ESHRE:
Approaching Accreditation of a PGD Centre

The Accreditation Visit

Darren Edwards

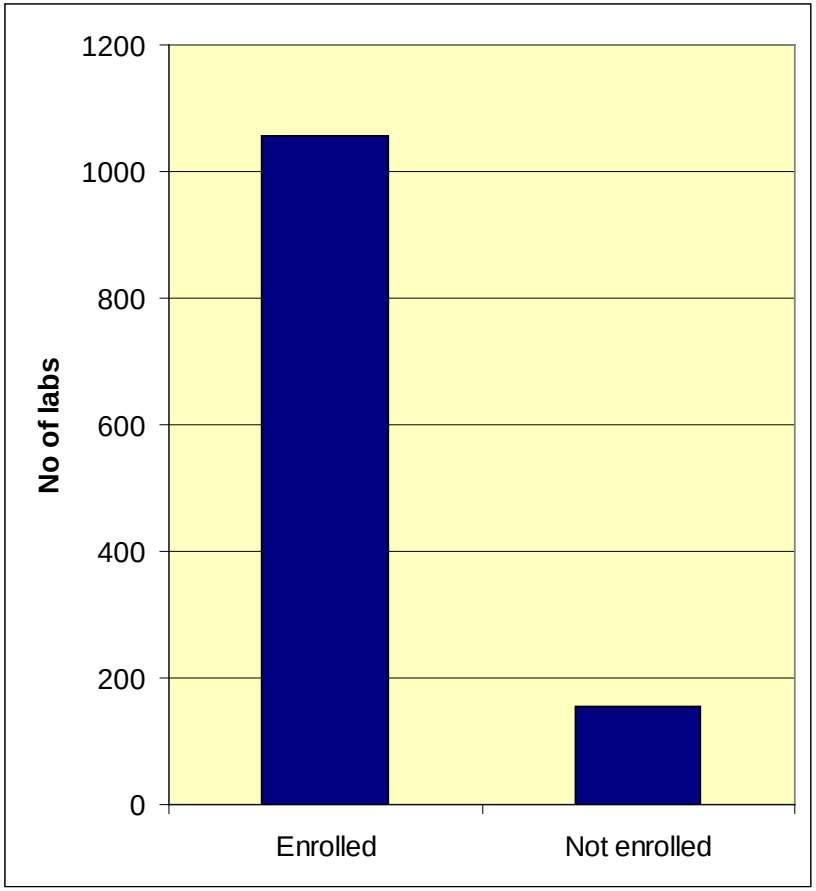
Regional Assessor, CPA (UK) Ltd

CPA (UK) Ltd

- **“CPA provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA).**

- **It involves an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review.”**

Laboratories known to CPA



87% of laboratories are enrolled with CPA

Overview of the Assessment Process

Pre-Assessment

- At the beginning of each four year period a new Application Form and Quality Manual is required. These are required in the first three months prior to the assigned period of the schedule.
- CPA accredits the complete service, and so adequate preparation based on accurate and current details is vital. Thus, applicants must declare their full repertoire, and any satellite laboratories, so that an appropriate assessment team is gathered.
- Any discrepancies or omissions may delay the process.

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Assessment :The Visits

- Main Visit:
  - full team assessment led by the Regional Assessor
- Surveillance Visit:
  - conducted within 2 years of main visit by the Regional Assessor

