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| CPA | Clinical Pathology Accreditation (UK) Ltd | General Overview Report – Main Visit |

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| CPA Ref No(s): | 1365 | Department: | Dept of Haematology & Blood Transfusion |
| Date of Visit: | 03/12/2012 to 06/12/2012 | Hospital: | Gloucestershire Hospitals NHS FT |
| Regional Assessor: | Cathy Tate | | |

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| **Number of findings** | 27 |

**Scope:**
Number of sites visited: 4
Repertoire as detailed on Application Form: Yes

**Areas/Repertoire assessed by Peer assessors:**

| **Vertical audits:** | **Examination audits:** |
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| Haematology (GRH) – FBC<br>Haematology (CGH) – Anticoagulant Control/INR<br>Blood Transfusion (GRH) – Group and Save & e-Crossmatch<br>Blood Transfusion (CGH) – BTS Manual Crossmatch<br>Immunology – Paraprotein Analysis<br>Immunology – Anti Nuclear Antibody by IIF | Haematology (GRH) – Blood Films<br>Haematology (GRH) – Coagulation - Referred Samples<br>Haematology (GRH) – Haemoglobinopathy Screening<br>Haematology (GRH) – Coagulation – D-Dimer<br>Haematology (CGH) – B12 Folate<br>Haematology (CGH) – Flow Cytometry CD4 Lymphocyte Counts<br>Blood Transfusion (GRH) – Departmental & External Blood Fridge<br>Immunology – Anti-endomysial Abs by IIF<br>Immunology – Rh. Factor Latex Screen<br>Immunology – Specimen Receipt/handling<br>Immunology – Specific IgE<br>Phlebotomy Services (GRH)<br>Phlebotomy Services (CGH)<br>Pathology Central Reception (GRH)<br>Pathology Central Reception (CGH) |

**EQA:** See separate statement

**Statements on:**

1. Non Conformities cleared on visit: NA

2. Outstanding Non Conformities: None
   The findings from the previous surveillance visit were reviewed and where not satisfactorily addressed were raised as new findings for this visit (findings 4/27, 25/27, 26/27, and 27/27).

3. Confidence in the competence of the organisation
   The department provides highly-regarded Haematology, Blood Transfusion, and Immunology Services to the Cheltenham & Gloucester Hospitals NHS Trust and the General Practices in the surrounding area. Apart from Immunology, which is based at the Gloucester site only, the services are delivered from both the Gloucester Royal Hospital (GRH) and the Cheltenham General Hospital (CGH) sites and the department also manages a number of external blood fridges. There has been some rationalisation of tests offered across the two

sites, and working practices have yet to be fully aligned. However this is an ongoing improvement process and the department is striving to provide patient-focussed services on all sites. On the evidence provided with the exception of the nonconformities identified, the department is working in conformity with its documented procedures and meets the requirements of the CPA Standards for the Medical Laboratory.

4. Adequacy of the Quality Management System (QMS)

There is a mature overarching pan-pathology QMS supplemented by department-specific procedures as appropriate. The QMS is managed and co-ordinated by the Pathology Quality Team which has undergone a temporary reorganisation with the recent resignation of the Quality Manager. However, the QMS remains effective and there is evidence that it is delivering service improvements.

5. Conformance with accreditation requirements:

A – Organisation and quality management systems

The legal entity for the department is the Cheltenham & Gloucester Hospitals NHS Trust. There is a well defined organisational structure which is supported by regular management meetings both at departmental and directorate level. The resignation of the incumbent Quality Manager has prompted a temporary reorganisation of the Quality Team which now comprises a very competent Assistant Quality Manager supported by the Pathology Manager. User needs and requirements are reviewed by biennial surveys, and through meetings with key users and attendance at the pathology management meetings by a GP representative. A service which provides users with direct access to clinical advice through a dedicated mobile telephone will again be offered in the new year after a temporary suspension. This and other initiatives provided examples of user-specified objectives implemented by the department. The Quality Manual and the associated procedures are of a high standard. Documents are controlled through an electronic system (Quality Workbench) although a large number of working instructions on display are not included and so are not appropriately controlled. There are suitable procedures in place for the control of records and clinical material with evidence of compliance to these in the laboratory. A good range of quality objectives have been established and the annual management review (AMR) takes place as part of a pan-pathology AMR. However, the records should include a review of all outcomes of the QMS to demonstrate that the process is effective.

