

**Inspection Tool for compliance with the minimum standards for veterinary laboratories in Kenya**

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**BIODATA**

Name of laboratory: \_\_\_\_\_ County: \_\_\_\_\_

Physical address \_\_\_\_\_

Postal address \_\_\_\_\_

Email \_\_\_\_\_ Tel \_\_\_\_\_

GPS Coordinates: \_\_\_\_\_ Inspection Date: \_\_\_\_\_

Type of laboratory: \_\_\_\_\_

Name of respondent: \_\_\_\_\_ Position of respondent: \_\_\_\_\_

Name of laboratory in-charge \_\_\_\_\_

**Inspectors:**

No.	Name	Signature
1		
2		
3		
4		
5		
6		

Is this a first audit?

If no, please provide previous audit report and corrective action

**Inspection Findings:**

Total applicable questions: \_\_\_\_\_ Percentage marks attained: \_\_\_\_\_

Recommendations: \_\_\_\_\_

NB: The cut-off for registration will be attaining at least 50% of the applicable questions for the laboratory

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- >50%: Qualifies for registration subject to having met mandatory requirements in the tool
  - 40-49%: Qualifies for provisional registration
  - <40%: Does not qualify for registration.
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This inspection tool highlights the key requirements in deciding if a veterinary laboratory in Kenya complies with the minimum standards for registration and licensing by Kenya Veterinary Board (KVB) pursuant to section 6(2)(e) of Veterinary Surgeons and Veterinary Paraprofessionals (VSVP) Act Cap 366 and VSVP Regulations of 2013. With each question, the assessor(s) is/are to mark one of the boxes numbered 1 to 4, based on the following criteria:

- 1 : The laboratory does not meet this requirement at all
- 2 : The laboratory meets some parts of this requirement
- 3 : The laboratory meets most parts of this requirement
- 4 : The laboratory meets this requirement fully

1.	<b>ACCOUNTABILITY AND OVERSIGHT</b>					
	Is the laboratory a legal entity?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Does the laboratory have a documented organization/ management structure (organogram), to ensure accountability and oversight including its place in any parent organization?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Does the organization have documented roles & responsibilities, authority and interrelationships of all personnel to ensure quality of laboratory services?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Does the laboratory have documented procedures for all its operations that are communicated and available to all staff	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Does the laboratory have a service charter that clearly indicates the mandate/objectives, services offered and expectations of the clients?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
2.	<b>EXECUTIVE MANAGEMENT</b>					
	Are the operational activities of the laboratory under the authority of a single individual?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Is the qualification of the person responsible for interpretation of laboratory results a veterinarian? Does he have relevant veterinary experience and or laboratory training?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table> Mandatory	1	2	3	4
1	2	3	4			
	If the scope of the laboratory is such that it is divided into various sections (e.g. bacteriology, virology, pathology, parasitology, etc.), are there designated persons responsible for these sections?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Is there a designated deputy laboratory in-charge to support in the management of the laboratory operations?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Are there designated personnel to perform support functions (e.g. human resource, finance, procurement, information technology (IT) and communication? (where applicable)	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
	Is there a designated officer responsible for releasing the test results so as to ensure the personnel are free from any undue influences that may adversely affect the quality of their work?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table>	1	2	3	4
1	2	3	4			
3.	<b>LOCATION AND OTHER GENERAL REQUIREMENTS</b>					
	Is the location suitable for the specialized requirements, services and operational environments of a laboratory?	<table border="1"><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr></table> Mandatory	1	2	3	4
1	2	3	4			

	Is the location including if part of a general-purpose building isolated from activities not related to the laboratory?	1	2	3	4
	Does the location have controlled human traffic to reduce impact of accidental release of dangerous materials?	1	2	3	4
	Is the location away from any known fire hazard?	1	2	3	4
	Are the standards of housekeeping adequate to ensure that the quality of data is not compromised?	1	2	3	4
	Is there a separate resting area for staff away from the testing area for the staff to have refreshments?	1	2	3	4
	Can the laboratory demonstrate existence of maintenance support services for its infrastructure, compound and plant equipment?	1	2	3	4
4.	<b>LABORATORY DESIGN (ACCOMODATION AND ENVIRONMENTAL CONDITIONS)</b>				
	Is the lab designed to ensure adequate ventilation, floors easy to clean and decontaminate, bench tops Impervious and chemically resistant, Vermin-proof for pests including rodents and insects etc.?	1	2	3	4
	Are there sufficient measures to ensure reliable electricity supply, sufficient electric outlets to minimize use of extension cables, sufficient sinks with adequate and uninterrupted running water, adequate lighting, chairs and furniture made of non-cloth materials for ease of cleaning and effective decontamination?	1	2	3	4
	Are there sufficient measures to ensure separation of incompatible activities to avoid cross contamination?	1	2	3	4
	Are there effective measures to ensure restricted access of unauthorized persons and materials?	1	2	3	4
	Are there clearly marked and operational emergency exits?	1	2	3	4
5.	<b>EQUIPMENT AND MAINTENANCE,</b>				
	Are the equipment regularly serviced and maintenance?	1	2	3	4
	Is there an inventory/record of equipment that are uniquely identified?	1	2	3	4
	Is there a record showing history of servicing, maintenance and calibration of equipment (where applicable)?	1	2	3	4
	Is all equipment which is subject to regular checks or calibrations labelled to show when the next calibration is due?	1	2	3	4
	Is calibration undertaken by a Calibration Entity accredited by a Competent Authority?	1	2	3	4
	Are equipment operated by trained and authorized personnel?	1	2	3	4
	Are operational manuals/procedures available for each equipment?	1	2	3	4
6.	<b>HUMAN RESOURCE/PERSONNEL</b>				
	Does the laboratory have personnel to meet the workload requirements?	1	2	3	4
		Mandatory			

