QUALITY MANUAL

CLINICAL BIOCHEMISTRY
SOUTH GLASGOW SECTOR
NHS GREATER GLASGOW & CLYDE
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1. Introduction and Scope

A Quality Management system (QMS) exists in Biochemistry (South Sector) in order to establish quality policy and objectives and ensure that those ideals and objectives are achieved through a process of quality planning and review. The QMS is the process developed to support the generation of an efficient and effective, high quality and appropriate laboratory advice, testing and recommendation service.

The Quality Management system ensures that:

- Laboratory management establishes written quality objectives, which are consistent with the quality policy and are regularly reviewed.
- This quality manual is reviewed regularly, updated as required and any changes communicated to all personnel concerned.
- There is a quality manager who has responsibility for the implementation and maintenance of the quality management system.
- There is a process of document control.
- The control of process and quality records are according to current legislation, regulations and guidelines.
- The control of clinical material is according to current legislation, regulations and guidelines.
- Laboratory management conducts an annual review of the laboratory’s quality management system and all its services.

This Quality Manual is cross-referenced to the procedures and forms used by the Biochemistry department. The layout of the Quality Manual follows that of the ISO 15189:2012 Standard for Medical Laboratories and is reviewed at the annual management review. In order to achieve an effective QMS, there is a hierarchy structure of documentation which covers all the processes undertaken by the laboratory.

South Glasgow is the largest of 3 sites in NHS Greater Glasgow and Clyde (GGC). All sites within GGC provide a routine clinical biochemistry service and also have specialist testing functions based on the needs of the users within their sites. Using electronic ordering and an inter-hospital delivery system, stable samples are directed to the appropriate specialist laboratory, with each of the laboratories providing contingency for the others. The service is delivered using common pre-analytical delivery, common laboratory Information technology (IT) and post
analytical IT systems such as clinical portal, Trakcare and Anglia Ice to provide results to the user.

2. General Information

The Queen Elizabeth University Hospital (QEUH) campus is composed of an adult hospital, which caters for adults over the age of 16 and contains 1109 inpatient beds, a children's hospital, which has 256 inpatient care beds for under 16s and the Maternity Unit, in addition to retained services from the Southern General Hospital such as the Institute of Neurological Sciences and other smaller units and facilities. The Hospital is located in Linthouse / Govan in the south-west of Glasgow and provides an extensive range of medical services.

The adult hospital is fully integrated with the children’s hospital and is often considered the same facility for management purposes however both retain some separate functions and entrances. While each part of the Queen Elizabeth University Hospital Campus has its own distinct identity and dedicated specialist staff, each aspect is completely integrated as a single facility with linkages for patient transfer, diagnostic services, emergency care and even a rapid access lift from the emergency helicopter pad on the roof of the adult hospital. For example, the new children’s hospital is not only linked to the adult hospital but also both the adult and children’s hospitals are linked to the redeveloped maternity hospital and to the Neurosciences Institute. Both the adult and children's hospital host accident and emergency departments.

A physical above ground link for patients and staff from the hospitals into the Maternity and Neurosciences Institute buildings exists, allowing most of the campus to be traversed without going outside. The facilities are also linked to the laboratory buildings via an underground tunnel and pneumatic tube system.

Services provided include a full routine and specialised clinical biochemistry service, toxicology services and specialist metabolic services for the Royal Hospital for Children.

These are all supported by medically qualified personnel that offer an excellent clinical support and advice service. An out of hours service operates giving an all year 24hr service. Participation in this service is undertaken by HCPC Registered Biomedical Scientists (BMS). The assays available to service users out-of-hours tend to be all general routine biochemistry analytes that are available on routine analytical platforms. However, this list is not exhaustive and is subject to change.
Contact details and information for users, including test repertoires can be found on our NHS GG&C intranet page:

http://www.staffnet.ggc.scot.nhs.uk/Acute/Diagnostics/All%20Laboratory%20Medicine/Biochemistry/SouthGlasgow/Pages/default49f7ded0f4fb432999497e56fc409289.aspx

Postal address:

Dept of Clinical Biochemistry
Laboratory Medicine and FM Building
Queen Elizabeth University Hospital
Govan Road
Glasgow G51 4TF

Tel: 0141 354 9060
Fax: 0141 232 4049

The **Victoria Ambulatory–Care Hospital** (ACH) is part of the South Glasgow University Hospitals Division. The New Victoria Hospital opened to patients for the first time in June 2009. When it opened the £100 million hospital was one of the most modern and well equipped in Scotland. Services have been redesigned around the needs of the patient to enhance the quality of care and speed up diagnosis and treatment. About 400,000 patients attend the hospital every year. In addition to outpatient clinics, day surgery and diagnostic services, the hospital provides a number of specialist services such as cardiology delivering day surgical procedures e.g. colonoscopy, haemodialysis and deliver chemotherapy.

