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Testing Laboratories Department

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PREPARATION
The Director of testing laboratories department

APPROVAL
The Directive Council

AUTHORIZATION
The President

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Contents

0. Introduction

This document defines the general criteria for the accreditation of medical laboratories by the ACCREDIA (the Italian accreditation body) Department of Testing Laboratories.

The objective of the application of these criteria is to promote the creation and maintenance of the trust of users in the testing activities of accredited laboratories as well as the impartiality and integrity of the related technical and commercial activities. ACCREDIA grants accreditation to laboratories which conform with the requirements of UNI EN ISO 15189, with this document and with all other applicable ACCREDIA, EA and ILAC documents.

Accreditation attests the technical competence of the laboratory to perform the activities contained in the field of application of accreditation.

1. Scope and field of application

1.1. This regulation refers to the requirements of the standard UNI EN ISO 15189:2024 "Medical laboratories - Requirements for quality and competence" and is intended to provide, for certain aspects, indications and clarifications necessary for the application of this standard. The numbering of the paragraphs coincides with those of the UNI EN ISO 15189 standard.

Additional sector-specific requirements may be defined by mandatory regulations or at international or national level (EA, ILAC, ISO, EN, UNI, etc.).

1.2. This document is applicable to all medical laboratories, both those that are organisationally and commercially independent and those that are dependent on a larger organisation (such as hospitals, public or private organisations, research centres, etc.).

1.3. In order to obtain and maintain accreditation the lab shall demonstrate conformity with all the requirements of the standard except for those declared, with justification, to be inapplicable, for all activities defined in the field of accreditation.

1.4. The Laboratory is obliged to comply with this document, the ACCREDIA document RG-09 and other documents, where applicable (e.g., RG-02, RT-26).

2. Reference standards and documents

The reference standard for this scheme is UNI EN ISO 15189:2024. The list of reference documents (LS-04) can be found at www.accredia.it.

For some technical sectors there are specific documents for the application of the UNI EN ISO 15189 standard. These documents, if not explicitly indicated as mandatory, are guidelines and do not constitute additional requirements but help in the consistent application of what is already re-quired; however, if the laboratory decides not to apply what is stated in them, it must demonstrate the validity and suitability for the scope of its work.

It is the responsibility of the Laboratory to ensure the validity of the applicable documents.

3. Terms and definitions

The definitions of UNI EN ISO 15189, of the reference standards (UNI EN ISO 9000, UNI CEI EN ISO/IEC 17000, UNI CEI 70099, UNI CEI EN 45020), of Regulation (EC) No. 765/2008 and of the applicable ACCREDIA Regulations (e.g., RG-02, RT-26) apply.

Internal procedure[1]: method designed or developed by the laboratory, or method specified in the instructions for use of in vitro diagnostic medical devices placed on the market in accordance with EU Reg. 2017/746 but used outside the intended purpose specified by the manufacturer or modified.

Internal procedures therefore include:

a. methods entirely developed by the laboratory;
b. methods developed or modified by the laboratory from a published source (scientific literature), or from design specifications produced by another laboratory or any other source;
c. methods involving the use of parts of existing in vitro diagnostic medical devices
d. methods combining an in vitro diagnostic medical device with another in vitro diagnostic medical device (IVD assembly) or with another type of product or parts of product, where the combination creates a new in vitro diagnostic medical device;
e. methods that modify an existing in vitro diagnostic medical device on the market to create a new in vitro diagnostic medical device;
f. methods used for a purpose other than that intended by the manufacturer, e.g., when a method declared 'for research use only' (RUO) or 'for laboratory use only' is used for diagnostic purposes.
g. methods not used in accordance with the manufacturer's instructions for use, including significant changes in the intended use, e.g., applying it to other types of samples.

Other terms commonly used to define an internal method are: in-house method, laboratory-developed tests (LDT).

IVD examination procedure[2]: method specified in the instructions for use of in vitro diagnostic medical devices placed on the market in accordance with EU Reg. 2017/746, used by the laboratory without modification and within the intended purpose specified by the manufacturer.

Also included, until the end of the transitional period of Regulation (EU) 2017/746, are those specified in the instructions for use of devices placed in accordance with Directive 98/79/EC.