- Clearance Visit – if required
- Preparation Visit – if required

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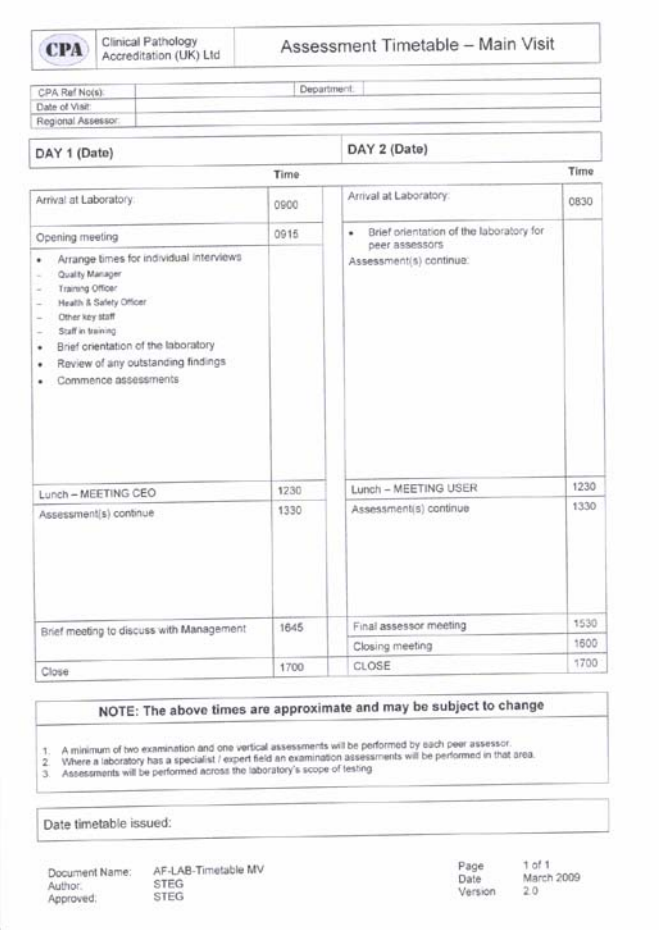
Assessment: Preparation



CPA | Clinical Pathology Accreditation (UK) Ltd | Assessment Timetable – Main Visit

CPA Ref No(s):	Department:
Date of Visit:	
Regional Assessor:	

DAY 1 (Date)	Time	DAY 2 (Date)	Time
Arrival at Laboratory:	0900	Arrival at Laboratory:	0830
Opening meeting	0915	• Brief orientation of the laboratory for peer assessors Assessment(s) continue:	
• Arrange times for individual interviews – Quality Manager – Training Officer – Health & Safety Officer – Other key staff – Staff in training • Brief orientation of the laboratory • Review of any outstanding findings • Commence assessments			
Lunch – MEETING CEO	1230	Lunch – MEETING USER	1230
Assessment(s) continue	1330	Assessment(s) continue	1330
Brief meeting to discuss with Management	1645	Final assessor meeting	1530
		Closing meeting	1600
Close	1700	CLOSE	1700

NOTE: The above times are approximate and may be subject to change

1. A minimum of two examination and one vertical assessments will be performed by each peer assessor.
2. Where a laboratory has a specialist / expert field an examination assessments will be performed in that area.
3. Assessments will be performed across the laboratory's scope of testing

Date timetable issued:

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Author: STEG
Approved: STEG

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Date March 2009
Version 2.0

- Responsibilities of CPA
- Responsibilities of applicant medical laboratories
- Pre visit document record review

Assessment: The Opening Meeting

Disclaimer

‘This assessment relies upon the sampling of laboratory activity. It follows that on completion of the assessment there may be undetected non-conformities. If laboratory management is aware of any non-conformity, it has a responsibility to declare it. Failure to do this will result in the contract with CPA (UK) Ltd being broken.’

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Assessment: The Opening Meeting

- **CODE OF CONDUCT**
- **CPA are aware that the assessors are invited guests in the department. Professional behaviour is expected from both the assessors and the laboratory personnel throughout the visit. If at any time during the visit there is cause for concern about the conduct of any CPA representative it must be brought to the attention of the regional assessor or CPA at the time.**
- **In turn CPA as an employer, has a duty of care to it's employees. CPA cannot and will not tolerate the use or threat of aggression against its representatives. Every applicant is obliged, under its contractual agreement with CPA to offer reasonable access and co-operation as necessary to enable the assessment team to monitor conformity against the relevant standards.**

