

## VERTICAL ASSESSMENT ISO 15189:2022 FOR MEDICAL LABORATORIES

Date/s of Evaluation	
Assessor/s & Observers	
Laboratory	
Area / Field of Operation	
Tests/Examinations Requested	
Laboratory Representative	
<p>Requirements for <b>ISO 15189</b> for Medical Laboratories. Paragraph number against right margin. (Give details below the requirements to <b>INDICATE WHAT HAS BEEN CHECKED</b> and comment on any positive aspects. Record all information pertaining to the selected data relevant to the standard questions below.)</p>	
	<b>Clause</b>
<b>REQUIREMENTS FOR REPORTS</b> (Select one or more final Test Report)	7.4.1.6
(a) Unique patient Identification, date of primary sample, type of primary sample collection and date of report on each page of report.	7.4.1.6(a,d)
(b) Clear, unambiguous identification of the examinations performed and the examination method used.	7.4.1.6 (e,f)
(c) Indication of any critical results, notification of user or authorised personnel as soon as relevant, and escalation procedure for laboratory personnel when responsible person cannot be contacted.	7.4.1.6 (i) & 7.4.1.3
(d) Examination results with reported in SI units or other applicable units and indication of biological reference.	7.4.1.6(g,h)
(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)	7.4.1.6 (j)
(f) Are examination results reported accurately,clearly, unambiguously and in accordance with any specific instructions in the examination procedure?	7.4.1.1(a)
(g) Is all information associated with issued reports retained in accordance with management system requirements?	8.4
(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?	7.4.1.8

<b>Comments:</b>		
<b>REQUESTS FOR PROVIDING LABORATORY EXAMINATIONS</b>		<b>7.2.3</b>
a) Is each request accepted by the laboratory for examinations(s) considered an agreement?		7.2.3.1(a)
b) Does the examination request provide sufficient information to ensure:		7.2.3.1 (b)
- unequivocal traceability of the patient to the request and sample?		
- identity and contact information of requester?		
- identification of the examination(s) requested?		
- informed clinical and technical advice, and clinical interpretation can be provided?		
c) Is examination request information provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user?		7.2.3.1(c)
d) How are oral requests managed?		7.2.3.2
<b>Comments:</b>		
<b>SAMPLE RECEIPT</b>		<b>7.2.6</b>
How was the primary sample traceable to an identified individual?		7.2.6.1 (a)
Was the criteria for acceptance and rejection of samples documented? Were the samples evaluated by authorised personnel to ensure compliance with acceptability criteria relevant for the requested examination(s).		7.2.6.1(b,e)
Is the date and time of sample receipt recorded, when relevant?		7.2.6.1(c)
Is the identity of the person that received the samples recorded, when relevant?		7.2.6.1(d)
How are compromised clinically critical or irreplaceable samples handled?		7.2.6.2(b)

<b>Comments:</b>		
<b>SAMPLE TRANSPORTATION</b>		<b>7.2.5</b>
<p>Are sample transportation instructions followed to ensure timely and safe transportation of samples?</p> <ul style="list-style-type: none"> <li>Was the time between sample collection and receipt specified and monitored, where relevant?</li> <li>Were temperature interval specified for sample collection and handling maintained?</li> <li>What is the frequency of evaluating adequacy of sample transportation systems?</li> </ul>		
<b>Comments:</b>		
<b>FACILITIES AND ENVIRONMENT</b>		<b>6.3</b>
(a) Were the requirements for facilities and environmental conditions necessary for the performance of the laboratory activities specified, monitored and recorded?		6.3.1
(b) What measures are put in place to prevent cross-contamination, where examination procedures pose a risk, or where work can be affected or influenced by lack of separation?		6.3.2(c)
(c) Were patient samples and materials used in the examination processes stored in a manner that prevents cross contamination and deterioration?		6.3.3(b)
(d) Were storage and disposal facilities for hazardous materials and biological waste appropriate to the classification of the materials in the context of any statutory or regulatory requirements?		6.3.3(c)
<b>Comments:</b>		

