QUALITY MANUAL

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**Stage**

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**Key**

- <5: Risk Assessment/Manual Handling Score
- 6-10: 6-10 Action within 12 months
- 10+: 10+ Urgent Action Required

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1 General Information

1.1 Title of laboratory or department

The Biochemistry Department at Bronglais Hospital, Aberystwyth is part of the Hywel Dda Local Health Board (LHB). This Board was newly formed on 1st October 2009 through the merger of the previous Hywel Dda NHS Trust (Bronglais, West Wales, Withybush and Prince Philip Hospitals) and the LHB's from Ceredigion, Carmarthenshire and Pembrokeshire.

The postal address is: Biochemistry Department
Bronglais General Hospital
Carodoc Road
Aberystwyth
Ceredigion
SY23 1ER

Telephone number: 01970 635557
Fax: 01970 635323

Biochemistry laboratories are also located at West Wales General Hospital Carmarthen, Withybush Hospital Haverfordwest and Prince Philip Hospital Llanelli, but joint management is still developing and day to day specialised issues remain essentially independent.

The Bronglais Biochemistry Department provides acute and community services to the population of Ceredigion, North Powys and South Gwynedd. Acute services are centred on the Bronglais General Hospital (BGH) in Aberystwyth with 150 beds. Closely associated with BGH are two community hospital at Tregaron (12 beds) and Cardigan (29 beds). In addition, services are provided to two psychiatric wards and four community hospitals at Llanidloes, Machynlleth, Newtown and Tywyn (120 beds in total).

The Pathology department, based at the Bronglais General Hospital, is comprised of three departments, namely Biochemistry, Haematology and Microbiology. The Haematology, Microbiology departments and Pathology reception are situated near Outpatients on the ground floor of the main hospital building. The Biochemistry laboratory has recently moved to new accommodation on the first floor. This is the first stage of a planned Blood Sciences (Biochemistry and Haematology) laboratory, which will become fully functional in 2 years time, once further hospital building and refurbishments have taken place. Accommodation for the Microbiology department will also be provided as part of the development, to enable all Pathology departments to operate from the same area.

Histology samples are received by the Biochemistry department, but are then sent to Prince Philip Hospital for analysis.

The Biochemistry department provides a comprehensive repertoire of general chemistry and immunochemistry analyses to both the acute sector (24/7), primary care and community hospitals within the area. Specimens from patients within the hospital are delivered to the Biochemistry department either by porter or via a vacuum tube system, which is linked directly to the Pathology reception and other key wards/sites within the main hospital complex. Samples from outside the hospital are collected by courier services managed by the Facilities Directorate. A limited phlebotomy service (managed by Haematology) is available in the hospital outpatient department for primary care patients requiring certain specific blood tests (e.g. those labile in transit).

The Biochemistry department also offers advice and support for POCT in primary and secondary care. Registration for POCT EQA is available through the Biochemistry department.

The Biochemistry department aims to provide a high quality, progressive clinical diagnostic service to all its users in a proficient and cost effective manner. In particular, to provide a consultative diagnostic service responsive to the needs of our users. Further details of the
services provided and contact numbers are provided in the departmental handbooks which are available on the health board intranet site and on the internet:

http://www.wales.nhs.uk/sitesplus/862/page/40341

1.2 The Quality Manual

This Quality Manual describes the Quality Management System of the Biochemistry Department at Bronglais Hospital. Throughout the text there are references to CPA(UK) Ltd Standards (in brackets) and to procedures [indicated by square brackets] written in fulfillment of these standards.

This Quality Manual (A6 Quality Manual) fulfils two functions. It describes the Quality Management System for the benefit of the department’s own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual is the index volume to separate volumes of management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with the CPA (UK) Ltd Standards (see table below). Under the title of each standard there is a brief description of the way in which the Biochemistry Department at Bronglais Hospital seeks to comply with the particular standard and references are given to appropriate procedures.

The sections of the standards relate to each other in the following manner:

Section A describes the organisation of a laboratory and its quality management system which uses resources (Sections B, C and D) to undertake pre examination, examination and post examination processes (Sections E, F and G). The quality management system and the examination processes are continually evaluated and quality assured (Section H). The results feed back to maintain and, where required, improve the quality management process and to ensure that the needs and requirements of users are met.

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<th>Paragraph in the Quality Manual</th>
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2 Quality Policy

The quality policy (A3 Quality Policy) of the Biochemistry department is given below and is displayed as a separate controlled document within the department (QPBIO200) and read by all staff. (Current edition number 001).

