CONFIDENTIAL

SINGAPORE ACCREDITATION COUNCIL
SINGAPORE LABORATORY ACCREDITATION SCHEME (SAC-SINGLAS)

MEDICAL TESTING LABORATORY ASSESSMENT CHECKLIST [ISO 22870: 2016]

Type of Assessment	:	Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification
Laboratory / Facility	:	
Address	:	
Tel / Fax	:	
Names of persons seen	:	
Field / Disciplines	:	
Date of visit	:	
Technical Assessor(s)	:	
Team Leader	:	Name & Signature / Date

Note: This checklist is to be used in conjunction with ISO 15189:2012 checklist.

References
ISO 15189:2012, ISO 22870: 2016, SAC-01, SAC-02, SAC-SINGLAS-006, PROF 001

Clause No	Description	Yes	No	N/A	Remarks
4	**MANAGEMENT REQUIREMENTS**				
4.1	**Organisation and Management responsibility**				
4.1.1	<u>To check ISO 15189: 2012</u> • Clause 4.1.1.2 *Legal Entity* • Clause 4.1.1.3 *Ethical Conduct* Does the management of laboratory services plan and develop the processes needed for POCT with the following as appropriate?				
a)	Quality objectives and requirements for POCT				
b)	The need to establish processes and documents, and provide resources specific to POCT				
c)	Required verification, validation and monitoring of activities specific to POCT				
d)	Records to provide evidence that POCT processes and procedures meet requirements				
	Does the governing body of the organisation be ultimately responsible for ensuring that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the healthcare organisation?				
4.1.2	<u>To check ISO 15189: 2012</u> • Clause 4.1.2.2 *Needs of users*				
4.1.2.1	Does the health professional grouping (e.g. Medical Advisory Committee) be responsible to the governing body for defining the scope of POCT to be made available? Do they take into consideration the clinical need for POCT, its financial implications, technical feasibility and the ability of the organisation to fulfil the need?				
4.1.2.2	Does the Laboratory Director appoint a multidisciplinary POCT management group with representation from the laboratory, administration and clinical programmes including nursing to advise on the provision of POCT?				
4.1.2.3	Does the management group ensure that responsibilities and authorities are defined and communicated within the organisation?				
4.1.2.4	Does the management group assist in evaluating and selecting POCT devices and systems?				

Clause No	Description	Yes	No	N/A	Remarks
4.1.2.5	Does the management group consider all proposals to introduce and product, device or system for POCT?				
4.1.3	To check ISO 15189: 2012 • Clause 4.1.1.1 *Organisation*				
4.2	**Quality management system**				
4.2.1	To check ISO 15189: 2012 • Clause 4.1.2.3 *Quality policy* • Clause 4.1.2.4 Quality objectives and planning • Clause 4.1.2.6 *Communication*				
4.2.2	To check ISO 15189: 2012 • Clause 4.2.1 *General requirements*				
4.2.2.1	The management of the laboratory services shall: (ISO 15189: 2012 Clause 4.2.1)				
a)	Identify the processes needed for the quality management system for POCT throughout the organisation				
b)	Determine the sequence and interaction of these processes				
c)	Determine criteria and methods needed to ensure that both control of these processes are effective				
d)	Ensure the availability of resources and information necessary to support the operation and monitoring of these processes				
e)	Monitor, measure and analyse these processes				
f)	Implement actions necessary to achieve planned results and continual improvement of these processes				
g)	Appoint a person with appropriate training and experience as quality manager responsible for POCT quality, which includes review of the requirements related to POCT				
	Are these processes managed by the organisation in accordance with the requirements of this document?				
4.2.2.2	Does the management of laboratory services plan and implement the monitoring, measurement, analysis and improvement processes needed to demonstrate the conformity of POCT to the quality system?				

