# ISO 15189:2012
# WORKING DOCUMENT

## NOTES:

1. This working document is intended as a checklist for the assessor when conducting Medical Testing Laboratory Accreditation Assessments according to ISO 15189:2012. This standard incorporates all elements of ISO 15189:2012, ISO 22870:2016, ISO 9001:2008, and ISO/IEC 17025:2005 relevant to medical testing laboratories.

2. **Please make notes in the Comments column any deficiencies in the laboratory's management system identified during the assessment. These observations may be useful when preparing the assessment report and indicate to the reviewer that a thorough assessment was conducted. It is also imperative to note evidence of compliance, making reference to procedures/work instructions, dates, and other specific observations. At a minimum should be 1 comment per major element of the checklist.**

3. Do not recommend specific solutions to deficiencies, as this would constitute a conflict of interest.

4. Assess the system only to the relevant standard and to the requested scope of accreditation. Do not be concerned with system requirements stemming from:

   - Company- or facility-imposed policies
   - Regulatory bodies
   - Subcontractors
   - Other sources

5. If additional questions arise during the assessment, indicate them (and the appropriate responses) either in the blank working document pages at the end of this document or in the empty rows included in some of the sections.

6. As applicable, POCT (Point-Of-Care-Testing) have been incorporated into this working document and are shaded in gray.

7. **Please read the questions carefully, as the "preferred" answer in some cases may be "no" or "not applicable."**

8. **If, at any time, the assessment team requires assistance in the interpretation of the requirements of ISO 15189:2012, contact the PJLA office immediately.**

Assessment Number: _____ Date(s): _____

Client: _____

Address: _____

_____

Contact/Management Rep.: _____

Lead Assessor: _____

Assessment Team: _____
(Include RAB/IRCA certificate numbers)

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **4.1 Organization and Management Responsibility** | | | | |
| 4.1.1 | Has the management of laboratory services planned and developed the processes needed for POCT? | ☐ | ☐ | |
| 4.1.1 | Process for POCT: | | | |
| 4.1.1 | a) quality objectives and requirements for POCT | ☐ | ☐ | |
| 4.1.1 | b) the need to establish processes and documents, and provide resources specific to POCT; | ☐ | ☐ | |
| 4.1.1 | c) required verification, validation, and monitoring of activities specific to POCT | ☐ | ☐ | |
| 4.1.1 | d) records to provide evidence that POCT processes and procedures meet requirements. | ☐ | ☐ | |
| 4.1.1 | Does the laboratory ensure that appropriate measures are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.1.1 | Does the laboratory meet the requirements of ISO 15189 when carrying out work at its permanent facilities and/or associated facilities? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.1.2 | Is the laboratory or organization of which the laboratory is part of an entity that can be held legally responsible for its activities? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.1.3 | Does laboratory management have arrangements in place to ensure the following: | ☐ | ☐ | |
| | a) That no involvement in any activities that would diminish confidence in the | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | laboratory's competence, impartiality, judgment or operational integrity? | | | |
| | b) management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work? | ☐ | ☐ | |
| | c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared? | ☐ | ☐ | |
| | d) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements? | ☐ | ☐ | |
| | e) confidentiality of information is maintained? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.1.4 | Is the laboratory directed by a person(s) with the competence and delegated responsibility for the services provided? | ☐ | ☐ | |
| 4.1.1.4 | Are the duties & responsibilities of the laboratory director documented? | ☐ | ☐ | |
| 4.1.1.4 | Does the laboratory director effectively provide professional, scientific, consultative/advisory, organizational, administrative and educational matters relevant to the services offered by the laboratory? | ☐ | ☐ | |