The Quality Policy of the Biochemistry Department, Bronglais General Hospital.

The biochemistry department performs a comprehensive repertoire of general chemistry and immunochemistry analyses to both the acute sector (24/7), primary care and to community hospitals within the area. It also provides non-acute services to other laboratories in the South West Wales region.

The biochemistry department aims to provide a high quality, progressive clinical diagnostic service to all its users in a proficient and cost effective manner. In particular, to provide a consultative diagnostic service responsive to the needs and requirements of its users.

In order to ensure that the needs and requirements of users are met, the department will:
- operate a quality management system to integrate the organisation, procedures, processes and resources
- set quality objectives and plans in order to implement this quality policy and achieve continual quality improvement
- ensure that all personnel are familiar with this quality policy to ensure user satisfaction
- ensure that all staff are familiar with the contents of the quality manual and all procedures relevant to their work
- commit to the health, safety and welfare of its entire staff.
- visitors to the department will be treated with respect, and due consideration will be given to their safety while on site
- uphold professional values and stay committed to good professional practice and conduct.

The biochemistry department will strive to continually comply with accreditation standards set by CPA (UK) ltd and is committed to:
- staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
- the proper procurement and maintenance of such equipment and other resources as are needed for the provision of the service
- the collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- the use of examination procedures that will ensure the highest achievable quality of all tests performed
- reporting results of examinations in ways which are timely, confidential, accurate and clinically useful
- the assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.
- complying with all relevant environmental legislation.

signed on behalf of the biochemistry department

Mr. R. G. Roberts
Consultant Biochemist, Head of Department
3  Organisation, Responsibilities and Authorities

3.1  Relationship to the Host Organisation

The Chief Executive of the Hywel Dda LHB is Trevor Purt and the Chairman Chris Martin, both based at the LHB Headquarters in Haverfordwest. The Medical Directors for the LHB are Dr Susan Fish and Dr Simon Mahon. A team of associate medical directors (AMD) report through to the LHB executive board. The AMD for Pathology is Dr John Murphy, Consultant Histopathologist based at WWGH, Carmarthen. Clinical and professional governance support is provided by Kathryn Davies, Director of Therapies and Health Sciences. Both Kathryn Davies and John Murphy sit on the LHB Clinical Governance Committee with accountability currently resting with the Medical Directors, Director of Nursing and Director of Therapies and Health Science. The organisational structures are shown in [MIPAT602 Hywel Dda Health Board Accountability Structures]. See also page 8 for the Hywel Dda Health Board Executive Structure.

Pathology is part of the Clinical Support Services Directorate. The current LHB General Manager for Clinical and Support Services is Mansell Bennett, based at GGH. Relevant pathology support is provided by Mrs Andrea Stien, Pathology Services Manager and Chris Blower (LHB Lead BMS for Biochemistry). The clinical support services organisational chart is detailed on page 10 and displayed as a separate controlled document in the department [MIPAT600 Clinical Support Services Organisational Chart]. The Hywel Dda Pathology management structure is detailed on page 11 and displayed as a separate controlled document within the department [MIPAT601 Pathology Management Structure].

3.2  Organisation and Responsibilities within the Biochemistry Department

The organisational chart for the Bronglais Biochemistry Department is shown on page 12 and displayed as a separate controlled document within the department [MIBIO200 Biochemistry Department Organisational Structure].

The head of the Bronglais Biochemistry Department is Mr. Gethin Roberts (MSc, FRCPath). His deputy is Dr Karen Poyser (PhD, FRCPPath) and both are responsible to Mansell Bennett for managerial and performance issues, and to John Murphy for clinical and service issues. In addition the head of department is also responsible to senior management for effective budget planning and financial management and the design of appropriate contingency plans for the service, should they be needed. He is responsible for providing a professional and quality service that is responsive to the changing needs of users, with an appropriately trained staff and ensuring that the department is run in accordance with all relevant LHB and national legislation, including applicable accreditation and regulatory agencies. He is supported in this role by Miss Eleanor Morgan, recently appointed as Blood Sciences Laboratory Manager who has responsibility for the day to day management and running of the department. (She also currently has identical responsibilities for the Bronglais Haematology department until such time as the departments are fully merged.) Her deputy for Biochemistry is Mr. Paul Davies (SBMS). Further specific details are given below.