The South Glasgow Biochemistry Service includes a satellite Blood Science lab situated at the Victoria ACH. This laboratory operates between the hours of 08.45 and 17.00 from Monday to Friday. This laboratory is part of the same management structure and shares the same QMS.

Postal address:

Dept of Clinical Biochemistry
Victoria ACH, Grange Road
Glasgow G42 9LF

Tel: 0141 347 8139
Tel: 0141 347 8141

The South Glasgow Biochemistry Laboratories operate as a “hub and spoke” service with the hub being located at the QEUH site. Biochemistry requests generated at both the QEUH and Victoria ACH sites are analysed and reported at the QEUH
laboratory with the exception of urgent requests for a limited test repertoire, originating from the Victoria ACH, which are analysed at the Victoria ACH satellite laboratory. The test repertoire at this site is designed to cover all analytes which may be expected to be required urgently. Samples are transferred between the sites by regularly scheduled NHS transport vans. All staff have their main base at the QEUH site with a Biomedical Scientist and an MLA being deployed to the Victoria ACH on a rotational basis. The equipment deployed at each site is similar to facilitate cross site working. All management and reporting processes are centralised at the QEUH site.

The aim of the South Glasgow Biochemistry Service is to provide an efficient Clinical Biochemistry service to both Hospital Clinicians and General Practitioners to aid in the speedy diagnosis of disease and in the monitoring of its treatment or progress thereafter. Details of the services offered and tests performed by these laboratories along with relevant protocols are contained in the Laboratory Handbook. It is committed to maintaining a safe working environment, a highly skilled workforce and utilising up to date technology to deliver the right result on the right specimen from the right patient that is accurate, properly interpreted and delivered within a clinically appropriate timescale.

South Glasgow Biochemistry Service is dedicated to ensuring that this philosophy remains central to the practice of Clinical Biochemistry.

3. Introduction to the Quality Manual
This Quality Manual describes the Quality Management System (QMS) in use throughout the South Glasgow Biochemistry Service. It encompasses all elements of quality delivery, including management systems, quality assurance and quality control. This manual fulfils two functions: It describes the QMS for the benefit of the laboratory’s own management and staff; and it provides information for users and for inspection/accreditation bodies.
4. Management Requirements

4.1. Organisation and management responsibility

4.1.1. Organisation

General
The organisation and management of the South Glasgow Biochemistry Service is detailed below. The laboratory accepts its responsibility to meet the requirements of ISO15189:2012 when carrying out work at its facilities at the Queen Elizabeth University Hospital and Victoria ACH.

Legal Entity
The South Glasgow Clinical Biochemistry Department is part of the acute services division of NHS Greater Glasgow & Clyde (GG&C) within the Diagnostic directorate. The Department provides a comprehensive and efficient analytical, clinical advisory and educational service of the highest quality to the Division hospitals, other hospitals and Primary Care services within and beyond the Greater Glasgow area. Greater Glasgow and Clyde is the organisation legally responsible and is cited on the Scottish Government and NHS Scotland website as the legal Health board.

http://www.scot.nhs.uk/organisations/

Chief Operating Officer: Robert Calderwood

Diagnostics Directorate:
Associate Medical Director Dr Rachel Green
Director Aileen MacLennan

Laboratory Medicine Directorate:
Clinical Director Dr Anne Cruickshank
General Manager Isobel Neil
Assistant General Manager Jane Gibb
Head of Service, Biochemistry Dr Colleen Ross

Ethical Conduct
NHS Greater Glasgow & Clyde Standing Financial Instructions EX_DOC_4 and Fraud Policy EX_DOC_5 ensure that work quality is not affected by external pressure, that users’ confidential information is protected and that a department cannot undertake activity that would diminish confidence in its
impartiality. Conduct of individual staff is governed by their Contract of Employment, Professional bodies: General Medical Council, HCPC, Staff Code of Conduct, Standing Financial Instructions, Caldicott report & the Data Protection Act. Staff are made aware of this information at induction and all staff attend a 3/yearly cycle of attendance at Statutory Mandatory Training by GG&C. Users’ confidential information is also governed by procedure Management of data & information M_IS_001 and by NHSGG&C Information Governance and Information Technology Security Framework on Staffnet.


