

ISO 15189 Medical Laboratory Accreditation



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ISO 15189 Medical Laboratory Accreditation

Accreditation: A tool to demonstrate the competence of medical laboratories and ensure the delivery of timely, accurate and reliable results.

Medical laboratory services are essential in the diagnosis and assessment of the health of patients. Their services encompass arrangements for requisition, patient's preparation, patient's identification, collection, transportation, storage, processing and examination of clinical samples, together with subsequent result validation, interpretation, reporting and advice. Medical laboratory services should therefore meet the needs of all patients, clinical personnel responsible for patient care and any other interested parties.

The laboratory's aim is to not only to provide accurate results, but to do so for the right patient within a meaningful timeframe with regard to clinical management, using appropriate laboratory procedures and with respect for ethics, confidentiality and the safety of the patient.

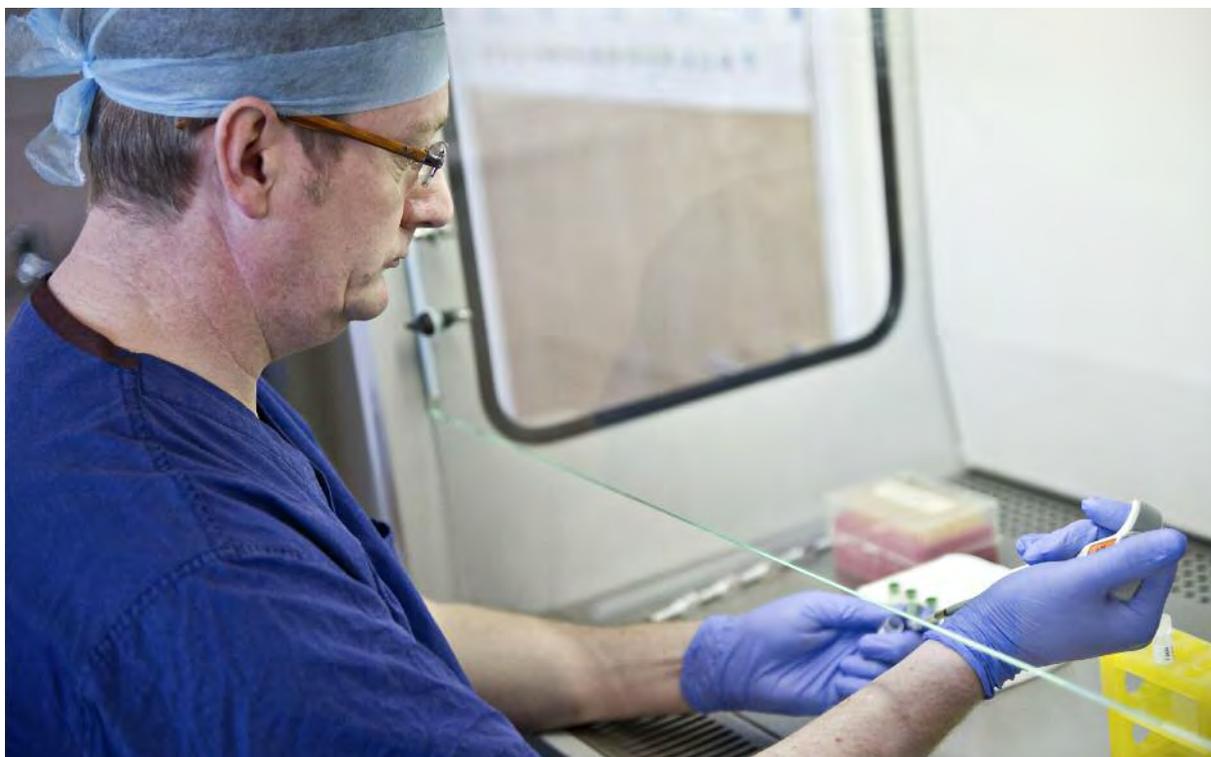


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A Recognition of Competence

To demonstrate the quality and reliability of their services, medical laboratories can seek accreditation to ISO 15189: *Medical laboratories – Particular requirements for quality and competence*, an internationally recognised standard that contains the requirements necessary for diagnostic laboratories to demonstrate their competence to deliver reliable services.