	Are the laboratory technical personnel qualified on the basis of appropriate education (at least a certificate in Animal Health and/or Laboratory science), training and experience?	1	2	3	4	Mandatory
	Are the technical personnel registered by the relevant professional bodies where applicable					
	Are there HR guidelines that amongst other considerations demonstrate procedures for staff motivation, discipline, relevant training, and induction process for staff?	1	2	3	4	
	Are there clearly defined job descriptions for each laboratory staff?	1	2	3	4	
	Is there a regular evaluation/appraisal to assess staff performance and competences?	1	2	3	4	
7.	<b>COMPLIANCE</b>					
	<b>7.1 Health and Safety</b>					
	Does the lab have health and safety guidelines and/or manual that includes risk mitigation measures?	1	2	3	4	Mandatory
	Does the lab have a designated health and safety officer with the responsibility and budget for health and safety of staff	1	2	3	4	
	Is there a health and safety training programme for the staff	1	2	3	4	
	Is there a First Aid station with a stocked first aid boxes and trained first-aiders?	1	2	3	4	Mandatory
	Are there sufficient and functional safety equipment (e.g. emergency showers or adequate water in containers, Eyewash, Appropriate fire equipment or Smoke/heat detectors)?	1	2	3	4	
	Does the lab undertake regular fire audits?	1	2	3	4	
	Does the lab have fire-fighting equipment and evidence on training and maintenance?	1	2	3	4	Mandatory
	Does the lab have a health and hazard identification procedure with a risk register in place?	1	2	3	4	Mandatory
	Does the lab have a Health and Safety incident and accident reporting, investigation and response procedure?	1	2	3	4	Mandatory
	Do the laboratory environment ensure a safe and comfortable work environment for staff and visitors?	1	2	3	4	
	Are there documented emergency response procedures and evidence of regular drills?	1	2	3	4	
	<b>7.2 Biosafety and Biosecurity</b>					
	Does the lab carry out periodic biosafety risk assessment and develop mitigation plans?	1	2	3	4	
	Does the lab have a Biosafety SOP/guidelines/manual?	1	2	3	4	
	Has the lab determined the containment level (BSL 1, 2, 3) to determine the types of samples and tests to be handled?	1	2	3	4	
	Does the lab provide dedicated PPE for staff and visitors?	1	2	3	4	Mandatory
	Does the lab have an occupational health procedure to handle laboratory acquired infections?	1	2	3	4	

Has the lab carried out a Biosecurity threat analysis and developed mitigation measures to manage the threats (where applicable)	1	2	3	4
Does the lab maintain an inventory of biological materials under its custody?	1	2	3	4
Are stored biological materials secured?	1	2	3	4
Does the lab have a hierarchy of controls to minimize exposure of humans, animals and environment to pathogenic agents or hazardous materials e.g. engineering (Biosafety cabinets, safety hoods, direction of air-flow), administrative (SOPs, signage, training) & PPE	1	2	3	4
<b>7.3 Animal Welfare (If applicable)</b>				
Is the use of animals in the laboratory approved by an Animal Care and Use Committee (ACUC)?	1	2	3	4
	Mandatory			
Is there an independent Veterinarian who is responsible for animal welfare programs in the facility?	1	2	3	4
	Mandatory			
<b>7.4 Environment</b>				

<i>7.4.1 Waste Management:</i>				
Does the laboratory have an effective waste disposal system in accordance with Environmental Management and Coordination Act (EMCA) Cap 387 (Waste Management Regulations, 2006)?	1	2	3	4
	Mandatory			
Does the waste management system identify all waste streams and methods of waste treatment to render the waste non-hazardous?	1	2	3	4
Does the laboratory have or has access to an autoclave bio-pits, an incinerator or Crematorium to treat all biological waste including animal carcasses and biomedical waste before disposal.	1	2	3	4
<i>7.4.2 Light:</i>				
Is the laboratory well light with segregation of tests that require light and those that should be in a dark room?	1	2	3	4
Is provision made to allow natural lighting where applicable?	1	2	3	4
Is the light in the laboratory adequate thus between 100 to 300 lux?	1	2	3	4
<i>7.4.3 Water</i>				
Are Laboratory workers provided with safe drinking water?	1	2	3	4
Is waste water from the Laboratory treated before disposal?	1	2	3	4
If tap water is used to prepare test solution the quality is ascertain as adequate for preparing the test solution?	1	2	3	4
<i>7.4.4 Air</i>				
Does the laboratory ensure adequate fresh and clean breathing air absent of excessive odour?	1	2	3	4
Is there adequate ventilation to ensure the recommended air change per hour (ACH) are achieved?	1	2	3	4
Where a laboratory carries out preparations of test reagents within the laboratory using hazardous chemicals, does the laboratory ensure strict adherence to material data safety sheets of the chemicals?	1	2	3	4
If the laboratory handles hazardous chemicals, does the laboratory have a chemical fume hood where hazardous chemicals are handled?	1	2	3	4
<i>7.4.5 Noise</i>				
Is the laboratory located in a quiet environment with noise levels less than 60 decibels?	1	2	3	4