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| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.1.4 | a) provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities? | ☐ | ☐ | |
| 4.1.1.4 | b) relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community and the patient population served and providers of formal agreements when required? | ☐ | ☐ | |
| 4.1.1.4 | c) ensure that there are an appropriate number of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users? | ☐ | ☐ | |
| 4.1.1.4 | d) ensure the implementation of the quality policy? | ☐ | ☐ | |
| 4.1.1.4 | e) implement a safe laboratory environment in compliance with good practice and applicable requirements? | ☐ | ☐ | |
| 4.1.1.4 | f) serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate? | ☐ | ☐ | |
| 4.1.1.4 | g) ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results? | ☐ | ☐ | |
| 4.1.1.4 | h) select and monitor laboratory suppliers? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.1.4 | i) select referral laboratories and monitor the quality of their service (see also 4.5)? | ☐ | ☐ | |
| 4.1.1.4 | j) provide professional development programs for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations? | ☐ | ☐ | |
| 4.1.1.4 | k) define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services? | ☐ | ☐ | |
| 4.1.1.4 | l) monitor all work performed in the laboratory to determine that clinically relevant information is being generated? | ☐ | ☐ | |
| 4.1.1.4 | m) address any complaint, request or suggestion from staff and/or users of laboratory services? | ☐ | ☐ | |
| 4.1.1.4 | n) design and implement a contingency plan to ensure that essential services are available during emergency situations (or other conditions when laboratory services are limited or unavailable)? | ☐ | ☐ | |
| 4.1.1.4 | o) plan and direct research & development (where appropriate)? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.1.2 Management Responsibility** | | | | |
| 4.1.2.1 | Has the laboratory management provided evidence of its commitment to the development and implementation of the quality management system and continually improve its effectiveness? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.2.1 | a) Does laboratory management communicate to the laboratory personnel the importance of meeting the needs and requirements of users (see 4.1.2.2) as well as regulatory and accreditation requirements? | ☐ | ☐ | |
| 4.1.2.1 | b) Has laboratory management have an established quality policy? | ☐ | ☐ | |
| 4.1.2.1 | c) ensures that quality objectives & planning are established (see 4.1.2.4)? | ☐ | ☐ | |
| 4.1.2.1 | d) defined responsibilities, authorities and interrelationships of all personnel (see 4.1.2.5)? | ☐ | ☐ | |
| 4.1.2.1 | e) establishes communication processes (see 4.1.2.6)? | ☐ | ☐ | |
| 4.1.2.1 | f) appointing a quality manager, (however named see 4.1.2.7)? | ☐ | ☐ | |
| 4.1.2.1 | g) conduct management reviews (see 4.15)? | ☐ | ☐ | |
| 4.1.2.1 | h) ensure that all personnel are competent to perform their assigned activities (see 5.1.6)? | ☐ | ☐ | |
| 4.1.2.1 | i) ensure availability of adequate resources to enable the proper conduct of pre-examination, examination and post-examination activities? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.1 | Has the laboratory defined a scope of POCT? | ☐ | ☐ | |
| 4.1.2.1 | Does the POCT scope include the following: | | | |
| | a) the clinical need for POCT. | ☐ | ☐ | |
| | b) its financial implications | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | c) technical feasibility | ☐ | ☐ | |
| | d) the ability of the organization to fulfil the need | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.2 | Does laboratory management ensure that laboratory services, including appropriate advisory & interpretative services, meet the needs of patients and those using the laboratory services? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.2 | Has the laboratory director or designate appointed a multidisciplinary POCT management group with representation from the laboratory, administration and clinical programs including nursing to advise on the provision of POCT? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.3 | Has laboratory management defined the intent of its quality management system in a quality policy? | ☐ | ☐ | |
| 4.1.2.3 | Has laboratory management ensured the quality policy:<br>a) is appropriate to the purpose of the organization? | ☐ | ☐ | |
| 4.1.2.3 | b) includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of ISO 15189, and continual improvement of the quality of laboratory services? | ☐ | ☐ | |
| 4.1.2.3 | c) provides a framework for establishing and reviewing quality objectives? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.2.3 | d) is communicated and understood within the organization? | ☐ | ☐ | |
| 4.1.2.3 | e) is reviewed for continuing suitability? | ☐ | ☐ | |
| 4.1.2.3 | The management group shall ensure that responsibilities and authorities are defined and communicated within the organization. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.4 | Has laboratory management established quality objectives? | ☐ | ☐ | |
| 4.1.2.4 | Do the quality objectives meet the needs and requirements of the users, at relevant functions and levels within the organization? | ☐ | ☐ | |
| 4.1.2.4 | Are the quality objectives measurable and consistent with the quality policy? | ☐ | ☐ | |
| 4.1.2.4 | Is the planning of the quality management system carried out to meet the requirements (see 4.2) and the quality objectives? | ☐ | ☐ | |
| 4.1.2.4 | Has laboratory management ensured that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.4 | The management group shall assist in evaluating and selecting POCT devices and systems.<br><br>*Performance criteria for POCT devices should include consideration of trueness, precision, detection limits, use limits and interferences. Practicability should also be considered.* | | | |
| **Additional Comments:** | | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.2.5 | Has laboratory management ensured that the responsibilities, authorities and interrelationships are defined, documented & communicated within the laboratory organization, including the appointment of person(s) responsible for each laboratory function and appointment of deputies for key managerial & technical personnel? | ☐ | ☐ | |
| **Additional Comments**: | | | | |
| 4.1.2.5 | The management group shall consider all proposals to introduce any product, device or system for POCT. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.6 | Does laboratory management have an effective means for communicating with staff? | ☐ | ☐ | |
| 4.1.2.6 | Are records kept of items discussed in communications and meetings with staff? | ☐ | ☐ | |
| 4.1.2.6 | Are the appropriate communication **processes** established between the laboratory and its stakeholders? | ☐ | ☐ | |
| 4.1.2.6 | Does the communication **process** include the effectiveness of the laboratory's pre-examination, examination, post-examination processes, and quality management system? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.1.2.7 | Has laboratory management appointed a quality manager who has, irrespective of other responsibilities, delegated responsibility and authority that includes: | | | |
| | a) ensuring that processes needed for the quality management system are established, implemented, & maintained? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.1.2.7 | b) reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement? | ☐ | ☐ | |
| 4.1.2.7 | c) ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.2 Quality Management System** | | | | |
| 4.2.1 | Has the laboratory established, documented, implemented and maintained a quality management system in accordance to ISO 15189:2012? | ☐ | ☐ | |
| 4.2.1 | Does the quality management system provide for the integration of all **processes** required to fulfil its quality policy and objectives and meet the needs and requirements of the users? | ☐ | ☐ | |
| 4.2.1 | a) Has the laboratory determined the processes needed for the quality management system and are the processes applied throughout the laboratory? | ☐ | ☐ | |
| 4.2.1 | b) Has the laboratory determined the sequence and interaction of these processes? | ☐ | ☐ | |
| 4.2.1 | c) Is there determined criteria and methods needed to ensure that both the operation and control of these processes are effective? | ☐ | ☐ | |
| 4.2.1 | d) Does the laboratory ensure the availability of resources and information | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | necessary to support the operation and monitoring of these processes? | | | |
| 4.2.1 | e) Does the laboratory monitor and evaluate these processes? | ☐ | ☐ | |
| 4.2.1 | f) Has the laboratory implemented actions necessary to achieve planned results and continual improvement of these processes? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.2.2 Documentation Requirements** | | | | |
| 4.2.2 | Has the management of laboratory services established, document, implement and maintain a quality management system and continually improve its effectiveness? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.2.2.1 | a) Does the quality management system documentation include statements of a quality policy and quality objectives? | ☐ | ☐ | |
| 4.2.2.1 | b) Does the quality management system documentation also include a quality manual? | ☐ | ☐ | |
| 4.2.2.1 | c) Does the quality management system include procedures and records required by ISO 15189:2012? | ☐ | ☐ | |
| 4.2.2.1 | d) Does the quality management system documentation ensure that the laboratories determined processes are effective, planned, operated, controlled and recorded? | ☐ | ☐ | |
| 4.2.2.1 | e) Are there copies of applicable regulations, standards and other normative documents? | ☐ | ☐ | |
| 4.2.2.1 | Has the management of laboratory services: | | | |
| 4.2.2.1 | identified the processes needed for the quality | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | management system for POCT throughout the organization? | | | |
| 4.2.2.1 | determined the sequence and interaction of these processes | ☐ | ☐ | |
| 4.2.2.1 | determined criteria and methods needed to ensure that both the operation and control of these processes are effective? | ☐ | ☐ | |
| 4.2.2.1 | ensured the availability of resources and information necessary to support the operation and monitoring of these processes? | ☐ | ☐ | |
| 4.2.2.1 | monitor, measure and analyze these processes? | ☐ | ☐ | |
| 4.2.2.1 | implement actions necessary to achieve planned results and continual improvement of these processes, | ☐ | ☐ | |
| 4.2.2.1 | appoint a person with appropriate training and experience as quality manager responsible for POCT quality, which includes review of the requirements related to POCT. | ☐ | ☐ | |
| 4.2.2.1 | Are these processes managed by the organization in accordance with the requirements of ISO 22870:2016€ and ISO 15189:2016? | ☐ | ☐ | |
| 4.2.2.1 | *Processes needed for the quality management system referred to above should include processes for management activities, provision of resources, service provisions and measurement provisions.* | | | |
| **Additional Comments:** | | | | |
| 4.2.2.2 | Has the laboratory established and maintained a quality manual that includes the following : | | | |
| | a) Does the quality manual make reference to the quality policy? | ☐ | ☐ | |
| 4.2.2.2 | b) Is there a description of the scope of the quality management system? | ☐ | ☐ | |
| 4.2.2.2 | c) A presentation of the organization and management structure of the laboratory and its place in any parent organization? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.2.2.2 | d) A description of the roles and responsibilities of laboratory management (including the laboratory director and quality manager) for ensuring compliance with ISO 15189:2012? | ☐ | ☐ | |
| 4.2.2.2 | e) A description of the structure and relationships of the documentation used in the quality management system? | ☐ | ☐ | |
| 4.2.2.2 | f) A description of the structure and relationships of the documentation used in the quality management system? | ☐ | ☐ | |
| 4.2.2.2 | g) the documented policies established for the quality management system and reference to the managerial and technical activities that support them? | ☐ | ☐ | |
| 4.2.2.2 | Does laboratory staff have access to and have been instructed on the use and application of the quality manual and the referenced documents? | ☐ | ☐ | |
| 4.2.2.2 | Has the management of laboratory services planed and implemented the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of POCT to the quality system? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.2.3 | Does the quality management system documentation include: | | | |
| | a) documented statements of a quality policy and quality objectives | ☐ | ☐ | |
| | b) quality manual | ☐ | ☐ | |
| | c) documented procedures required by this document | ☐ | ☐ | |
| | d) documents needed by the organization to ensure the effective planning, operation and control of its processes | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | e) records required by this document | ☐ | ☐ | |
| | *The documentation may be in any form or type of medium that can be maintained and retrieved up to the specified retention times, which is dependent upon local, regional and national requirements.* | | | |
| **Additional Comments:** | | | | |
| 4.2.4 | Has the laboratory director or suitably qualified designate ensured that: | | | |
| 4.2.4 | a) POCT quality objectives are established and are measurable | ☐ | ☐ | |
| 4.2.4 | b) the planning of the quality management system is carried out in order to meet the requirements of the service, as well as the quality objectives | ☐ | ☐ | |
| 4.2.4 | c) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.2.5 | Has the organization established and maintained a quality manual that includes: | | | |
| | a) the scope of the quality management system | ☐ | ☐ | |
| 4.2.5 | b) the documented procedures established for the quality management system, or reference to them | ☐ | ☐ | |
| 4.2.5 | c) a description of the interactions between the processes of the quality management system | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.3 | Does the laboratory control documents required by the quality management system and ensure that unintended use of any obsolete document is prevented? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.3 | Does the laboratory have a documented procedure to ensure that the following conditions are met:<br>a) All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue? | ☐ | ☐ | |
| 4.3 | b) Are documents identified to include a title, a unique identifier on each page, the date of the current edition and/or edition number, page number to total number of pages, and authority for issue? | ☐ | ☐ | |
| 4.3 | c) Current authorized editions and their distribution are identified by means of a list? | ☐ | ☐ | |
| 4.3 | d) Ensure that only current, authorized applicable documents are available at points of use? | ☐ | ☐ | |
| 4.3 | e) Where a laboratory's document control system allows for the amendment of documents by hand, pending the re-issue of documents, are the procedures and authorities for such amendments defined? | ☐ | ☐ | |
| 4.3 | Are amendments clearly marked, initialed and dated, dates with a specified time period of the revision? | ☐ | ☐ | |
| 4.3 | f) Changes to documents are identified? | ☐ | ☐ | |
| 4.3 | g) Documents remain legible? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.3 | h) Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose? | ☐ | ☐ | |
| 4.3 | i) Obsolete controlled documents are dated and marked as obsolete? | ☐ | ☐ | |
| 4.3 | j) At least one copy of an obsolete controlled document is retained for a specified time period or in accordance with applicable specified requirements? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.4 Service Agreements** | | | | |
| 4.4.1 | Does the laboratory have documented procedures for the establishment and review of agreements for providing medical laboratory services? | ☐ | ☐ | |
| 4.4.1 | Does the laboratory consider all requests taken for examination as an agreement? | ☐ | ☐ | |
| 4.4.1 | Do agreements take into account the request, the examination and the report and specify the information needed on the request to ensure appropriate examination and result interpretation? | ☐ | ☐ | |
| 4.4.1 | Have the following conditions been met when the laboratory enters into an agreement to provide medical laboratory services:<br>a) Are the requirements of the customers and users, and of the provider of the laboratory services, including the examination processes to be used defined, documented and understood by all parties? | ☐ | ☐ | |
| 4.4.1 | b) Does the laboratory have the capability and resources to meet the requirements? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.4.1 | c) Does the laboratory personnel have the skills and expertise necessary for the performance of the intended examinations? | ☐ | ☐ | |
| 4.4.1 | d) Are the examination procedures selected appropriate in order to meet the customers' needs? | ☐ | ☐ | |
| 4.4.1 | e) Have customers and users been informed of deviations from the agreement that impact upon the examination results if applicable? | ☐ | ☐ | |
| 4.4.1 | f) Has references been made to any work referred by the laboratory to a referral laboratory or consultant? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.4.2 | Have reviews of agreements to provide services include all aspects of the agreement? | ☐ | ☐ | |
| 4.4.2 | Do the records of these reviews include any changes to the agreement and any pertinent discussions? | ☐ | ☐ | |
| 4.4.2 | For amended agreements, did the laboratory follow the same agreement review process and demonstrated that they have communicated these to all affected parties? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.5 Examination by Referral Laboratories** | | | | |
| 4.5.1 | Does the laboratory have a documented procedure for selecting and evaluating referral laboratories and consultants who provide | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | opinions as well as interpretation for complex testing in any discipline? | | | |
| 4.5.1 | Does the procedure ensure that the following conditions are met: | | | |
| | a) Are the referral laboratories and/or referral consultants competent to perform the requested examinations?<br><br>Are the quality of performances monitored appropriately? | ☐<br><br>☐ | ☐<br><br>☐ | |
| 4.5.1 | b) Are the arrangements with referral laboratories and consultants reviewed and evaluated periodically to ensure that the relevant parts of ISO 15189 are met? | ☐ | ☐ | |
| 4.5.1 | c) Have the records of periodic reviews maintained? | ☐ | ☐ | |
| 4.5.1 | d) Has a register of all referral laboratories, and consultants from whom opinions are sought, been maintained? | ☐ | ☐ | |
| 4.5.1 | e) Does the laboratory have a pre-defined period for requests and results of all samples? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.5.2 | Does the referring laboratory ensure the examination results of the referral laboratory are provided to the person making the request? | ☐ | ☐ | |
| 4.5.2 | Do the examination reports clearly indicate that results were provided by a referral laboratory or consultant? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.5.2 | Do the examination reports clearly identify the author providing additional remarks as applicable? | ☐ | ☐ | |
| 4.5.2 | Has the laboratory adopted the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements? | ☐ | ☐ | |
| | In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, do the laboratory ensure this process is not hindered by commercial or financial considerations? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.6 | Does the laboratory have a documented procedure for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service? | ☐ | ☐ | |
| 4.6 | Has the laboratory selected and approved suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's requirements? | ☐ | ☐ | |
| 4.6 | Has the following criteria for selection been established: | ☐ | ☐ | |
| 4.6 | Does the laboratory have a maintained list of selected and approved suppliers of equipment, reagents and consumables? | ☐ | ☐ | |
| 4.6 | Does the purchasing information describe the requirements for the product or service to be purchased? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.6 | Does the laboratory monitor the performance of suppliers to ensure that purchased services or items consistently meet the stated criteria? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.7 | Has the laboratory established arrangements for communicating with users on the following:<br>a) Advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination? | ☐ | ☐ | |
| 4.7 | b) Advising on individual clinical cases? | ☐ | ☐ | |
| 4.7 | c) Professional judgments on the interpretation of the results of examinations? | ☐ | ☐ | |
| 4.7 | d) Promoting the effective utilization of laboratory services? | ☐ | ☐ | |
| 4.7 | e) consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.8 | Does the laboratory have a documented procedure for the management of complaints or other feedback received from clinicians, patients, laboratory staff or other parties? | ☐ | ☐ | |
| 4.8 | Have records been maintained for all complaints documented including the investigation and the action taken? | ☐ | ☐ | |
| **Additional Comments:** | | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **4.9 Identification and Control of Nonconformities** | | | | |
| 4.9 | Does the laboratory have a documented procedure to identify and manage nonconformities in any aspect of the quality management system, including pre-examination, examination or post-examination processes? | ☐ | ☐ | |
| 4.9 | Does the procedure ensure that: | ☐ | ☐ | |
| | a) the responsibilities and authorities for handling nonconformities are designated? | | | |
| 4.9 | b) the immediate actions to be taken are defined? | ☐ | ☐ | |
| 4.9 | c) the extent of the nonconformity is determined? | ☐ | ☐ | |
| 4.9 | d) examinations are halted and reports are withheld as necessary? | ☐ | ☐ | |
| 4.9 | e) the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorized individual responsible for using the results is informed? | ☐ | ☐ | |
| 4.9 | f) the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary? | ☐ | ☐ | |
| 4.9 | g) the responsibility for authorization of the resumption of examinations is defined? | ☐ | ☐ | |
| 4.9 | h) each episode of nonconformity is documented and recorded, with these records being reviewed at regular | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | specified intervals to detect trends and initiate corrective action? | | | |
| 4.9 | In cases when it is determined that nonconformities in pre-examination, examination and post examination processes could recur or that there is doubt about the laboratory's compliance with its own procedures, has the laboratory taken action to identify, document and eliminate the cause(s)? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.9 Identification and Control of Nonconformities** | | | | |
| 4.9.2 | Does the organization ensure that POCT that does not conform to requirements is identified and controlled to prevent its unintended use? | ☐ | ☐ | |
| 4.9.2 | Are the controls and related responsibilities and authorities for dealing with nonconforming POCT defined in a documented procedure? | ☐ | ☐ | |
| 4.9.2 | Does the organization deal with nonconforming POCT by one or more of the following ways:<br>a) by taking action to eliminate the detected nonconformity | ☐ | ☐ | |
| 4.9.2 | b) by authorizing its use, release and acceptance | ☐ | ☐ | |
| 4.9.2 | c) by taking action to preclude its original intended use or application | ☐ | ☐ | |
| 4.9.2 | Are the records of the nature of nonconformities and any subsequent actions taken maintained appropriately? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.9.3 | Has the organization determined, collected and analyzed appropriate data to evaluate where continual improvement of the effectiveness of the quality management system can be made? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | Is the data generated as a result of monitoring and measurement, as well as from other relevant sources? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.9.4 | The analysis of data shall provide information relating to:<br>a) healthcare provider/patient/customer satisfaction | ☐ | ☐ | |
| 4.9.4 | b) conformity to POCT requirements | ☐ | ☐ | |
| 4.9.4 | c) characteristics and trends of POCT, including opportunities for preventive action | ☐ | ☐ | |