Clause No	Description	Yes	No	N/A	Remarks
4.2.3	To check ISO 15189: 2012 • Clause 4.2.2.1 *Documentation Requirements - General*				
4.2.4	To check ISO 15189: 2012 • Clause 4.1.1.3 *Quality policy* • Clause 4.1.1.4 *Quality objectives* Does the laboratory director or suitably qualified designate ensure that:				
a)	POCT quality objectives are established and are measurable				
b)	The planning of the quality management system is carried out in order to meet the requirements of the services, as well as the quality objectives, and				
c)	The integrity of the quality management system is maintained when changes to the quality management system are planned and implemented				
4.2.5	To check ISO 15189: 2012 • Clause 4.2.2.2 *Quality Manual* Does the organisation establish and maintain a quality manual that includes:				
a)	Scope of the quality management system				
b)	Documented procedures established for the quality management system or reference to them				
c)	Description of the interactions between the processes of the quality management system				
4.3	**Document Control** To check ISO 15189: 2012 Clause 4.3				
4.4	**Service agreements** To check ISO 15189: 2012 Clause 4.4				
4.5	**Examination by referral laboratories**				N.A.
4.6	**Examination by external services and supplies** To check ISO 15189: 2012 Clause 4.6				
4.7	**Advisory Services** To check ISO 15189: 2012 Clause 4.7				
4.8	**Resolution of Complaints** To check ISO 15189: 2012 Clause 4.8				

Clause No	Description	Yes	No	N/A	Remarks
4.9	**Identification and control of non-conformities**				
4.9.1	To check ISO 15189: 2012 • Clause 4.9				
4.9.2	Does the organisation ensure that POCT that does not conform to requirements is identified and controlled to prevent its unintended use? Are the controls and related responsibilities and authorities for dealing with nonconforming POCT defined in a documented procedure? Nonconforming POCT shall be dealt in the following ways a) taking action to eliminate the detected nonconformity b) authorising its use, release and acceptance c) taking action to preclude its original intended use or application Does the laboratory maintain records of the nature of nonconformities and the subsequent actions taken?				
4.9.3	Does the organisation determine, collect and analyse appropriate data to evaluate where continual improvement of the effectiveness of the quality management system can be made? This shall include data generated as a result of monitoring and measurement, as well as from other relevant sources.				
4.9.4	The analysis of data shall provide information relating to:				
a)	Healthcare provider / patient / customer satisfaction (see 4.12)				
b)	Conformity to POCT requirements (see 4.2)				
c)	Characteristics and trends of POCT, including opportunities for preventive action, and				
d)	Suppliers				
4.10	**Corrective Action**				
4.10.1	To check ISO 15189: 2012 • Clause 4.10				

Clause No	Description	Yes	No	N/A	Remarks
4.10.2	Did the organisation take action to eliminate the cause of nonconformities in order to prevent recurrence? Is the corrective action appropriate to the effects of the nonconformities encountered?				
4.10.3 a) b) c) d) e) f)	Does the laboratory have a documented procedure established to define the requirements for: Reviewing nonconformities (including healthcare provider / patient / client complaints) Determining the causes of nonconformities Evaluating the need for action to ensure that nonconformities do not recur Determining and implementing action needed Records of the results of action taken Reviewing corrective action taken				
4.11	**<u>Preventive Action</u>**				
4.11.1 4.11.2 4.11.3 a) b) c) d) e)	<u>To check ISO 15189: 2012</u> • Clause 4.11 Does the organisation determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence? Is the preventive action appropriate to the effects of the potential problems? Is a documented procedure established to define the requirements for: Determining potential nonconformities and their causes Evaluating the need for action to prevent occurrence of nonconformities Determining and implementing action needed Records of results of action taken Reviewing preventive action taken				
4.12	**<u>Continual Improvement</u>**				
4.12.1	<u>To check ISO 15189: 2012</u> • Clause 4.12 *Continual Improvement* • Clause 4.14.6 *Risk Assessment* • Clause 4.14.7 *Quality Indicators*				

Clause No	Description	Yes	No	N/A	Remarks
4.12.2	Does the quality assurance programme periodically review the relative benefits of POCT, monitor the test ordering patterns, carry out audits to verify record keeping and review critical value reports?				
4.13	**Control of records**				
4.13.1 4.13.2	To check against ISO 15189: 2012 • Clause 4.13 Are records established and maintained to provide evidence of conformity to requirements and effective operation of the quality management system? Are records legible, readily identifiable and retrievable? Does the laboratory have a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records?				
4.14	**Internal Audits**				
4.14.1 a) b)	To check against ISO 15189: 2012 • Clause 4.14.1 *Evaluation and audits – General* • Clause 4.14.5 *Internal audit* Does the laboratory director, or designated suitably qualified person, and the multidisciplinary POCT management group receive and review reports of the quality assurance programme? Are suggested modifications arising from such reviews incorporated into the POCT policy, processes and procedures?				
4.15	**Management review**				
4.15.1 4.15.2 4.15.3	To check ISO 15189: 2012 • Clause 4.15 Does the laboratory director, or designated suitably qualified person, implement a periodic management review that includes: - Cost-benefit analysis and an evaluation of the clinical need - The clinical effectiveness and the cost efficiency of POCT activities - The identification of opportunities for improvement Does the input to management review include information on:				

