



REPUBLIC OF KENYA
MINISTRY OF HEALTH



KENYA MEDICAL LABORATORY TECHNICIANS AND TECHNOLOGISTS BOARD

JOINT EXTERNAL EVALUATION (JEE) OF IHR CORE CAPACITIES - MEDICAL LABORATORYORATORY INDICATORS.

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

QUALITY ASSURANCE SERVICES

	JOINT EXTERNAL EVALUATION (JEE) OF IHR CORE CAPACITIES - MEDICAL LABORATORYORATORY INDICATORS.		DOCUMENT CONTROL Serial: KMLTTB/JEE/LABS/01 Version 001 Date: 12 TH OCTOBER, 2026
	OWNERSHIP	REGISTRAR	



INTRODUCTION

The Kenya Medical Laboratory Technicians and Technologists Board (KMLTTB) is a body corporate with statutory mandate to exercise general supervision and control over the training, practice, business and employment of medical laboratory technicians and technologists under Cap 253A Laws of Kenya. The Board also advises the Government in relations to all aspects thereof including validation of invitro diagnostics through Legal Notice NO.113 of 2011

JOINT EXTERNAL EVALUATION (JEE) OF IHR CORE CAPACITIES - MEDICAL LABORATORY INDICATORS.

WHO tool used to evaluate countries' capacity to detect outbreaks per International Health Regulations 2005. Medical Laboratories D1 in JEE 3rd Edition 2022.

JEE MEDICAL LABORATORY ASSESSMENT - 5 INDICATORS - SCORE 1-5

SN.O		INDICATOR	WHAT IS ASSESSED	SCORE 1 = NO CAPACITY, 5 = SUSTAINABLE
1.	D1.1	Specimen referral and transport system	Is there courier, triple packaging, cold chain, boda, 47 counties to NPHL/KEMRI, One Health vet Medical laboratories? Tracking? Turnaround time?	
2.	D1.2	Medical Laboratory Quality System	SLMTA/SLIPTA stars, ISO 15189 accredited Medical laboratories count, EQA participation, KMLTTB licensed Medical laboratories, biosafety standard compliance	
3.	D1.3	Medical Laboratory testing capacity	Can Kenya test 10 priority diseases? List: Influenza, Polio, HIV, TB, Malaria, Cholera, Meningitis, RVF, Ebola,	



			COVID/Mpox. Tier system: Periphery, Intermediate [ELISA], National [PCR]	
4.	D1.4	Effective National Medical laboratory Network	Does human, animal, food, environment Medical laboratories talk? Medical laboratory Information System interconnect? NPHL coordination? Data sharing for One Health?	
5.	D1.5	Biosafety and Biosecurity	BSL-2, BSL-3 Medical laboratories, trained BSOs, SOPs for BSC, autoclave validated, waste management NEMA licensed, pathogen inventory, IATA certified shippers [mRDT][Culture][Sequencing]	

How JE Assessment is done in a Medical Laboratories - QAO Checklist

Tool uses: Document review and Site visit and Interviews and Simulation

A.

PRE-ASSESSMENT DOCUMENTS TO PROVIDE:		
1.	Medical laboratory licensing register KMLTTB Class -F	
2.	SLIPTA audit reports	
3.	EQA performance 2 years	
4.	Specimen referral SOP and logbook and TAT data	
5.	Biosafety manual and BSC certification and autoclave logs and waste contract	
6.	AMR WHONET/GLASS reports	
7.	Testing menu per level	



B. SITE ASSESSMENT QUESTIONNAIRE - Per Medical laboratory:

1.

Specimen Referral:		
1.	How specimen collected?	
2.	Triple packaging?	
3.	Who transports?	
4.	Cost?	
5.	Time from Turkana to NPHL?	
6.	Time from Turkana to NPHL?	
7.	Tracking system?	
8.	Lost specimen %?	

Score 5 if: National courier system functional, <24h TAT, <5% rejection, covers all 47 counties, One Health included.

2.

Quality System:		
1.	Is Medical laboratory licensed by KMLTTB?	
2.	- Class?	
3.	Is QMS documented?	
4.	Internal audit done?	
5.	SLIPTA star?	
6.	EQA last 2 cycles?	
7.	Corrective action?	
8.	Staff licensed?	

Score 5 if: 100% licensed Medical Laboratories, >80% enrolled EQA, >50% SLIPTA 3 stars, 10 Medical Laboratories ISO 15189 accredited, KMLTTB ISO 17024 for personnel.

3.

Testing Capacity:		
1.	Show equipment:	
2.	Can you run PCR?	
3.	Culture?	
4.	Sequencing?	
5.	10 priority diseases?	



6.	SOPs available in the Medical Laboratory?	
7.	Reagents stock-out last 3 months?	
8.	Staff competence?	

Score 5 if: National can do sequencing, intermediate can do PCR, periphery can do mRDT and microscopy, no stockout >7 days.

4.

Network:		
1.	How results reported?	
2.	LIMS?	
3.	DHIS2?	
4.	Email?	
5.	WhatsApp?	
6.	Is vet Medical laboratory result shared?	
7.	FAO/WHO coordination?	
8.	Meeting minutes?	

Score 5 if: Integrated LIMS human, veterinary and environment, real-time reporting, quarterly One Health Medical Laboratory TWG.

5.

Biosafety/Biosecurity:		
	Check:	
1.	BSC certified within 1 year?	
2.	Autoclave validated with biological indicator?	
3.	Spill kit?	
4.	PEP available Medical Laboratory?	
5.	Waste segregation 3 bins and yellow bag?	
6.	NEMA handler?	
7.	Access control to Medical Laboratory?	
8.	Pathogen inventory?	
9.	IATA shippers?	



Score 5 if: All Medical Laboratories have certified BSC, validated autoclave, licensed waste handler, BSO trained, inventory, BSL-3 functional at National referral Laboratory Authority.

SCORING EXAMPLE - Class E/F County Medical Laboratory:

D1.1: Has boda (rider) but no tracking, TAT 3 days = Score 2

D1.2: Licensed Class E/F, SLIPTA 1 star, EQA 80%, no internal audit = Score 3

D1.3: Can do culture, GeneXpert, no PCR = Score 3

D1.4: Reports via paper, no LIMS = Score 2

D1.5: BSC not certified 2 years, autoclave no indicator, waste mixed = Score 1[Developed]

