Colored areas indicate where a written document is required

Appendix D - Internal Audit Checklist (Example)

Requirement	Compliance			Lab Document Reference
	Y	N	NA	
4. MANAGEMENT REQUIREMENTS				
4.1 Organization and Management				
4.1.1 The laboratory shall have a clearly defined organizational system and structure. This shall be supported with organizational charts and job descriptions. Organizational charts shall indicate key personnel and the laboratory's place within the larger organization. Relationships between management, technical operations, support services, and quality activities shall be specified.				Organizational Chart and CVs
4.1.2 The laboratory shall appoint a member of staff as quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed at all times; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources;				Organizational Chart and CVs
4.2 Quality System				
4.2.1 Each diagnostic laboratory shall have a documented Quality Assurance Program to systematically monitor and evaluate the quality of all services.				
4.2.2 The laboratory management shall define and document the policies and objectives to be achieved by implementing the quality system. The laboratory management shall ensure that these policies and objectives are documented in a quality manual.				Quality Manual
4.2.3 The quality manual shall include or make reference to the supporting procedures including technical procedures. It shall outline the structure of the documentation used in the quality system. The quality manual shall be maintained up to date.				Quality Manual
4.3 Document Control				
4.3.1 The document control system shall ensure that only the current version of the correct document is in use in the laboratory, and that documents needed for staff to perform their work are available at the work location.				
4.3.2 The laboratory shall have documented policy, procedures and/or work instructions that describe how laboratory documents affecting the quality of tests, including test methods, are reviewed, approved, issued, updated, revised, amended, retained or archived, and discarded. Procedures shall be reviewed and approved by authorized, qualified staff.				Document Control procedure
4.3.3 Changes to documents shall be identified clearly and reviewed and approved by an authorized, qualified officer, administrator or supervisor having access to pertinent background information concerning the change.				
4.3.4 Documents shall be uniquely identified and accurately cross-referenced.				
4.3.5 Documents shall include page numbers and total number of pages or a mark to signify the end of the document				
4.4 Review of requests, tender or contract				
4.4.1 The laboratory shall have documented policy and procedures that describe how the laboratory ensures that it is capable of and has the capacity for doing particular testing. The procedures shall ensure adequate review of the proposed work with laboratory staff and the client. The laboratory shall keep a record of the review and of client agreement.				Procedure for contract review, Submission forms, fee schedules, etc.
4.5 Subcontracting of test services				
4.5.1 When a laboratory offers tests that are subcontracted, whether because of unforeseen reasons (e.g. workload, need for further expertise, or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting or agency arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with OIE requirements or ISO 17025 for the work in question.				
4.5.2 The laboratory shall advise the customer of the arrangement.				
4.6 Purchasing services and supplies				
4.6 The laboratory shall have a policy and procedures to ensure that services and supplies meet pre-established specifications and will not adversely affect the quality of test results. These procedures shall include a description of contract development, the criteria for selection, evaluation, use, handling, and storage of materials and reagents having an effect or potential effect on test results.				Purchasing procedure
4.8 Control of nonconforming testing and/or calibration work				
4.8.1 The laboratory shall have a policy and procedures that ensure that nonconforming testing (conditions that exist which have or could adversely affect the reliability of test results) is detected and promptly corrected. The laboratory shall have procedures for informing clients if test results are questionable or incorrect, particularly if this possibility is identified after test results have been reported to the client. These procedures shall describe who has the authority to withhold test results, implement corrective action, and authorize resumption of work.				Nonconforming work procedure
4.9 Corrective and Preventive Action				
4.9.1 The laboratory shall have a policy and procedures for implementing corrective action when nonconforming work or departures from the policies and procedures in the quality system have been identified. The policy and procedures shall ensure:				Corrective action procedure, form, etc.
a) designation of appropriate authorities responsible for implementation of corrective action(s);				

