



CPA is a UKAS company



Clinical Pathology Accreditation

*Delivering
Confidence
in Healthcare*

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About Clinical Pathology Accreditation (CPA)

Clinical Pathology Accreditation (CPA) is the leading, reputable and authoritative provider of accreditation services in the health sector. CPA is a non-profit distributing organisation that acts in the public interest. It assesses and declares the competence of Medical Laboratories in the public and independent sector, and External Quality Assessment (EQA) Schemes in the UK and overseas. Although accreditation is voluntary, the majority of UK medical laboratories are currently enrolled, demonstrating that they have been assessed against the accepted standards. CPA has also provided accreditation to laboratories in Europe and the Middle East.

Background

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. The Company was incorporated on the 6 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.

In 1998, CPA signed an agreement with the United Kingdom Accreditation Service (UKAS), the UK's national accreditation body, as both organisations shared common interests relating to laboratory accreditation. This relationship strengthened in 2009 as CPA became a wholly-owned subsidiary of UKAS as part of a strategy by both companies to contribute to the modernisation of pathology services in the UK, and to ensure that accreditation is delivered independently of Government and the professions.

About UKAS

UKAS is the national accreditation body in the UK, recognised by Government, to assess and declare the competence of organisations against internationally recognised standards. It is independent from 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, the standard setting out requirements for accreditation bodies assessing and accrediting conformity assessment bodies.

Scale of operation

CPA employs a permanent staff of 25 high calibre professionals and contracts the services of an additional 300 external consultants and medical and scientific experts as required. In the UK, the Department of Health requires that all medical pathology laboratories register with CPA. The Care Quality Commission (CQC), the UK Regulator for health and social care recognises CPA accreditation to support its regulatory responsibilities.

“Accreditation is a significant enabler of quality. It provides Commissioners with confidence that medical laboratories services are safe and reliable, and striving to continuously improve for the benefit of patients.”

Dr John Goepel,
NHS Consultant



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What are the benefits of CPA accreditation?

CPA accreditation is an enabler of quality; it is patient-focused, impartial, objective and operates within a peer review model. It provides many benefits:

For Commissioners:

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

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

For Patients

CPA accreditation demonstrates that medical laboratories comply with a standard, confirming that:

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

For Medical Laboratories:

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

- prevents unnecessary duplication of gathering information on performance related to the Care Quality Commission (CQC) registration process
- encourages the sharing of best practice, inter-collegial friendship and contacts
- stimulates innovation
- brings together other kinds of quality assessment in a single package
- allows participation in any EQA scheme
- reduces risk, controls cost.

CPA organises three regional conferences each year, which provide an excellent platform to learn from CPA senior management and assessors and to establish new contacts. CPA assessors attend the conferences, which provide laboratory staff the opportunity to gain a greater understanding of the standards and the expectations of CPA. CPD points are available to attendees due to the educational value of the agenda and content matter.

“...Accreditation is absolutely essential to ensure quality of supply...”

Lord Carter Coles, Chair, *Independent Review of NHS Pathology Services*



What services does CPA provide?



CPA carries out the assessment and accreditation of Clinical Pathology Services, External Quality Assessment Schemes (EQA) and Point of Care testing services within the hospital. CPA services are delivered using independent peer assessors. They are active practitioners and therefore understand current practices and techniques. They are well placed to establish an ongoing dialogue with a laboratory that enables it to carry out a holistic approach to assessment that delivers value and reflects the following quality characteristics:

- open, transparent and fair
- technically and administratively proficient
- reliable, repeatable and responsive
- simple to use.

CPA is committed to providing a service of the highest quality and is aware and takes into consideration the needs and requirements of all interested parties. In order to ensure that the needs and requirements of all interested parties are met, CPA:

- operates a quality management system to integrate the organisation, procedures, processes and resources
- sets quality objectives and plans in order to implement this quality policy
- ensures that all personnel are familiar with this quality policy to ensure customer satisfaction
- commits to health, safety and welfare of its entire staff
- upholds professional values and is committed to good professional practice and conduct.