ISO 15189 covers the essential elements for medical laboratories to demonstrate the quality and competence of their services, as well as to consistently deliver technically valid test or “examination” results as they are referred to in the standard. The standard, which was developed with strong involvement from the medical, scientific and clinical community, is for the use of medical laboratories to foster a culture of continuous improvement through developing their management systems and maintaining their own technical competence; and for accreditation bodies to confirm or recognise the competence of these laboratories through accreditation.



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Medical Laboratory Accreditation

Accreditation to ISO 15189 involves the independent assessment of a laboratory to determine competence, impartiality and consistency. It addresses the qualifications and on-going competency of personnel involved in medical laboratory examinations, the laboratory accommodation, equipment, re-agents and supplies, pre-analytical and analytical factors, quality assurance considerations, and post-analytical factors.

Specialist scientific and clinical assessors, with expertise in the relevant discipline of practice, conduct a thorough evaluation of all factors in the laboratory that affect the production of test data, including:

- technical competence of staff;
- validity and appropriateness of test methods, including pre and post analytical elements such as sample collection and clear and effective reporting;
- sample quality, including patient identification, handling and transport to maintain sample integrity;
- a review of the history relating to previous patient results and any known clinical diagnoses;
- procedures relating to the use of “referral laboratories” such as specialised testing centres for specific diseases;
- traceability of measurements and calibrations to relevant standards;
- suitability, calibration and maintenance of test equipment;
- testing environment;
- quality assurance of test data;
- acceptable turnaround time;
- application of appropriate ethical values.



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ISO 15189 is based on ISO/IEC 17025 (*General requirements for the competence of testing and calibration laboratories*) and ISO 9001 (*Quality management systems – Requirements*). It therefore incorporates the quality systems elements addressed in ISO 9001 certification, as well as the general requirements of a testing laboratory.

Accreditation to ISO 15189 places five additional critical criteria on medical laboratories which include:

- providing advice on the type of sample, and testing that may be required;
- interacting with clinical staff by placing a responsibility on the laboratory to liaise with clinicians who refer patient samples for testing about the quality of their service;
- providing opinions on results of testing in relation to diagnosis and patient care;
- collecting samples or if not, providing information on collection procedures, sample containers and sample volumes;
- ethical practice – first duty is to the patient, not to the ‘customer’.

To ensure continued compliance, accredited laboratories are regularly reassessed to check that they are maintaining their standards of technical expertise. These laboratories will also be required to participate in regular proficiency testing programs (known as external quality assurance programs or EQAS) as an on-going demonstration of their competence.



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ISO 15189 Laboratory Accreditation versus ISO 9001 Certification

The ISO 9001 standard is widely used in manufacturing and service organisations to evaluate their system for managing the quality of their products or service. Certification of an organisation's quality management system against ISO 9001 confirms the compliance of the management system to this standard.

ISO 15189 accreditation on the other hand provides recognition of the medical laboratory's competence including both the management system and technical practice. Whilst medical laboratories may be certified to ISO 9001, such certification does not make any statement about the technical competence of a laboratory.



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What are the Benefits of Accreditation?

Accreditation is an enabler of quality and a core component of good clinical management; it is patient-focused, impartial, objective, and operates within a peer review model. It provides many benefits such as those detailed below.

For Healthcare Regulators

The need to drive up the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for regulators of healthcare services. Accreditation can be used as a tool to support the commissioning or specification of medical laboratory services that are technically competent, safe and reliable, and that continually improve the experience for patients by:

- providing an independent assurance of quality and safety that supports world-class decisions on how to deliver better care and value for patients;
- providing a mechanism for measuring quality improvement;
- supporting consistency in the quality of care; and
- encouraging innovation

For Patients

Accreditation requires that the laboratory assesses the value and relevance of the testing in relation to the patient's clinical management. It demonstrates that medical laboratories comply with an international standard, confirming that:

- there is consistency in the quality of care;
- the service has up-to-date-technologies and its procedures and techniques reflect current best practice; and
- staff providing the service are competent to undertake the tasks they perform.