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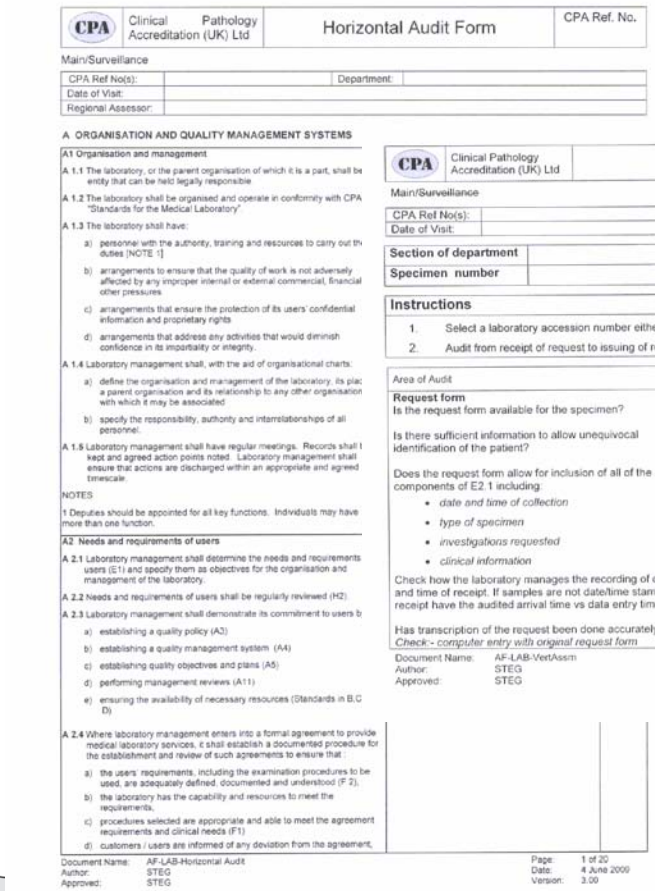
Types of Audit

Assessment Forms:



CPA Clinical Pathology Accreditation (UK) Ltd | Horizontal Audit Form | CPA Ref. No.

Main/Surveillance

CPA Ref No(s):		Department:	
Date of Visit:			
Regional Assessor:			

A ORGANISATION AND QUALITY MANAGEMENT SYSTEMS

A1 Organisation and management

A 1.1 The laboratory, or the parent organisation of which it is a part, shall be entity that can be held legally responsible

A 1.2 The laboratory shall be organised and operate in conformity with CPA "Standards for the Medical Laboratory"

A 1.3 The laboratory shall have:

a) personnel with the authority, training and resources to carry out th duties [NOTE 1]

b) arrangements to ensure that the quality of work is not adversely affected by any improper internal or external commercial, financial other pressures

c) arrangements that ensure the protection of its users' confidential information and proprietary rights

d) arrangements that address any activities that would diminish confidence in its impartiality or integrity.

A 1.4 Laboratory management shall, with the aid of organisational charts:

a) define the organisation and management of the laboratory, its plac a parent organisation and its relationship to any other organisation with which it may be associated

b) specify the responsibility, authority and interrelationships of all personnel.

A 1.5 Laboratory management shall have regular meetings. Records shall t kept and agreed action points noted. Laboratory management shall ensure that actions are discharged within an appropriate and agreed timescale.

NOTES

1 Deputies should be appointed for all key functions. Individuals may have more than one function.

A2 Needs and requirements of users

A 2.1 Laboratory management shall determine the needs and requirements users (E1) and specify them as objectives for the organisation and management of the laboratory.

A 2.2 Needs and requirements of users shall be regularly reviewed (H2).

A 2.3 Laboratory management shall demonstrate its commitment to users b

a) establishing a quality policy (A3)

b) establishing a quality management system (A4)

c) establishing quality objectives and plans (A5)

d) performing management reviews (A11)

e) ensuring the availability of necessary resources (Standards in B,C D)

A 2.4 Where laboratory management enters into a formal agreement to provide medical laboratory services, it shall establish a documented procedure for the establishment and review of such agreements to ensure that :

a) the users' requirements, including the examination procedures to be used, are adequately defined, documented and understood (F 2),

b) the laboratory has the capability and resources to meet the requirements,

c) procedures selected are appropriate and able to meet the agreement requirements and clinical needs (F1)

d) customers / users are informed of any deviation from the agreement,

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CPA Clinical Pathology Accreditation (UK) Ltd | Vertical Assessment Form

Main/Surveillance

CPA Ref No(s):		Department:	
Date of Visit:		Regional Assessor:	Darren Edwards

Section of department		**Examination or procedure**	
Specimen number		**Form number**	**of**

Instructions

1. Select a laboratory accession number either from the computer record or from work sheets/day book etc.
2. Audit from receipt of request to issuing of report.