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[1] In this document, the word 'method' can sometimes also be understood as 'measurement procedure' or 'examination procedure".

[2] The term 'IVD examination procedure' replaces the previously used term 'recognised examination procedure".

4. General requirements

4.1 Impartiality

The requirement of the standard applies.

Please remember, when applying the requirements, to take into account what is stated in Note 2 to §8.5.2 of the standard.

4.2 Confidentiality

The requirement of the standard applies.

4.3 Patient-related requirements

The requirement of the standard applies.

5. Structural and governance requirements

5.1 Legal entity

The requirement of the standard applies.

5.2 Laboratory director

The requirement of the standard applies.

5.3 Laboratory activities

5.3.1 The requirement of the standard applies.

Accreditation is granted to a laboratory only for those activities it carries out on its own and for which ACCREDIA verifies its competence. The outsourcing of activities on an ongoing basis is therefore excluded from the scope of accreditation.

It should be noted that the outsourcing of accredited activities on a non-continuous basis is only the case where the laboratory has the resources and expertise to perform the activities, but for unforeseen reasons finds itself unable to perform them in whole or in part.

The activity of sample collection (sampling), regardless of where it is carried out (at home, in a mobile blood collection unit, at a temporary location, etc.), including the transport of samples to the site where the tests are performed, can be accredited provided it is conducted under the responsibility of the laboratory applying for

accreditation and solely for the purpose of obtaining samples intended for the subsequent performance of accredited tests. Therefore, sample collection intended for transfusion is not accreditable, whereas collection aimed at donor testing is accreditable.

Point-of-Care Testing (POCT) may be included in the accreditation if the laboratory also ensures for these examinations the applicable requirements of EN ISO 15189, including those indicated in Annex A.

5.3.2 The requirement of the standard applies.

Among the requirements that the Laboratory must fulfil for compliance with ISO 15189 are also included the legislative requirements for the exercise of the laboratory activity subject to accreditation. For these requirements, compliance must be demonstrated by providing evidence of the authorisation to operate issued by the competent authority.

5.3.3 The requirement of the standard applies.

5.4 Organization and authority

5.4.1 The requirement of the standard applies.

The laboratory must have an organisational chart that clearly illustrates its organisation and its relationships with any other functions that have an influence on the laboratory's operations (e.g., purchasing, personnel records, consumables warehouse, departments/units where POCTs are located, internal departments that deal with equipment maintenance/calibration). These functions, even if not dependent on the laboratory, must operate in accordance with the applicable points of UNI EN ISO 15189 and the laboratory must co-ordinate with them to comply with the applicable requirements.

5.4.2 The requirement of the standard applies.

5.5 Objectives and policies

The requirement of the standard applies.

5.6 Risk management

The requirement of the standard applies.

6. Resource requirements

6.1 General

The requirement of the standard applies.

6.2 Personnel

6.2.1 The requirement of the standard applies.

6.2.2 The requirement of the standard applies.

When defining personnel competence requirements, the Laboratory must take into account any mandatory requirements applicable to the activities subject to accreditation (e.g., registration in professional registers, possession of specialisations)

6.2.3 The requirement of the standard applies.

6.2.4 The requirement of the standard applies.

6.2.5 The requirement of the standard applies.

6.3 Structures and environmental conditions

The requirement of the standard applies.

6.4 Equipment

The requirement of the standard applies.

Please remember to also manage the equipment in the emergency trolley.

6.5 Calibration of equipment and metrological traceability

6.5.1 The requirement of the standard applies.

6.5.2 The requirement of the standard applies.

6.5.3 The requirement of the standard applies.

In addition, clarifications on the policy of metrological traceability of measurement results are given below:

a) Traceability obtained by means of a competent laboratory

In accordance with the provisions of the document ILAC P10, when metrological traceability of the results is required and this traceability is not given by the use of certified reference materials, which are dealt with in the next point, the equipment must be calibrated by:

1 - National Metrological Institutes (NMI) and other designated institutes whose services are suitable and covered by the CIPM-MRA[3] agreement within the limits of the internationally accepted metrological capabilities (CMC) and published in the KCDB by the BIPM[4].

