REPUBLIC OF KENYA
MINISTRY OF HEALT

KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

KMLTTB POLICY ON COMPREHENSIVE, END-TO-END GENOMIC SURVEILLANCE

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

KMLTTB QUALITY ASSURANCE SERVICES

	KMLTTB POLICY ON COMPREHENSIVE, END-TO-END GENOMIC SURVEILLANCE		DOCUMENT CONTROL Serial: KMLTTB/GENOMIC/SUV/01 Version 001 Date:5th JUNE, 2026
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Make Testing a Safe Reality

1. INTRODUCTION

A comprehensive, end-to-end genomic surveillance system relies on five core pillars outlined below.

i. Sample Sourcing and Selection: Systematic collection of high-quality diagnostic samples from geographic hotspots, vulnerable populations, and unusual clinical presentations.
ii. Next-Generation Sequencing (NGS): High-throughput extraction and sequencing of whole pathogen genomes using platforms like Illumina or Oxford Nano pore.
iii. Bioinformatics and Data Processing: Conversion of raw sequencing reads into clean genetic assemblies and the identification of precise mutations.
iv. Phylogenetic and Contextual Analysis: Merging genomic sequences with patient metadata (e.g., location, vaccination history, clinical severity) to construct evolutionary family trees and determine transmission chains.
v. Global Data Sharing: Rapid submission of genetic sequences and metadata into open-access repositories like GISAID or NCBI Sequence Read Archive (SRA) to power global risk assessments.

2. Relationship with Medical Laboratory Surveillance

Genomic surveillance and medical laboratory surveillance are deeply interdependent, functioning as complementary layers of the public health ecosystem

End-to-end genomic surveillance requires compliance with international biosafety, laboratory quality, data privacy, and ethical frameworks. These regulatory requirements govern the entire pipeline—from sample collection and Next-Generation Sequencing (NGS) to secure bioinformatics analysis and global data sharing.

The regulatory and operational structure for genomic surveillance is typically broken down into four foundational pillars:

i. **Laboratory & Quality Standards**
ii. Laboratories must meet rigorous technical accreditations to ensure sequencing data is accurate, reproducible, and legally defensible.
iii. **Quality Management Systems (QMS):** Laboratories must adhere to clinical and public health standards (e.g., ISO 15189).
iv. **Bioinformatics Validation:** Pipelines and software must be validated to ensure variant calling and data integrity. Compliance with standards such as **ISO 23418** (bioinformatics) and **ISO 20397** (massively parallel sequencing) is highly recommended by KMLTTB.

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v. **Certification/Accreditation:** KMLTTB must audit the end-to-end process and issue a clean bill of health.

3. Genomic surveillance in transplant and transfusion medicine

Genomic surveillance in transplant and transfusion medicine involves tracking genetic variations in donors, recipients, and pathogens to optimize matching, prevent adverse reactions, and ensure product safety. Regulatory frameworks demand strict validation, bioinformatics traceability, and robust data sharing to maintain clinical efficacy and patient privacy.

4. Regulatory Requirements & Data Governance

End-to-end genomic surveillance requires rigorous compliance and data integrity to function safely in high-stakes clinical settings:

i. **Laboratory Accreditation:** Sequencing and genotyping workflows must meet certifications (ISO 15189) due to the high risk of contamination and interpretation errors.
ii. **Data Provenance:** Genomic data must be securely documented in Laboratory Information Management Systems (LIMS), providing a clear description of the data's origin and the precise analytic pipelines applied.
iii. **Interoperability Standards:** To facilitate rapid donor matching and vigilance surveillance, institutions rely on standardized, global exchange frameworks like HL7 and HL7 FHIR to securely share complex genetic profiles.
iv. **Vigilance & Ethics:** Regulatory and professional bodies oversee the safety and bio vigilance of genomic data. Patient and donor data sharing must also adhere to global ethical mandates, such as the Global Alliance for Genomics and Health (GA4GH), to protect welfare and ensure transparent consent.

