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.
About UKAS, CPA & Medical Laboratory Accreditation

Since 1992, Clinical Pathology Accreditation (CPA) has been the leading, reputable and authoritative provider of medical laboratory accreditation, External Quality Assessment (EQA) Scheme accreditation and more recently, Point of Care Testing Accreditation in the UK and overseas.

CPA is now a wholly owned subsidiary of the United Kingdom Accreditation Service (UKAS) and as part of the strategy of both companies to contribute to the modernisation of pathology services in the UK, a transition of accreditation for all CPA accredited medical laboratories began in October 2013. This transition will see CPA accredited laboratories transfer to UKAS accreditation against ISO 15189:2012 before the end of 2018.

About CPA

CPA originated from an 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. CPA, a non-profit distributing organisation acting in the public interest, was incorporated on 6th January 1992 as a joint venture between these organisations.

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.

In 1998, CPA signed an agreement with UKAS as both organisations shared common interests relating to medical laboratory accreditation. This relationship strengthened in 2009 as CPA became a wholly owned subsidiary of UKAS.

About UKAS

UKAS is the national accreditation body in the UK, recognised by Government to assess and declare the competence of organisations against internationally agreed standards. UKAS is independent of Government, subject to peer review and has a duty to act in the public interest.

Following the implementation of European Regulation EC 765/2008, UKAS has been formally appointed as the National Accreditation Body providing, for the first time, a legal basis for accreditation. The influence and use of UKAS accreditation continues to grow across a wide range of areas to support the delivery of informed and effective purchasing, good governance and public confidence.

UKAS fully complies with the international standard ISO/IEC 17011: 2004, which details the requirements for accreditation bodies assessing accrediting conformity assessment bodies.
The Transition to UKAS Accreditation

All medical laboratories accredited against the CPA Standards are now having to undergo a transition from CPA accreditation to UKAS accreditation, against the internationally recognised standard ISO 15189:2012 Medical Laboratories – Requirements for quality and competence.

The transition is being rolled out based on existing visit schedules so that a laboratory’s transition visit coincides with their next CPA main visit. The transition visit includes an assessment against the requirements of the CPA Standards and also ISO 15189:2012. The assessment of both standards runs concurrently in one visit to allow laboratories to maintain their CPA accreditation until they are granted UKAS accreditation against ISO 15189:2012.

CPA no longer carries out assessments against the CPA Standards alone, with the exception of surveillance visits until March 2016, and is no longer accepting any new applications for accreditation against the CPA Standards. Similarly, the transition only applies to CPA accredited organisations so any new or non-accredited organisations are required to apply directly to UKAS for assessment against ISO 15189:2012.
It is anticipated that the transition will be completed in 2018, at which time CPA accreditation will be formally withdrawn.

Reasons for the transition
The CPA Standards were based upon the requirements of ISO 15189:2007 so moving towards assessment directly against ISO 15189:2012 means that gap analysis between the two standards is no longer necessary, and as ISO 15189:2012 is an internationally agreed standard; it will provide medical laboratories with international recognition of their accreditation.

Timeline for the Transition

- **September** – Pilot assessments completed
- **October** – Transition assessments began
- **2013**
- **2014**
  - September – First grants of UKAS accreditation against ISO 15189:2012 were made
  - Transition assessments on-going
- **2015**
  - Transition assessments on-going
  - Last CPA surveillance visit
- **2016**
  - Transition assessments on-going
- **2017**
  - Transition assessments on-going
  - Withdrawal of CPA accreditation and the CPA Standards
- **2018**
  - Annual assessment
  - Continuous Quality Improvement
  - Year 1
  - Year 2
  - Year 3
  - Year 4
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
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 patients
- 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. UKAS 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.
EQA & POCT Accreditation Transition

External Quality Assessment (EQA) Accreditation

EQA providers are in the process of transitioning from CPA accreditation against the EQA Standards to UKAS accreditation against the requirements of ISO/IEC 17043: 2010 Conformity assessment – General requirements for proficiency testing. The transition of EQA accreditation began in 2012.

The EQA transition process is similar to that for medical laboratories; a transition assessment will take place when the EQA Providers next main visit is due and the assessment will be against the CPA EQA Standards and ISO 17043:2010. This will allow the provider to maintain their CPA accreditation until such time that they are granted UKAS accreditation.

CPA will continue to support existing accreditation to the CPA EQA Standards until 31 March 2016, after that date the standards will be withdrawn.

Point of Care Testing (POCT) Accreditation

POCT accreditation will also be transitioning from CPA accreditation against the POCT Standards to UKAS accreditation against ISO 22870:2006 Point-of-care testing (POCT) – Requirements for quality and competence. ISO 22870:2006 will be assessed in conjunction with ISO 15189:2012 and will be included in the ISO 15189:2012 transition assessment. The POCT transition assessment process and timescales will follow that of the ISO 15189: 2012 transition.

“...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
Where to find the details of accredited services

The latest information about UKAS and CPA accredited medical laboratories can be found on the UKAS website www.ukas.com

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 or CPA accreditation symbols.
UKAS & CPA Governance

The CPA Professional Advisory Committee (PAC) &
UKAS Medical Laboratory Technical Advisory Committee (TAC)

The CPA PAC and the UKAS Medical Laboratory TAC is a joint committee that advises both CPA and UKAS on scientific, medical and technical matters relating to the accreditation of medical laboratories. This ensures that the relevant clinical information is considered, stakeholder’s views are captured and the provision of accreditation remains relevant, up to date and of high value to the healthcare sector.

The committee consists of key stakeholders as well as patient representatives and representatives of all pathology disciplines. Strong links are maintained with the professional bodies; Association of Clinical Pathologists, the Royal College of Pathologists, the Association for Clinical Biochemistry and the Institute of Biomedical Science, with each of these bodies well represented across the committee membership.

Other healthcare accreditation schemes

Imaging Services Accreditation Scheme (ISAS)

ISAS is a patient-focused assessment and accreditation scheme for diagnostic imaging services within the UK. Developed by The Royal College of Radiologists (RCR) and the College of Radiographers (CoR), and delivered by UKAS, ISAS 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.

For further information please email ImagingCustomerService@ukas.com or visit www.isas-uk.org

Improving Quality in Physiological Services (IQIPS)

IQIPS is a professionally led programme hosted by The Royal College of Physicians (RCP). It aims to improve services, care and safety for patients undergoing physiological tests, examinations and procedures. UKAS manages and delivers formal third-party assessments and accreditation against the IQIPS standards for the IQIPS accreditation programme. The programme is open to eight physiological science disciplines across the NHS and private sector.

For further information please email IQIPSCustomerService@ukas.com or visit www.ukas.com
How to contact UKAS

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

Telephone: 020 8917 8400

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CPA is a UKAS company