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[3] CPM-MRA: CIPM Mutual Recognition Arrangement

[4] KCDB: BIPM Key Comparison DataBase: contains information on internationally accepted metrological capabilities (CMC)

The presence of the CIPM MRA note and/or logo on the Calibration Certificates demonstrates the coverage of the CMCs; where the note and/or logo are not present, their inclusion being discretionary, the laboratory must verify the coverage of the CMCs by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org.

or by

2 - Accredited calibration laboratories whose services are suitable and whose accreditation is granted by ABs signatory to the EA-MLA or ILAC-MRA agreement for the scope "calibration" in the framework and within the limits provided for by the CMCs published by ABs.

The use of calibration certificates issued within the framework of these two possibilities is to be considered of equal validity, notwithstanding the different value of the calibration uncertainties, which must be adapted to the needs of the laboratory.

If it is not possible to obtain metrological traceability from either of the two cases reported above, the following alternatives are acceptable, provided that appropriate evidence is available on the competence of the supplier, with particular reference to traceability and measurement uncertainty of the calibrations provided:

3a - National Metrological Institutes whose services are suitable but not covered by the CIPM-MRA agreement. This case should not be chosen on the basis of purely economic or logistical reasons, but should be considered as a last resort when cases 1 and 2 are not available.

or

3b - Calibration laboratories whose services are suitable, but not covered by ILAC agreements or by regional agreements recognized by ILAC. This option should only be chosen if type 1, 2 and 3a suppliers are not available. The modalities by which the CAB has assessed the supplier are subject to assessment by ACCREDIA.

In cases 3a and 3b the laboratories must ensure evidence of the declared metrological traceability and measurement uncertainty; this evidence is evaluated by ACCREDIA (see the guide reported in ILAC P10 Appendix A).

Calibrations carried out by the manufacturer of the equipment or by other laboratories not accredited for the specific calibrations are not accepted, except for case 3b above.

b) Traceability by means of certified values of certified reference materials

If the metrological traceability is provided by producers of reference materials (RMP) through certified reference materials (CRM), it is considered, in accordance with ILAC P10, that the certified values assigned to a CRM have a valid metrological traceability when produced by:

4 - NMIs whose production service is included in the KCDB of the BIPM.

The presence of the CIPM MRA note and/or logo on the reference material certificate is a demonstration of this inclusion; where the note and/or logo are not present, their inclusion being discretionary, the laboratory must verify that the service is included by consulting the BIPM website at: www.bipm.org or kcdb.bipm.org.

or

5 - RMPs accredited to ISO 17034, whose service is included in the field of accreditation,

or

6 - Organizations listed in the JCTLM database (www.bipm.org).

Regarding case 5, considering that the accreditation process for RMPs is still evolving and CRMs may not be available at accredited RMPs, if the CRMs are produced by non-accredited RMPs, the laboratory must demonstrate that such CRMs come from a competent RMP and are suitable for the intended use. The extent of the verifications made by the laboratory regarding the manufacturer depends on the information available as well as on the nature of the material.

If it is not technically possible to document the metrological traceability to the international system of measurement units (SI), the laboratory must, in accordance with ILAC P10:

7a - use certified values of certified reference materials supplied by a competent producer,

or

7b - provide evidence of adequate comparison to reference measurement procedures with specified methods or consensus references clearly described and accepted as suitable for the intended use.

Note 1: When metrological traceability to SI units alone is not appropriate or applicable for that specific application, a clearly defined measurand should be selected. Establishing metrological traceability includes both proof of the identity of the measured property and the comparison of the results with an appropriate declared reference. The comparison is established by ensuring that measurement procedures are adequately validated and/or verified, that measurement equipment is correctly calibrated, and that measurement conditions (such as ambient conditions) are assured in the form necessary to provide a reliable result.

Note 2: Surplus materials are often available from suppliers of VEQ[5] (PT). The use of these materials to ensure the validity of the results should not be carried out if the supplier of these materials cannot provide further information on the stability of the value of the property and the matrix of the test material.

Note 3: If the value assigned to the material by the VEQ (PT) supplier is determined based on the consensus value of the participants and the VEQ (PT) participants have used different measurement procedures and the result is operationally defined, this assigned value cannot be used to establish the metrological traceability of results (see also ISO 33405).