Laboratory Director
Dr Shona Twaddle MB, ChB, FRCPath, MSc, BSc is a consultant medical Biochemist, Head of Department and Lead Clinician. She fulfils the role of Laboratory Director.

Competence is demonstrated in the following ways:

- Participation in Continuing Professional Development (CPD)
- Membership of the Royal College of Pathologists
- Appointment as a consultant by an Advisory Appointments Committee
- Evidence of continuing practice in the specialty
- Recorded attendance at regular departmental meetings to review service issues and to set quality objectives

The director undergoes annual joint review and has a job plan. The responsibilities of the director are defined in this quality manual.

Day to day management of South Glasgow Biochemistry Service laboratory is under the direction of the Technical Services Manager, Sector Manager and the Quality, Health and Safety and Training Manager and the laboratory director delegates these tasks and other clinical responsibilities to suitable members of the team. See Duties and Responsibilities of Laboratory Director MP_004 for details of delegated responsibilities.
The Lead Clinician/Head of department and Technical Services Manager represent South Glasgow Biochemistry at Greater Glasgow & Clyde management team meetings.

4.1.2. Management Responsibility

**Management Commitment**

Management have shown commitment to the development & implementation of the QMS and to continually improving its effectiveness by:-

- Ensuring laboratory personnel are aware of the importance of meeting the needs and requirements of users as well as regulatory requirements by having these as standing agenda items at management meetings and staff meetings.
- Establishing a quality policy. An original copy signed by the Head of Department is displayed on the quality notice board. The Quality Policy is reviewed prior to the Annual Management Review.
- Establishing quality objectives & plans. See QM_GBIO_002 for the most recent version. This will be updated after each Annual Management Review.
- Defining responsibilities, authorities & inter-relationships (see key roles and responsibilities below)
- Establishing communication processes (see Communication below)

A quality manager is in post specifically for the South Glasgow Biochemistry Service.

There is an annual management review, conducted in June which is focused on the fiscal year April – March. The review is carried out using the Annual Management Review Procedure QP_MR_004.

Competency assessment is a key component of our training programme. It is assessed and reviewed according to criteria established in our Training Policy M_GBIO_TR_002.

Management ensures adequate resources are available by careful selection, induction and training of appropriately qualified staff. Accommodation is a recently completed state-of-the-art laboratory in the New Laboratory Medicine and Facilities Management building at the Queen Elizabeth University Hospital (see 5.2).
**Needs of users**

South Glasgow Biochemistry are committed to providing appropriate testing, advisory and interpretive services to our users. This is stated in our quality policy QP_004. Needs & requirements of users forms part of the annual management review.

Medical, Clinical Scientists & Biomedical Scientists are in daily contact with users to provide support and advice.

The needs of the users are kept under constant review. In practice, this is achieved by user-satisfaction questionnaires, meetings with specific key users and by individual contact between the Director, Technical Services Manager, Medical Consultants, Clinical Scientists and others who use the service. Assessment of user satisfaction and complaints is conducted on a regular basis and consideration of the findings is made between the Director, Laboratory Managers, Consultant / Principal Clinical Scientists.

Recommendations arising from these exercises are translated into requirements which form the focus of objective setting and planning within the quality management system, and consideration of the findings form part of the annual management review.

**Quality policy**

The Quality Policy of the South Glasgow Biochemistry Service is given below and is published as a separate controlled document QP_005 which is displayed within each Biochemistry laboratory within the South Glasgow Biochemistry Service.

**Quality Objectives and Planning**

The Quality Objectives and Plans QM_GBIO_002 describes this processes by which objective will be accomplished. This is established by providing a background to the objective and plan to be executed. The South Glasgow Biochemistry service define the quality objectives of the laboratory in consultation with the parties involved and are responsible for ensuring that plans are made to meet these objectives. The management review, 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.
Responsibility, Authority and Interrelationships

The Clinical Laboratory is part of the Diagnostics Directorate of the Acute Division of NHS Greater Glasgow and Clyde. The organisational relationships are shown below.