Area of Audit	Star
Request form Is the request form available for the specimen?	
Is there sufficient information to allow unequivocal identification of the patient?	E2.1
Does the request form allow for inclusion of all of the components of E2.1 including: • *date and time of collection* • *type of specimen* • *investigations requested* • *clinical information*	E2.1
Check how the laboratory manages the recording of date and time of receipt. If samples are not date/time stamped on receipt have the audited arrival time vs data entry time?	E5.1
Has transcription of the request been done accurately? *Check:- computer entry with original request form*	

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Author: STEG
Approved: STEG

CPA Clinical Pathology Accreditation (UK) Ltd | Examination Assessment Form

Main/Surveillance

CPA Ref No(s):		Department:	
Date of Visit:		Regional Assessor:	Darren Edwards

Form No/Total Forms	**Name of person observed**	**Name of Peer Assessor**
of		
Section of department	**Procedure observed**	

Instructions

1. Select a laboratory procedure
2. Tick the box(es) below to signify which area of work is covered by the procedure(s) examined

Area Examined

E3 Specimen collection and handling		F2 Examination procedures	
E4 Specimen transportation		F3 Assuring the quality of examinations	
E5 Specimen reception		G1 Reporting results	
E6 Referral to other laboratories		G3 The telephoned report	
		G4 The amended report	

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Approved: STEG

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Smart Assessment – An Example

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Meetings

For a main assessment visit the applicant is asked to arrange two separate meetings usually to be held over lunchtime:

On the first day of the visit the Regional Assessor meets with the Chief Executive, or equivalent, of the owning organisation.

On the second day the assessment team will meet with representatives of the clinical user group.

It is important to note that these meetings are held in confidence and there must be no representative from the applicant medical laboratory present

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Raising Findings

- A **non-conformity** is defined as *'the failure to fulfil the requirements of a standard, in whole or in part'.* Assessors are asked to distinguish between two categories of non-conformity: critical non-conformity and non-critical non-conformity and additionally to record observations.
- The findings are recorded on the Non-conformity or Observation Form provided by CPA:

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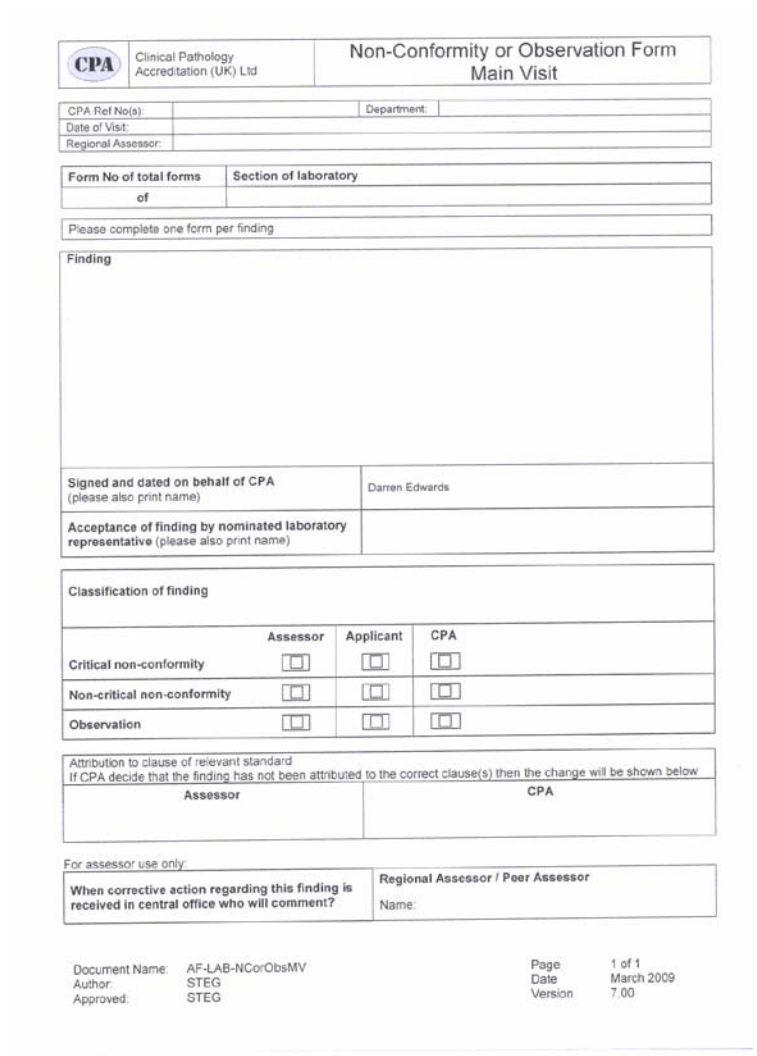
Assessment: Forms



