ETHIOPIAN ACCREDITATION SERVICE	**ISO 15189 VERTICAL ASSESSMENT FORM FOR MEDICAL LABORATORIES**	**F07/07B**

For office use: EAS Acc. No	
Laboratory:	
Field of operation:	
Assessor/s , Technical Expert & Observers:	
Laboratory Representative:	
Date of Evaluation:	

This report covers the following:

Type of Assessment (Tick box):	Initial:		Follow up:		Re-assessment:		

INSTRUCTIONS

1) **PURPOSE: This form shall not be used by technical assessors as a checklist but for recording traceable factual evidence of the vertical assessment of all the technical inputs that were required in the production of the test which has been selected. Clause numbers of the relevant standards are therefore not quoted and the vertical assessment need not be limited to the technical aspects listed. All facts recorded should be sufficient so as to verify that the test was, or was not, performed under pre-defined controlled conditions and, as a consequence, the result produced has, or has not, a known measurement uncertainty.**

2) **SELECTION OF REPORT: Select a report at random and choose one or more accredited test or in order to trace back to check that all the technical input controls were valid, effective and conform to the laboratory's system requirements and to the requirements of either ISO 15189.**

3) **RECORD OF ASSESSMENT: Record what was checked, how it was checked and if it is adequate to meet the technical requirement of the relevant standard. Use the blank portions of the form underneath the aspects to be assessed and, if necessary, continue recording data on the back of each page and cross referencing such notes to the original notes.**

Report No: _____ **Customer Name:** _____ **Date issued:** _____

Parameter(s)/Test(s) Selected and Results: _____

CONTROLS TO BE ASSESSED (Key: C = Comply, NC = not comply, NA = not applicable)	**C NC NA**
1) Test Report:	
Assess the report for compliance to the relevant requirements for reporting of results and check: a) Test report number and date of report b) Clear unambiguous identification of the examination and the examination procedures where appropriate c) Identification of all examinations that have been performed by a referral laboratory d) Comments on sample quality, suitability where applicable critical results and interpretive comments on results e) Identification of the person(s) reviewing the results and authorizing the release of the report. f) The records are permanent ,legible without mistakes in transcription and the amendments are captured along with the identify of personnel making amendments g) If the results transmitted as an interim report and the final report was forwarded to the requester h) If the results was a revised report and the report clearly identified a revision & includes reference to the date and patients Identity in the original report	

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2) Request forms:	
Asses the request form for compliance to the requirements of the standards and check: a) Patient identification gender, date of birth location/contact details and unique identification. b) Name or other unique identifier of clinician / health care provider/ legally authorized person, destination for the report and contact details. c) Type of primary sample and where relevant, the anatomical site of origin. d) Examination requested. e) Clinical relevant information about the patient and the request for examination performance and result and interpretation purposes. f) Date and where relevant, time of primary sample collection. g) Date and time of sample receipt.	
3) Sample Reception:	
Trace back to the raw date and check: a) The primary sample was traceable to identified individuals. b) The samples were recorded in an accession book / work sheets/ computer etc. c) The identity of the person that received the samples recorded. d) Samples were evaluated and they met the acceptance criteria relevant for the requested examination(s). e) That any comments on sample quality that might compromise examination results have been recorded	

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4) Sample Transportation	
Check samples were monitored during transportation to ensure that transportation : a) Was within the time frame appropriate to the nature of the requested examination and laboratory discipline concerned; and b) Within in the temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples	
5) Control of Records:	
Trace back to the raw data of the person(s) who performed the tests selected and **check**: a) Adequacy of traceability to the person(s) performing the test b) Adequacy of raw data/original records of environmental and equipment control parameters required by the test such as humidity, temperature, time, pressure, force, etc. c) Adequacy of raw data and intermediate records in - legibility, permanency, corrections, and authorization. d) Appropriateness of calculation and data transfer checks by the laboratory. e) Calculation of results and data transfers - re-calculate the results under assessment to verify and check data transfers. f) Randomly check correctness of data transfers.	

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6) Training:	
Assess the training records of the person(s) who performed the selected tests and **check:** a) The laboratory personnel have qualifications (appropriate education, training, experience and demonstrated skills needed). b) The technologist /technicians job. Description. c) Availability and validity of proof of competency of the person(s) on the specified date of the work. d) Appropriateness of methodology to prove competence by objective evidence over a period of time that the person(s) can meet the performance capability of the method. e) Compliance to the system requirements for proving competency.	
7) performance capability of selected examination procedure:	
Assess the validation/verification of the tests performed and **check:** a) Non standard method, laboratory developed methods and standard methods used outside their intended scope are validated and the performance capabilities of the methods are available and appropriate. b) Validated examination procedures used are verified by the laboratory before being introduced in routine use and the results are recorded. c) The performance claims for the examination procedure confirmed during the verification process are relevant to the intended use of examination results. d) The validation /verification results are reviewed by authorized staff.	