Within the South Glasgow Biochemistry Service there is a medical consultant or scientist of equivalent standing in charge. All consultants are professionally responsible and managerially accountable to the Lead Clinician. The Lead Clinician is professionally responsible and managerially accountable to the Head of Service. The Technical Service Manager is managerially responsible to the Assistant General Manager and professionally accountable to the Lead Clinician.
Organisation and Department Management Structure

The table below illustrates the agreed personnel deputising in specific roles.
Key Roles and Responsibilities

**The Laboratory Director (CL)**
The Director is a competent individual with responsibility for, and authority over the whole laboratory. The Director is an individual who ensures, on behalf of the laboratory, that all aspects of the laboratory including management organisation and quality, personnel, premises and environment, equipment, information systems, materials and pre- and post-examination processes function correctly. See above for information regarding deputising responsibilities.

**Technical Services Manager (TSM)**
Responsible for the delivery, management and ongoing development of an effective clinical Biochemistry service. The TSM oversees effective administration of all service related matters, including responsibility as budget holder for the department budgets. The TSM is the professional lead and line manager for all Biomedical Scientists, supervisors/managers and support staff. This encompasses responsibility for recruitment, training, performance and professional development.

**Laboratory Sector Manager (SM)**
The Laboratory Sector Manager is responsible for coordinating the use and provision Biochemistry Point of Care Equipment and liaising with users within South Sector Secondary Care. They are also deputy to the TSM and provides direct supervision and management of Technical Managers, Senior Specialist Biomedical Scientists,
Specialist Biomedical Scientists, Health Care Scientist Support Workers and Administrative & Clerical Staff.

**Quality, Health and Safety and Training Manager**

The Quality, Health and Safety Manager and Training Manager is responsible for ensuring the that the quality management system functions correctly, as laid out in this manual. They are also responsible through the higher management structure for ensuring the health, safety and welfare of staff and visitors within the laboratory as well as ensuring compliance with national and local training requirements.

**Communication**

The Clinical Biochemistry Department holds regular staff meetings, which include all staff grades and categories. Meeting is conducted to ensure staff communication on laboratory matters and active participation by all staff is encouraged. These meetings also offer opportunities for staff to suggest changes and quality improvements. Minutes of the meetings are taken, recorded on Q-Pulse and are available electronically to the staff via Q-Pulse.

The communication and committee structure of internal and external meetings is shown below.

**Laboratory Management Executive Meeting**

The Executive is responsible for the direction of the Service including Quality Management. They are held twice monthly as necessary and as matters dictate with Quality Management, including clinical incidents, complaints, IQC, EQA, CPA, section reports, staffing and Health & Safety as standing agenda items.

Chaired by Dr Shona Twaddle (Medical Consultant, Lead Clinician & Head of Department). Attended by:

- Dr Anne Cruickshank (Medical Consultant, Clinical Director for Diagnostics Greater Glasgow & Clyde)
- Dr Rajeev Srivastava (Medical Consultant)
- Dr Peter Galloway (Medical Consultant, South Glasgow & RHSC and national Training Programme Director)
- Frank Finlay (Consultant Clinical Scientist, and Training Supervisor for Trainee Clinical Biochemists)
- Dr Jane McNeilly (Consultant Clinical Scientist)
- Dr Roy Talbot (Clinical Scientist)
- Colin Smith (Technical Services Manager)
Rose Boyle (Laboratory Sector Manager)  
Laura Jane Scott (Quality, Health & Safety and Training Manager)  
Dr Alan Reid (Clinical Scientist Staff Rep),  
John Allison (BMS Staff Reps)  
Lisa McColl (Office Manager)  

**Biochemistry & Immunology Management Team Meeting (BIMT)**  
The BIMT is GGC wide. They are held monthly but may vary in frequency as necessary and as matters dictate. Its membership is as follows:  
- Head of Service  
- General Manager  
- Assistant General Manager  
- Lead Clinicians  
- Technical Service Managers  
- Laboratory Systems Manager  
- Secretarial support  
- Management Accountant  
- Human Resources Manager  
- Staff Side Representative  