| 4.9.4 | d) suppliers | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.10 | Does the laboratory have a corrective action process to eliminate the cause(s) of nonconformities and is the corrective actions appropriate to the effects of the nonconformities encountered? | ☐ | ☐ | |
| 4.10 | Does the laboratory have a documented procedure for the following?:<br>a) reviewing nonconformities | ☐ | ☐ | |
| 4.10 | b) determining the root causes of nonconformities | ☐ | ☐ | |
| 4.10 | c) evaluating the need for corrective action to ensure that nonconformities do not recur | ☐ | ☐ | |
| 4.10 | d) determining and implementing corrective action needed | ☐ | ☐ | |
| 4.10 | e) recording the results of corrective action taken | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.10 | f) reviewing the effectiveness of the corrective action taken | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.10.2 | Has the organization taken action to eliminate the cause of nonconformities in order to prevent recurrence.? | ☐ | ☐ | |
| 4.10.2 | Are the corrective actions appropriate to the effects of the nonconformities encountered? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.10.3 | Is there a documented procedure established to define requirements for: | ☐ | ☐ | |
| | a) reviewing nonconformities (including healthcare provider/patient/client complaints) | | | |
| 4.10.3 | b) determining the causes of nonconformities | ☐ | ☐ | |
| 4.10.3 | c) evaluating the need for action to ensure that nonconformities do not recur | ☐ | ☐ | |
| 4.10.3 | d) determining and implementing action needed | ☐ | ☐ | |
| 4.10.3 | e) records of the results of action taken | ☐ | ☐ | |
| 4.10.3 | f) reviewing corrective action taken | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.11 | Has the laboratory determined action to eliminate the causes of potential nonconformities in order to prevent their occurrence? Are the preventive actions appropriate to the effects of the potential problems? | ☐ | ☐ | |
| 4.11 | The laboratory shall have a documented procedure for: | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.11 | a) reviewing laboratory data and information to determine where potential nonconformities exist | ☐ | ☐ | |
| 4.11 | b) determining the root cause(s) of potential nonconformities | ☐ | ☐ | |
| 4.11 | c) evaluating the need for preventive action to prevent the occurrence of nonconformities | ☐ | ☐ | |
| 4.11 | d) determining and implementing preventive action needed | ☐ | ☐ | |
| 4.11 | e) recording the results of preventive action taken (see 4.13) | ☐ | ☐ | |
| 4.11 | f) reviewing the effectiveness of the preventive action taken | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.11.2 | Has the organization determined action to eliminate the causes of potential nonconformities in order to prevent their occurrence? | ☐ | ☐ | |
| 4.11.2 | Are the preventive actions appropriate to the effects of the potential problems? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.11.3 | Has a documented procedure been established to define requirements for: | ☐ | ☐ | |
| | a) determining potential nonconformities and their causes | | | |
| 4.11.3 | b) evaluating the need for action to prevent occurrence of nonconformities | ☐ | ☐ | |
| 4.11.3 | c) determining and implementing action needed | ☐ | ☐ | |
| 4.11.3 | d) records of results of action taken | ☐ | ☐ | |
| 4.11.3 | e) reviewing preventive action taken | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **Additional Comments:** | | | | |
| 4.12 | Does the laboratory continually improve the effectiveness of the quality management system, including the pre-examination, examination and post-examination processes, through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy and quality objectives? | ☐ | ☐ | |
| 4.12 | Does the laboratory ensure improvement activities are directed at areas of highest priority based on risk assessment? | ☐ | ☐ | |
| 4.12 | Are action plans for improvement developed, documented and implemented, as appropriate. | ☐ | ☐ | |
| 4.12 | Is the effectiveness of the actions taken be determined through a focused review or audit of the area concerned? | ☐ | ☐ | |
| 4.12 | Has laboratory management ensured that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care? | ☐ | ☐ | |
| 4.12 | When the continual improvement program identifies opportunities for improvement, does laboratory management address them regardless of where they occur? | ☐ | ☐ | |
| 4.12 | Does laboratory management communicate to staff improvement plans and related goals? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.12.2 | Has a quality assurance program been periodically reviewed the relative benefits of | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | POCT, monitor the test ordering patterns, carry out audits to verify record keeping and review critical value reports? | | | |
| **Additional Comments:** | | | | |
| 4.13 | Does the laboratory have a documented procedure for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records? | ☐ | ☐ | |
| 4.13 | Are records created concurrently with the performance of each activity that affects the quality of the examination? | ☐ | ☐ | |
| 4.13 | Does the laboratory ensure that dates and, where relevant, the time of amendments of the records are captured along with the identity of personnel making the amendments? | ☐ | ☐ | |
| 4.13 | Has the laboratory defined the time period that various records pertaining to the quality various records pertaining to the quality management system, including pre-examination, examination and post-examination processes, are to be retained? | ☐ | ☐ | |
| 4.13 | Does the laboratory retain records of reported results retrievable for as long as medically relevant or as required by regulation? | ☐ | ☐ | |
| 4.13 | Does the laboratory provide a suitable environment for the storage of records to prevent damage, deterioration, loss or unauthorized access? | ☐ | ☐ | |
| 4.13 | Do the records include the following:<br>a) supplier selection and performance, and changes to the approved supplier list | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.13 | b) staff qualifications, training and competency records | ☐ | ☐ | |
| 4.13 | c) request for examination | ☐ | ☐ | |
| 4.13 | d) records of receipt of samples in the laboratory | ☐ | ☐ | |
| 4.13 | e) information on reagents and materials used for examinations (e.g. lot documentation, certificates of supplies, package inserts) | ☐ | ☐ | |
| 4.13 | f) laboratory workbooks or worksheets | ☐ | ☐ | |
| 4.13 | g) instrument printouts and retained data and information | ☐ | ☐ | |
| 4.13 | h) examination results and reports | ☐ | ☐ | |
| 4.13 | i) instrument maintenance records, including internal and external calibration records | ☐ | ☐ | |
| 4.13 | j) calibration functions and conversion factors | ☐ | ☐ | |
| 4.13 | k) quality control records | ☐ | ☐ | |
| 4.13 | l) incident records and action taken | ☐ | ☐ | |
| 4.13 | m) accident records and action taken | ☐ | ☐ | |
| 4.13 | n) risk management records | ☐ | ☐ | |
| 4.13 | o) nonconformities identified and immediate or corrective action taken | ☐ | ☐ | |
| 4.13 | p) preventive action taken | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.13 | q) complaints and action taken | ☐ | ☐ | |
| 4.13 | r) records of internal and external audits | ☐ | ☐ | |
| 4.13 | s) inter-laboratory comparisons of examination results | ☐ | ☐ | |
| 4.13 | t) records of quality improvement activities | ☐ | ☐ | |
| 4.13 | u) minutes of meetings that record decisions made about the laboratory's quality management activities | ☐ | ☐ | |
| 4.13 | v) records of management reviews | ☐ | ☐ | |
| 4.13 | Does the laboratory ensure that the above records are made available to be evaluated during management reviews? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.13 Quality and Technical Records** | | | | |
| 4.13.2 | Have records been established and maintained to provide evidence of conformity to requirements and of effective operation of the quality management system? | ☐ | ☐ | |
| **Additional Comments***:* | | | | |
| **4.14 Evaluation and Audits** | | | | |
| 4.14.1 | Has the laboratory planned and implemented the evaluation and internal audit processes needed to: | ☐ | ☐ | |
| | a) demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.14.1 | b) ensure conformity to the quality management system | ☐ | ☐ | |
| 4.14.1 | c) continually improve the effectiveness of the quality management system. | ☐ | ☐ | |
| 4.14.1 | Does the laboratory ensure that the results of evaluations and improvement activities are provided for management review? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.2 | Do authorized personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received? | ☐ | ☐ | |
| 4.14.2 | Does the laboratory periodically review its sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measured? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.3 | Does the laboratory seek information relating to user perception as to whether the service has met the needs and requirements of users? | ☐ | ☐ | |
| 4.14.3 | Do the methods for obtaining and using this information include cooperation with users or their representatives in monitoring the laboratory's performance, provided that the laboratory ensures confidentiality to other users? | ☐ | ☐ | |
| 4.14.3 | Are the records kept of information collected and actions taken? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **Additional Comments:** | | | | |
| 4.14.4 | Does laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service? | ☐ | ☐ | |
| 4.14.4 | Have suggestions been evaluated, implemented as appropriate and feedback provided to the staff? | ☐ | ☐ | |
| 4.14.4 | Are records of suggestions and action taken by the management maintained? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.5 | Has the laboratory conducted internal audits at planned intervals to determine whether all activities in the quality management system, including pre-examination, examination, and post-examination: | | | |
| | a) conform to the requirements of ISO 15189 and to requirements established by the laboratory? | ☐ | ☐ | |
| 4.14.5 | b) are implemented, effective, and maintained? | ☐ | ☐ | |
| 4.14.5 | Are the audits conducted by personnel trained to assess the performance of managerial and technical processes of the quality management system? | ☐ | ☐ | |
| 4.14.5 | Does the audit program take into account the status and importance of the processes and technical and management, areas to be audited, as well as the results of previous audits? | ☐ | ☐ | |
| 4.14.5 | Is the audit criteria, scope, frequency and methods defined and documented? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.14.5 | Is the process for the selection of auditors and conduction of audits organized to ensure objectivity and impartiality of the audit process? | ☐ | ☐ | |
| 4.14.5 | Are the auditors, wherever resources permit, independent of the activity audited? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.6 | Does the laboratory evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.7 | Has the laboratory established quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes? | ☐ | ☐ | |
| 4.14.7 | Is the process of monitoring quality indicators planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement? | ☐ | ☐ | |
| 4.14.7 | Are the indicators periodically reviewed, to ensure their continued appropriateness? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.14.8 | Has the laboratory taken appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of ISO 15189? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.14.8 | Have records been kept of the reviews and of the corrective actions and preventive actions taken? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **4.15 Management Review** | | | | |
| 4.15.1 | Does laboratory management review the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness and support of patient care? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.15.2 | The input to management review shall include information from the results of evaluations of at least the following: | | | |
| | a) the periodic review of requests, and suitability of procedures and sample requirements | ☐ | ☐ | |
| 4.15.2 | b) assessment of user feedback | ☐ | ☐ | |
| 4.15.2 | c) staff suggestions | ☐ | ☐ | |
| 4.15.2 | d) internal audits | ☐ | ☐ | |
| 4.15.2 | e) risk management | ☐ | ☐ | |
| 4.15.2 | f) use of quality indicators | ☐ | ☐ | |
| 4.15.2 | g) reviews by external organizations | ☐ | ☐ | |
| 4.15.2 | h) results of participation in inter-laboratory comparison programs (PT/EQA) | ☐ | ☐ | |
| 4.15.2 | i) monitoring and resolution of complaints | ☐ | ☐ | |
| 4.15.2 | j) performance of suppliers | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.15.2 | k) identification and control of nonconformities | ☐ | ☐ | |
| 4.15.2 | l) results of continual improvement including current status of corrective actions and preventive actions | ☐ | ☐ | |
| 4.15.2 | m) follow-up actions from previous management reviews; | ☐ | ☐ | |
| 4.15.2 | n) changes in the volume and scope of work, personnel, and premises that could affect the quality management system; | ☐ | ☐ | |
| 4.15.2 | o) recommendations for improvement, including technical requirements. | ☐ | ☐ | |
| 4.15.2 | Has the laboratory director, or a designated suitably qualified person, implemented a periodic management review that includes | | | |
| | a) a cost-benefit analysis and an evaluation of the clinical need | ☐ | ☐ | |
| 4.15.2 | b) the clinical effectiveness and the cost efficiency of POCT activities | ☐ | ☐ | |
| 4.15.2 | c) the identification of opportunities for improvement | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.15.3 | Does the review analysis of the input information for causes of nonconformities, trends and patterns that indicate process problems? | ☐ | ☐ | |
| 4.15.3 | Does the review include assessing the opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 4.15.3 | Is the quality and appropriateness of the laboratory's contribution to patient care, to the extent possible, objectively evaluated? | ☐ | ☐ | |
| 4.15.3 | Do the inputs to management review include information on: | ☐ | ☐ | |
| | a) results of audits | | | |
| 4.15.3 | b) healthcare provider/patient/client feedback | ☐ | ☐ | |
| 4.15.3 | c) process performance and service conformity | ☐ | ☐ | |
| 4.15.3 | d) status of preventive and corrective actions | ☐ | ☐ | |
| 4.15.3 | e) follow-up actions from previous management reviews | ☐ | ☐ | |
| 4.15.3 | f) changes that could affect the quality management system | ☐ | ☐ | |
| 4.15.3 | g) recommendations for improvement | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 4.15.4 | Are the outputs from the management review incorporated into a record that documents any decisions made and actions taken during management review related to: | ☐ | ☐ | |
| | a) improvement of the effectiveness of the quality management system and its processes? | | | |
| 4.15.4 | b) improvement of services to users? | ☐ | ☐ | |
| 4.15.4 | c) resource needs? | ☐ | ☐ | |
| 4.15.4 | Does the laboratory director, or designated suitably qualified person, make changes to policy, processes or procedures resulting from the management review? | ☐ | ☐ | |
| **Additional Comments:** | | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **5 Technical Requirements** | | | | |
| 5.1.1 | Does the laboratory have a documented procedure for personnel management | ☐ | ☐ | |
| 5.1.1 | Do the procedures maintain all personnel records to indicate compliance with requirements? | ☐ | ☐ | |
| 5.1.1 | Has the organization determined and provided the human resources needed to:<br>a) implement and maintain the POCT quality management system and continually improve its effectiveness | ☐ | ☐ | |
| 5.1.1 | b) ensure that required training is provided to personnel performing POCT from all services, programs and departments | ☐ | ☐ | |
| 5.1.1 | c) enhance healthcare provider/patient/client satisfaction by meeting customer requirements | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.2 | Does the laboratory management have documented personnel qualifications for each position? | ☐ | ☐ | |
| 5.1.2 | Do the personnel make judgements with reference to examination have the appreciable theoretical and practical background and experience? | ☐ | ☐ | |
| 5.1.2 | Do the qualifications demonstrate skills needed suitably to the tasks performed? | ☐ | ☐ | |
| 5.1.2 | The laboratory director, or other suitably qualified person, shall be responsible for | ☐ | ☐ | |
| 5.1.2 | procuring, evaluating and selecting all POCT devices, reagents and systems, including quality control material | ☐ | ☐ | |
| 5.1.2 | establishing documented quality policy and protocols for the performance of all POCT and associated quality control and quality assurance | ☐ | ☐ | |
| **Additional Comments:** | | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | | | | |
| 5.1.3 | Does the laboratory have job descriptions that describe responsibilities, authorities & tasks for all personnel? | ☐ | ☐ | |
| 5.1.3 | Has the management group allocated responsibilities and designate staff undertaking POCT? | ☐ | ☐ | |
| 5.1.3 | Are the allocation of duties and responsibilities of different groups of staff defined in the operating procedures? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.4 | Does the laboratory have a program to introduce new staff to the organization, the department or area in which the person will work, the terms and conditions of employment, staff facilities, health and safety requirements (including fire and emergency), and occupational health services? | ☐ | ☐ | |
| 5.1.4 | Has the laboratory director, or other suitably qualified person, appointed a person with appropriate training and experience to manage the training and competency assessment? | ☐ | ☐ | |
| 5.1.4 | a) Has the manager developed, implemented, and maintained an appropriate theoretical and practical training program for all POCT personnel? | ☐ | ☐ | |
| 5.1.4 | Has the manager assigned a responsibility for training on a specific POCT instrument / system to an appropriate technical specialist or technologist? | ☐ | ☐ | |
| 5.1.4 | b) Have personnel completed the training and demonstrated competence carry out POCT? | ☐ | ☐ | |
| 5.1.4 | c) Have the records of training/attestation (or certification) and of retraining and re-attestation | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | (or recertification) retained? | | | |
| 5.1.4 | d) Has the content of the training program and the knowledge/skill level assessment process been documented? | ☐ | ☐ | |
| 5.1.4 | Do the knowledge/skill requirements include the ability to demonstrate an understanding of the appropriate use of the device, the theory of the measurement system (chemistry and detector) and appreciation of the pre-analytical aspects of the analysis? | ☐ | ☐ | |
| 5.1.4 | Do they also include the following: | | | |
| | a) a sample collection | ☐ | ☐ | |
| 5.1.4 | b) its clinical utility and limitations | ☐ | ☐ | |
| 5.1.4 | c) expertise in the analytical procedure | ☐ | ☐ | |
| 5.1.4 | d) reagent storage | ☐ | ☐ | |
| 5.1.4 | e) quality control and quality assurance | ☐ | ☐ | |
| 5.1.4 | f) technical limitations of the device | ☐ | ☐ | |
| 5.1.4 | g) response to results that fall outside of predefined limits | ☐ | ☐ | |
| 5.1.4 | h) infection control practices | ☐ | ☐ | |
| 5.1.4 | i) correct documentation and maintenance of the results | ☐ | ☐ | |
| | e) Has retraining/recertification intervals and a continuing education | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | programs been established by the management group? | | | |
| | f) Is POCT operator performance monitored as part of the quality assurance program? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.5 | The laboratory shall provide training for all personnel which includes the following areas:<br>a) the quality management system | ☐ | ☐ | |
| 5.1.5 | b) assigned work processes and procedures | ☐ | ☐ | |
| 5.1.5 | c) the applicable laboratory information system | ☐ | ☐ | |
| 5.1.5 | d) health and safety, including the prevention or containment of the effects of adverse incidents; | ☐ | ☐ | |
| 5.1.5 | e) ethics | ☐ | ☐ | |
| 5.1.5 | f) confidentiality of patient information. | ☐ | ☐ | |
| 5.1.5 | Is the effectiveness of the training program periodically reviewed? | ☐ | ☐ | |
| 5.1.5 | Does the laboratory ensure that personnel undergoing training, are supervised at all times? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.6 | Upon appropriate training, does the laboratory assess the competence of each person to perform assigned managerial or technical tasks according to established criteria? | ☐ | ☐ | |
| 5.1.6 | Does the laboratory reassess training at regular intervals and does retraining occur | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | when necessary? | | | |
| 5.1.6 | Does the competence of laboratory staff assessed by using combinations or all of the following approaches under the same conditions as the general working environment? | ☐ | ☐ | |
| 5.1.6 | a) direct observation of routine work processes and procedures, including all applicable safety practices | ☐ | ☐ | |
| 5.1.6 | b) direct observation of equipment maintenance and function checks | ☐ | ☐ | |
| 5.1.6 | c) monitoring the recording and reporting of examination results | ☐ | ☐ | |
| 5.1.6 | d) review of work records | ☐ | ☐ | |
| 5.1.6 | e) assessment of problem solving skills | ☐ | ☐ | |
| 5.1.6 | f) examination of specially provided samples, such as previously examined samples, inter-laboratory comparison materials, or split samples. | ☐ | ☐ | |
| 5.1.6 | Are competency assessments for professional judgment specific and fit for purpose? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.7 | Does the laboratory ensure that the reviews of staff performance consider the needs of the laboratory and of the individual in order to maintain or improve the quality of service given to the users and encourage productive working relationships? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.8 | Is a continuing education program available to personnel who participate in managerial | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | and technical processes? | | | |
| 5.1.8 | Have personnel taken part in continuing education? | ☐ | ☐ | |
| 5.1.8 | Is the effectiveness of the continuing education program periodically reviewed? | ☐ | ☐ | |
| 5.1.8 | Do personnel take part in regular professional development or other professional liaison activities? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.1.9 | Are records of the relevant educational and professional qualifications, training and experience, and assessments of competence of all personnel maintained? | ☐ | ☐ | |
| 5.1.9 | Are the records readily available to relevant personnel and do they include the following: | | | |
| | a) educational and professional qualifications | ☐ | ☐ | |
| 5.1.9 | b) copy of certification or license, when applicable | ☐ | ☐ | |
| 5.1.9 | c) previous work experience; | ☐ | ☐ | |
| 5.1.9 | d) job descriptions | ☐ | ☐ | |
| 5.1.9 | e) introduction of new staff to the laboratory environment | ☐ | ☐ | |
| 5.1.9 | f) training in current job tasks | ☐ | ☐ | |
| 5.1.9 | g) competency assessments | ☐ | ☐ | |
| 5.1.9 | h) records of continuing education and achievements | ☐ | ☐ | |
| 5.1.9 | i) reviews of staff performance | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.1.9 | j) reports of accidents and exposure to occupational hazards | ☐ | ☐ | |
| 5.1.9 | k) immunization status, (when relevant to assigned duties) | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.2 Accommodation and Environmental Conditions** | | | | |
| 5.2.1 | Does the laboratory have space allocated for the performance of its work that is designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients and visitors? | ☐ | ☐ | |
| 5.2.1 | Does the laboratory evaluate and determine the sufficiency and adequacy of the space allocated for the performance of the work? | ☐ | ☐ | |
| 5.2.1 | Where applicable, are similar provisions made for primary sample collection and examinations at sites other than the main laboratory premises, for example point-of-care testing (POCT) under the management of the laboratory? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.2.2 | Does the laboratory and associated office facilities provide an environment suitable for the tasks to be undertaken? | ☐ | ☐ | |
| 5.2.2 | Do they ensure the following conditions are met? | | | |
| | a) Access to areas affecting the quality of examinations is controlled.<br><br>Does access control take into consideration safety, confidentiality, quality and prevailing practices? | ☐<br><br>☐ | ☐<br><br>☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.2.2 | b) Medical information, patient samples, and laboratory resources are safeguarded from unauthorized access. | ☐ | ☐ | |