<b>EXAMINATION PROCESSES</b>	<b>7.3</b>
<p>Was the examination procedure documented to the extent necessary to ensure the consistent application of activities and the validity of results?</p> <p>Were documented procedures written in a language understood by the laboratory personnel and available in appropriate locations?</p> <p>Is the examination procedure validated for its intended use?</p> <p>If yes, did the laboratory conduct a verification to ensure that the required performance as specified by the manufacturer or method can be achieved?</p> <p>Was the verification procedure available?</p> <p>Were the performance specifications for the examination method confirmed during the verification relevant to the intended use of the examination results?</p> <p>Was the extent of the verification of examination methods sufficient to ensure the validity of results pertinent to clinical decision making?</p> <p>Were the verification results reviewed by authorised personnel and was the review recorded indicating whether the results meet the specified requirements?</p> <p>If the examination procedure is a non-standard method/ laboratory designed or developed method / standard method used outside its intended scope / modified is the examination procedure validated?</p> <p>Were the specific validation requirements for the intended use of the examination fulfilled?</p> <p>Were the validation results reviewed by authorised personnel and was the review recorded indicating whether the results meet the specified requirements?</p> <p>Was the measurement uncertainty(MU) for this examination procedure evaluated and maintained for its intended use, where relevant?</p> <p>Was the MU compared against performance specifications and documented?</p> <p>What is the frequency of MU evaluations review?</p> <p>Were the reference intervals and clinical decision values for this examination procedure defined, their basis recorded and communicated to users?</p>	<p>7.3.6(a)</p> <p>7.3.6(b)</p> <p>7.3.1 (a)</p> <p>7.3.2</p> <p>7.3.2(b)</p> <p>7.3.2( c)</p> <p>7.3.2 (d)</p> <p>7.3.3</p> <p>7.3.3(b)</p> <p>7.3.3(c)</p> <p>7.3.4(a)</p> <p>7.3.4(a)</p> <p>7.3.4(b)</p> <p>7.3.5</p>
<p><b>Comments:</b></p>	

ENSURING THE VALIDITY OF EXAMINATION RESULTS	7.3.7
<p>Does the laboratory have a procedure for monitoring the validity of results? Is the monitoring planned and reviewed?</p>	7.3.7.1
<p>Is data recorded in such a way that trends and shifts are detected and where practicable, statistical techniques applied to review the results?</p>	
<p><u>Internal Quality Control(IQC)</u></p>	
<p>Does the laboratory have an IQC procedure for monitoring the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making?</p>	7.3.7.2(a)
<p>1) Does the procedure also allow for the detection of either lot- to-lot reagent or calibrator variation, or both, of the examination method?</p>	7.3.7.2(a)
<p>2) Is the use of third-party IQC material considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer?</p>	7.3.7.2(a)
<p>Does the laboratory select IQC material that is fit for its intended purpose? When selecting IQC material, do the factors to be considered include:</p>	7.3.7.2(b)
<p>1) stability with regard to the properties of interest?</p>	
<p>2) the matrix is as close as possible to that of patient samples?</p>	
<p>3) the IQC material reacts to the examination method in a manner as close as possible to patient samples?</p>	
<p>4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method?</p>	
<p>Is the IQC performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result?</p>	7.3.7.2(d)
<p>Is the IQC data reviewed with defined acceptability criteria at regular intervals and in a timeframe that allows a meaningful indication of current performance?</p>	7.3.7.2(f)
<p>Does the laboratory prevent the release of patient results in the event that IQC fails the acceptability criteria?</p>	7.3.7.2(g)
<p>When IQC defined acceptability criteria are not fulfilled and indicate results are likely to contain clinically significant errors, are the results rejected and relevant patient samples re-examined after the error has been corrected?</p>	
<p>Are results from patients that were examined after the last successful IQC event evaluated?</p>	
<p><u>External Quality Assessment - Refer to SADCAS F134(e)</u></p>	7.3.7.3

**Comments:**

<b>EQUIPMENT</b>	<b>6.4</b>
Does the laboratory have processes for selection, procurement, installation, acceptance testing, handling, transport, storage, use, maintenance and decommissioning of equipment to ensure proper functioning and prevent contamination or deterioration	6.4.1
Which equipment was used to perform the examinations and was the equipment uniquely identified?	6.4.2 (c)
Is a register maintained for equipment that can influence laboratory activities?	
Does the laboratory maintain and replace equipment as needed to ensure the quality of examination results?	6.4.2(d)
Does the laboratory have a preventive maintenance programme based on manufacturer's schedule and instructions and are deviations recorded?	6.4.5(a)
Are defective equipment taken out of service clearly labelled or marked as being out of service until it has been verified to perform correctly?	6.4.5(c)
Does the laboratory examine the effect of the defect or deviation from specified requirements and initiate actions when non-conforming work occurs?	6.4.5(c) & 7.5
When applicable, does the laboratory decontaminate equipment before service, repair or decommissioning and provide suitable space for repairs and provide appropriate personal protective equipment?	6.4.5(d)
Does the laboratory have procedures for responding to any manufacturer's recall or other notice and take actions recommended by the manufacturer?	6.4.6
Does the laboratory maintain records for each item of equipment which can influence the results of laboratory activities)	6.4.7 & 8.3
<u>Equipment calibration and metrological traceability (Refer to SADCAS F 121)</u>	6.5
Does the laboratory have procedures for the calibration of equipment that directly or indirectly affect examination results?	6.5.2