**Quality Team Meeting**  
Meets monthly but may vary in frequency as necessary and as matters dictate. Its membership is as follows:  
- Lead Clinician  
- Medical Consultants  
- Clinical Scientists  
- Technical Service Manager  
- Laboratory Sector Manager  
- Quality, Training, Health & Safety Manager  
- Senior Biomedical Scientists  
- Secretarial support  

**Sectional EQA and IQC meetings**  
These are held in the respective sections (core, metabolic and toxicology) monthly. They run below the quality team meeting and reports from these sections are part of the Quality Team meeting agenda. They are attended by:  
- Quality, Health and Safety and Training Manager  
- Clinical Scientists
Senior BMS staff

*All Staff meeting (General Staff Meeting)*
Held monthly in two back to back sessions to allow most staff to attend. Chaired by the Technical Services Manager. All staff are encouraged to attend. Agenda items include service delivery, health and safety, quality and staffing. This meeting provides a forum for staff suggestions.

*Laboratory Health & Safety Partnership Committee*
Meets six times a year but may vary in frequency as necessary and as matters dictate. Its membership is as follows:
- Assistant General Manager
- Technical Head of Department from each discipline or their deputy (Chairperson and secretory rotation)
- Health & Safety Managers and/or Officers from his/her own discipline.
- Secretarial support
The meetings are conducted as a multidisciplinary meet to discuss issues within the Laboratory Medicine and FM Building. The proceedings are recorded accordingly by the current chair from Biochemistry.

*Scientific Forum*
Meets every 2-3 months and comprises Consultants from biochemistry across GG&C (both medical and scientists) with representation from TSMs. It considers matters that are referred to it by BIMT (and others) that require clinical direction, e.g. is a new test fit for purpose in terms of diagnostic performance, are reference ranges in use appropriate, are reporting practices consistent across sectors, are critical limits for phoning of abnormal results consistent across sectors/appropriate for clinical significance. It is also a forum in which consensus can be reached on items such as where we send samples for tests not performed within GG&C, and how to implement and communicate to users changes that affect all sectors e.g. change in specimen type, introduction of new tests.

*Quality Manager*
Laura Jane Scott is the appointed Quality Manager with delegated responsibility for establishing, implementing and maintaining a quality management system and reporting to management on its performance and needs for improvement. The Quality Manager is a member of the Laboratory Management Executive Group. The Quality Manager’s job description is available in personnel files.
4.2. Quality Management System

4.2.1. General requirements
Creation of this quality manual provides documentary evidence of the existence of a QMS within the laboratory. Laboratory management will endeavour to improve the effectiveness of this QMS in accordance with the requirements of International Standard ISO 15189:2012.

This Quality Manual can be regarded as the index volume to the management, laboratory, clinical and quality procedures. Subsequent sections of this Quality Manual are arranged so that they equate with sections of ISO 15189:2012. There is a brief description of the way in which the laboratory seeks to comply with the particular section of the standard and references are given to appropriate procedures.

The quality management system and the examination processes are continually evaluated and quality assured. 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.

4.2.2. Documentation Requirements
Evidence that we have established a quality management system includes:-
Our Quality Manual, Quality Policy, the appointment of a Quality Manager and the implementation of a quality management system.

The key documentation demonstrating this are as follows:-
Q_004 Quality Manual
QP_005 Quality Policy
MP_GBIO_AMR_004 Annual Management Review
QP_G_002 Document control
QP_G_003 Control of process & quality records
QP_G_003 Control of clinical material
EX_DOC_130 UKAS Technical Policy Statements (TPS) (web link)

A licensed copy of the ISO 15189:2012 standard is held in the Quality Managers office.
Knowledge of the quality manual is checked and reinforced by e-mail prompting via Q-Pulse for all individuals, at staff meetings, at the annual joint review and at KSF sessions. The current version is available in Q-Pulse. The quality manual is reviewed by the Quality Manager and Head of Department, or following an adverse event or internally or externally sourced audit which suggests that deficiencies exist or improvements could be made.

The quality manual (and any subsequent revisions) is circulated to all laboratory staff electronically via Q-Pulse. Staff are required to read the contents and acknowledge that they have done so in Q-Pulse.

The quality policy is available on Q-pulse and is displayed on the Quality notice board and in the satellite clinics/lab.