| 5.2.2 | c) Do facilities for examination allow for correct performance of examinations? (energy sources, lighting, ventilation, noise, water, waste disposal, and environmental conditions) | ☐ | ☐ | |
| 5.2.2 | d) That the communication systems within the laboratory is appropriate to the size and complexity of the facility to ensure the efficient transfer of information? | ☐ | ☐ | |
| 5.2.2 | e) That safety facilities and devices provided are verified functioning on at regular intervals? | ☐ | ☐ | |
| 5.2.2 | Does the premises, in which POCT is undertaken and the equipment are used, conform to applicable national legislation or to regional or local requirements? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.2.3 | Are storage space and conditions shall be provided that ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results and any other items that could affect the quality of examination results? | ☐ | ☐ | |
| 5.2.3 | Are clinical samples and materials used in examination processes shall be stored in a manner to prevent cross contamination? | ☐ | ☐ | |
| 5.2.3 | Are storage and disposal facilities for dangerous materials shall be appropriate to the hazards of the materials and as specified | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | by applicable requirements? | | | |
| 5.2.3 | Has the organization determined and managed the work environment needed to achieve good working conditions as well as conformity to POCT requirements and the device manufacturer's recommendations? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.2.4 | Is there be adequate access to washrooms, to a supply of drinking water and to facilities for storage of personal protective equipment and clothing. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.2.5 | Do patient sample collection facilities have separate reception/waiting and collection Areas? | ☐ | ☐ | |
| 5.2.5 | Does the laboratory give consideration to the accommodation of patient privacy, comfort? | ☐ | ☐ | |
| | Are the needs (e.g. disabled access, toilet facility) and accommodation of appropriate accompanying person (e.g. guardian or interpreter) during collection? | ☐ | ☐ | |
| 5.2.5 | Do facilities where patient sample collection procedures are performed, does the laboratory ensure sample collection is undertaken in a manner that does not invalidate the results or adversely affect the quality of the examination? | ☐ | ☐ | |
| 5.2.5 | Does the laboratory ensured sample collection facilities are maintained appropriate first aid materials for both patient and staff needs? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.2.6 | Have the laboratory premises been maintained in a functional and reliable condition? | ☐ | ☐ | |
| 5.2.6 | Are the work areas clean and well maintained? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.2.6 | Does the laboratory monitor, control and record environmental conditions, as required by relevant specifications or where they may influence the quality of the sample, results and/or the health of staff? | ☐ | ☐ | |
| 5.2.6 | Does the laboratory utilize appropriate actions to ensure the results are not invalidated or adversely affected by required quality of any examination? (Factors including light, sterility, dust, noxious or hazardous fumes, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration levels and workflow logistics) | ☐ | ☐ | |
| 5.2.6 | Is there effective separation between laboratory sections in which there are incompatible activities? | ☐ | ☐ | |
| 5.2.6 | Are there procedures in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated? | ☐ | ☐ | |
| 5.2.6 | Does the laboratory provide a quiet and uninterrupted work environment where it is needed? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.3 Laboratory equipment, reagents, and consumables** | | | | |
| 5.3.1.1 | Does the laboratory have a documented procedure for the selection, purchasing and management of equipment? | ☐ | ☐ | |
| 5.3.1.1 | Has the laboratory furnished with all equipment needed for the provision of services (including primary sample collection, sample preparation, sample processing, examination and storage)? | ☐ | ☐ | |
| 5.3.1.1 | In those cases, where the laboratory needs to use equipment outside its permanent control, does laboratory management ensure that the requirements of ISO 15189 are met? | ☐ | ☐ | |
| 5.3.1.1 | Has the laboratory replaced equipment as | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | needed to ensure the quality of examination results? | | | |
| **Additional Comments:** | | | | |
| 5.3.1.2 | Does the laboratory verify upon installation and before use that the equipment is capable of achieving the necessary performance and that it complies with requirements relevant to any examinations concerned (see also 5.5.1)? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.1.3 | Is equipment operated at all times by trained and authorized personnel? | ☐ | ☐ | |
| 5.3.1.3 | Are current instructions on the use, safety and maintenance of equipment, including any relevant manuals and directions for use provided by the manufacturer of the equipment and readily available? | ☐ | ☐ | |
| 5.3.1.3 | Does the laboratory have procedures for safe handling, transport, storage and use of equipment to prevent its contamination or deterioration? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.1.4 | Does the laboratory have a documented procedure for the calibration of equipment that directly or indirectly affects examination results? | ☐ | ☐ | |
| 5.3.1.4 | Does the procedure include:<br>a) taking into account conditions of use and the manufacturer's instructions? | ☐ | ☐ | |
| 5.3.1.4 | b) recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment? | ☐ | ☐ | |
| 5.3.1.4 | c) verifying the required measurement accuracy and the functioning of the | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | measuring system at defined intervals? | | | |
| 5.3.1.4 | d) recording the calibration status and date of recalibration? | ☐ | ☐ | |
| 5.3.1.4 | e) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated? | ☐ | ☐ | |
| 5.3.1.4 | f) safeguards to prevent adjustments or tampering that might invalidate examination results. | ☐ | ☐ | |
| 5.3.1.4 | Does the laboratory provide metrological traceability to a reference material or reference procedure of the higher metrological order available? | ☐ | ☐ | |
| 5.3.1.4 | If metrological traceability has not been possible or relevant, has the laboratory demonstrated other means for providing confidence in the results? (Including but not limited to use of certified reference materials, examination or calibration by another procedure, mutual consent standards or methods) | ☐ | ☐ | |
| 5.3.1.4 | If applicable, are the methods used clearly established, specific, characterized, and mutually agreed upon by all parties concerned? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.1.5 | Does the laboratory have a documented program of preventive maintenance which, at a minimum, that follows the manufacturer's instructions? | ☐ | ☐ | |
| 5.3.1.5 | Has equipment been maintained in a safe | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | working condition and in working order? | | | |
| 5.3.1.5 | Does examination of electrical safety, emergency stop devices where they exist and the safe handling and disposal of chemical, radioactive and biological materials by authorized persons? | ☐ | ☐ | |
| | Are the manufacturer's schedules and instructions used? | ☐ | ☐ | |
| 5.3.1.5 | Whenever equipment is found to be defective, has it been taken out of service and clearly labelled? | ☐ | ☐ | |
| 5.3.1.5 | Has the laboratory ensured that defective equipment is not used until it has been repaired and shown by verification to meet specified acceptance criteria? | ☐ | ☐ | |
| 5.3.1.5 | Does the laboratory examine the effect of any defects on previous examinations and institute immediate action or corrective action? | ☐ | ☐ | |
| 5.3.1.5 | Has the laboratory taken reasonable measures to decontaminate equipment before service, repair or decommissioning, provide a suitable space for repairs and provide appropriate personal protective equipment? | ☐ | ☐ | |
| 5.3.1.5 | If equipment was removed from the direct control of the laboratory, has the laboratory ensured that its performance was verified before being returned to laboratory use? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.1.6 | Have adverse incidents and accidents that can be attributed directly to specific equipment investigated and reported to the manufacturer and appropriate authorities, as required? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.1.7 | Are records maintained for each item of equipment that contributes to the performance of examinations? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | Do the equipment records include, but not be limited to, the following: | | | |
| 5.3.1.7 | a) identity of the equipment | ☐ | ☐ | |
| 5.3.1.7 | b) manufacturer's name, model and serial number or other unique identification | ☐ | ☐ | |
| 5.3.1.7 | c) contact information for the supplier or the manufacturer | ☐ | ☐ | |
| 5.3.1.7 | d) date of receiving and date of entering into service | ☐ | ☐ | |
| 5.3.1.7 | e) location | ☐ | ☐ | |
| 5.3.1.7 | f) condition when received (e.g. new, used or reconditioned) | ☐ | ☐ | |
| 5.3.1.7 | g) manufacturer's instructions | ☐ | ☐ | |
| 5.3.1.7 | h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory | ☐ | ☐ | |
| 5.3.1.7 | i) maintenance carried out and the schedule for preventive maintenance | ☐ | ☐ | |
| 5.3.1.7 | j) equipment performance records that confirm the equipment's ongoing acceptability for use? | ☐ | ☐ | |
| | Do the performance records include the following: | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | copies of reports/certificates of all calibrations?<br>verifications of dates, times, results and adjustments?<br>the acceptance criteria and due date of the next calibration?<br>verification to the fulfilment of ISO 15189:2012 requirements? | ☐<br>☐<br>☐<br>☐ | ☐<br>☐<br>☐<br>☐ | |
| 5.3.1.7 | k) damage to, or malfunction, modification, or repair of the equipment.? | ☐ | ☐ | |
| 5.3.1.7 | Are the records maintained and readily available for the lifespan of the equipment or longer, as specified in the laboratory's Control of Records procedure? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2 | The laboratory director, or designated suitably qualified person, shall be responsible for the selection criteria and for the procurement of equipment, materials and reagents. | | | |
| | a) An inventory shall be maintained of all POCT equipment including serial number and unique identification, manufacturer/supplier, date purchased and service history, including dates out-of-service. | ☐ | ☐ | |
| 5.3.2 | b) Reagents, kits and equipment shall be verified prior to routine use. | ☐ | ☐ | |
| 5.3.2 | c) There shall be written procedures for the maintenance and operation of POCT equipment. | ☐ | ☐ | |
| 5.3.2 | d) The management group shall recommend that any POCT device or system be withdrawn from service if critical requirements are not met or | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | safety becomes an issue. | | | |
| 5.3.2 | e) A record shall be kept of materials and reagents purchased for POCT that allows an audit trail with regard to any particular test performed. | ☐ | ☐ | |
| 5.3.2 | f) Periodic and episodic maintenance of equipment shall be monitored and documented. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.1 | Does the laboratory have a documented procedure for the reception, storage, acceptance testing and inventory management of reagents and consumables? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.2 | Where the laboratory is not the receiving facility, is there verification that the receiving location has adequate storage and handling capabilities to maintain purchased items in a manner that prevents damage or deterioration? | ☐ | ☐ | |
| 5.3.2.2 | Does the laboratory store received reagents and consumables according to manufacturer's specifications? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.3 | Has all new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, been verified for performance before use in examinations? | ☐ | ☐ | |
| | Has the laboratory verified all consumables that can affect the quality of examinations for performance before use in examinations? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.4 | Has the laboratory established an inventory control system for reagents and consumable? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | Does the system for inventory control segregate uninspected and unacceptable reagents and consumables from those that have been accepted for use? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.5 | Are instructions for the use of reagents and consumables, including those provided by the manufacturers, readily available? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.6 | Are adverse incidents and accidents that can be attributed directly to specific reagents or consumables investigated and reported to the manufacturer and appropriate authorities, as required? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.3.2.7 | Are records maintained for each reagent and consumable that contributes to the performance of examinations? | ☐ | ☐ | |
| 5.3.2.7 | Do these records include but not be limited to the following: | | | |
| | a) identity of the reagent or consumable | ☐ | ☐ | |
| 5.3.2.7 | b) manufacturer's name and batch code or lot number | ☐ | ☐ | |
| 5.3.2.7 | c) contact information for the supplier or the manufacturer | ☐ | ☐ | |
| 5.3.2.7 | d) date of receiving, the expiry date, date of entering into service and, where applicable, the date the material was taken out of service; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.3.2.7 | e) condition when received (e.g. acceptable or damaged); | ☐ | ☐ | |
| 5.3.2.7 | f) manufacturer's instructions; | ☐ | ☐ | |
| 5.3.2.7 | g) records that confirmed the reagent's or consumable's initial acceptance for use? | ☐ | ☐ | |
| | h) performance records that confirm the reagent's or consumable's ongoing acceptance for use? | ☐ | ☐ | |
| 5.3.2.7 | Do the records for reagents prepared or completed in-house, in addition to the relevant information above, reference the person or persons undertaking their preparation and the date of preparation? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.4 Pre-examination Processes** | | | | |
| 5.4.1 | Does he laboratory have documented procedures and information for pre-examination activities to ensure the validity of the results of examinations? | ☐ | ☐ | |
| | | | | |
| 5.4.2 | Does the laboratory have information available for patients and users of the laboratory services? | ☐ | ☐ | |
| 5.4.2 | The information shall include as appropriate:<br>a) the location of the laboratory; | ☐ | ☐ | |
| 5.4.2 | b) types of clinical services offered by the laboratory including examinations referred to other laboratories? | ☐ | ☐ | |
| 5.4.2 | c) opening hours of the laboratory? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.4.2 | d) Are the examinations offered by the laboratory including, as appropriate, information concerning samples required, primary sample volumes, special precautions, turnaround time, (which may also be provided in general categories or for groups of examinations), biological reference intervals, and clinical decision values? | ☐ | ☐ | |
| 5.4.2 | e) instructions for completion of the request form; | ☐ | ☐ | |
| 5.4.2 | f) instruction for preparation of the patient; | ☐ | ☐ | |
| 5.4.2 | g) instructions for patient-collected samples; | ☐ | ☐ | |
| 5.4.2 | h) instructions for transportation of samples, including any special handling needs; | ☐ | ☐ | |
| 5.4.2 | i) any requirements for patient consent (e.g. consent to disclose clinical information and family history to relevant healthcare professionals, where referral is needed); | ☐ | ☐ | |
| 5.4.2 | j) the laboratory's criteria for accepting and rejecting samples; | ☐ | ☐ | |
| 5.4.2 | k) a list of factors known to significantly affect the performance of the examination or the interpretation of the results; | ☐ | ☐ | |
| 5.4.2 | l) availability of clinical advice on ordering of examinations and on interpretation of examination results; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.4.2 | m) the laboratory's policy on protection of personal information; | ☐ | ☐ | |
| 5.4.2 | n) the laboratory's complaint procedure. | ☐ | ☐ | |
| | Does the laboratory have information available for patients and users that includes an explanation of the clinical procedure to be performed to enable informed consent? | ☐ | ☐ | |
| | Where relevant, does the importance of provision of patient and family information, (e.g. for interpreting genetic examination results), explained to the patient and user? | ☐ | ☐ | |
| 5.4.2 | Has the organization ensured identification of the sample and its clerical traceability to the patient? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.4.3 | Does the request form or an electronic equivalent allow space for the inclusion of, but not be limited to, the following:<br>a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier? (Unique identification includes an alpha and/or numerical identifier such as a hospital number, or personal health number.) | ☐ | ☐ | |
| 5.4.3 | b) name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.4.3 | c) type of primary sample and, where relevant, the anatomic site of origin; | ☐ | ☐ | |
| 5.4.3 | d) examinations requested; | ☐ | ☐ | |
| 5.4.3 | e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes | ☐ | ☐ | |
| 5.4.3 | f) date and, where relevant, time of primary sample collection | ☐ | ☐ | |
| 5.4.3 | g) date and time of sample receipt. | ☐ | ☐ | |
| 5.4.3 | Does the laboratory have a documented procedure concerning verbal requests for examinations that includes providing confirmation by request form or electronic equivalent within a given time? | ☐ | ☐ | |
| 5.4.3 | Has the laboratory practiced their willingness to cooperate with users or their representatives in clarifying the user's request? | ☐ | ☐ | |
| 5.4.3 | Has the organization exercised care with samples obtained for POCT from its patients while such samples are under the organization's control or are being used by the organization? | ☐ | ☐ | |
| 5.4.3 | Has the organization identified and safeguarded samples for analysis? | ☐ | ☐ | |
| 5.4.3 | If any sample is lost, damaged or otherwise found to be unsuitable for use, has the laboratory reported to the responsible healthcare professional and records maintained? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.4.4 Primary sample collection and handling** | | | | |
| 5.4.4.1 | Does the laboratory have documented | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | procedures for the proper collection and handling of primary samples? | | | |
| 5.4.4.1 | Are there documented procedures available to those responsible for primary sample collection whether or not the collectors are laboratory staff? | ☐ | ☐ | |
| 5.4.4.1 | Where the user(s) requires deviations and exclusions from, or additions to, the documented collection procedure, are they recorded and included in all documents containing examination results and communicated to the appropriate personnel? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.4.4.2 | Does the laboratory have instructions for pre-collection activities? | ☐ | ☐ | |
| 5.4.4.2 | Do the instructions include the following:<br>a) completion of request form or electronic request | ☐ | ☐ | |
| 5.4.4.2 | b) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients) | ☐ | ☐ | |
| 5.4.4.2 | c) type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives | ☐ | ☐ | |
| 5.4.4.2 | d) special timing of collection, where needed | ☐ | ☐ | |
| 5.4.4.2 | e) clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs). | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| **Additional Comments:** | | | | |
| 5.4.4.3 | Does the laboratory's instructions for collection activities include the following:<br>a) determination of the identity of the patient from whom a primary sample is collected? | ☐ | ☐ | |
| 5.4.4.3 | b) verification that the patient meets pre-examination requirements [e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.? | ☐ | ☐ | |
| 5.4.4.3 | c) instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives? | ☐ | ☐ | |
| 5.4.4.3 | d) in situations where the primary sample is collected as part of clinical practice, has information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions been determined and communicated to the appropriate clinical staff? | ☐ | ☐ | |
| 5.4.4.3 | e) instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected; | ☐ | ☐ | |
| 5.4.4.3 | f) recording of the identity of the person collecting the primary sample | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | and the collection date, and, when needed, recording of the collection time; | | | |
| 5.4.4.3 | g) instructions for proper storage conditions before collected samples are delivered to the laboratory; | ☐ | ☐ | |
| 5.4.4.3 | h) safe disposal of materials used in the collection. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.4.5 | Does the laboratory have instructions for post-collection activities that include packaging of samples for transportation? | ☐ | ☐ | |
| 5.4.5 | Does he laboratory have a documented procedure for monitoring the transportations of samples to ensure they are transported as follows: | ☐ | ☐ | |
| | a) within a time frame appropriate to the nature of the requested examinations and the laboratory discipline concerned? | | | |
| 5.4.5 | b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples? | ☐ | ☐ | |
| 5.4.5 | c) in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.4.6 | Does the laboratory have a procedure for | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | sample reception? | | | |
| 5.4.6 | Does the procedure ensure the following conditions are met:<br>a) Samples are unequivocally traceable, by request and labelling, to an identified patient or site. | ☐ | ☐ | |
| 5.4.6 | b) Laboratory-developed and documented criteria for acceptance or rejection of samples are applied. | ☐ | ☐ | |
| 5.4.6 | c) Where there are problems with patient or sample identification, sample instability due to delay in transport or inappropriate container(s), insufficient sample volume, or when the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample?<br><br>Does the final report indicate the nature of the problem and, where applicable, that caution is required when interpreting the result? | ☐<br><br>☐ | ☐<br><br>☐ | |
| 5.4.6 | d) All samples received are recorded in an accession book, worksheet, computer or other comparable system.<br><br>Are the date and time of receipt and/or registration of samples shall be recorded?<br>Whenever possible, has the identity of the person receiving the sample been recorded? | ☐<br><br>☐<br><br>☐ | ☐<br><br>☐<br><br>☐ | |
| 5.4.6 | e) Authorized personnel shall evaluate received samples to ensure that they | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | meet the acceptance criteria relevant for the requested examination(s). | | | |
| 5.4.6 | f) Do the instructions for the receipt, labelling, processing and reporting of samples specifically marked as urgent?<br><br>Including details of any special labelling of the request form and sample, the mechanism of transfer of the sample to the examination area of the laboratory, any rapid processing mode to be used, and any special reporting criteria to be followed? | ☐<br><br>☐ | ☐<br><br>☐ | |
| 5.4.6 | Are all portions of the primary sample unequivocally traceable to the original primary sample? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.4.7 | Does the laboratory have procedures and appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage? | ☐ | ☐ | |
| 5.4.7 | Do laboratory procedures include time limits for requesting additional examinations or further examinations on the same primary sample? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.5 Examination processes** | | | | |
| 5.5.1.1 | Does the laboratory select examination procedures which have been validated for their intended use? | ☐ | ☐ | |
| 5.5.1.1 | Has the identity of persons performing activities in examination processes be recorded? | ☐ | ☐ | |
| 5.5.1.1 | Do the specified requirements (performance | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | specifications) for each examination procedure relate to the intended use of that examination? | | | |
| **Additional Comments:** | | | | |
| 5.5.1.2 | Are validated examination procedures used without modification subject to independent verification by the laboratory before being introduced into routine use? | ☐ | ☐ | |