Internal calibrations

It should be noted that if the laboratory carries out the calibration of its own instrumentation used for measurement itself (hereinafter referred to as internal calibration), the reference standards used for calibration (e.g., the reference thermometer used for calibrating temperature gauges, or the weigher used for calibrating

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[5] The term VEQ (Valutazione Esterna della Qualità) corresponds to the acronym EQA (External Quality Assessment), also known as Proficiency Testing (PT).

scales) must in turn be calibrated in accordance with the above cases and be the property of the laboratory or the legal entity to which the laboratory belongs.

Such internal calibration must also be carried out using appropriate calibration procedures and competent personnel.

Internal calibration is also considered to be that performed by personnel from outside the laboratory, provided that the laboratory possesses the reference standards and has incorporated the calibration procedure used by external personnel into its management system. The documented instructions concerning calibration operations (calibration procedures) must, where applicable, give indications (or contain references to other documents) for:

- the issuing of calibration reports;
- the affixing of labels or other identification of the calibration status of the equipment being calibrated;
- the evaluation of calibration results (acceptability criteria of calibration results).

Please note that calibration procedures that do not refer to recognised calibration methods (e.g., ISO 8655-6 for calibration of piston micropipettes) are only accepted if validated by the laboratory.

It is also considered to be an internal calibration when it is carried out by a metrology service belonging to the same organisation as the laboratory, but which is not integrated into the laboratory (e.g., in the case of hospitals, Clinical Engineering). In this case, the metrology service must have a management system that meets the applicable requirements of UNI EN ISO/IEC 17025. [See, in this regard, the guidance in Annex A of ILAC P10 document] This system may be autonomous or integrated into that of the medical laboratory. The metrology service will be subject to ACCREDIA evaluation and on-site assessments will, where possible, be combined with those of the laboratory. The internal metrology service carrying out an internal calibration will not be able to issue a calibration report with the ACCREDIA logo or offer its services under accreditation to third parties, implying that the metrology service is accredited to ISO/IEC 17025.

6.6 Reagents and consumables

The requirement of the standard applies.

6.7 Agreements regarding the performed service

The requirement of the standard applies.

The laboratory must inform its users about the meaning of accreditation and the accreditation of the activities covered by the service agreements.

All activities covered by accreditation must be contractually managed as accredited (see §7.4.1), unless explicitly requested otherwise by the user. In that case, the user's request must be clearly stated in the contractual agreements (ref. EA 3/01).

It should be noted that in cases where accreditation is mandatory or when the reports must be provided to a third party, it is not possible to agree with the user to perform activities as non-accredited (ref. EA 3/01).

6.8 Products and services provided externally

The requirement of the standard applies.

Accreditation for examinations provided externally on a continuous basis is excluded (see section 5.3 of ISO 15189).

7. Process requirements

The requirement of the standard applies.

7.1 General

The requirement of the standard applies.

7.2 Pre-examination processes

The requirement of the standard applies.

For the accreditation of pre-examination activities, also refer to §5.3.1 of this document.

7.3 Examination processes

7.3.1 General

The requirement of the standard applies.

In the case of missing information on performance characteristics in the instructions for use, or in the absence of documented information from the method manufacturer/developer, the performance characteristics relevant to the intended use are to be determined by the laboratory.

7.3.2 Verification of examination methods

The requirement of the standard applies.

It should be noted that in order to be able to compare laboratory performance with that specified by the producer or procedure, it is important that the statistics and terminology are the same.

7.3.3 Validation of examination methods

The requirement of the standard applies.

Methods subject to validation include in-house methods (see definition para. 3), thus including those declared by the manufacturer for research use (RUO), when used by the laboratory for diagnostic purposes.

Appropriate validation procedures are those based on recognised protocols, (e.g. regulated or defined by scientific reference organisations such as CLSI, IFCC, EFLM, or other national organizations that have demonstrated the adoption of a process based on the consensus of the stakeholders).

The laboratory that applies for accreditation, with fixed scope, of examinations performed according to in-house methods, must send ACCREDIA a copy of these methods, accompanied by the validation and suitability statement (summary of the records foreseen in §7.3.3. e) of the standard). Each revision must be sent to ACCREDIA; if the laboratory does not send ACCREDIA such documentation, the relative examinations will be excluded from accreditation.