4.3. Document control
The master list of all controlled documents is held on Q-Pulse. Each section leader or responsible person maintains and updates a record of all controlled documents. The Quality Manager is responsible for all aspects of the document control system.

SOPs, forms, worksheets and external documents have a unique identifying code, review date, version number, pagination and name of author and authoriser. Only active documents are available at workstations with obsolete or inactive documents removed and stored indefinitely electronically. The laboratory use procedures QP_G_002 and the Ideagen Quality software package Q-Pulse to fulfil this standard.

4.4. Service Level Agreements
The contractual arrangement between the laboratory and its users is defined in an SLA which covers basic aspects of safe delivery, turnaround and phoning significantly abnormal results. The individual sample details are disclosed via manual request forms or for sites within NHSGGC electronically using Sunquest Integrated Care Environment (ICE) system for primary care or trak care for secondary care. Currently ongoing roll out of NPEx across Scottish labs (and others) will allow this to become the common electronic system for non-NHSGGC requests.

Referred work is carried out by either GGC laboratories which fall under the same overall management structure or other CPA/ UKAS accredited laboratories. If any formal service level agreements do have to be set up, the process is detailed in MP_GBIO_001.
4.5. Examination by Referral Laboratories

The general requirements for sample referral to reference laboratories are described in the Laboratory Test Database LF_GEN_013. This is then supplemented by more detailed departmental methods. All procedures adhere to current UN 3373 regulations regarding the transportation of samples.

Referral facilities are only used:
When the requested test or examination procedure is outside of our stated repertoire and to undertake the test in-house would be inappropriate in terms of ensuring the quality of the result and / or it would be economically non-viable.

To provide an expert opinion on a case initially tested and reported by the laboratory.

Laboratory management are responsible for selecting and monitoring the quality and competency of referral laboratories and consultants on an ongoing basis. See MP_REF_001.

Wherever possible samples are referred only to those laboratories that are CPA/UKAS accredited. Turnaround times produced by referral centres are checked periodically. Annually referral centres are checked by sending out an Evaluation of Referral Laboratories Letter. On completion of this letter/form QF_RL_001 the laboratory can detail each referral laboratories CPA/UKAS status, performance in EQA and average turnaround time. This will ensure that the quality of our service is not compromised by the actions of a third party.

The laboratory retains responsibility for ensuring that the results of tests undertaken by referral laboratories are provided to the test requester.

Any referral tests undertaken are clearly identified as having been generated by the referral laboratory on the report issued to the test requester.

4.6. External Supplies and Services

The selection and purchase of laboratory equipment is governed by the Procurement and Management of Equipment SOP MP_005 which is available via the Documents Module of Q- Pulse.

We aim to continually improve the quality of our service by carefully selecting suppliers, and by regularly reviewing their performance.
An annual review is made as the end of the financial year approaches and in due time for raising standing orders for the new financial year. Services & supplies are procured via Service Contracts. Consideration is taken of:

- Quality of service
- Professionalism
- Costs
- Contractual obligation
- Recent performance
- Availability of stock
- Time to delivery
- Partnership

Due consideration is afforded any material, kit or reagent before trial/demonstration etc are commenced. Results are collated, users’ opinions sought and resource implications gathered before a decision is made with the service to the patient in mind.

See M_MM_009 Policy and Procedure for the Management of materials for more detail.

A list of approved suppliers of equipment, reagents and consumables is kept within PECOS electronic ordering system and within the shared GGC biochemistry drive.

4.7. Advisory Services
We aim to maintain close contact with our users in order to ensure that the service meets their needs & requirements.

Information for service users, such as sample requirements, clinical limitations of specific tests and frequency of performing specific tests is made available for users via the laboratory handbooks on the Biochemistry website.

The laboratory handbook MP_006 has been prepared after consultation with users and includes:

- Contact details of key members of staff
- The location of the laboratories
• Services offered by the laboratories
• Opening times of the laboratories
• Details of out of hours services and/or shift system in place in each hospital
• Instructions for the completion of the request form
• Instructions for the transportation of samples, including any special handling needs
• Availability of clinical advice and interpretation
• The names and addresses of laboratories to which work is routinely referred
• The repertoire for each department including specimens required, sample volumes, special precautions, how to perform Point of Care Testing (POCT), how to perform function tests, turnaround times and reference ranges
• A list of those key factors which are known to affect the performance of the test or the interpretation of the results
• The time limits for requesting additional examinations

Leaflets, supplied by the appropriate hospital directorate, are given to patients prior to any medical or surgical intervention being performed. They include:

• An explanation of any clinical procedure to be performed
• Instructions regarding preparation for the procedure

Interpretative reports and clinical advice are the responsibility of the consultant Biochemists and Clinical Scientists. Such staff are available to discuss results with clinical colleagues. Advice on individual clinical cases or obtaining professional judgement on specific results can be obtained by contacting the laboratory.