Clause No	Description	Yes	No	N/A	Remarks
a)	Results of audits				
b)	Healthcare provider / patient / client feedback				
c)	Process performance and service conformity				
d)	Status of preventive and corrective actions				
e)	Follow-up actions from previous management reviews				
f)	Changes that could affect the quality management system				
g)	Recommendations for improvement?				
4.15.4	Resulting from the management review, has the laboratory director or designate make changes to policy, processes or procedures?				
5	**TECHNICAL REQUIREMENTS**				
5.1	**Personnel**				
	To check ISO 15189: 2012 • Clause 4.1.1.4 *Laboratory Director* • Clause 5.1 *Personnel*				
5.1.1	Does the organisation determine and provide human resources needed to:				
a)	Implement and maintain the POCT quality management system and continually improve its effectiveness				
b)	Ensure that required training is provided to personnel performing POCT from all services, programmes and departments				
c)	Enhance healthcare provider / patient / client satisfaction by meeting customer requirements?				
5.1.2	Is the Laboratory Director, or other suitably qualified person responsible for:				
a)	Procuring, evaluating and selecting all POCT devices, reagents and systems, including quality control material				
b)	Establishing documented quality policy and protocols for the performance of all POCT and associated quality control and quality assurance?				
5.1.3	To check ISO 15189: 2012 • Clause 4.1.2.5 *Responsibility, authority and interrelationships*				

Clause No	Description	Yes	No	N/A	Remarks
	Does the management group allocate responsibilities and designate staff undertaking POCT? Is the allocation of duties and responsibilities of different groups of staff defined in the operating procedures?				
5.1.4	<u>To check ISO 15189: 2012</u> • Clause 5.1.2 *Personnel Qualification* • Clause 5.1.6 *Competence Assessment* • Clause 5.1.8 *Continuing education and professional development*				
a)	Does the manager develop, implement and maintain and appropriate theoretical and practical training programme for all POCT personnel?				
b)	Does the personnel that is carrying out POCT show that he / she has completed the training and demonstrated competence? Are records of training / attestation (or certification) and of retraining and re-attestation (or recertification) retained?				
c)	Are the content of the training programme and the knowledge / skill level assessment process documented? *The knowledge / skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system and appreciation of the pre-analytical aspects of the analysis include:* - *Sample collection* - *Clinical utility and limitations* - *Expertise in the analytical procedure* - *Reagent storage* - *Quality control and quality assurance* - *Technical limitations of the device* - *Response to results that fall outside of the predefined limits* - *Infection control practices* - *Correct documentation and maintenance of the results*				
d)	Does the management group establish retraining / / recertification intervals and a continuing education programme?				
e)	Is the POCT operator performance monitored as part of the quality assurance programme?				

Clause No	Description	Yes	No	N/A	Remarks
5.2	**Accommodation and environmental conditions**				
5.2.1	<u>To check ISO 15189: 2012</u> • Clause 5.2				
5.2.2	Is the premise (in which the POCT is undertaken and the equipment are used) conform to applicable national legislation or to regional or local requirements?				
5.2.3	Does the organisation determine and manage the work environment needed to achieve good working conditions as well as conformity to POCT requirements and the device manufacturer's recommendation?				
5.3	**Equipment**				
5.3.1	<u>To check ISO 15189: 2012</u> • Clause 5.3 *Equipment* • Clause 5.9.2 *Automated selection and reporting of results* • Clause 5.10 *Laboratory information management*				
5.3.2	Is the laboratory director, or designated suitably qualified person responsible for the selection criteria and for the procurement of equipment, materials and reagents?				
a)	Is there an inventory maintained of all POCT equipment including serial number, and unique identification, manufacturer / supplier, date purchase and service history, including dates out-of-service?				
b)	Are the reagents, kits and equipment verified prior to routine use?				
c)	Are there written procedures for the maintenance and operation of POCT equipment?				
d)	Does the management group recommend that any POCT devices or system be withdrawn from service if critical requirements are not met or safety becomes an issue?				
e)	Are there records of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed?				
f)	Is periodic and episodic maintenance of equipment monitored and documented?				