For Medical Laboratories:

Accreditation provides proof that a laboratory complies with best practice. It also offers authoritative assurance of the technical competence of a laboratory to undertake specified analysis or measurements according to validated methods. Accreditation:

- provides an opportunity for external perspectives on the laboratory's practice;
- can prevent the unnecessary duplication of information gathering on performance often required by regulatory bodies;
- encourages the sharing of best practice;
- stimulates innovation;
- reduces risk; and
- provides international recognition.



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How to find an Accredited Laboratory

Thousands of medical laboratories worldwide are accredited to ISO 15189. These laboratories usually issue reports bearing some type of symbol or endorsement indicating their accreditation; however, the scope of accreditation should be checked, and should be supplied by the laboratory upon request.

Accreditation bodies in many economies publish lists or directories of the laboratories they have accredited, together with laboratories contact details and information on their testing capabilities. If necessary, you can contact the accreditation body and find out further information.

To find out if your economy has one or more laboratory accreditation bodies involved in accrediting medical laboratories, visit the **ILAC** website and use the directory of laboratory accreditation bodies available on this website. You will also find **directories of accredited laboratories** for many economies on this website.



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International Recognition

Through a system of international agreements, accredited laboratories receive a form of international recognition which allows their data to be more readily accepted in overseas markets. Such international agreements, called Mutual Recognition Arrangements (MRAs), are crucial in enabling test data to be accepted between different economies.

Many accreditation bodies have signed a Multi-Lateral Mutual Recognition Agreement called the ILAC Arrangement. Full details for the ILAC Arrangement and the list of signatories can be found on the **ILAC** website.



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About ILAC

ILAC facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement – the ILAC Arrangement – among Accreditation Bodies (ABs) in order that the data and test results issued by laboratories and inspection bodies, collectively known as Conformity Assessment Bodies (CABs), accredited by ILAC Accreditation Body members are accepted globally. Thereby, technical barriers to trade, such as the re-testing of products each time they enter a new economy is reduced, in support of realising the free-trade goal of *“accredited once, accepted everywhere”*.

In addition, accreditation reduces risk for business and its customers by assuring that accredited CABs are competent to carry out the work they undertake within their scope of accreditation.

Further, the results from accredited facilities are used extensively by regulators for the public benefit in the provision of services that promote an unpolluted environment, safe food, clean water, energy, health and social care services.

ABs that are members of ILAC and the CABs they accredit are required to comply with appropriate international standards and the applicable ILAC application documents for the consistent application of those standards.

ILAC is the global association for the accreditation of laboratories, inspection bodies, proficiency testing providers and reference material producers, with a membership consisting of accreditation bodies and stakeholder organisations throughout the world.

It is a representative organisation that is involved with:

- the development of accreditation practices and procedures,
- the promotion of accreditation as a trade facilitation tool,
- supporting the provision of local and national services,
- the assistance of developing accreditation systems,
- the recognition of competent testing (including medical) and calibration laboratories, inspection bodies, proficiency testing providers and reference material producers around the world.

ILAC actively cooperates with other relevant international organisations in pursuing these aims.

ABs having signed the ILAC Arrangement are subject to peer evaluation via formally established and recognised regional cooperation bodies using ILAC rules and procedures prior to becoming a signatory to the ILAC Arrangement.

The ILAC website provides a range of information on topics covering accreditation, conformity assessment, trade facilitation, as well as the contact details of members. Further information to illustrate the value of accredited conformity assessment to regulators and the public sector through case studies and independent research can also be found at:

www.publicsectorassurance.org



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