Clinical staff are also available to assist users to obtain the most effective utilisation of the laboratory service. Laboratory staff are also able to offer advice to assist with the correction of specific problems that may be experienced by users, such as instances of sample rejection due to a failure to meet laboratory acceptance criteria.

4.8. Resolution of Complaints
This is fulfilled by procedure M_001 and accessing the StaffNet NHS Complaints Procedure and trust Complaint Policy available via StaffNet.

Complaints which are escalated beyond the laboratory director are handled by the GG&C Complaints Department. They are disseminated via General Managers for departmental investigations.
The laboratory investigates all complaints received from clients or other parties and any anomalies identified relating to the laboratory’s activities. A Q-Pulse CA/PA record is generated of any such complaints or anomalies and of any actions taken by the laboratory in response. The laboratory aims-

- To take all complaints seriously
- To deal with the client in a courteous manner
- To try to resolve the issue immediately at a local level
- To inform the client about the progress of the complaint
- To make corrective action as soon as possible
- To investigate root cause analysis to prevent recurrence

All complaints are reviewed at the annual management review meeting.

4.8.1. Staff Complaints
Staff who wish to complain should do so to their line manager in the first incidence. Any complaints/ issues that cannot be resolved should be escalated to the Service Manager/ Technical Services Manager. There is a staff side union representative on site who is available for advice on staff issues. This service is available to all staff. This information is included in MP_003 Information for Staff.

4.9. Identification and Control of Non-Conformances
This standard is fulfilled by procedure QP_NC_001 Identification and Control of Non Conformities. The procedure includes:

- Designating the responsibilities and authorities for the management of the nonconformities
- Defining the remedial actions to be taken
- Halting the examinations and withholding the report as necessary
- Consideration of the medical significance of any nonconforming examinations and, where appropriate, informing the user (requesting clinician)
- Recalling the results of any nonconforming examinations already released or appropriately identifying such results, as necessary
- Defining the responsibility for authorisation of resumption of examinations
- Documenting and recording each episode of nonconformity, with these records being reviewed at regular specified intervals by laboratory management to detect trends and initiate corrective actions

Nonconformities may arise from different sources and may include:
• Clinician complaints
• Errors noticed by staff or reported by users
• Internal Quality Control indications
• Instrument calibrations
• Checking of consumable materials
• Staff suggestions
• Laboratory Management Reviews
• Internal audits
• External audit

4.10. Corrective Action
This standard is fulfilled by procedure for Quality Improvement QP_G_008.

4.11. Preventative Action
This standard is fulfilled by procedure for Quality Improvement QP_G_008.

4.12. Continual Improvement
All standard operating procedures are reviewed regularly as per the requirements of the document control system in order to ensure the accuracy of the content and also as an opportunity to identify potential sources of improvement in Quality Management or Technical Practices. Suggested changes are logged via the change request facility within the Q-Pulse Document Module as per QP_G_002 Document Control.

Actions taken to improve the quality of service are periodically reviewed for effectiveness. Such reviews include monitoring the levels of non-conformances traceable to the area or activity the quality improvement action is associated with.

The Laboratory has produced a number of performance indicators, which are used to monitor the Laboratory’s contribution to patient care and also to indicate future quality objectives and performance improvements.

4.13. Control of Records
The Laboratory aims to comply with the national guidance document The retention and storage of pathological records and specimens as co-authored by the Royal College of Pathologists (RCPPath) and the Institute of Biomedical Science (IBMS).
The storage facilities for these records provide a suitable environment so that access is restricted and so that loss due to damage or deterioration is minimised.

Please refer Control of Process and Quality Records QP_G_004 for further details of the documents that are retained and their specific retention periods.

The list of approved suppliers available to the laboratory is maintained via the PECOS system and in the GGC shared drive.