3.2.1  Responsibilities

The key roles and responsibilities within laboratory management are detailed below.

a)  Head of Department/Deputy

- Provision of a professional and high quality clinical laboratory service and contingency planning should it be needed
- Development of the service by managing the department and its staff
- Providing clinical guidance and scientific advice and assistance to hospital clinicians and general practitioners on the selection, performance and interpretation of clinically relevant tests in order to facilitate the diagnosis, treatment, monitoring and understanding of the disease
- Responsible for the selection of equipment and analytical methods used
Taking an active role in strategic planning for the department by developing and agreeing future plans and strategies for clinical services

- Responsible for departmental budget and finance
- Providing education and training to medical students and junior doctors
- Supporting R&D developments within the department and LHB
- Participate in audit and clinical governance

b) Lead BMS Biochemistry

- Responsible for strategic leadership and decision making including staffing and major procurement of equipment across the LHB
- Provides support and advice for more complex HR issues (e.g., BMS interviews, disciplinary matters) across the LHB
- Chair of the POCT working group and takes responsibility for addressing non-conformances and escalating clinical governance issues across the LHB
- Responsible for financial resource management of biochemistry across the LHB
- Responsible for the technical development of the service across LHB

c) Blood Sciences Laboratory Manager

- Day to day responsibility for the management of the department and organisation of staff and workload
- Operational management of the department and its scientific and support staff including budget, contract and personnel matters
- Responsible for provision of services through the management of the department, staff and quality of the process
- Responsible for the provision of laboratory tests to assist clinicians diagnose disease and evaluate the effectiveness of the necessary treatment
- Responsible for staff management to include appraisals, recruitment, discipline, training and development of all staff
- Responsible for economical purchasing of reagents, consumables and control of departmental budget
- Working under guidance of Lead BMS to ensure the economical procurement of major capital equipment
- Responsible for developing the service in line with the requirements of service users, proposing and implementing departmental policies
- Establishing and maintaining good communications within the laboratory and with users of the service

d) Quality Manager

- Ensuring the quality management system is implemented and maintained
- Reporting to laboratory management on the functioning and effectiveness of the quality management system
- Co-ordinating awareness of the needs and requirements of users
3.2.2 Clinical Support Services Directorate Organisational Chart

This is also displayed as a separate document within the department [MIPAT600].
3.2.3 Pathology Management Structure

This is also displayed as a separate document within pathology [MIPAT601].

Pathology Services Manager
Mrs. Andrea Stien
(Withybush General Hospital, West Wales General Hospital, Bronglais General Hospital, Prince Philip Hospital)

Pathology Quality Manager
(WGH, WWGH, BGH, PPH)
Mrs. Hannah Albery

Lead BMS Biochemistry
(WGH, WWGH, BGH, PPH)
Mr. Chris Blower

CBMS Biochemistry
WGH

CBMS Biochemistry
WWGH

CBMS Biochemistry
PPH

Blood Sciences Manager BGH

CBMS Haematology
WGH

CBMS Haematology
WWGH

CBMS Haematology
PPH

CBMS Microbiology
WGH

CBMS Histopathology
WWGH/WWGH
3.2.4 Biochemistry Department Organisational Structure (BGH)
This is also displayed as a separate document within the department [MIBIO200].

Consultant Clinical Biochemist
Mr. Gethin Roberts

Principal Clinical Biochemist
Dr. Karen Poyser

Pathology Services Manager
Mrs Andrea Stiens

Lead BMS
Mr Chris Blower

Blood Sciences Laboratory Manager*
Miss. Eleanor Morgan

Senior BMS** Biochemistry
(x2)

BMS (Biochemistry)
(x 7)

MLA (Biochemistry)
(x 5)

Senior BMS Haematology

BMS (Haematology)

MLA (Haematology)

NB. Arrows indicate lines of accountability

* ~ Health and Safety Officer
** ~ Training Officer
4 Organisation and Quality Management System

A1 Organisation and management

The Pathology department operates as an entity within the Clinical Support Services Directorate, Bronglais General Hospital (BGH), of the Hywel Dda Health Board. The general manager for the Clinical Support services directorate has overall managerial responsibility for Pathology and is ultimately responsible to the Chief Executive who bears legal responsibilities for all Health Board activities. Further information regarding the organisation and management of the Biochemistry department can be found in section 3 of this quality manual.

Deputies have been appointed for key functions within the department.

