hydroxyurea compliance, HPLC if indicated
- c) Renal: Creatinine, eGFR, Urine ACR, Urinalysis
- d) Liver: LFTs, Ferritin, Iron Studies Serum Iron, TIBC, Transferrin Saturation
- e) Transcranial Doppler TCD referral for children 2-16y
- f) Eye exam referral, Audiometry if on chelation
- g) Urine pregnancy test for females on hydroxyurea
- h) Growth monitoring and Nutritional panel: B12, Folate if macrocytic

E. TREATMENT-SPECIFIC MONITORING

1. Hydroxyurea Therapy:

- a) Baseline: CBC, Retic, HbF%, Pregnancy test, LFT, RFT, HIV, HBV, HCV
- b) 2-weekly for first 2 months, then monthly: CBC, ANC Hold if $ANC < 2.0 \times 10^9$, L or Platelets < 80 , MCV marker of compliance, Retic, HbF%
- c) LFT, RFT monthly x3 then 3-monthly

2. Chronic Transfusion Program:

- a) Pre-transfusion mandatory: ABO, Rh, Crossmatch, Extended phenotype, Antibody Screen DAT Indirect Coombs, HbS% pre-transfusion target $< 30\%$
- b) Per transfusion: Hb, HbS%
- c) Quarterly: Ferritin, LFT, RFT, Viral serology NAT where available, Calcium, Magnesium
- d) Annually: Iron overload assessment - Ferritin trend, MRI T2 liver, cardiac where available. If not, transferrin saturation 75% triggers chelation workup.
- e) HLA typing if considered for HSCT.



3. Iron Chelation Therapy:

- a. Ferritin monthly, LFT, RFT, Urine protein, creatinine ratio, Audiometry, Ophthalmology annually, Zinc, Vitamin C

F. ACUTE CRISIS, COMPLICATION WORKUP Mandatory Emergency Panel

Prescribe as STAT panel in all emergency units:

1. **Vaso-Occlusive Crisis:** CBC, Retic, LFT, RFT, CRP, Blood Culture if febrile, Group and Crossmatch, HbS% if recent transfusion
2. **Acute Chest Syndrome:** CBC, Blood and Sputum Culture, ABG, Chest X-ray, ABO Grouping, Crossmatch, Malaria test
3. **Severe Anemia** , Hemolysis Hb <5 or drop 2g,dL from baseline: CBC, Retic, DAT, Bilirubin, LDH, U and E, Blood Group Crossmatch, Malaria, Parvovirus B19 PCR if available
4. **Splenic Sequestration, Stroke:** CBC, Retic, Coagulation Profile PT, INR, aPTT, ABG, Type and Crossmatch, Neuroimaging referral
5. **Sepsis:** CBC, Blood Culture x2, Urine Culture, CRP, Procalcitonin, Malaria, HIV screen if unknown.

G. QUALITY AND REPORTING REQUIREMENTS BY KMLTTB

1. **Internal QC:** Daily controls for hematology analyzers, HPLC low, high HbS controls
2. **EQA:** Mandatory enrollment in KMLTTB, WHO AFRO EQA for Hb electrophoresis, HPLC
3. **Turnaround:** Newborn screening confirmatory <7 days, routine HPLC <14 days
4. **Referral System:** Medical laboratory Class B-C to perform solubility only, MUST refer positives to Class E-G, for HPLC. Document chain-of-custody for DBS.
5. **Reporting Standard:** All reports must include method, interpretation by qualified MLS Professional duly registered and licensed by KMLTTB, reference ranges for age, recommendation for genetic counseling, and entry into National SCD Registry.
6. **Biosafety and Waste:** EDTA samples as biohazard, heamoglobinopathy waste autoclaved.

This panel ensures early diagnosis, prevents misclassification of trait as disease, monitors life-threatening complications, and may support SHA reimbursement for diagnostics, medicines and transfusions.

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