B – Personnel

There is appropriate direction of the service through the Pathology Specialty Director and through the Consultant Haematologist Head of Department, and a Consultant Immunologist provides direction of the Immunology aspects of the service by contractual arrangement. The Consultant Haematologist is also supported by a further six Consultant Haematologists who all participate in laboratory reporting. The roles of training, and health and safety (H&S) have been appointed to individuals within the department, whilst the Quality Manager role is a pan-pathology position and has recently become vacant. Staffing levels in the Haematology and Blood Transfusion laboratories appear to be adequate however consideration should be given to the impact the out-of-hours and weekend rotas have on the resilience of the Immunology section. In addition, the Phlebotomy Service was found to be inadequately staffed at the Gloucester site. The Phlebotomy Service is managed by Pathology Central Services, and so is outside of the managerial responsibility of the Haematology Department. However it was assessed during this visit and findings relating to the service need to be addressed to ensure that the all of the departments are in conformity

with the CPA standards for the Medical Laboratory.
Within the Haematology Department there was evidence of good personnel management, staff were found to be very knowledgeable and motivated, and good training programmes are in place, although some records of training and CPD are not held as management records. A mechanism for competency assessment is in place and requires only minor changes to the procedure and recording process to be in full conformity. There is good access to reference material, further education and development is supported, and staff are registered in a digital morphology CPD scheme.

C – Premises and environment
The department is secure with adequate staff facilities. Availability and suitability of space is variable across the two sites; the Blood Transfusion laboratory at Gloucester was notably poor. The space available for the Phlebotomy Service at CGH was also found to be inadequate. An assessor noted that the Main Theatre Blood Fridge at GRH was poorly situated. Health and Safety (H&S) procedures are provided as a combination of pan-pathology and departmental procedures, and COSHH and risk assessments are of good quality. H&S appears to be well managed; it is regularly audited through pan-pathology and departmental schedules, and there is an appropriate risk escalation process through the Pathology H&S committee.

D – Equipment, information systems and materials
Within the department instruments are generally of a high standard and well maintained, with good records. Apart from the issues raised regarding the Main Theatre Fridge, the external Blood Fridges were found to be well-managed; they were secure, alarmed, serviced and mapped appropriately. Reagent management was found to be good, and all data and information procedures were in place and appropriately referenced.

E – Pre examination process
Information for users was available on the Trust website and was comprehensive and well presented. In addition an excellent Pathology Newsletter is produced with updates and items of interest. Specimens are transported by hospital staff and drivers, and by external couriers. Procedures are in place and hazard information cards have been issued to the external couriers. The Specimen Reception areas on both sites are part of General Pathology Services, and were found to be managed by very professional and enthusiastic supervisors at both sites. Appropriate procedures for specimen reception and referral were available, although within Blood Transfusion the time of sample receipt is not recorded.

F – Examination process
Examination procedures were of good quality, and there has been good performance in external quality assessment (EQA) schemes, with evidence of appropriate investigation and corrective action as required. The Immunology section includes a simple but effective ‘traffic-light’ system to display performance in EQA schemes. The assessors shared the department’s concerns over the reported lack of quality assurance carried out for INR tests performed within GP surgeries, however, the laboratory have no managerial responsibility for these clinics nor the tests performed there.

G – The post examination phase
Users were satisfied with the availability and quality of reports, and the supporting clinical advice for all aspects of the service, including during ‘out-of-hours’. Users reported that they valued the interpretive comments given (the assessors noted some immunology reports

lacked required details), and that turnaround times (TATs) are good.

H – Evaluation and quality assurance
Evaluation and improvement procedures are provided as pan-pathology documents and include all required detail. The department carries out and participates in clinical audits and collaborative studies with other clinical specialties. QMS, H&S and examination process audits are scheduled and although good audits are carried out, the department should ensure that the repertoire is adequately audited across both sites. Good records are held and the quality team monitor outcomes to ensure that actions are completed. There is good review of all of EQA, complaints, and incidents at both departmental and pan-pathology meetings, however there was no robust mechanism in place to ensure that audit outcomes are communicated to staff. Effective training for auditors is delivered by the Assistant Quality Manager. Nonconformities are recorded on NCR forms and also entered into 'Quality Workbench' software where corrective action is monitored by the Assistant Quality Manager. Clinical incidents are reported through the Trust 'Datix' system and are also effectively monitored. Nonconformities are reviewed for trends although not all sources are included and corrective action could be more rigorously monitored. A good range of quality indicators have been established and are included in the Pathology 'dash-board' system of monitoring.

Regional Assessor Signature: Cathy Tate Date: 07/12/2012