A2 Needs and requirements of users

The needs of the users are kept under constant review by the Heads of Department and the Quality Manager. This is done proactively through the use of satisfaction surveys. Information is also gathered in response to compliments & complaints by users regarding the service and also during discussions with users of the service either verbally or written. As results of questionnaires and users views are fed back, they are presented to the directorate, to senior staff in the Pathology Department and to the Quality Manager for consideration and action to be taken. This will be demonstrable through the minutes of meetings and the replies to users. The reply will be either to work with them to effect change or explaining to them the reasons behind why a process has to be performed in particular way.

Needs and requirements of users are also addressed via involvement in multidisciplinary meetings, which the Head of Department, or deputy, attend.

- Obstetrics and Gynaecology Liaison group (GR/KP)
- Ceredigion Heart Failure group (GR)
- Hywel Dda Nutrition Team (KP)

Close working links exist with the midwives, osteoporosis team, gastroenterology team, diabetes team and the cardiology team in particular. In addition there is close working co-operation between the diabetes specialist nurses and the biochemistry POCT co-ordinator.

The laboratory also supports clinical trials work and liaises closely with the two clinical research nurses. Gethin Roberts, as Head of Department, is the primary contact for any new studies and Karen Poyser is the named contact taking responsibility for samples needing special storage and/or transport to off-site laboratories. Karen Poyser is GCP trained and also attends the R&D committee.

The needs are translated into requirements which form the focus of objective setting and planning (A5 Quality Objectives and Plans) within the quality management system. Assessment of user satisfaction and complaints (H1 Assessment of User satisfaction and Complaints) is conducted on a regular basis and consideration of the findings form part of the annual management review (A11 Management Review).
Where laboratory management has entered into formal agreements to provide medical laboratory services, a documented procedure is in place for the establishment and review of such agreements.

A3 Quality policy
The Quality Policy of the Pathology department is detailed in section 2 of this quality manual and is displayed within the laboratory [QPBIO200 Quality policy]. The quality policy is signed and issued by persons with appropriate authority (Head of Department) and communicated to all staff within the department. The quality policy is reviewed for suitability and effectiveness at the annual management review.

A4 Quality management system
The components and relationship within the quality management system are described in section 4 of this quality manual and under standards A5 to A10.

A5 Quality objectives and plans
Quality objectives are defined at the annual management review in consultation with the individual departments. The quality manager is responsible for ensuring that plans are made to meet these objectives and that they are consistent with the quality policy and regularly reviewed. The management review (see A11 below) which is undertaken on an annual basis determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the quality management system.

A6 Quality manual
This standard is fulfilled by the production of this quality manual. The Quality Manual is maintained by the Pathology Quality Manager. The Pathology Quality Manager is also responsible for ensuring that up to date versions are available both to staff and to users of the service and that any changes are communicated to all personnel concerned.

A7 Quality manager
The quality manager (QM) for the Biochemistry department is Dr Karen Poyser who works with the laboratory management team and other senior staff to ensure proper running of the quality management system. The QM is managerially responsible to the Head of Department and other senior Pathology staff. The quality manager reports to the clinical heads of departments and works closely with the CBMS and Pathology Quality Manager. The quality manager has defined authority for:

- Ensuring that the quality management system is implemented and maintained
- Reporting to laboratory management on the functioning and effectiveness of the QMS
- Co-ordinating and developing awareness of the needs and requirements of users

The Pathology Quality Manager for the Health Board is Mrs. Hannah Albery, who is charged with quality policy and service development, and the implementation and management of the Hywel Dda Local Health Board Pathology Service’s quality management systems to ensure compliance with both regulatory [Medicines & Healthcare products Regulatory Agency (MHRA), Human Tissue Authority (HTA)] and accreditation [Clinical Pathology Accreditation (CPA)] requirements.
Unless otherwise stated, references to Quality manager in text refer to the Biochemistry department Quality Manager.

A8  Document control
This standard is fulfilled by [MPPAT604 Procedure for the Preparation and Control of Documents]. This procedure ensures that all documents are:
- Approved for use and appropriately authorised prior to issue
- Regularly reviewed, revised, updated and re-issued
- Readily available at the point of use
and use of obsolete documents is prevented.

Q-Pulse is being introduced as the departmental document control system. The Pathology quality manager and the Blood Sciences Laboratory Manager at Bronglais are the system administrators. The Pathology quality manager has overall responsibility for all documents in the system.

A9  Control of process and quality records
This standard is fulfilled by [MPPAT609 Procedure for the Control of Process and Quality Records].

A10  Control of clinical material
This standard is fulfilled by [MPBHB202 Procedure for the Control of Clinical Material] held within the laboratory (see also E3).