| 5.5.1.2 | Has the laboratory obtained information from the manufacturer/method developer for confirming the performance characteristics of the procedure? | ☐ | ☐ | |
| 5.5.1.2 | Does independent verification by the laboratory confirm, through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met? | ☐ | ☐ | |
| 5.5.1.2 | Are the performance claims for the examination procedure confirmed during the verification process relevant to the intended use of the examination results? | ☐ | ☐ | |
| 5.5.1.2 | Does the laboratory document the procedure used for the verification and record the results obtained? | ☐ | ☐ | |
| 5.5.1.2 | Has the staff with appropriate authority review the verification results and record the review? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.5.1.3 | Does the laboratory validate examination procedures derived from the following sources:<br>a) non-standard methods | ☐ | ☐ | |
| 5.5.1.3 | b) laboratory designed or developed methods | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.5.1.3 | c) standard methods used outside of their intended scope | ☐ | ☐ | |
| 5.5.1.3 | d) validated methods subsequently modified | ☐ | ☐ | |
| 5.5.1.3 | Is the validation as extensive as is necessary and confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled? | ☐ | ☐ | |
| 5.5.1.3 | Does the laboratory document the procedure used for the validation and record the results obtained? | ☐ | ☐ | |
| 5.5.1.3 | Has the staff with the authority reviewed the validation results and is there a documented record the review? | ☐ | ☐ | |
| 5.5.1.3 | When changes are made to a validated examination procedure, have the influence of such changes been documented and, when appropriate, a new validation carried out? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.5.1.4 | Has the laboratory determined measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples? | ☐ ☐ | ☐ ☐ | |
| 5.5.1.4 | Has the laboratory define the performance requirements for the measurement uncertainty of each measurement procedure and regularly review estimates of measurement uncertainty? | ☐ | ☐ | |
| 5.5.1.4 | Does the laboratory consider measurement uncertainty when interpreting measured quantity values? | ☐ | ☐ | |
| 5.5.1.4 | Upon request, does the laboratory make its estimates of measurement uncertainty | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | available to laboratory users? | | | |
| 5.5.1.4 | Where examinations include a measurement step but do not report a measured quantity value, has the laboratory calculated the uncertainty of the measurement step where it has utility in assessing the reliability of the examination procedure or has influence on the reported result? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.5.2 | Has the laboratory defined the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users? | ☐ | ☐ | |
| 5.5.2 | When a particular biological reference interval or decision value is no longer relevant for the population served, were appropriate changes made and communicated to the users? | ☐ | ☐ | |
| 5.5.2 | When the laboratory changes an examination procedure or pre-examination procedure, has the laboratory reviewed associated reference intervals and clinical decision values, as applicable? | ☐ | ☐ | |
| 5.5.2 | Have the procedure manuals for each POCT system made available to all users? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.5.3 | Have examination procedures been documented? | ☐ | ☐ | |
| 5.5.3 | Are they written in a language commonly understood by the staff in the laboratory and be available in appropriate locations? | ☐ | ☐ | |
| 5.5.3 | Do condensed document format (e.g. card files or similarly used systems) correspond to the documented procedure? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.5.3 | Are all documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, subject to document control? | ☐ | ☐ | |
| 5.5.3 | In addition, to document control identifiers, does documentation include, when applicable to the examination procedure, the following:<br>a) purpose of the examination? | ☐ | ☐ | |
| 5.5.3 | b) principle and method of the procedure used for examinations? | ☐ | ☐ | |
| 5.5.3 | c) performance characteristics? | ☐ | ☐ | |
| 5.5.3 | d) type of sample (e.g. plasma, serum, urine); | ☐ | ☐ | |
| 5.5.3 | e) patient preparation? | ☐ | ☐ | |
| 5.5.3 | f) type of container and additives? | ☐ | ☐ | |
| 5.5.3 | g) required equipment and reagents? | ☐ | ☐ | |
| 5.5.3 | h) environmental and safety controls? | ☐ | ☐ | |
| 5.5.3 | i) calibration procedures (metrological traceability)? | ☐ | ☐ | |
| 5.5.3 | j) procedural steps? | ☐ | ☐ | |
| 5.5.3 | k) quality control procedures? | ☐ | ☐ | |
| 5.5.3 | l) interferences (e.g. lipaemia, haemolysis, bilirubinemia, drugs) and cross reactions? | ☐ | ☐ | |
| 5.5.3 | m) principle of procedure for calculating results including, where relevant, the | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | measurement uncertainty of measured quantity values? | | | |
| 5.5.3 | n) biological reference intervals or clinical decision values? | ☐ | ☐ | |
| 5.5.3 | o) reportable interval of examination results; | ☐ | ☐ | |
| 5.5.3 | p) instructions for determining quantitative results when a result is not within the measurement interval; | ☐ | ☐ | |
| 5.5.3 | q) alert/critical values, where appropriate; | ☐ | ☐ | |
| 5.5.3 | r) laboratory clinical interpretation; | ☐ | ☐ | |
| 5.5.3 | s) potential sources of variation; | ☐ | ☐ | |
| 5.5.3 | t) references. | ☐ | ☐ | |
| 5.5.3 | Is the manufacturer's recommendations regarding minimum quality control of a specific instrument system accepted, following documented review? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.5.4 | Is instrument-generated quality control acceptable ( provided that regulatory authorities have accepted it)? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.6 Ensuring Quality of Examination Results** | | | | |
| 5.6.1 | Does the laboratory ensure the quality of examinations by performing them under defined conditions? | ☐ | ☐ | |
| 5.6.1 | Does the laboratory have appropriate pre and post-examination processes shall be implemented? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.6.1 | Does the laboratory avoided fabricating any results? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.2 | Is the quality manager responsible for the design, implementation and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory? | ☐ | ☐ | |
| 5.6.2 | Has the relationship between values obtained in the laboratory and POCT been established and published or available upon request? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.2.1 | Has the laboratory designed quality control procedures that verify the attainment of the intended quality of results? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.2.2 | The laboratory shall use quality control materials that react to the examining system in a manner as close as possible to patient samples? | ☐ | ☐ | |
| 5.6.2.2 | Are quality control materials periodically examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.2.3 | Does the laboratory have a procedure to prevent the release of patient results in the event of quality control failure? | ☐ | ☐ | |
| 5.6.2.3 | When the quality control rules are violated and indicate that examination results are likely to contain clinically significant errors, are the results rejected and relevant patient samples re-examined after the error condition has been corrected and within-specification performance is verified? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.6.2.3 | Has the laboratory evaluated the results from patient samples that were examined after the last successful quality control event? | ☐ | ☐ | |
| 5.6.2.3 | Has quality control data been reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system? | ☐ | ☐ | |
| 5.6.2.3 | When such trends are noted, are preventive actions taken and recorded? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.3 | The quality manager may assign responsibility for quality control on a specific POCT instrument/system to an appropriately qualified person. | ☐ | ☐ | |
| 5.6.3 | When such activities are assigned, does the quality manager remain accountable to the laboratory director, or designated person, for the quality of all POCT testing? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.3.1 | Does the laboratory participate in an inter-laboratory comparison program(s) (such as an external quality assessment programs or proficiency testing programs) appropriate to the examination and interpretations of examination results.? | ☐ | ☐ | |
| 5.6.3.1 | Does the laboratory monitor the results of the inter-laboratory comparison program(s) and participate in the implementation of corrective actions when predetermined performance criteria are not fulfilled? | ☐ | ☐ | |
| 5.6.3.1 | Has the laboratory established a documented procedure for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison program? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.6.3.1 | Do the inter-laboratory comparison program chosen by the laboratory, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures, where possible? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.3.2 | Whenever an inter-laboratory comparison is not available, has the laboratory developed other approaches and provide objective evidence for determining the acceptability of examination results? | ☐ | ☐ | |
| 5.6.3.2 | Whenever possible, does this mechanism utilize appropriate materials such as: | | | |
| | certified reference material | ☐ | ☐ | |
| | samples previously examined | ☐ | ☐ | |
| | material from cell or tissue repositories | ☐ | ☐ | |
| | exchange of samples with other laboratories | ☐ | ☐ | |
| | control materials that are tested daily in inter-laboratory comparison programs. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.3.3 | Does the laboratory integrate inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples? | ☐ | ☐ | |
| 5.6.3.3 | Are inter-laboratory comparison samples examined by personnel who routinely examine patient samples using the same procedures as those used for patient samples? | ☐ | ☐ | |
| 5.6.3.3 | Does the laboratory ensure that they have not communicated with other participants in the inter-laboratory comparison program about sample data until after the date for submission of the data? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.6.3.3 | Has the laboratory ensured that they have not referred inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.3.4 | Are performances in inter-laboratory comparisons reviewed and discussed with relevant staff? | ☐ | ☐ | |
| 5.6.3.4 | When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), does staff participate in the implementation and recording of corrective action? | ☐ | ☐ | |
| 5.6.3.4 | Is the effectiveness of corrective action monitored? | ☐ | ☐ | |
| 5.6.3.4 | Are the returned results evaluated for trends that indicate potential nonconformities and has preventive action be taken? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.4 | Does the laboratory have a defined means of comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals? | ☐ | ☐ | |
| 5.6.4 | When measurement results that are metrologically traceable to the same reference, are the results are described as having metrological comparability providing that calibrators are commutable? | ☐ | ☐ | |
| 5.6.4 | Does the laboratory notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measure and (e.g. glucose) and when examination methods are changed? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.6.4 | Does the laboratory document, record and, as appropriate, expeditiously act upon results from the comparisons performed? | ☐ | ☐ | |
| 5.6.4 | When problems or deficiencies are identified are they acted upon and records of actions retained? | ☐ | ☐ | |
| 5.6.4 | Where available, participation in an external quality assessment (EQA) shall be required (see ISO/IEC 17043). | | | |
| 5.6.4 | In the absence of an EQA scheme, has the laboratory director, or designated person, should establish an internal quality assessment scheme involving the circulation of samples or replication of the test within the laboratory? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 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? | ☐ | ☐ | |
| 5.6.5 | Does the suggested modifications arising from such review shall be incorporated into the POCT policy, processes, and procedures? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.6.6 | The laboratory director shall 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 program | ☐ | ☐ | |
| 5.6.6 | b) Split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites. | ☐ | ☐ | |
| 5.6.6 | c) Frequency of internal QC should be specified for each device. | ☐ | ☐ | |
| 5.6.6 | d) Corrective action to be taken for out-of-control results shall be | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | documented. | | | |
| 5.6.6 | e) Action taken on nonconforming QC results shall be documented. | ☐ | ☐ | |
| 5.6.6 | f) QC results shall be recorded for regular review by the quality manager or designated person. | ☐ | ☐ | |
| 5.6.6 | g) Process control for consumable supplies and reagents shall be documented and monitored. | ☐ | ☐ | |
| 5.6.6 | h) In-patient self-testing using POCT devices, if allowed, shall be monitored to validate the accuracy and comparability of the results to those of the central laboratory. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.7 Post-examination processes** | | | | |
| 5.7.1 | Does the laboratory have procedures to ensure that authorized personnel review results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results? | ☐ | ☐ | |
| 5.7.1 | When the procedure for reviewing results involves automatic selection and reporting, does the laboratory review criteria established, approved and documented? | ☐ | ☐ | |
| 5.7.1 | Does the organization handle and dispose safely of all samples, reagents and kits according to local, regional or national regulations? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.7.2 | Does the laboratory have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.7.2 | Has the laboratory defined the length of time clinical samples are to be retained? | ☐ | ☐ | |
| 5.7.2 | Is the retention time defined by the nature of the sample, the examination and any applicable requirements? | ☐ | ☐ | |
| 5.7.2 | Where repeat testing is clinically indicated, is the original sample used where available? | ☐ | ☐ | |
| 5.7.2 | If the original sample was not used, has a new sample shall be obtained? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.8 Reporting of results** | | | | |
| 5.8.1 | Are the results of each examination reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures? | ☐ | ☐ | |
| 5.8.1 | Does the laboratory have a defined format and medium of the report (i.e. electronic or paper) and the manner in which it is to be communicated from the laboratory? | ☐ | ☐ | |
| 5.8.1 | Does the laboratory have a procedure to ensure the correctness of transcription of laboratory results? | ☐ | ☐ | |
| 5.8.1 | Do the reports include the information necessary for the interpretation of the examination results? | ☐ | ☐ | |
| 5.8.1 | Does the laboratory have a process for notifying the requester when an examination is delayed that could compromise patient care? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.8.2 | Does the laboratory ensure that the following report attributes effectively communicate laboratory results and meet the users' needs: | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | a) comments on sample quality that might compromise examination results; | ☐ | ☐ | |
| 5.8.2 | b) comments regarding sample suitability with respect to acceptance/rejection criteria; | ☐ | ☐ | |
| 5.8.2 | c) critical results, where applicable; | ☐ | ☐ | |
| 5.8.2 | d) interpretive comments on results, where applicable, which may include the verification of the interpretation of automatically selected and reported results (see 5.9.2) in the final report. | ☐ | ☐ | |
| 5.8.2 | Are POCT results reported with the necessary details? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| 5.8.3 | Does the report include, but not be limited to, the following: | | | |
| | a) a clear, unambiguous identification of the examination including, where appropriate, the examination procedure; | ☐ | ☐ | |
| 5.8.3 | b) the identification of the laboratory that issued the report; | ☐ | ☐ | |
| 5.8.3 | c) identification of all examinations that have been performed by a referral laboratory; | ☐ | ☐ | |
| 5.8.3 | d) patient identification and patient location on each page; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.8.3 | e) name or other unique identifier of the requester and the requester's contact details; | ☐ | ☐ | |
| 5.8.3 | f) date of primary sample collection (and time, when available and relevant to patient care); | ☐ | ☐ | |
| 5.8.3 | g) type of primary sample; | ☐ | ☐ | |
| 5.8.3 | h) measurement procedure, where appropriate; | ☐ | ☐ | |
| 5.8.3 | i) examination results reported in SI units, units traceable to SI units, or other applicable units; | ☐ | ☐ | |
| 5.8.3 | j) biological reference intervals, clinical decision values, or diagrams/nomograms supporting clinical decision values, where applicable; | ☐ | ☐ | |
| 5.8.3 | k) interpretation of results, where appropriate; | ☐ | ☐ | |
| 5.8.3 | l) other comments such as cautionary or explanatory notes (e.g. quality or adequacy of the primary sample which may have compromised the result, results/interpretations from referral laboratories, use of developmental procedure); | ☐ | ☐ | |
| 5.8.3 | m) identification of examinations undertaken as part of a research or development program and for which no specific claims on measurement performance are available; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.8.3 | n) 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 | o) date of the report, and time of release (if not contained in the report, readily available when needed); | ☐ | ☐ | |
| 5.8.3 | p) page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.). | ☐ | ☐ | |
| 5.8.3 | Have the POCT results been permanently recorded in the patient’s medical record? | ☐ | ☐ | |
| 5.8.3 | Is the identity of the person performing the test should be recorded? | ☐ | ☐ | |
| | | | | |
| 5.8.4 | Do the records distinguish between POCT results and those from the central laboratory or its satellites? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.9 Release of Results** | | | | |
| 5.9.1 | Has the laboratory established documented procedures for the release of examination results, including details of who may release results and to whom? | ☐ | ☐ | |
| 5.9.1 | Do the procedures ensure that the following conditions are met: | ☐ | ☐ | |
| | a) When the quality of the primary sample received is unsuitable for examination, or could have compromised the result, this is indicated in the report? | | | |
| 5.9.1 | b) Examinations that have fallen within the “alert” or “critical” intervals, was | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | a physician (or other authorized health professional) notified immediately? | | | |
| 5.9.1 | Are records are maintained of actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications? | ☐ | ☐ | |
| 5.9.1 | c) Results are legible, without mistakes in transcription, and reported to persons authorized to receive and use the information. | ☐ | ☐ | |
| 5.9.1 | d) When results are transmitted as an interim report, the final report is always forwarded to the requester. | ☐ | ☐ | |
| 5.9.1 | e) Are here are processes for ensuring that results distributed by telephone or electronic means reach only authorized recipients?<br><br>Are the results provided orally followed by a written report and are there records of all oral results provided? | ☐<br><br>☐ | ☐<br><br>☐ | |
| **Additional Comments:** | | | | |
| 5.9.2 | Has the laboratory implemented a system for automated selection and reporting of results? | ☐ | ☐ | |
| 5.9.2 | Has it established a documented procedure to ensure that:<br>a) the criteria for automated selection and reporting are defined, approved, | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | readily available and understood by the staff; | | | |
| 5.9.2 | b) the criteria are validated for proper functioning before use and verified after changes to the system that might affect their functioning; | ☐ | ☐ | |
| 5.9.2 | c) there is a process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination; | ☐ | ☐ | |
| 5.9.2 | d) there is a process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria, when appropriate; | ☐ | ☐ | |
| 5.9.2 | e) results selected for automated reporting shall be identifiable at the time of review before release and include date and time of selection | ☐ | ☐ | |
| 5.9.2 | f) there is a process for rapid suspension of automated selection and reporting? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.9.3 Revised Reports** | | | | |
| 5.9.3 | When an original report is revised are there written instructions to ensure the revisions are following: | | | |
| | a) the revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report; | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.9.3 | b) the user is made aware of the revision; | ☐ | ☐ | |
| 5.9.3 | c) the revised record shows the time and date of the change and the name of the person responsible for the change; | ☐ | ☐ | |
| 5.9.3 | d) the original report entries remain in the record when revisions are made. | ☐ | ☐ | |
| | Are the results that have been made available for clinical decision making and revised retained in subsequent cumulative reports and clearly identified as having been revised? | ☐ | ☐ | |
| | When the reporting system cannot capture amendments, are changes or alterations, and a record of such kept? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.10 Laboratory information management** | | | | |
| 5.10.1 | Does the laboratory have access to the data and information needed to provide a service which meets the needs and requirements of the user? | ☐ | ☐ | |
| 5.10.1 | Does the laboratory have a documented procedure to ensure that the confidentiality of patient information is maintained at all times? | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.10.2 Authorities and Responsibilities** | | | | |
| 5.10.2 | Does the laboratory ensure that the authorities and responsibilities for the management of the information system are defined, including the maintenance and modification to the information system(s) that may affect patient care? | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| 5.10.2 | Has the laboratory define the authorities and responsibilities of all personnel who use the system, in particular those who:<br>a) access patient data and information; | ☐ | ☐ | |
| 5.10.2 | b) enter patient data and examination results; | ☐ | ☐ | |
| 5.10.2 | c) change patient data or examination results; | ☐ | ☐ | |
| 5.10.2 | d) authorize the release of examination results and reports. | ☐ | ☐ | |
| **Additional Comments:** | | | | |
| **5.10.3 Information System Management** | | | | |
| 5.10.3 | Are the system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information meet the following criteria:<br>a) validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation; | ☐ | ☐ | |
| 5.10.3 | b) documented, and the documentation, including that for day to day functioning of the system, readily available to authorized users | ☐ | ☐ | |
| 5.10.3 | c) protected from unauthorized access; | ☐ | ☐ | |
| 5.10.3 | d) safeguarded against tampering or loss; | ☐ | ☐ | |
| 5.10.3 | e) operated in an environment that complies with supplier specifications | ☐ | ☐ | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription; | | | |
| 5.10.3 | f) maintained in a manner that ensures the integrity of the data and information and includes the recording of system failures and the appropriate immediate and corrective actions; | ☐ | ☐ | |
| 5.10.3 | g) in compliance with national or international requirements regarding data protection. | ☐ | ☐ | |
| 5.10.3 | Does the laboratory verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information? | ☐ | ☐ | |
| 5.10.3 | When a new examination or automated comments are implemented, does the laboratory verify that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory? | ☐ | ☐ | |
| 5.10.3 | Does the laboratory have documented contingency plans to maintain services in the event of failure or downtime in information systems that affects the laboratory's ability to provide service? | ☐ | ☐ | |
| 5.10.3 | When the information system(s) are managed and maintained off-site or subcontracted to an alternative provider, does laboratory management ensure that the provider or operator of the system complies with all applicable requirements of ISO 15189? | ☐ | ☐ | |
| **Additional Comments:** | | | | |