CPA is committed to:

- the highest standards of service delivery to customers
- staff recruitment, training, development and retention at all levels to provide a full and effective service to its customers
- the use of standard operating procedures, instructions and forms that will ensure the highest achievable quality service is provided
- the reporting of assessment results in ways, which are timely, confidential, accurate and reliable
- the assessment of customer satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

The CPA Standards

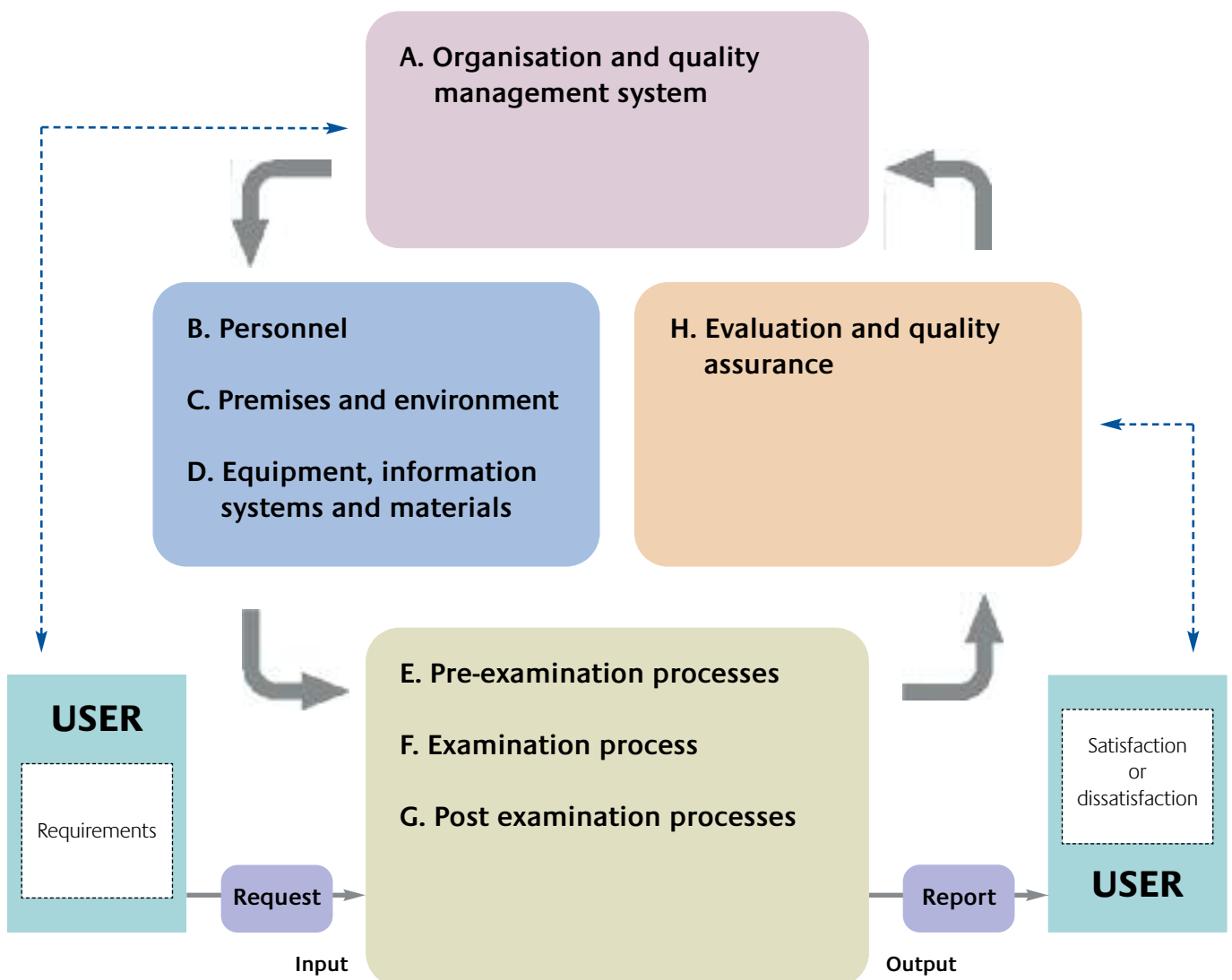
CPA assesses to standards that have been developed over a number of years by the organisation, taking into account the requirements of international standards, the professions, healthcare regulators, and other relevant stakeholders.

The CPA Standards

The CPA standards for Medical Laboratories ensure a thorough assessment of all aspects of an organisation's operations, from the management, to staff and services, to patients and commissioners.

It covers the organisation and quality management, the resources, and the evaluation and quality assurance activities required to ensure that pre-examination, examination and post-examination activities

of the laboratory are conducted in such a manner that they meet the needs and requirement of the users.





ISO 15189

ISO 15189 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 own competence. Accreditation to ISO 15189 is delivered by UKAS.

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

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

Management Competence

- Quality management systems
- Controlling documents and records
- Qualifying external services and suppliers
- Resolving complaints
- Assessing user feedback
- Internal auditing

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 <http://www.ilac.org/ilacarrangement.html>



The accreditation process

Accreditation is an on-going business process rather than a one-off achievement. Laboratories are assessed every two years and have to renew their registration every year, confirming that they are continuing to operate according to strict guidelines.