	Are there equipment in the laboratory that generate noise of over 70 decibels?	1	2	3	4
	<b>7.5 Gene Regulation (If applicable)</b>				
	If the laboratory is working with GMOs, does it have approval by NBA?	1	2	3	4
	Are there sufficient measures undertaken to ensure segregation of GMO work from non-GMO work?	1	2	3	4
8.	<b>SCIENTIFIC SERVICES</b>				
	<b>8.1 Diagnostic and/or Forensic Service Delivery</b>				
	Does the laboratory have appropriate equipment and consumables for the test procedure(s) and in adequate amounts to meet scope and workload requirements?	1	2	3	4
	Are reagents sourced from reputable manufacturers and accompanied by validation data?	1	2	3	4
	Are reagents used within expiry dates, prepared and used according to manufacturer's instructions, stored under appropriate conditions and properly labelled?	1	2	3	4
	Are there sufficient measures undertaken to separate incompatible activities?	1	2	3	4
	Is Access to and use of test areas controlled?	1	2	3	4
	Is there a system for Identification of test items that is retained throughout the life of the item in the laboratory?	1	2	3	4
	Are the test procedures in use fit for the intended purpose?	1	2	3	4
	Does the lab have documented SOPs for all its test procedures?	1	2	3	4
	Is there a referral system for tests the laboratory cannot perform, require second opinion or further testing?	1	2	3	4
	Is there a list of subcontractors that the laboratory uses whenever need arises?	1	2	3	4
	Does the lab maintain an inventory of changes in staff that have access to controlled biological substances?	1	2	3	4
	Does the lab maintain an inventory of test materials including a sample retention and archival plan?	1	2	3	4
	Are there storage facilities to preserve integrity of samples before and after testing?	1	2	3	4
	<b>8.2 Quality Assurance</b>				
	Does the lab have documented quality control procedures for monitoring the validity of tests undertaken?	1	2	3	4
	Is there a mechanism for maintenance of the raw data and data transfers?	1	2	3	4
	Does the lab have training guidelines, procedures and/or plans for training laboratory staff?	1	2	3	4
	Does the lab carry out regular skills training and development such as cross-training within the lab, one-on-one mentoring, external trainings, exchange programmes, apprenticeships etc. for the laboratory staff and evaluation of competencies?	1	2	3	4
	<b>8.3 Research</b>				
	Can the laboratory demonstrate adoption of new technology as part of continuous improvement? (where applicable)	1	2	3	4

	Does the laboratory engage in research such as development and adoption of new methods? (Where applicable)	1	2	3	4
9.	<b>SUPPORT SERVICES</b>				
	<b>9.1 Information Management</b>				
	Does the lab have an information & data management system (computerized or manual)?	1	2	3	4
	Is the information & data management system managed by a designated and competent staff?	1	2	3	4
	Has the laboratory adopted sufficient measures to protect integrity of data, archiving, traceability, retrieval, privacy, confidentiality and protection of staff and sensitive items?	1	2	3	4
	Does the laboratory have guidelines for retention & archiving data and administrative information?	1	2	3	4
	<b>9.2 Finance and Procurement</b>				
	Can the laboratory demonstrate availability of resources to ensure achievement of the mandate/objectives without compromising quality of services provided?	1	2	3	4
	Is there a documented and transparent pricing policy of the services and products offered by the laboratory	1	2	3	4
	Is there a documented list of approved suppliers to ensure quality of equipment, consumables and services to ensure quality of test results is not compromised?	1	2	3	4
	Are laboratory staff involved in the procurement process to ensure quality of equipment, consumables and services to ensure quality of test results is not compromised?	1	2	3	4
	<b>9.3 Communication</b>				
	Does the laboratory have communication guidelines that include modalities for internal communication within the laboratory and external communication with clients and other stakeholders?	1	2	3	4
	Does the laboratory release results to the clients in a clear and understandable format	1	2	3	4
	Does the laboratory have guidelines to ensure compliance with obligatory national disease reporting and notification?	1	2	3	4
	Does the laboratory have a procedure for release and dissemination of scientific data and information?	1	2	3	4
		Mandatory			