| ISO Req. | Characteristic | Yes | No | Comments regarding deficiencies/effectiveness (if applicable) |
|---|---|---|---|---|
| | | | | |

| PJLA PL-1,2,3, SOP-3 Requirements and WI-8 For Testing Labs |
|---|
| ***Objective Evidence of Laboratory's utilization of PJLA's accreditation symbol must be included in the package. This includes but not limited to (Website page, letterhead, test/examination reports including subcontracted results if utilized) *** <br><br> ***If any of the requirements of the PJLA Policies, WI-8 or SOP-3 requirements are not followed a nonconformance must be written*** |

| SOP-3 PJLA Accreditation Symbol Procedure | | | | |
|---|---|---|---|---|
| | | Y | N | |
| | For applicant laboratories:<br><br>Does the applicant laboratory use the PJLA Logo? *Note- Applicant laboratories are not permitted to use the PJLA logo until official accreditation is granted by executive committee approval. If Y is indicated this shall be a nonconformity.* | ☐ | ☐ | |
| | **For accredited laboratories**:<br><br>Is the accredited laboratory utilizing the correct symbol (i.e. medical testing)? | ☐ | ☐ | |
| | Does the laboratory reference its accreditation number within close proximity of the accreditation symbol? | ☐ | ☐ | |
| | If the laboratory does use the actual accreditation symbol and issues an endorsed or accredited report are they specifying the following on their report in lieu of the actual symbol:<br><br>-accreditation number<br><br>-program (i.e. medical testing) | ☐<br><br>☐<br><br>☐<br><br>☐ | ☐<br><br>☐<br><br>☐<br><br>☐ | |