5. Role in Transfusion Medicine

Genomic surveillance has shifted the paradigm from basic serology to precision blood matching, directly benefiting patient safety and inventory management:

i. **Extended Antigen Genotyping:** Next-Generation Sequencing (NGS) is utilized to predict complex red blood cell (RBC) antigens (e.g., Kell, Kidd, Duffy, and Rh variants). This is vital for chronically transfused patients, like those with sickle cell disease, to prevent severe alloimmunization.
ii. **Pathogen Surveillance:** Blood operators should routinely use Nucleic Acid Testing (NAT) and viral sequencing to monitor for emerging infectious variants and safeguard the blood supply from transfusion-transmitted diseases.
iii. **Pharmacogenomics:** Genetic data is used to optimize therapies such as iron chelation or anticoagulants customized to an individual's metabolic profile.
iv. **Role in Transplant Medicine**
v. Precision genomics ensures optimal graft survival and manages both recipient and donor risks:

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vi. **HLA Matching:** High-resolution HLA genotyping is critical to successfully match solid organ and stem cell donors, directly decreasing the likelihood of acute or chronic graft rejection.
vii. **Metagenomics Next-Generation Sequencing (mNGS):** In immunocompromised organ recipients, mNGS provides comprehensive surveillance and rapid diagnosis of bloodstream infections (BSIs) or antimicrobial resistance (AMR), allowing for targeted, life-saving antimicrobial therapies.
viii. **Pharmacogenomics in Immunosuppression:** Pre-transplant genomic testing helps clinicians predict how a recipient will metabolize immunosuppressive drugs (e.g., tacrolimus), allowing for optimized dosing to prevent toxicity or organ rejection.

End-to-end genomic surveillance relies on standardized next-generation sequencing (NGS) workflows, rigorous laboratory accreditations (ISO 15189), and adherence to strict bioethical regulations. It plays a crucial role in medical laboratory research by enabling real-time pathogen tracking, antimicrobial resistance monitoring, and rapid epidemiological interventions on a global and local scale.

6. The End-to-End Genomic Surveillance Workflow

To ensure data is robust enough to guide health policy, clinical microbiology and research laboratories follow four standardized phases.

i. **Sample Acquisition & Preparation:** Identifying clinical or environmental samples and extracting high-quality genetic material.
ii. **Sequencing:** Utilizing platforms like Illumina or Oxford Nanopore to decode the pathogen's genome.
iii. **Bioinformatics Analysis:** Processing raw sequence data to identify variants, mutations, and resistance genes.
iv. **Data Interpretation & Integration:** Merging genomic variants with demographic and clinical metadata to map transmission routes.
v. **Regulatory & Quality Standards**

7. Because genomic surveillance

Because genomic surveillance yields life-saving public health data, medical laboratories are strictly governed to ensure safety, efficacy, and accuracy.

i. **Quality Management Systems (QMS):** Medical Laboratories must operate under stringent frameworks, using KMLTTB standards.
ii. **Analytic and Clinical Validity:** KMLTTB regulates IVDs such as sequencing hardware and bioinformatics pipelines, focusing heavily on Medical Laboratory-Developed Tests (MLDTs) to ensure they are analytically robust and clinically useful.
iii. **Research Ethics:** Any genomic research involving human subjects requires institutional review board (IRB) or KMLTTB Research Ethics Committee approval to strictly protect patient privacy.

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8. Role in Medical Laboratory Research

Genomic surveillance bridges the gap between basic medical Laboratory research and frontline epidemiology.

i. **Pathogen Evolution:** It allows researchers to monitor how viruses and bacteria mutate, which dictates whether diagnostic primers and vaccine formulations remain effective.
ii. **Antimicrobial Resistance (AMR):** By conducting Whole-Genome Sequencing (WGS), laboratories can detect hidden resistance mechanisms before they cause untreatable outbreaks.
iii. **Policy Integration:** Sequencing research directly feeds into national health policies. For instance, integrated frameworks like the Nigeria Centre for Disease Control and Prevention (NCDC) National Genomics Surveillance Strategy map out exactly how research data informs policy decisions.

9. Data Governance & Ethics

Sharing genomic data openly is essential for global pandemic preparedness, but it must be balanced with privacy.

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