Medical Laboratory Accreditation
Accreditation is a mark of quality and is objective proof that a laboratory is not only competent, but safe, patient-focused, efficient and reliable.
UKAS & Medical Laboratory Accreditation

UKAS accredits medical laboratories against the international standard ISO 15189: 2012, which specifies the global requirements for quality and competence. UKAS accreditation provides reassurance to patients, commissioners and healthcare providers of the quality of a diagnostic service. Through independent and impartial evaluation against recognised standards, accreditation seeks to validate and recognise success, as well as drive up the quality and consistency of service delivery by aspiring towards excellence with quality patient outcomes at its core.

UKAS is the sole national accreditation body of the UK, recognised by Government to assess and declare the competence of an organisation against internationally agreed standards. UKAS is appointed as the national accreditation body by Accreditation Regulations 2009 (SI No 3155/2009). UKAS is independent of Government, subject to peer review and has a duty to act in the public interest.

Background

Medical laboratory accreditation began in the early 1990’s with Clinical Pathology Accreditation (CPA) UK Limited a joint initiative of the Royal College of Pathologists, the Association of Clinical Pathologists, the Institute of Biomedical Science and the Association for Clinical Biochemistry, supported by the Department of Health.

Initially, accreditation was confined to medical laboratories, but in 1996 this was extended to the accreditation of EQA schemes and later, Point of Care Testing services.

CPA became a wholly owned subsidiary of UKAS in 2009 and as part of the strategy of both companies to contribute to the modernisation of pathology services in the UK, a transition to UKAS accreditation for all CPA accredited medical laboratories and EQA Providers began in October 2013. This transition saw all CPA accredited laboratories transfer to UKAS accreditation against ISO 15189:2012 by 2018.

CQC Recognition – providing valuable information to regulators

CQC recognises the potential value of clinical service accreditation and peer-review schemes as information sources to support its inspections.

Such schemes have the potential to provide useful intelligence and provide independent assurance that accredited services meet standards.

UKAS medical laboratory accreditation is recognised by CQC and has been approved for use within CQC hospital inspection methodology.
NHS England, NHS Improvement and the CQC are committed to, and strongly endorse, participation in accreditation schemes for diagnostic services. Participants in these schemes undergo a rigorous independent review of their services, at regular intervals in time, and have systems in place for ongoing and continuous quality management and service improvement.”

*NHS England, NHS Improvement, Care Quality Commission (CQC), Communication to Chief Executives and Medical Directors of all NHS Trusts, October 2018*
How to Apply

To make an application to UKAS for assessment and accreditation against ISO 15189, visit www.ukas.com to download a copy of the relevant application forms:

- UKAS Application Form
- UKAS Agreement
- AC6 Medical Testing Laboratory Accreditation Application Form

Completed applications can be sent by post, or by email to applications@ukas.com. A non-refundable application fee is payable on application and information about how to pay can be found within the application documents.

UKAS Training Academy

UKAS has a comprehensive training portfolio designed for both novice and experienced UK and international participants to learn more about assessment and accreditation practices, standards, and conformity assessment systems.

Delivered by technical and accreditation experts, UKAS training courses can take your skills to the next level you need to make a practical difference in your organisation.

Visit www.ukas.com for details of our range of training courses available and to book your place. Discounts are available for bookings of multiple delegates.

We can be flexible with course location and can deliver any of our courses in-house at your organisation.

Please contact training@ukas.com to discuss your requirements.
ISO/IEC 15189:2012

ISO/IEC 15189:2012 is a globally recognised standard that specifies requirements for quality and competence particular to medical laboratories. It is for use by medical laboratories in developing their quality management systems and assessing their competence.

The standard focuses on the continuum of care directly connected with improved patient safety, risk mitigation and operational efficiency, specifically in medical laboratories.

### International Recognition

As a full member of the International Laboratory Accreditation Cooperation (ILAC), UKAS is a signatory to Multilateral Mutual Recognition Arrangements, which allow for the global acceptance and recognition of accredited test reports. As a consequence, accredited laboratories will find that their certificates are accepted in over 80 global economies.

Laboratories will also be able to bid on a level playing field for contracts in overseas territories, as procurers will have confidence that they have been assessed to the same standard as their local providers.

A full list of ILAC signatory accreditation bodies can be found on the ILAC website [www.ilac.org](http://www.ilac.org)

### Technical Competence

- Technical competence of staff
- Validity and appropriateness of test methods
- Traceability of measurements and calibration to international standards
- Testing environment
- Sampling, handling and transporting test items
- Validity of information systems
- Pre-examination and post-examination activities

### Management Competence

- Quality management systems
- Controlling documents and records
- Qualifying external services and suppliers
- Resolving complaints
- Assessing user feedback
- Internal auditing
- Advisory services
- Agreements with users of the service
The Benefits of Medical Laboratory Accreditation

**Benefits for Commissioners:**
Raising the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for Commissioners of Healthcare services. Accreditation is a tool that can be used by Commissioners to support informed and effective purchasing, good governance and public confidence by:

- Providing independent assurance of quality and safety that supports objectives to deliver better care and value for patents
- Providing a mechanism for measuring quality improvement
- Supporting consistency in the quality of care
- Encouraging innovation and continuous service improvements

**Benefits for Patients:**
Accreditation demonstrates to patients that the medical laboratory has been through a robust cycle of assessment and complies with a defined standard. Through independent assurance, it gives confidence to the patient that:

- The laboratory consistently delivers a high quality and safe service
- The laboratory has up-to-date technologies and its procedures and techniques reflect current best practice
- The staff providing the service are competent to undertake the tasks they perform
- Outcomes are reliable and can be trusted
- The laboratory is committed to continuous service improvement

**Benefits for Medical Laboratories:**
Accreditation allows medical laboratories to demonstrate that they comply with defined standards and best practice. It provides authoritative assurance of the technical competence of the laboratory to undertake specific analysis or measurements according to validated methods. Accreditation:

- Prevents unnecessary duplication of gathering information on performance related to the Care Quality Commission (CQC) registration process
- Encourages the sharing of best practice
- Stimulates innovation and can act as a leverage for change or service improvement
- Brings together other kinds of quality assessment into a single package
- Reduces risk and controls cost
- Provides a competitive edge during any tender process

UKAS accreditation can also provide valuable information to regulators. Medical Laboratory accreditation is recognised by CQC and has been approved for use within the CQC inspection methodology. UKAS also has agreements in place with the Human Tissue Authority and with Public Health England, in relation to newborn and antenatal screening, that allow joint assessments to be conducted. Joint assessments incorporate the additional quality requirements within UKAS assessments to ISO 15189: 2012, avoiding the need for multiple assessments.
External Quality Assessment (EQA) Accreditation

UKAS accredits Proficiency Testing (PT) Providers against the requirements of ISO/IEC 17043: 2010 Conformity assessment – General requirements for proficiency testing. Previously known as EQA accreditation delivered by CPA, the transition of CPA EQA accreditation to UKAS PT accreditation was completed in 2016, when the CPA EQA Standards were withdrawn.

The purpose of proficiency testing is to assess performance of laboratories for their conduct of specific tests or measurements. It provides an opportunity to undertake comparisons and have independent appraisal of a laboratory’s data compared to reference values, other performance criteria or to the performance of similar laboratories. Without such opportunities there are risks that a laboratory’s data may have errors, biases or significant differences compared to similar laboratories.

Point of Care Testing (POCT) Accreditation

UKAS accredit POCT providers against ISO 22870:2006 Point-of-care testing (POCT) – Requirements for quality and competence, which is assessed in conjunction with ISO 15189:2012. CPA POCT accreditation transitioned to UKAS as part of the medical laboratory transition process, which was completed in 2018.

“...

...accreditation schemes are so important. Independent assessment provides an objective view of what is being delivered and the standards and approach of the process itself do an enormous amount to embed a quality culture.”

Professor Sue Hill OBE, Chief Scientific Officer, NHS England
How to Find Accredited Services

The latest information about UKAS accredited medical laboratories can be found on the UKAS website.

Definitions of the accreditation statuses available for medical laboratories are listed below:

- **Accredited** – accreditation has been granted following a full assessment where there is full conformity with the relevant standard.

- **Suspended** – accreditation has been temporarily suspended. Suspensions can be applied to a laboratory’s entire accredited scope, or just to specific activities, which means that this work is not currently accredited. This status can either be imposed, or at the laboratories’ request, for a variety of different reasons.

Any applicant laboratories currently in the Initial Assessment phase are not published on the UKAS website due to confidentiality agreements.

Only accredited laboratories are permitted to display the UKAS accreditation symbol.
Diagnostic Imaging Accreditation

UKAS accredits diagnostic imaging services against the requirements of the QSI Standard; a standard developed by The Royal College of Radiologists (RCR) and the College of Radiographers (CoR). UKAS accreditation is formal recognition that an imaging services provider has demonstrated the competence to deliver against key performance measures related to patient experience, clinical outcomes, patient and staff safety and efficient use of resources.

Medical Physics & Clinical Engineering (MPACE)

UKAS accredits MPACE services against the requirements of BS 70000. The overall aim is promote the delivery of quality services and outcomes in areas that include the correct diagnosis and safe treatment for illnesses and rehabilitation such as cancer and mobility. It also covers the commissioning, maintenance and innovation of medical equipment.

Improving Quality in Physiological Services (IQIPS)

The IQIPS scheme is a professionally-led assessment and accreditation scheme that aims to improve services, care and safety for patients undergoing physiological tests, examinations and procedures. Accreditation is available for eight physiological science disciplines across the NHS and private sector.

For further information about any of these areas, please email sales@ukas.com
How to Contact UKAS

If you would like further information about UKAS, or medical laboratory accreditation, please visit the UKAS website www.ukas.com

Tel: +44 (0) 1784 429000

Email: MedLabsCustomerService@ukas.com