| | | | | |
|---|---|---|---|---|
| | -the standard (i.e. ISO 15189:2012)<br>-a reference to PJLA as the accrediting body | ☐ | ☐ | |
| | Is the symbol reproduced in a size that is clearly distinguishable? | ☐ | ☐ | |
| | Is the symbol reproduced in a single-color (black or a single color belonging to the house-style of the accredited lab)? | ☐ | ☐ | |
| | Is the symbol identifiable? | ☐ | ☐ | |
| | Is the accredited laboratory properly stating their accreditation status? "Accredited to ISO 15189:2012" | ☐ | ☐ | |
| | Is the accredited laboratory properly using the symbol on: | | | |
| | a) promotional material and business stationary? | ☐ | ☐ | |
| | b) test or calibration certificates or labels? | ☐ | ☐ | |
| | c) website? | ☐ | ☐ | |
| | d) technical literature? | ☐ | ☐ | |
| | e) business reports | ☐ | ☐ | |
| | f) quotations or proposals for work? *(symbols may only be listed for accredited laboratories)* | ☐ | ☐ | |
| | If statements of opinion and interpretations are outside of the scope of the accreditation, does the laboratory include a disclaimer in the report or certificate close to the accreditation symbol? | ☐ | ☐ | |

| | | | | |
|---|---|---|---|---|
| | (such as *"the opinions/interpretations expressed on this report are outside the scope of this laboratory's accreditation.")* | | | |
| | Is the accredited laboratory appropriately using the symbol by <u>not</u> placing the symbol on: | | | |
| | legal documents (i.e. contracts or checks) | ☐ | ☐ | |
| | on test/calibration certificates or any other material referencing work or items not covered by scope of accreditation? | ☐ | ☐ | |
| | any documentation of sites that are not accredited by PJLA | ☐ | ☐ | |
| | on subcontractor's certificates or documentation | ☐ | ☐ | |
| | on products or items which laboratory has tested | ☐ | ☐ | |
| | Where tests outside the scope of the accreditation are included on reports, certificates or enclosed letters with results, has the laboratory clearly defined "This laboratory is not accredited for the tests or marked"? | ☐ | ☐ | |
| **Subcontracted Tests** | | | | |
| | If the accredited laboratory included the results of subcontracted tests on reports or certificates can they demonstrate that they have: | | | |
| | a) obtained approval from the subcontracted laboratory? | ☐ | ☐ | |
| | b) obtained approval from the subcontractor to report excerpts from the subcontractor's report on the certificate? | ☐ | ☐ | |