<b>Comments:</b>	
<b>REAGENTS AND CONSUMABLES</b>	
	<b>6.6</b>
<p>Does the laboratory store reagents and consumables according to the manufacturers' specifications and monitor the environmental conditions where relevant?</p> <p>When the laboratory is not the receiving facility, do they verify that the receiving facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration?</p> <p>Is new formulation of examination kits with changes in reagents or procedure, or new lot or shipment verified for performance before use or before release of results, as appropriate?</p> <p>Does the inventory management system established by the laboratory segregate reagents and consumables that have been accepted for use from those that have not been inspected or accepted?</p> <p>Are instructions for use of reagents and consumables, including those provided by the manufacturers, readily available?</p> <p>Are adverse incidents and accidents (attributed to specific reagents or consumables) investigated and reported to manufacturer and/or supplier and appropriate authorities, as required?</p> <p>Does the laboratory have procedures for responding to any manufacturer's recall or other notice and taking actions recommended by the manufacturer?</p> <p>Are the following records available:</p> <ul style="list-style-type: none"> <li>• Identity of the reagent or consumable.</li> <li>• Manufacturer's name, and batch code/ lot number</li> <li>• Date of receipt and condition when received, expiry date, date of first use and where applicable date when taken out of service</li> <li>• Records that confirmed the reagent's or consumable's initial and ongoing acceptance for use</li> </ul>	<p>6.6.2</p> <p>6.6.3</p> <p>6.6.4</p> <p>6.6.5</p> <p>6.6.6</p> <p>6.6.6</p> <p>6.6.7</p>
<b>Comments:</b>	

<b>PERSONNEL</b>		<b>6.2</b>
<p>(a) Does the laboratory have access to a sufficient number of competent persons to perform its activities?</p> <p>(b) Was the Scientist/Technologist/Technician deemed competent and authorised to perform specific laboratory activities?</p> <p>(c) Are all personnel, internal and external, that could influence the laboratory activities act impartially, ethically, and work in accordance with the laboratory's management system?</p> <p>(d) Does the laboratory have a programme to introduce personnel to the organisation, department or area in which the person will work and the terms and conditions of employment</p> <p>(e) Did the Scientist/Technologist/Technician have qualifications (appropriate education, training, technical knowledge, experience and skills ) as specified by the laboratory?</p> <p>(f) Is there a process of managing competence of personnel and was frequency of competence assessments defined ?</p>		<p>6.2.1(a)</p> <p>6.2.2(b) &amp; 6.2.3</p> <p>6.2.1(b)</p> <p>6.2.1(d)</p> <p>6.2.2(a)</p> <p>6.2.2(c)</p>
<b>PROCESS REQUIREMENTS</b>		<b>7</b>
<p>Does the laboratory identify potential risks to patient care in the pre-examination, examination and post-examination processes?</p> <p>Are the identified risks and effectiveness of the mitigation processes monitored and evaluated according to the potential harm to the patient?</p>		7.1
<b>NONCONFORMING WORK</b>		<b>7.5</b>
<p>Does the laboratory have a process to address any aspect of its laboratory activities or examinations that do not conform to its own procedures' quality specifications, or the user requirements?</p> <p>Does the process ensure that:</p> <ol style="list-style-type: none"> <li>1. The responsibilities and authorities for the management of nonconforming work are specified?</li> <li>2. Intermediate and long-term actions are specified and based upon the risk analysis process established by the laboratory?</li> <li>3. Examinations are halted, and reports withheld when there is a risk of harm to patients?</li> <li>4. An evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance?</li> </ol>		7.5



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

*(This area is intentionally left blank for providing general or additional comments and matters to follow up at the next assessment.)*

<b>Name:</b> Technical Assessor		<b>Signature:</b>	<b>Date:</b>
<b>Name:</b> Team Leader		<b>Signature:</b>	<b>Date:</b>