A11  Management review
The Head of Department conducts an annual review, which considers the following items of information
- Reports from managerial and supervisory personnel
- Assessment of user satisfaction and complaints (H2)
- Internal audit of quality management system (H3)
- Internal audit of examination processes (H4)
- External quality assessment reports (H5)
- Reports of assessments by outside bodies
- Status of preventive, corrective and improvement actions (H6)
- Quality indicators that monitor the laboratory’s contribution to patient care
- Major changes in organisation and management, resource or process
- Quality Manual and Quality Policy
- Follow up of previous management reviews.

Records are kept and key objectives for subsequent years are defined and plans formulated for their implementation. A summary is produced and sent to CPA in fulfillment of annual registration requirements.

5  Personnel
B1  Laboratory director
The Biochemistry department at Bronglais is directed by Mr. Gethin Roberts – Consultant Clinical Biochemist.

Following a staff retirement in June 2011, Mr Roberts also provides Head of Department cover for the Biochemistry Department at Withybush General Hospital, Haverfordwest pending a new appointment. He also provides Consultative cover for both Withybush and West Wales General Hospital,
Carmarthen during annual leave and sickness, in line with a local agreement set up between the departments.

When Mr. Gethin Roberts is absent, operational cover is provided for Bronglais by his deputy, Dr Karen Poyser, Principal Biochemist, including the other LHB sites.

Mr. Roberts also currently takes the lead Consultant Biochemist role for Hywel Dda (a rotational position)

B2 Staffing
The Consultant Head of Department and the Blood Sciences Laboratory Manager are responsible for ensuring that adequate and appropriately trained staff are employed in accordance with the demands of the service and national legislation and regulations. All Biomedical Scientists are registered with the Health Professions Council. The State Registration status of qualified staff is checked annually by the Blood Sciences Laboratory Manager.

Quality Manager (LHB): Mrs Hannah Albery
Quality Manager (Biochem): Dr Karen Poyser
Training Officer: Mr Paul Davies, SBMS Biochemistry
Health and Safety Officer: Miss Eleanor Morgan, Blood sciences laboratory manager
POCT Co-ordinator: Mr Aled Rees, SBMS Biochemistry

B3 Personnel management
This standard is fulfilled in part by the Human Resources (HR) Directorate of the LHB, and in part by the Biochemistry Department itself. In most cases these procedures are produced and updated by the HR department. Where procedures are specific to Biochemistry they are produced and updated by the department [MPBIO202 Procedure for Personnel Management].

Staff recruitment and retention is undertaken by the Biochemistry department, under the direction of HR. Current Staff Vacancy, Job Specification and Person Specification forms may be found in the HR department.

Interview arrangements and referee contacts are organised by HR. Written records of the outcomes of interviews are kept in the HR department.

B4 Staff orientation and induction
All staff attend a comprehensive two-day corporate induction course. Staff also attend a departmental induction. Records of staff orientation and induction are kept by the personnel department. Records of departmental induction are kept by the blood sciences laboratory manager as part of staff records [MFPAT602 Pathology Induction Checklist].

Records of staff orientation and induction are kept in the Training File in the blood sciences laboratory manager’s office. Attendance of the LHB induction program is mandatory for all new staff, but the blood sciences laboratory manager also organises a local program for departmental specific issues (e.g. H&S).
B5  Job descriptions and contracts
Each member of staff has a job description prepared using the Job Description template supplied by HR. This template contains a generic section for all LHB employees prepared by HR. The remainder of the job description describes the title and purpose of the job, accountability, duties and responsibilities. Job descriptions are reviewed as part of the annual joint review. All staff are provided with contracts of employment by HR on commencement or change of post.

B6  Staff records
Confidential staff records are kept in individual files locked within the Blood Sciences laboratory managers office. These include:
- Personal and employment details, terms and conditions, annual reviews.
- Job description
- Relevant educational and professional qualifications and records of study leave
- Occupational health record
- Record of any disciplinary action

Other records kept by the Blood Sciences laboratory manager include:
- Staff induction and orientation
- Attendance at fire lectures and other mandatory staff training sessions
- Absence records
- Accident records are kept in the incident file in the Consultant Biochemist's office.

Some staff records are kept by the HR department and the occupational health department within the Health Board.

Certificates of registration and records of continuing professional development are the responsibility of each individual member of staff. Personal portfolio files are provided. Records of training and competency assessments are kept by the blood sciences laboratory manager.