| | | | | |
|---|---|---|---|---|
| | c) objective evidence that the subcontractor itself is accredited for the specific tests concerned and results have been included in the subcontractor's endorsed report or certificate? | ☐ | ☐ | |
| | Does the laboratory use any oversight or recognition body logo or symbol on their certificates, reports or any other material?<br><br>If yes, which body's logo or symbol are they using? | ☐ | ☐ | |
| Additional Comments: | | | | |

| **PL-1 Proficiency Testing Requirements for Applicant and Accredited Laboratories.**<br><br>***Note requirements as outlined in ISO 15189:2012 shall also be assessed in addition to the following PJLA PT requirements.*** | | | | |
|---|---|---|---|---|
| | Has the laboratory conducted PT(s) for all testing areas applied for, including all sub-disciplines as defined in PL-1 within 6 months from the initial date of their assessment?<br><br>If no please indicate the plan of action *(i.e. ncr until a passing score is obtained complete LF-8 or remove from the scope modify LF-68.* | ☐ | ☐ | |
| | Has the laboratory obtained a passing score on all PTs conducted? If no please indicate the plan of action *(i.e. ncr until a passing score is obtained complete LF-8 or remove from the scope modify LF-68.* | ☐ | ☐ | |
| | Are the results meaningful (i.e. demonstrating the laboratory's competence in performing specified tests)? | ☐ | ☐ | |

| | | | | |
|---|---|---|---|---|
| | Has the laboratory developed a PT plan to incorporate all areas of the scope to ensure the following: | | | |
| | -All areas of examination processes as defined by PJLA Policy have been included<br>-All sub-disciplines are scheduled for a PT at least twice per year not to exceed a 6-month interval<br>-Third party providers accredited to ISO 17043 are utilized or that when they are not available PJLA's approval has been obtained for other means of PT (inter lab, intra lab, repeatability studies). | ☐<br>☐<br>☐ | ☐<br>☐<br>☐ | |
| | For any unfavorable results gathered during proficiency testing, was appropriate corrective action taken? | ☐ | ☐ | |

| **PL-2 Measurement Traceability Policy-**<br>***Note requirements as outlined in ISO 15189:2012 shall also be assessed in addition to the following PJLA PT requirements.*** | | | |
|---|---|---|---|
| Does the laboratory have documented policies and procedures regarding measurement traceability and is the reference traceability included on test reports? | ☐ | ☐ | |
| Does the laboratory have documented procedures detailing the verification, transport and storage of reference standards? | ☐ | ☐ | |
| Has the laboratory employed the services of an external calibration provider(s) that are accredited to ISO 15189:2012 for the calibration(s) performed? | ☐ | ☐ | |
| If not, can the laboratory demonstrate reverse traceability, an uninterrupted chain, back to NIST or another NMI? | ☐ | ☐ | |
| Does the laboratory have on file and available the current certificates and scopes of accreditation for the external calibration laboratories employed? | ☐ | ☐ | |

| **PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories-**<br>***Note requirements as outlined in ISO 15189:2012 shall also be assessed in addition to the following PJLA PT requirements.*** | | |
|---|---|---|
| For applicant laboratories: | | |
| Has the laboratory determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patient samples? | ☐ | ☐ |
| Has the laboratory defined the performance requirements for the measurement uncertainty of each measurement procedure? | ☐ | ☐ |
| Has the laboratory considered the measurement uncertainty when interpreting measured quantity values? | ☐ | ☐ |

| | | |
|---|---|---|
| When examinations do not report a measured quantity value the does the laboratory calculate the uncertainty of the measurement step where it has utility in assessing the reliability for any part of the examination procedure that has influence on the reported result? | ☐ | ☐ |
| *(Well recognized test methods that specify limits to the values of major sources of uncertainties will meet this requirement)* | | |
| Are stated uncertainties periodically reviewed and updated to evaluate changes to be made to any influence listed in an uncertainty calculation? | ☐ | ☐ |
| Does the laboratory include a metrological statement or reference estimated uncertainties on test reports? | ☐ | ☐ |
| **Additional Comments:** | | |

| **WI-8- Scope of Accreditation for Testing Laboratories including Flexible Scopes** | | |
|---|---|---|
| Is the laboratory's scope in accordance to WI-8? If no, please request a revised scope to be completed prior to finalizing the LF-68 scope request form. | ☐ | ☐ |
| **For applicant labs:** If the laboratory has a flexible scope, does the laboratory have a clear listing of tests that are performed under each process of examination of their applicant scope available in accordance to WI-8? | ☐ | ☐ |
| Are all identified process of examinations relevant, defined appropriately and accurately in accordance to WI-8?<br><br>If no, then the laboratory shall be required to resubmit a revised flexible scope listing, including all tests being performed at the current time.<br><br>If yes, assessors should conduct a sampling of tests indicated under each process of examination to be confident in their ability to perform all tests under each discipline. | ☐ | ☐ |
| Does the laboratory have where it is applicable fully documented procedures for the validation of method modifications (including modifications of parameters and matrices) and for the verification of additional methods to be covered under the flexible accreditation scope? | ☐ | ☐ |

| | | |
|---|---|---|
| Does the laboratory have a procedures and responsibilities to review their flexible scope periodically by the responsible management and take into account the results of internal and external quality control? | ☐ | ☐ |
| **For accredited labs:** If the laboratory has a flexible scope, have they provided an updated listing of any new tests performed under their defined sub disciplines?<br><br>Note- for new tests added, the assessor should attempt to witness or verify them as part of the sampling process. If the laboratory has added a new technology/equipment a full assessment must be conducted in this area. Laboratories should notify PJLA for a special assessment in these cases, if they plan on issuing accredited reports. If this did not take place, then the assessor should confirm that no accredited reports were conducted based on the new technology/equipment. If this is found, then the laboratory shall be issued an NCR against SOP-3 and PJLA should be notified immediately to decide whether a flexible scope will continue for the laboratory.<br><br>Additional questions listed above should also be re-verified upon accreditation. | ☐ | ☐ |
| **Additional Comments:** | | |

| Surveillance of Previous Nonconformities and Corrective Action |
| --- |
| The assessor shall verify that previous nonconformities have been resolved and that corrective actions have been effectively implemented. |
| **Additional Comments:** |