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8) Uncertainty of Measurement:	
Assess the measurement uncertainty of the selected tests and **check:** a) Appropriateness of the methodology used to calculate the uncertainty. b) Relevance of the uncertainty to the typical range of results and customer requirements. c) Methodology used to provide an uncertainty estimate/measurement capability when required.	
9) Ensuring quality of examination results:	
Assess the technical quality control measures applicable to the selected tests and **check:** a) The quality control rules met before the release of patient results b) Appropriateness and effectiveness for ensuring the controlled performance of the accredited work. c) Effectiveness of the control limits or tolerances been used and their relevance to the validation data. d) Adequacy of controls at the time when the selected results were produced. e) Evidence of actions implemented when breaches have occurred. f) Appropriateness of method of recording, evaluating and reviewing control data and updating control limits.	

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10) Proficiency testing/ Inter-laboratory comparisons	
Assess the external inter-laboratory QC participation in relation to the selected tests and **check:** a) Appropriateness of the schemes and frequency of participation for the work performed. b) Appropriateness of the corrective/preventive action taken when relevant. c) The laboratory's performance in relation to its stated performance capability of the method.	
11) Calibration of equipment and/or standards used:	
Assess the equipment and standards used in the performance of the selected test and **check:** a) Validity and traceability of reference standards and materials, used for in-house calibrations/verifications, and that they were calibrated by a competent calibration body traceable to national or international standards. b) Validity and traceability of the equipment/standards used to calibrate or monitor variables at the time the work was performed to national or international standards. c) That the range of calibration covers the operating range of the parameter measured in the test. d) That the resolution and measurement uncertainty of the equipment or standard is sufficiently higher than the tolerance of the parameter required be monitoring or verifying. e) Suitability of in-house verification schemes and techniques by intermediate checks to ensure continued validity of the calibration status of reference, primary, transfer or working standards f) Appropriate application of correction factors, when relevant. g) Traceability to appropriate reference standards and reference materials. **NOTE: Laboratory Equipment includes hard ware and software of instruments, measuring systems and laboratory information system.**	

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12) Equipment maintenance and operation:	
Assess the equipment used in the performance of the selected tests and **check:** a) The equipment upon installation and before being used verified for being capable of achieving the necessary performance (records that confirm the equipments initial acceptability for use) b) Capability to meet the requirements of the test and of achieving the required accuracy. c) Availability of instructions on the use and maintenance of the equipment. d) Maintenance records are up to date and that the equipment was within its maintenance cycle at the time the selected results were produced. e) Equipment set-up and calibration controls are in place in order to ensure optimization of operation before and during work and such controls include any manufacturers recommendations for optimization and/or calibration. f) That the equipment was optimized by set-up and/or calibration controls during the production of the selected results.	
13) Accommodation and environmental conditions:	
Assess the accommodation and environmental conditions during the performance of the selected tests and **check:** a) Suitability of facilities in terms of services to effectively perform the test. b) That all variables that could affect the quality of the selected result are being monitored and controlled. c) Effective separation of neighboring areas to prevent any cross-contamination. d) Effective access control to areas affecting the quality of work. e) That housekeeping is adequate and effective.	

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14) Inspection and Verification of Supplies:	
Assess the inspection and verification process for supplies used during the performance of the selected tests and **check:** a) Supplies that affect the quality of the work are inspected or verified prior to use to meet the quality criteria as required for the methods and that such measures are adequate and proportionate to the impact on quality. b) Reagents and consumables are stored according to manufacturers' specifications. c) Supply/stock control is adequate to ensure uninterrupted performance of work. d) That the laboratory is using supplies from approved suppliers.	
15) Handling of clinical samples:	
Trace the sample upon which the selected tests were performed or similar samples if no longer available and **check:** a) That it is uniquely identified to ensure that there can be no confusion regarding its identify at any time. b) That its identity matches the sample description in the selected report. c) Suitability of storage and retention time before, during and after testing.	

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16) Customer's Requirements:	
Trace the customer request and Service agreement and **check:** a) That the customer's requirements have been met by the issue of the selected report. b) That all records of communications with the client of any changes, amendments and progress updates regarding the work are retained and evidence of resolution of such changes with the customer are available.	
Follow-up on Findings of Previous Assessment	
Assessor signature: Date:	