B7  Staff annual joint review
All staff participate in an annual joint review known within the Hywel Dda Health Board as a PDR (Personal Development Review). BMS/MLA records are kept by departmental blood sciences laboratory manager. All staff performing PDRs receive training in the process and all those staff participating receive a full explanation of the process.

B8  Staff meetings and communication
- **Biochemistry staff meetings** are held at least three times per year. They are led by the Head of Department (HoD) and enable discussion of current issues affecting the laboratory and services provided. These meetings are attended by all laboratory staff. Minutes are held by the Pathology Secretary and on Q-Pulse.
- **Biochemistry senior staff meetings** are held on a regular basis with at least 3 meetings being held per year. These are attended by the Head of Department, blood sciences laboratory manager, SBMS and departmental quality manager. Minutes are held by the Pathology Secretary and on Q-Pulse.
- **Pathology Advisory Group meetings** take place on a regular basis with at least 6 meetings being held per year. The membership is as follows:
  - Chairman – Mr Gethin Roberts
B9 Staff training and education

All staff training takes place in accordance with the appropriate professional bodies viz.
- The Royal College of Pathologists
- Association of Clinical Biochemists
- Institute of Biomedical Scientists
- Health Professions Council

Trainee staff have a designated supervisor. Further details of all staff training are given in departmental training procedures.

All staff are encouraged to participate in training and development. This is achieved through formal academic courses, CPD, departmental seminars, tutorials and reflective learning.
A formal competency assessment program is in use throughout the department. Competency is assessed initially following training and periodically thereafter. Retraining and reassessment may occur if indicated e.g., poor EQA results.

The training program includes all assigned work processes and procedures, the quality management system, the laboratory computer system, health and safety and the ethics and confidentiality of information.

There are also a number of mandatory courses and updates that all staff are required to attend.

Staff undertaking further studies have access to the Hospital Postgraduate Centre with library and full internet facilities. All staff are encouraged to attend appropriate meetings or courses. Financial support is provided in accordance with LHB policy.

Records of training and education are kept by the blood sciences laboratory manager or by staff themselves as part of CPD records.
6 Premises and Environment

C1 Premises and environment
The premises provide a safe working environment in line with current legislation. There is adequate space, and facilities for staff. Access is restricted to authorised personnel, with appropriate signs to restrict access, coded locks and doorbell for visitors. Patients are not permitted into the Biochemistry Department.

C2 Facilities for staff
Staff have adequate separate toilet facilities
There is a conveniently located rest room with basic catering and washing facilities
There is a changing area with storage lockers. Protective clothing is stored separately.

C3 Facilities for patients
Patients are not permitted within the Biochemistry Department. A phlebotomy service is provided by haematology staff within the Outpatient Department of the main hospital.

C4 Facilities for storage
There is a departmental store room for consumables.
Process and quality records are kept according to [MPPAT609 Procedure for the Control of Process and Quality Records]. Clinical material is stored within the laboratory as described in [MPBHB202 Procedure for the Control of Clinical Material] held within the laboratory.

There are locked fireproof cabinets provided for storage of
- Inflammable solvents
- Corrosive liquids
- Poisons

Reagents are stored in designated refrigerators, freezers, or at room temperature if appropriate. All units are continuously monitored and alarms set for failure.
Drugs, vaccines and other therapeutics are not kept within the laboratory.

A limited amount of waste clinical material is held within the laboratory, but is collected by the portering staff for appropriate disposal (relates to C5 and E4).

C5 Health and safety
The Biochemistry Department is committed to ensure a safe working environment for staff and visitors.

The current laboratory was established in September 2010 as phase I of the ‘Front of House’ modernisation scheme for the hospital. It has been designed to become part of a fully integrated ‘Blood Sciences’ department, with Haematology and Microbiology moving into adequate areas in phase II of the development. Phase II is due for completion in 2014.

There is a designated Health and Safety Officer whose name is prominently displayed in the laboratory on the Health and Safety notice board.
Health and safety procedures specific to the Biochemistry Department are provided within [MPBHB200 Health and Safety Manual]. All staff are required to sign that they have read and understood the content of this handbook.

The laboratory adheres to COSHH regulations and local health and safety requirements. Further details are given in the Health and Safety handbook and in individual laboratory procedures. Risk Assessments are also carried out and available in the department.

The Consultant Microbiologist at the LHB is the nominated person responsible for infection control. An up to date copy of the LHB Infection Control Manual is kept in the Consultant Clinical Biochemist’s office. An up to date copy of the organisation’s major incident plan and the Biochemistry [MPBIO208 Major Incident Plan] is also kept in the Consultant Biochemist’s office.