CPA Clinical Pathology Accreditation (UK) Ltd

Non-Conformity or Observation Form
Main Visit

CPA Ref No(s):		Department:	
Date of Visit:			
Regional Assessor:			

Form No of total forms	Section of laboratory
of	

Please complete one form per finding

Finding

Signed and dated on behalf of CPA (please also print name)	Darren Edwards
Acceptance of finding by nominated laboratory representative (please also print name)	

Classification of finding

	Assessor	Applicant	CPA
Critical non-conformity	☐	☐	☐
Non-critical non-conformity	☐	☐	☐
Observation	☐	☐	☐

Attribution to clause of relevant standard
If CPA decide that the finding has not been attributed to the correct clause(s) then the change will be shown below

Assessor	CPA

For assessor use only:

When corrective action regarding this finding is received in central office who will comment?	**Regional Assessor / Peer Assessor** Name:

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Author:	STEG	Date	March 2009
Approved:	STEG	Version	7.00

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Top Ten Findings – A Summary

- A8.1 Document Control
- C5.1 Health and Safety
- D1.2 Procedures for Management of Equipment
- A6.3 Personnel Familiar with the Quality Manual
- E1.2 Information for Users
- C5.3 H&S Procedures
- F2.1 Examination Procedures
- A1.5 Regular Meetings
- A10.1 Controlling Clinical Material
- A9.1 Controlling Process Records

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The Closing Meeting and Debrief

- The assessment team close the on site assessment with a meeting in two parts:
- The first part allows the assessor(s) to present balanced feedback including positive aspects and to offer thanks to the staff for their hospitality.
- The second part is to sign off any findings: It is important that the personnel representing the laboratory have the authority to agree these findings with the assessor(s).

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Reports and Clearances

- Copies of the findings are left with the laboratory.
- All documentation, including a report, is submitted to CPA for decision making and granting accreditation:
  - CPA reserve the right to remove, alter the level of the findings, or the Standards to which the findings have been made.
- Once the applicant is in receipt of the report, evidence may be submitted to clear any reported findings:
  - The procedure is for the applicant to complete a clearance form for each finding. The completed forms must be submitted along with a copy of the original finding form and supported by appropriate evidence. This evidence must be submitted to provide sufficient time for the clearance to be processed in advance of the expiry date.

Extension of Scope of Accreditation and Major Changes

- Once accredited, the applicant medical laboratories are informed by letter. Accreditation can be declared from the date of the letter and the Executive Manager issues a certificate of accreditation.
- In order to maintain the validity of the certificate, CPA requires evidence that the laboratory continues to conform to the CPA standards. It is the applicant's responsibility to ensure that the annual registration form is submitted to CPA to allow sufficient time for it to be processed and the letter issued.

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Best Wishes

CPA