For any laboratory seeking accreditation, CPA will carry out an assessment to establish that:

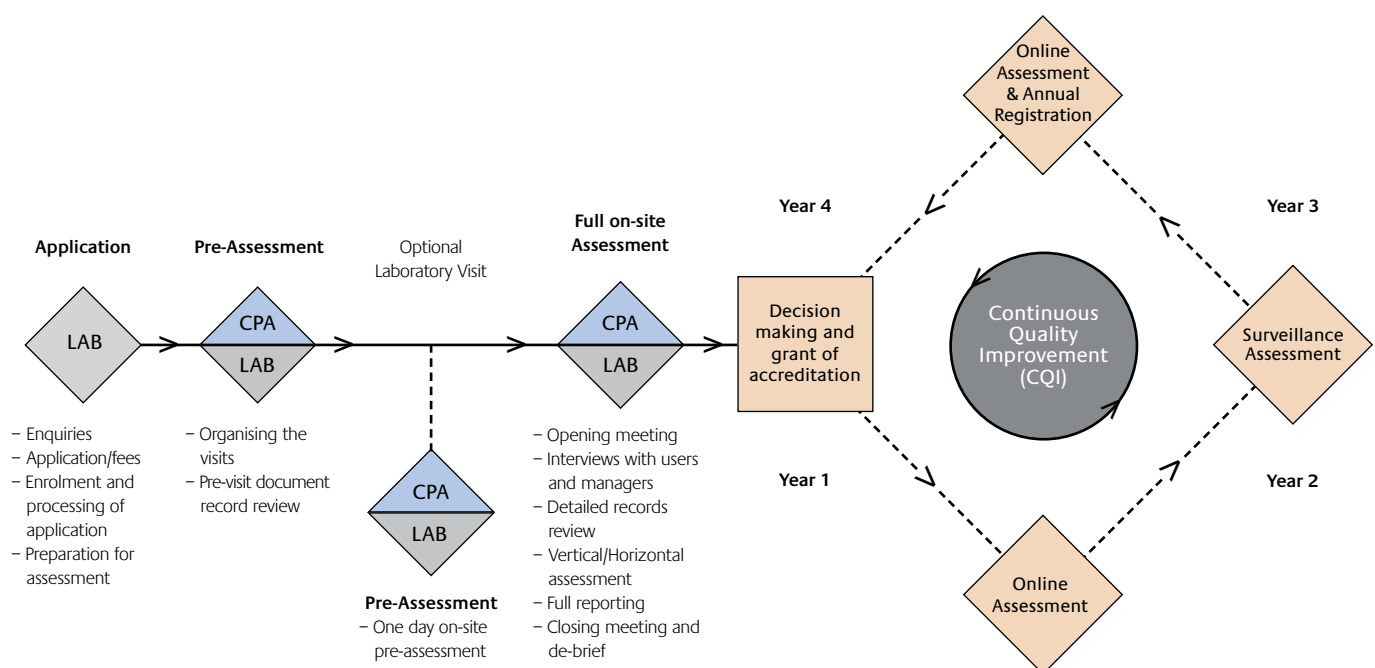
- the laboratory is impartial;
- the laboratory is technically competent to do the work in question;
- the resources and facilities are appropriate and sufficient for the work;
- the laboratory's actual performance is to the required standard;
- the laboratory is capable of sustaining the required level of performance.

The first step in seeking accreditation is for an applicant to assess themselves against the

relevant CPA Standards (Medical Laboratory or EQA) and then submit a completed application form to CPA accompanied by a copy of the organisation's Quality Manual.

On receipt of the documentation the applicant is enrolled and CPA assesses the application. If the application is not acceptable the department remains enrolled and CPA assists the medical laboratory with progressing its application. If the application is acceptable arrangements are made for an assessment visit. This is carried out on site by a team of peer assessors appointed by CPA.

Following the on site assessment, a report is submitted to CPA by the assessors. The report may recommend accreditation, identify conditions that must be met before accreditation is granted, or recommend that accreditation be refused and the applicant advised to reapply at a later date. The Assessment Manager will consider the recommendations and issue a decision. The final decision about accreditation status rests with CPA.



The CPA standard requires that laboratories participate in a relevant, recognised EQA scheme. CPA, unlike many other accreditation bodies, does not require that laboratories participate in a CPA accredited scheme, but are free to choose a scheme that suits the laboratory's budget and repertoire of tests. This can significantly reduce the cost of accreditation.



Who is currently accredited?

As part of the Modernisation of Pathology Strategy, the Department of Health in England requires that all medical laboratories enrol with an accreditation programme. The Scottish Government and the Welsh Assembly Government have similar requirements.