7 Equipment, Information Systems and Reagents

D1 Procurement and management of equipment
Equipment procurement is carried out according to [MPBIO204 Procedure for the Procurement and Management of Equipment]. An equipment inventory is held by the department on Q-Pulse. An Asset Register of all biochemistry equipment is maintained by the LHB Finance Department and is updated annually. Maintenance contract and service records are held by the blood sciences laboratory manager. Records of instrument maintenance, calibration and monitoring are kept within the laboratory.

D2 Management of data and information
Virtually all clinical information relating to Biochemistry is stored on the laboratory computer system. Other relevant information is stored as described in [MPPAT609 Procedure for the Control of Process and Quality Records] held within the department.

Details about the use and maintenance of the Telepath computer system are found in the following procedures: [LPBIO213 Telepath User Guide] in laboratory and [MPBIO209 Systems Security Policy - Telepath].

Matters relating to confidentiality of records and data protection are managed by the Hospital Data Protection Officer Bob Mander (WWGH) and Caldicott Guardian Dr. Sue Fish (Medical Director), both of whom speak at the statutory induction day for all new staff. The LHB Information Management and Technology Department has produced, an Information Security Policy, which gives guidance to all employees on general standards of security and confidentiality in line with The Data Protection Act 1998, Freedom of Information Act 2000, and other relevant legislation and directives. This policy is available via the LHB Intranet.

Specific confidentiality/security matters relevant to Biochemistry staff are detailed in the [MPPAT202 Procedure for the Management of Data and Information] held in the laboratory.

D3 Management of materials
The requirements for this standard are detailed in the [MPBIO206 Procedure for Management of reagents, calibration and QC material] and [LPBIO208 Procedure for fridge/freezer monitoring] held within the laboratory. All reagents kits and chemicals are stored in accordance with manufacturer’s
8 Pre-Examination Process

E1 Information for users and patients
Information for users is provided in the Pathology User Guide [LIPAT201 – LIPAT206 A Guide to Pathology Services at Bronglais General Hospital]. This can be accessed electronically via the LHB Intranet. Current reference ranges for Biochemistry tests are also available on the Intranet [LIBIO252].

Information for patients is also available as applicable.

E2 Request form
A pre-printed hospital pathology request form is available for the joint requesting of Biochemistry, Haematology and Immunology tests (the latter being sent to the Biochemistry laboratory for referral to specialist centres). Space is provided for data essential for patient identification, requesting doctor, required tests and clinical details. GPs have recently been provided with printers to give location-specific bar-coded labels for request forms, to ensure that results are returned to the correct requesting location.

E3 Specimen collection and handling
The requirements for this standard are detailed in the [LPBIO200 Procedure for Specimen Collection and Handling]. Additional operating procedures [LPBIO209 Procedure for Urgent work] and [LPBIO208 Procedure for emergency specimen handling] are held within the laboratory.

E4 Specimen transportation
Specimen collection and transportation is provided by the Facilities Directorate and is monitored and reviewed by the Pathology Department. Further details relating to specimen transportation and packaging are covered by [LPPAT200 The Safe Transport of Pathological Material].

E5 Specimen reception
The requirements for this standard are detailed in [LPBIO202 Specimen Reception].

E6 Specimen Referral
The requirements for this standard are detailed in the [LPBIO204 Procedure for the Referral of Specimens to other Laboratories].

9 Examination Process

F1 Selection and validation of examination procedures
The laboratory constantly strives to keep abreast of new clinical or technical developments and seeks to employ new methodology where appropriate. The decision to introduce new tests is taken by joint assessment of current literature, developments in technology, requests from hospital Consultants, NSF and NICE guidelines. New instruments, tests and reagents are validated before use according to the [MPBIO211 Procedure for Validation of New Tests] held in the Main Laboratory. Validation is undertaken for all new methods and kept by the Quality Manager as part of the laboratory controlled documentation.
F2 Examination procedures
Written Standard Operating Procedures exist for all routine examinations undertaken within the laboratory. These are grouped into four specific document directories, namely [Roche Procedures], [Olympus Procedures] [HPLC] and [Miscellaneous Procedures].