Clause No	Description	Yes	No	N/A	Remarks
5.4	**Pre-examination procedures**				
5.4.1 5.4.2	<u>To check ISO 15189: 2012</u> • Clause 5.4.1 *General* • Clause 5.4.4.2 *Instructions for pre-examination procedures* Does the organisation ensure identification of the sample and its clerical traceability to the patient?				
5.4.3	Does the organisation exercise care with samples obtained for POCT from its patients while such samples are under the organisation's control or are being used by the organisation? Does the organisation identify and safeguard samples for analysis? Are samples that are lost, damaged or otherwise found to be unsuitable for use reported to the responsible healthcare professional and records maintained?				
5.5	**Examination Procedures**				
5.5.1 5.5.2 5.5.3 5.5.4	<u>To check ISO 15189: 2012</u> • Clause 5.5 Are procedure manuals for each POCT system made available to all users? • *The manufacturer's recommendation regarding minimum quality control of a specific instrument system may be accepted, following documented review.* Is the instrument-generated quality control acceptable provided that regulatory authorities have accepted it?				
5.6	**Assuring the quality of examination procedures**				
5.6.1 5.6.2	<u>To check ISO 15189: 2012</u> • Clause 5.6 The Quality Manager is responsible for the design, implementation and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory. Is the relationship between values obtained in the laboratory and POCT established and published or available upon request?				

Clause No	Description	Yes	No	N/A	Remarks
5.6.3	Does the Quality Manager remain accountable to the laboratory director, or designated person for the quality of all POCT testing? • *The Quality Manager may assign responsibility for quality control on a specific POCT instrument / system to an appropriate qualified person.*				
5.6.4	Did the laboratory participate in external quality assessment (EQA) programme? *In the absence of an EQA scheme, the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of test within the laboratory.*				
5.6.5	Does the laboratory director, or designated person, and the multidisciplinary POCT management group receive and review the external or internal quality assessment data? Are the modifications arising from the review incorporated into the POCT policy, processes and procedures?				
5.6.6	Does the laboratory director validate the following processes for service provision:				
a)	Trueness and precision and, where appropriate, linearity of the instrument response shall be verified by the QC programme				
b)	Split patient samples, or other acceptable QC materials used to verify performance of the POCT systems used in multiple sites				
c)	Frequency of internal QC specified for each device				
d)	Documented corrective action taken for out-of-control results				
e)	Documented actions taken on nonconforming QC results				
f)	Record of QC results for regular review by quality manager or designated person				
g)	Documented and monitored process control for consumable supplies and reagents				
h)	Is in-patient self-testing using POCT devices monitored to validate the accuracy and comparability of the results to those of the central laboratory?				

Clause No	Description	Yes	No	N/A	Remarks
5.7	**Post-examination procedure**				
5.7.1	<u>To check ISO 15189: 2012</u> • Clause 5.7 Does the organisation handle and dispose safely all samples, reagents and kits according to local, regional or national regulations?				
5.7.2	Is the original sample or a new sample obtained when repeat testing is clinically indicated?				
5.8	**Reporting of Results**				
5.8.1 5.8.2 5.8.3 5.8.4	<u>To check ISO 15189: 2012</u> • Clause 5.8 *Reporting of results* • Clause 5.9 *Release of results* Are POCT results reported with necessary details? Are the POCT results permanently recorded in the patient's medical record? The identity of the person performing the test should be recorded. Does the record distinguish between POCT results and those from the central laboratory or its satellites?				
C.	**<u>Follow up on last year findings</u>**				

Clause No	Description	Yes	No	N/A	Remarks
D.	**<u>Other Observation and Comments</u>** Safety				
E.	**<u>Additional Comments</u>**				