All enrolled Medical Laboratories may be found on the CPA website. All enrolled medical laboratories will fall into one of four main categories; Accredited, Conditional Approval, Awaiting Assessment and Non Accredited.

ACCREDITED –

Accreditation is granted, after assessment, when there is full conformity with all CPA standards. A certificate of accreditation is provided.

CONDITIONAL APPROVAL –

Non-conformities have been recorded. These must be corrected for accreditation to be granted.

AWAITING ASSESSMENT –

CPA have accepted the application for accreditation and Quality Manual and the medical laboratory is awaiting assessment.

NON-ACCREDITED –

The medical laboratory is not currently accredited, conditionally approved, or awaiting assessment with CPA.

CPA currently assesses approximately 1250 Laboratories. Most laboratories are in the UK, but CPA has also accredited laboratories in Europe, Middle East and the USA.

Only accredited laboratories are allowed to claim CPA accreditation and use the CPA logo.





CPA Governance

Professional Advisory Committee

CPA is a wholly-owned subsidiary of UKAS. The company takes advice on policy matters relating to accreditation of medical laboratories from a Professional Advisory Committee (PAC). This Committee consists of the key stakeholders, professional bodies, and patient representative groups, to ensure that the provision of accreditation remains relevant, up to date and of high value to the healthcare sector. The Committee maintains strong links with the professional

bodies; Association of Clinical Pathologists, the Royal College of Pathologists, the Association for Clinical Biochemistry, and the Institute of Biomedical Science.

The specialties of Clinical Biochemistry, Haematology, Histopathology, Immunology and Microbiology are each represented by a consultant and a Biomedical Scientist. There is a single representative for Genetics. Two consultants and a Biomedical Scientist

represent EQA activity. There are additional advisors in Transfusion Medicine, Cytopathology, Virology, Andrology and Histocompatibility & Immunogenetics.

The PAC meets on a regular basis to advise CPA and to ensure that stakeholder views are captured and that peer review remains at the heart of the assessment.

Other Healthcare Accreditation Services

ISAS

The Imaging Services Accreditation Scheme (ISAS), provided by UKAS, is a patient focused scheme based on the principle of independent assessment against a standard, developed by the Professions. Accreditation is the formal recognition that an imaging services provider has demonstrated that it has the organisational 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 or to register your interest in becoming accreditation, please email imagingcustomerservice@ukas.com or visit the ISAS website www.isas-uk.org



Point of Care Testing Services

Point of Care testing accreditation is assessed against ISO 22870:2006 (Point of Care Testing – particular requirements for quality and competence), applied in conjunction with ISO 15189. Such accreditation, which is an important element in establishing and maintaining confidence in a point of care testing service, is delivered by UKAS. CPA can also provide Point of care testing accreditation when carried out under the oversight of a CPA accredited pathology laboratory.

How to contact CPA

If you would like further information it can be found on our website at:
www.cpa-ukas.co.uk

By phone: +44 (0)20 8917 8400

This is a general number and enquiries may be routed to particular individuals as appropriate.

In writing to:

Clinical Pathology Accreditation
21-47 High Street
Feltham
Middlesex
TW13 4UN

By email: office@cpa-uk.co.uk

By fax: +44 (0)20 8917 8500

Registered Office:

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TW13 4UN
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Tel: +44 (0)20 8917 8400

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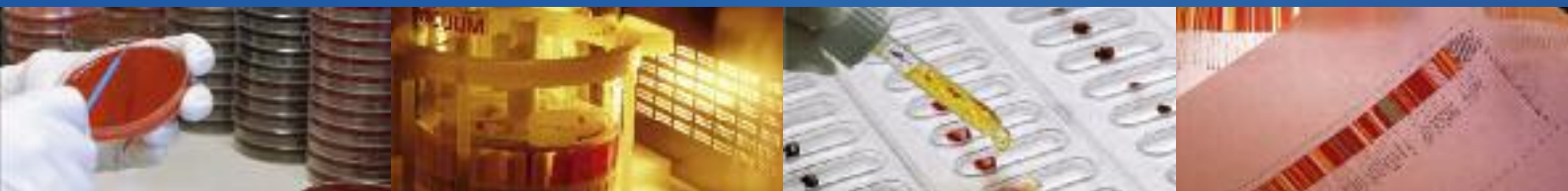
Website: www.cpa-uk.co.uk

Registered Number: 3076190
(England and Wales)



CPA is a UKAS company

CPA is always seeking to recruit competent Peer Assessors, both in the UK but also overseas. This role will support your continuing professional development. To apply, please complete the application form available on the website and send along with your CV to **office@cpa-uk.co.uk**



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