VERTICAL ASSESSMENT
ISO 15189:2012 FOR MEDICAL LABORATORIES

Date/s of Evaluation	
Assessor/s & Observers	
Laboratory	
Area / Field of Operation	
Laboratory Representative	

Requiremens for **ISO 15189** for Medical Laboratories. Paragraph number against right margin. *(Give details below the requirements to INDICATE <u>WHAT</u> HAS BEEN CHECKED and comment on any positive aspects. Record all information pertaining to the selected data relevant to the standard questions below.)*		**Clause**
Test Report *(Select one or more final Test Report)*		5.8.3
(a) Test report number and date of report		5.8.3 (o)
(b) Clear, unambiguous identification of the examinations and the examination procedure		5.8.3 (a)
(c) Identification of all examinations that have been performed by a referral laboratory		5.8.3 (b)
(d) Comments on sample quality, suitability, where applicable critical results and interpretive comments on results		5.8.2
(e) Identification of the person(s) reviewing the results and authorizing the release of the report (if not contained in the report, readily available when needed)		5.8.3 (n)
(f) Are records permanent, legible without mistakes in transcription and are amendments captured along with the identity of personnel making amendments		4.13/ 5.9.1 (c)
(g) Were results transmitted as an interim report and was the final report forwarded to the requester?		5.9.1 (d)
(h) Is this a revised report? If yes, is it clearly identified as a revision and includes reference to the date and patient's identity in the original report?		5.9.3

Comments:

REQUEST FORM INFORMATION		5.4
a) patient identification, gender, date of birth, location/contact details and unique identifier		5.4.3(a)
b) name or other unique identifier of clinician/ healthcare provider/legally authorised person, destination for the report and contact details		5.4.3 (b)
c) type of primary sample and where relevant, the anatomical site of origin		5.4.3 (c)
d) Examination requested		5.4.3 (d)
e) clinically relevant information about the patient and the request, for examination performance and result and interpretation purposes		5.4.3(e)
f) date and where relevant, time of primary sample collection		5.4.3 (f)
g) date and time of sample receipt		5.4.3 (g)
Comments:		

SAMPLE RECEPTION		5.4.6
How was the primary sample traceable to an identified individual?		5.4.6 (a)
Were the samples recorded in an accession book / worksheet / computer, etc?		5.4.6(d)
Is the identity of the person that received the samples recorded?		5.4.6(d)
Were samples evaluated and did they meet the acceptance criteria relevant for the requested examination(s)		5.4.6 (e)
Comments:		

SAMPLE TRANSPORTATION		5.4.5
Were samples monitored during transportation to ensure that transportation: • was within time frame appropriate to the nature of the requested examination and laboratory discipline concerned; and • within temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples.		
Comments:		

PRE-EXAMINATION HANDLING, PREPARATION AND STORAGE		5.4.7
(a) Were environmental conditions monitored and controlled?		5.2.6
(b) Which environmental conditions were monitored that can affect the examination results		5.2.6
(c) Did the storage and environmental conditions provide continuing entigrity (temperature within intervals specified and prevention of cross contamination)		5.2.6
Comments:		

EXAMINATION PROCESSES		5.5
Was an Examination Procedure used and is it subject to document control		5.5.3
Is the examination procedure validated for its intended use?		5.5.1.1
If yes, did the lab conduct an independent verification?		5.5.1.2
If the examination procedure is non-standard method/ laboratory designed or developed method / standard method used outside its intended scope / modified developed, is the examination procedure validated?		5.5.1.3
Were the specific validation requirements for the intended use of the examination fulfilled?		5.5.1.3
Were the validation results reviewed by authorised staff?		5.5.1.3
What is the measurement uncertainty for this examination procedure?		5.5.1.4
What are reference intervals and clinical decision values for this examination procedure?		5.5.2
Comments:		

Ensuring quality of examination results		5.6
Were the quality control rules met before the release of patient results?		5.6.2.3
Does the laboratory participate in an interlaboratory comparison programme appropriate to the examination and interpretations of examination results?		5.6.3.1
Were the results for interlaboratory comparison evaluated and where predetermined performance criteria was not fulfilled, did staff implement corrective actions?		5.6.3.4
Comments:		

LABORATORY EQUIPMENT		5.3
Which equipment was used to perform the examinations – identity of equipment?		5.3.1.1
Was this equipment available in the lab? If not, how did management ensure that the requirements of this standard were met?		5.3.1.1
Was the equipment upon installation and before being used verified for being capable of achieving the necessary performance (records that confirm the equipment's initial acceptability for use)?		5.3.1.2
Is each item of equipment uniquely labelled, marked or otherwise identified?		5.3.1.2
Equipment calibration and metrological traceability (Refer to SADCAS F 121)		5.3.1.4
Documented procedure for calibration of equipment?		
Was the equipment calibrated?		
Is accuracy and functioning of equipment verified at defined intervals? (Refer to SADCAS TR 09)		
Is there records of maintenance carried out ?		
Are there equipment performance records that confirms the equipment's ongoing acceptability for use (reports/certificates of all calibrations and/or verifications including dates, times of results, adjustments, the acceptance criteria and due dates of the next calibration and/or verification)?		5.3.1.5 5.3.1.7
Comments:		

Reagents and consumables		5.3.2
Were reagents and consumables stored according to manufacturer 's specifications?		5.3.2.2
Were reagents and consumables that can affect the quality of examination verified for performance before use and is there a record that confirms the reagents' or consumables' initial acceptance for use?		5.3.2.3
Are the following records available:		5.3.2.7
Batch code or lot number;		
Date of receiving, the expiry date, date of entering into service.		
Comments:		

PERSONNEL		5.1
(a) Was the technologist/technician deemed competent at the time of this examination? (b) Did the technologist/technician have qualifications (appropriate education, training, experience and demonstrated skills needed) as documented by the laboratory? (c) Do personnel that made judgement with reference to examination have the applicable theoretical and practical background and experience? (d) Does the technologist/technician have a job description?		

GENERAL / ADDITIONAL COMMENTS AND MATTERS TO FOLLOW UP AT NEXT ASSESSMENT

Signed: **Technical Assessor**	
Signed: **Team Leader**	