Requirement	Compliance			Lab Document Reference
	Y	N	NA	
b) investigative procedures are implemented to determine the root cause of the problem;				
c) upon identification, appropriate corrective action(s) are implemented;				
d) documentation of any required changes to operational procedures;				
e) once implemented, corrective action(s) are monitored to ensure effectiveness in overcoming the problem; and				
4.10 Records				
4.10.1.1 The laboratory shall establish and maintain procedures for identification, collection, indexing, access, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions.				Records Management procedure
4.10.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention time of records shall be established.				
4.10.1.3 All records shall be held secure and in confidence.				
4.10.1.4 The laboratory shall have procedures to protect and back-up data and records held on computers and to prevent unauthorized access to or amendment of data or records on computers.				Records Management procedure and/or IT procedure
4.10.2.1 The laboratory shall retain for a defined period of time, original observations, derived data, calibration records, staff records, a copy of each test report issued, and any other information necessary to recreate the activity. The records for each test shall contain sufficient information to facilitate identification of factors affecting the quality of test results and to enable the test to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel.				
4.10.2.2 Observations, data and calculations shall be clearly and permanently recorded and identifiable to the specific test at the time they are made.				
4.10.2.3 When mistakes occur in records, each mistake shall be crossed out (not erased, made illegible, nor deleted), and the correct value entered alongside. All such alterations to records shall be dated, signed or initialed by the person making the correction. In the case of computer-collected data, similar measures shall be taken to avoid loss or change of original data.				
4.11 Internal audits				
4.11.1 The laboratory shall periodically and in accordance with a predetermined schedule and procedure conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the quality system and the Standard. The internal audit program shall address all elements of the quality system, including testing activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. Personnel shall not audit their own activities except when it can be demonstrated that an effective audit can be carried out.				Internal Audit procedure and schedule
4.11.2 When audit findings cast doubt on the effectiveness of the operations or on the quality of the laboratory's test results, the laboratory shall take timely and effective corrective and preventive action, and shall notify clients in writing if investigations show that the laboratory results may have been affected (see 4.8).				
4.11.3 The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded. The laboratory management shall ensure that these corrective actions are discharged within an appropriate and agreed-upon time-frame.				
4.12 Management reviews				
4.12.1 The quality system and test related activities shall be reviewed by management at least once per year.				
4.12.2 The laboratory shall have a procedure for performing a management review. The review shall take into consideration:				Management Review procedure
a) the suitability of policies and procedures;				
b) reports of recent internal audits;				
c) corrective and preventive actions;				
d) assessments by external bodies;				
e) the results of interlaboratory comparisons or proficiency tests;				
f) other relevant factors, such as quality control activities, resources and staff training.				
4.12.3 Findings from management reviews and the actions that arise from them shall be recorded. The management shall ensure that those actions are discharged within an appropriate and agreed-upon timeframe.				
5. TECHNICAL REQUIREMENTS				
5.2 Personnel				
5.2.1 The laboratory shall ensure the initial and ongoing competence of all laboratory personnel to do their assigned work.				
5.2.2 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and diagnostic interpretation, and the management shall authorize only staff who are documented as qualified and competent to do testing and related work.				Training procedure
5.2.3 The laboratory shall have a system which ensures the establishment and maintenance of a training program relevant to the present and anticipated needs of the laboratory.				Training procedure, training manual, orientation, etc.
5.3 Accommodation and environmental conditions				

5.3.21The laboratory shall monitor, control and record environmental conditions as required by relevant specifications or where they may influence the reliability of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic interference, radiation, humidity, airflow, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned. Test activities shall be stopped when the environmental conditions jeopardize the test results.				Monitoring Environmental Conditions procedure
5.4 Test methods				
5.4.1 General				
Requirement	**Compliance**			**Lab Document Reference**
	Y	**N**	**NA**	
5.4.12The laboratory shall have written instructions for all tests and related procedures used in its routine activities, the calibration and operation of all relevant equipment, and the collection, handling, transport and storage of specimens and preparation of samples for testing.				Test procedures
5.4.3 Laboratories using test methods prepared by national and international standards-setting bodies and other external technical organizations shall have a system to receive updates of these methods in a timely manner.				Document Control procedure
5.4.5 Selection of methods				
5.4.6 Analysts shall have a record of documented proficiency in the performance of a test. Proficiency shall be documented on an ongoing basis, at appropriate intervals. Assessment of proficiency shall be based on objective data, using blind samples of appropriate number and composition. These samples should be well-characterized.				Training/Proficiency test procedure and records
5.4.7Test methods shall contain enough critical and descriptive information such that experienced personnel can properly perform the test within pre-established control limits without reference to other information sources. In addition, it shall include as appropriate:				Test procedures
a) evidence of document control;				
b) relevant references;				
c) a description of intended analyte(s) (e.g. antibody) and any quantities or ranges to be determine (e.g. titer);				
d) any reference standards or reference materials required (e.g., reference strains, reference standards for antibody);				
e) a description of the appropriate matrix or specimen for testing, including species (e.g. bovine serum);				
f) safety considerations, including biocontainment level needed;				
g) a list of and specifications for equipment, materials, and reagents, including software;				
h) conditions for acceptance of specimens as fit for testing;				
i) conditions for specimen identification, collection, handling, transportation and storage;				
j) conditions for sample preparation;				
k) a description of the controls used and their acceptance limits;				
l) checks to be made prior to beginning the test procedure (e.g. equipment checks and calibrations);				
m) acceptance criteria for test results;				
n) data to be recorded, and the method of analysis/transformation, presentation, and/or interpretation (e.g. how an absorbance reading is transformed and interpreted as a positive or negative result relative to a cut-off) and recording; and				
o) most current description of the test procedure.				
5.5.1 Equipment				
5.5.2 Equipment and its software used for diagnostic activities shall be capable of achieving the accuracy required and shall comply with specifications relevant to the procedures concerned. Calibration programs shall be established for key equipment where these properties have a significant effect on the results.				Maintenance and calibration procedure and records
5.5.3 Equipment shall be operated by authorized, qualified personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate laboratory personnel.				Equipment manuals / procedures
5.5.4 Each item of equipment used for test activities significant to a test result shall be uniquely identified.				
5.5.5 Records shall be maintained of each item of equipment significant to the tests performed. The records shall include at least the following:				
a) identity of the item of equipment;				
b) manufacturer's name, type identification, and serial number or other unique identification;				
c) verification that equipment complies with the specification				
d) the current location, where appropriate;				
e) the manufacturer's instructions, if available, or reference to their location;				
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;				
g) maintenance carried out to date and the maintenance plan				
h) damage, malfunction, modification or repair to the equipment.				
5.5.6 Maintenance procedures shall be established				Maintenance and calibration procedure and records
5.5.7 Equipment calibrations shall be performed by qualified personnel using procedures appropriate to intended use, accuracy and precision required, and at appropriate intervals as historical data indicate.				Maintenance and calibration procedure and records

