



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

MANDATORY MEDICAL LABORATORY INVESTIGATIONS FOR HAEMOLYTIC DISEASE OF THE NEWBORN (HDN) / HAEMOLYTIC DISEASE OF THE FETUS AND NEWBORN (HDFN).

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

	MANDATORY MEDICAL LABORATORY INVESTIGATIONS FOR HAEMOLYTIC DISEASE OF THE NEWBORN (HDN) / HAEMOLYTIC DISEASE OF THE FETUS AND NEWBORN (HDFN).		DOCUMENT CONTROL CODE: KMLTTB/LABS/HDN/INV/01 Version: 001 Revision Date: 24 th September, 2026
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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 sciences (MLS) training and practising professionals 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 standards 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. This shall be the hallmark of quality Healthcare and patient safety.

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.

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) mandates specific analysis guidelines for investigating Haemolytic Disease of the Newborn (HDN) / Haemolytic Disease of the Fetus and Newborn (HDFN). Because HDN is a life-threatening alloimmune condition characterized by the transplacental transfer of maternal IgG antibodies that destroy fetal red blood cells, KMLTTB structures these investigations across distinct medical laboratory facility classes (primarily KMLTB **Class C/KMPDC Level IV** up to reference Medical laboratories) to support both antenatal monitoring and postnatal critical care.

The required medical laboratory analyses, methodologies, and quality standards for HDN are outlined below based on the KMLTTB Medical Laboratory Classification Schedule and legal training standards.

1. Mandatory Medical Laboratory Testing Menu for HDN Workup

KMLTTB targets testing toward three distinct phases: maternal antenatal profiling, fetal/neonatal diagnostic confirmation, and tracking the severity of active hemolysis.

A. Maternal Antenatal Profiling & Quantification

These tests identify mothers at risk of alloimmunization and track the progression of antibody concentration:

1. **ABO and Rhesus (RhD) Phenotyping:** Performed on all pregnant women at first booking to determine compatibility.
2. **Maternal Antibody Screening:** Utilizing a 2-cell or 3-cell screen to check for irregular or unexpected IgG antibodies (e.g., Anti-D, Anti-c, Anti-E, Anti-Kell).
3. **Indirect Antiglobulin Test (IAT) / Indirect Coombs:** To detect unbound maternal alloantibodies.
4. **Antibody Titration:** Serial titrations (especially for Anti-D or Anti-Kell) to track antibody concentration. A critical rise in titre flags an urgent need for specialist fetal surveillance.

B. Neonatal / Cord Blood Diagnostic Confirmation

Conducted immediately post-delivery using cord blood or neonate heel-prick samples to definitively confirm an immune-mediated hemolytic process:

1. **Direct Antiglobulin Test (DAT) / Direct Coombs:** The definitive test to demonstrate that maternal IgG antibodies have coated the baby's red blood cells *in vivo*.
2. **ABO and Rhesus (RhD) Grouping on the Newborn:** Confirms the presence of the corresponding target antigen inherited from the father.
3. **Antibody Elution:** If the DAT is positive but the antibody specificity is unknown, an elution is required to detach and identify the specific maternal IgG bound to the neonatal red cells.

C. Hemolysis & Organ System Monitoring (Neonatal)

These tests measure the biological damage, guide the need for phototherapy, and determine the threshold for exchange transfusion:

1. **Total Serum Bilirubin (TSB) – Fractional Analysis:** Serial testing of **Unconjugated (Indirect) Bilirubin** is legally mandated to monitor the risk of kernicterus (bilirubin-induced neurological damage).
2. **Full Blood Count (FBC) / Complete Blood Count (CBC):** Specifically checking for progressive anemia through falling **Hemoglobin (Hb)** and **Packed Cell Volume (PCV)**.

3. **Peripheral Blood Film (PBF) Reporting:** Crucial for identifying morphological hallmarks, such as widespread **Spherocytes** (highly indicative of ABO HDN) or nucleated RBCs (erythroblasts).
4. **Reticulocyte Count:** Quantitative measurement of bone marrow compensatory response (typically sharply elevated in active HDN).

D. Fetomaternal Hemorrhage (FMH) Quantitation (Postpartum)

1. **Rosette Test:** A qualitative screening assay utilized postpartum on Rh-negative mothers who delivered Rh-positive infants to detect fetomaternal hemorrhage.
2. **Kleihauer-Betke (KB) Acid Elution Test:** If the Rosette test is positive, this quantitative assay calculates the exact volume of fetal blood that entered maternal circulation to adjust the mandatory dosage of prophylactic **Anti-D Immunoglobulin (RhIg)**.

2. Methodological & Technological Standards

KMLTTB mandates specific testing methodologies based on Medical laboratory tiering to minimize diagnostic error:

Testing Component	Approved Technical Modality / Platform
Immunohematology (Grouping, DAT, IAT)	Column Agglutination Technology (Gel Cards) or automated microplate systems are highly preferred over traditional tube methods for Class C/D laboratories due to enhanced standardization and sensitivity.
Bilirubin Quantitation	Automated clinical chemistry analyzers utilizing modern Spectrophotometry / Colorimetry or dedicated neonatal bilirubinometers.
FBC & Reticulocyte Counting	Automated 3-part or 5-part hematology analyzers backed by manual microscopic review of stained slides.

3. Regulatory Compliance & Quality Assurance

To protect patient safety in critical neonatal care, Medical laboratories performing these investigations must strictly adhere to KMLTTB's legal and administrative framework:

1. **Mandatory Pre-Transfusion Protocols:** Any Medical laboratory preparing Blood products for an Exchange Transfusion in an HDN case must crossmatch the donor red cells using **maternal serum** (not neonatal serum), as the culprit antibodies originate from the mother.
2. **Point of Care Testing (POCT) Restrictions:** Under the KMLTTB POCT Regulatory Policy, transcutaneous bilirubinometers or cartridge-based blood gas analyzers used in neonatal units must be strictly validated, calibrated daily, and overseen by licensed Medical laboratory personnel.
3. **Personnel Requirements:** Blood group Serologies, antibody titrations, and Kleihauer-Betke evaluations are highly technical and must be executed and authorized exclusively by KMLTTB-registered and currently licensed Medical Laboratory Professionals or Blood Transfusion Specialists.
4. **External Quality Assessment (EQA):** The Medical laboratory must be actively enrolled in an accredited proficiency testing scheme for immunohematology (ABO/Rh, antibody screening, and DAT) and clinical chemistry (bilirubin)

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