F3 Assuring the quality of examinations
The quality of examinations is ensured by the routine assessment of specimen integrity and noting of inappropriate specimen type or delayed receipt. It is also assured by running of both internal quality control (IQC) and external quality assurance (EQA) materials alongside routine patient samples. Records of daily/weekly QC and instrument performance are kept on the relevant departmental sheets. Other quality related issues are covered through the internal audit process (related to H3-H7).

Further details are given in the individual test and instrument procedures and [MPBIO212 Management of participation in external quality assurance schemes].

10 Post-Examination Process

G1 Reporting results
Electronic reports are generated for all tests undertaken within the Biochemistry laboratory. GP practices receive reports electronically via a GP link; followed by a printed report, where specifically requested. All other requesting locations receive a printed report. Hospital clinicians may view authorised reports electronically by means of a web browser. Further details of reporting and interpretation of results is described in [LPBIO212 Procedure for reporting test results].

G2 The report
See G1 above

G3 The telephoned report
This procedure is fulfilled by [LPBIO212 Procedure for reporting test results].

G4 The Amended report
Occasionally it may be necessary to amend reports. Details can be found in [LPBIO212 Procedure for reporting test results].

G5 Clinical advice and interpretation
This is provided by the Head of Department or Deputy, and is available on a 24 hour, 7 day a week basis.

11 Evaluation and Quality Assurance

H1 Evaluation and improvement processes
This standard is fulfilled by the procedure [MPPAT607 Procedure for continual quality improvement]. In addition, a Quality Improvement plan is held by the pathology quality manager detailing quality objectives. This plan is regularly reviewed.
The results of all evaluation and improvement processes are available to staff and users as required. Evaluation and improvement data also forms part of the Annual Management review.

H2  Assessment of user satisfaction and complaints
User satisfaction or complaints are usually dealt with informally by the Head of Department, or Deputy, through routine contact with users. Complaints arising from management procedural issues within the lab are dealt with internally at Biochemistry Staff meetings and recorded in the minutes. Complaints arising from a clinical incident are dealt with according to the Hywel Dda Health Board complaints procedure. All complaints are logged on the pathology complaints database which is held by the pathology quality manager. Further details are given in the [MPPAT607 Procedure for continual quality improvement]. Compliments/complaints relating to Pathology are reviewed regularly at Bronglais Pathology Advisory Group meeting or directly with the Pathology services manager.

User satisfaction is formally reviewed via a pan-pathology questionnaire organised via the Pathology Advisory Group and users comments recorded, reviewed and acted upon.

H3  Internal audit of quality management system
An internal audit of the QMS [QFPAT611 Internal Audit of QMS] is performed annually by the pathology quality manager. Results, non-conformities, recommendations and timescales for corrective and preventive actions are documented.

The results of internal audits are regularly evaluated and the decisions taken documented, monitored, reviewed and acted upon. The results are discussed at departmental staff meetings and quality management meetings.

H4  Internal audit of examination processes
Internal audit of examination processes are carried out by personnel trained in audit within the Biochemistry department according to a preset schedule [Q-Pulse Audit Module]. Results of these audits are recorded with non-conformities, recommendations and time scales for actions documented.

The results are discussed at departmental meetings and quality management meetings.

H5  External quality assessment
The Biochemistry department fully participates in approved External Quality Assurance Schemes appropriate to the examinations and interpretations provided.

Requirements for this standard are detailed in the [MPBIO212 Management of participation in external quality assurance schemes] held within the laboratory.

H6  Quality improvement
There is a procedure for continual quality improvement which includes remedial action, corrective action, preventive action, monitoring of quality indicators and improvement processes [MPPAT607 Procedure for continual quality improvement].

QUALITY MANUAL
In addition, the Consultant and Principal Biochemists regularly attend the Bronglais Hospital Clinical Audit meetings, especially when topics relating to use of the laboratory are presented. Recommendations for new procedures or improvements in laboratory practice raised by the medical staff can thus be addressed in this forum (related to A2, F1). The Head of Department and Principal Biochemist also participate in all audits undertaken by the All Wales Clinical Biochemistry Audit Group. Recommendations from this group are then implemented within the Department and across all Welsh laboratories.

Recommendations from national audits and guidelines from other professional bodies are recorded and implemented as ‘Quality Improvement’ issues as appropriate.

Quality indicators have been established by laboratory management and are used to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes and their relationship to effective patient care.

H7 Identification and control of non-conformities

Procedures have been established by laboratory management to ensure that all non-conformities in pre-examination, examination and post-examination processes are effectively managed to minimise the risks to the users of the service [MPPAT608 Procedure for the Identification and Control of Non-conformities].