5.5.8 Equipment that has been subjected to overloading or mishandling, or gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service, clearly labeled or marked, and appropriately stored until it has been repaired and shown to perform correctly. The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and shall institute the "Control of nonconforming work" procedure (4.8).				
5.5.9 Whenever practical, all equipment under the control of the laboratory and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration or verification and the date when the next calibration or verification is due.				

Requirement	Compliance			Lab Document Reference
	Y	N	NA	
5.5.10 When, for whatever reason, equipment goes outside the direct control of the laboratory, the laboratory shall ensure that the function and calibration status of the equipment are checked and shown to be satisfactory before the equipment is returned to service.				
5.5.11 Test equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test results.				
5.6 Measurement traceability				
5.6.1 Where indicated and when possible, the laboratory shall have traceability of all measurements, including the calibration of equipment, to Standard International (SI) units.				
5.6.2 Where traceability to SI units of measurement is not possible, the best available means for providing confidence in the results shall be applied such as:				
a) the use of suitable reference standards of materials certified to give a reliable characterization of the material;				
b) mutual-consent standards or methods that are clearly specified and agreed upon by all parties concerned;				
c) participation in a suitable program of interlaboratory comparisons or proficiency testing.				
5.6.3 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.				Measurement Traceability procedure
5.7 Specimens				**ONLY APPLICABLE IF LAB COLLECTS SAMPLES**
5.7.1 General: The lab shall have procedures for the collection of specimens to ensure that they are both appropriate to the test being undertaken and suitable for testing.				
5.7.1.1 The laboratory shall have procedures for the collection, processing where indicated, and preservation of specimens. Collection and related procedures shall be available at the location where collection is undertaken.				
5.7.1.2 The laboratory shall have procedures for recording relevant data and operations relating to specimen collection that forms part of the test that is undertaken. Records shall include the collection procedure used, identification of the collector, environmental conditions (if relevant) and diagrams or other means to identify the collection location as necessary (e.g., in the case of tissue specimens) and, if appropriate, the statistics that sampling procedures are based upon.				
5.7.1.3 When sampling from populations, as appropriate, the laboratory shall have a statistically defined plan for sample collection.				
5.8 Handling of specimens				
5.8.1 The laboratory shall have procedures which ensure the integrity of specimens. These shall include transportation, receipt, handling, protection, retention and/or disposal of specimens.				Handling of specimens / accessioning procedure(s)
5.9 Ensuring the quality of test results				
5.9.1 The laboratory shall have quality control procedures for monitoring the validity of test results.				Quality control procedure(s)
5.10 Reporting test results				
5.10.1 The results of each test performed by the laboratory shall be reported accurately, clearly, unambiguously, and objectively, and in accordance with any specific instructions in the test method or contract.				Reporting procedure
5.10.2 Unless the laboratory has valid reasons for not doing so, each test report shall include at least the following information:				
a) a title (e.g. 'Test Report');				
b) name and address of laboratory, and, if different, the location where the tests were performed;				
c) unique identification (see 5.8.2.) at the beginning and on each page of the test report to ensure that the page is recognized as a part of the test report, and a clear identification of the end of the report;				
d) name and address of the client placing the order;				
e) description and unambiguous identification of the specimen(s) tested;				
f) unique identification of the test method(s) used.				
g) date of receipt of specimen(s) and date(s) of performance of the test where relevant to the validity and application of the results;				
h) test results;				
i) reference to specimen collection procedures used by the laboratory or by the client where these are relevant to the validity or application of the results;				
j) where appropriate and needed, opinions and diagnostic interpretations of the test results;				
k) the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report;				
5.10.3 When the test report contains results of tests performed by subcontractors, these results shall be clearly identified.				