In the case of flexible accreditation, for examinations performed according to in-house methods, ACCREDIA reserves the right to request copies of these procedures and the relevant validation and suitability statements (summary of the records provided for in §7.3.3 e) of the standard).

7.3.4 Evaluation of measurement uncertainty (MU)

The requirement of the standard applies.

The communication of the measurement uncertainty to the applicant must also contain the associated confidence level and the coverage factor used. It is generally accepted to use a coverage factor k = 2, corresponding to a confidence level of 95%. Example of a statement of the confidence level and coverage factor used: "The uncertainty reported in this document is the expanded uncertainty and is obtained by multiplying the compound standard uncertainty by a coverage factor k = 2, which for a normal distribution leads to a confidence level of approximately 95%".

7.3.5 Biological reference intervals and clinical decision limits

The requirement of the standard applies.

7.3.6 Documentation of examination procedures

The requirement of the standard applies.

7.3.7 Ensuring the validity of examination results

The requirement of the standard applies.

7.3.7.1. General

The requirement of the standard applies.

7.3.7.2 Internal Quality Control (IQC)

The requirement of the standard applies.

7.3.7.3 External Quality Assessment (EQA)

The requirement of the standard applies.

As part of its assessments, ACCREDIA uses, among other things, the results of external quality assessments (EQA) to verify and evaluate the laboratory's compliance with the requirements of UNI EN ISO 15189.

In order to obtain or maintain accreditation, the laboratory is required to provide evidence of successful participation in EQAs, if available and appropriate. If suitable EQAs are not available, self-organized interlaboratory comparisons between two or more laboratories may be recognized.

A strategy and plan for EQAs must be described within the management system documentation. The frequency of participation in EQAs for each specific area of technical competence must be established by the laboratory, taking into due consideration the mandatory requirements, risk, representativeness, and other aspects outlined in the ACCREDIA Regulation RT-39.

The plan must be reviewed at least once a year and modified if necessary.

The laboratory must maintain a summary table of the results of all EQAs and any interlaboratory comparisons, covering the current year and at least the previous three years, where available. The table must include at least the following information:

- assignment to the relevant technical area
- dates of the EQA implementation
- EQA provider
- sample matrix
- determined parameters
- parameters for which the EQA was not passed, where applicable, including assessment criteria such as score, z-score, En.

7.3.7.4 Comparability of examination results

The requirement of the standard applies.

7.4 Post-examination processes

7.4.1 Reporting of results

The requirement of the standard applies.

Regarding the use of the mark (or reference to accreditation) on reports, please refer to the document RG-09.

Please note that the use of the ACCREDIA mark (and/or reference to accreditation) on reports is only allowed if the report contains at least one accredited examination performed by the laboratory itself.

Regarding point c) of 7.4.1.7, if the external laboratory that performed the examinations is accredited ISO 15189 for those specific activities, it is not necessary to indicate that those examinations are not accredited, provided that the accreditation number of the external laboratory is indicated and, in the case of a non-Italian accreditation body, the name of the accrediting body.

Concerning report corrections, it is specified that reports must be corrected and reissued in case of

- incorrect or misleading use of the ACCREDIA Mark or reference to accreditation
- errors in examination results

- any other deficiency or error that may lead to their misuse or compromise the correct understanding of the results.

When a report containing this type of deficiency is identified, the laboratory must provide, as part of the management of the non-compliant activity, to review all the reports issued, trace, correct and re-issue all those affected by the same deficiencies.

In the case of corrections, the new document issued by the laboratory must clearly indicate whether the original report is cancelled and replaced.

In exceptional cases where it is necessary to correct purely formal (editorial) aspects of reports already issued without changing their validity, it may be acceptable to issue a general correction document, provided that the information required by the standard in §7.4.1.8 is guaranteed (e.g., clear identification of reports affected by the same deficiency, corrected information, reasons for correction).

7.4.2 Post-examination handling of samples

The requirement of the standard applies.

7.5 Non conforming activity

The requirement of the standard applies.

Please note that for non-conforming activities that impact on the possibility of maintaining the re-quirements for accreditation, the laboratory must communicate ACCREDIA the accreditation self-suspension for the non-conforming activities.

7.6 Data control and information management

The requirement of the standard applies.

7.7 Complaints

The requirement of the standard applies.

7.8 Business continuity planning and emergency preparedness

The requirement of the standard applies.

8. Management system requirements

8.1 General requirements

8.1.1. The requirement of the standard applies.

At the first accreditation and renewal stage, the Laboratory shall provide ACCREDIA with sufficient information to allow an understanding of how the Laboratory operates to achieve and maintain compliance with the requirements of UNI EN ISO 15189 and ACCREDIA.

To this end, the Laboratory must indicate at least the following on the appropriate ACCREDIA forms (*self-assessment*):

- a brief description of how the laboratory applies the requirements of UNI EN ISO 15189, without excessive reference to procedures and/or annexes
- the main responsibilities involved in the implementation of procedures and record keeping
- in the case of laboratories with several locations, including those where samples are collected and taken (sample collection facilities), an indication of where the activities are carried out and records kept
- in the case of laboratories seeking accreditation also for examinations performed at the point of care (POCT) a brief description of how the laboratory applies the requirements of Annex A of UNI EN ISO 15189, without excessive reference to procedures and/or annexes
- any exclusions or inapplicability of certain requirements, together with the corresponding reasons.

As an alternative to *self-assessment*, the laboratory may prepare a Management System Manual including the above information.

In the event of significant changes to the Laboratory's organisation and/or adopted policies and procedures, ACCREDIA may request an update of the *Self-Assessment*/Management System Manual.

Please note that the self-assessment is a form prepared by ACCREDIA and filled in by the Laboratory, for the purpose of submitting the application for accreditation and, as such, does not replace what is required by the UNI EN ISO 15189 standard at § 8.2.1.

8.1.2 The requirement of the standard applies.

8.1.3 The requirement of the standard applies.

8.2 Management system documentation

The requirement of the standard applies.

8.3 Control of management system documents

8.3.1 The requirement of the standard applies.

In the case of updates to documents of external origin (e.g. standards, methods, instructions for use of IVDs and equipment, and other documents that the laboratory must incorporate into its management system), unless a transitional period is defined otherwise, and without prejudice to any mandatory provisions, the laboratory is obliged to apply the new versions within three months of issue.

8.3.2 The requirement of the standard applies.

Handwritten corrections are permitted on documents for internal use only, if there is an urgency. Such amended documents shall be updated promptly.

8.4 Control of records

8.4.1 The requirement of the standard applies.

8.4.2 The requirement of the standard applies.

8.4.3 The requirement of the standard applies.

In particular, all records must be kept for a period of time at least equal to that defined by the leg-islation applicable to the activities subject to accreditation and, if not provided for, must be main-tained for at least 48 months.

8.5 Actions to address risks and opportunities for improvement

The requirement of the standard applies.

8.6 Improvement

The requirement of the standard applies.

8.7 Nonconformities and corrective actions

The requirement of the standard applies.

8.8 Evaluations

8.8.1. General

The requirement of the standard applies.

8.8.2. Quality indicators

The requirement of the standard applies.

In order to promote the appropriateness of the improvement objectives that the laboratory defines and monitors, the use of harmonised indicators is recommended (See for example the list of indica-tors of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group and the CLSI document QMS12).

8.8.3 Internal audits

The requirement of the standard applies.

Internal audits may be performed either by internal personnel or by external assessors, provided that objectivity and impartiality of the process is ensured and provided that the personnel perform-ing the audit demonstrates the necessary competence with regard to knowledge of the UNI EN ISO 15189 standard and the requirements of accreditation.

Second- and third-party audits cannot replace internal laboratory audits.

8.9 Management review

8.9.1. The requirement of the standard applies.

Extraordinary reviews may become necessary as a result of findings whose corrective actions re-quire special investments (e.g., purchase of new equipment, recruitment of staff) or organisational-structural changes (laboratory layout, staff reorganisation).

8.9.2 The requirement of the standard applies.

8.9.3 The requirement of the standard applies.

Annex A – additional requirements for point-of-care testing (POCT)

The requirement of the standard applies.

The laboratory may only apply for accreditation of examinations performed in the proximity of patients (POCT) if it ensures compliance with the applicable requirements of UNI EN ISO 15189, including those set out in Annex A. The laboratory does not necessarily have to have the same examinations requested at the POCT in its scope of accreditation.

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