A programme of evaluation and audits is created annually within the department to demonstrate that the pre-examination, examination and post-examination processes are being conducted in a manner that meets the requirements of our users and fulfils the ISO 15189 standard.

The Laboratory uses internal audit to provide evidence that the QMS is conformed to, effective, implemented and maintained across all departments. Assessment audit tool template documents have been devised and are available via Q-Pulse.

The effectiveness of preventive actions, corrective actions and subsequent improvements resulting from these audits is evaluated and monitored as part of management review.

4.14.2. Periodic Review of Requests and Suitability of Procedures and Sample Requirements

All procedures conducted within the laboratory and the sample requirements for them are reviewed by the Biochemistry management Team (BIMT) and the Scientific Forum. Information from the Scientific Forum feeds into the Biochemistry Management Team (BIMT) and vice versa and is included within the laboratory directors report for the AMR. Local assessment of procedures and sample requirements are also included within individual section reports compiled by supervisory technical staff so the requirements are fed both from management and technical levels.

4.14.3. Assessment of user feedback

There are regular opportunities for service user feedback on the effectiveness of the laboratory’s service via dedicated commissioner meetings, formal clinical rounds,
MDT participation and via periodic service user feedback surveys. Minutes of these afore mentioned meetings are held with specific action points noted and assigned to specific staff together with an agreed timescale for implementation. Ad hoc positive user feedback is captured in Q-pulse using a feedback notice as detailed in M_001 Complaints and Feedback Policy.

4.14.4. Staff Suggestions
The Laboratory is committed to ensuring that staff feel suitably empowered to make suggestions for quality improvement. They can make these suggestions via departmental meetings, in one to one discussions with senior staff and via the Q-Pulse CAPA Module. Staff are encouraged to use Q-pulse to record suggestions as suggestions raised this way are auditable and have defined target dates for response.

4.14.5. Internal Audit
To be compliant with the ISO 15189 requirements and to ensure adequate monitoring and evaluation of processes, the laboratory audits the full scope of activities (including pre examination, examination and post examination) and quality management requirements yearly.

Audits are completed by trained personnel and a list of trained auditors is kept by the Quality Manager who schedules the audits and personnel responsible for performing them. All staff are encouraged to attend audit training and auditors are scheduled to perform audits out with their area of work wherever practicable.

The records of internal audit include:
- The scope of the audit
- The auditor and auditees
- Any nonconformities or deficiencies found along with recommendations and time scale for corrective and preventative actions
- A summary of the audit

The results of internal audit are regularly evaluated and decisions taken are documented, monitored, reviewed and acted upon. Audit findings are communicated to the appropriate personnel. All Audits carried out are readily available for scrutiny within QPulse.

The following are defined in the following Standard operating procedures:
• Internal audit of the Quality Management System QP_G_010
• Internal audit of Examination Procedure QP_WA_001
• Internal audit of Pre Examination, Examination and Post Examination Process QP_G_009
• Procedure for Quality Improvement QP_G_008

The laboratory reduces the risk of potential failures by carrying out preventative action as detailed in QP_G_008 Quality Improvement Processes. All errors reported to have actual or potential clinical effect are reported through DATIX at the discretion of senior staff and, if required, escalated to the clinical risk team.

4.14.7. Quality Indicators
The laboratory sets and reviews quality indicators regularly as detailed in Q_005.

All non conformances or potential issues raised by external organisations during audit are acted upon within the allotted time scales and recorded. All new documents or changes to documents as a result of non conformity identified by external organisations should have this detail noted in the document record.

4.15. Management Review
We aim to regularly review our quality management system, in order to ensure its continued suitability, adequacy & effectiveness in support of patient care. The Annual Management Review (AMR) will cover the fiscal year April – March. Whenever possible the AMR meeting should be held as soon as possible within the next 2 months of the ending of the fiscal year. The agenda MI_003 should be distributed to the members of the Quality Management Group and anyone else involved in producing reports for the meeting.

Reports are requested from managerial and supervisory personnel as per QP_MR_004 Annual Management Review.

Records are kept of all reports and minutes of the AMR recorded in Q-pulse. An executive summary of the management review will be sent to UKAS.
5. Technical Requirements

5.1. Personnel

5.1.1. General
Refer to MP_003 Information for staff

5.1.2. Personnel qualifications
A record of each staff member’s training and copies of HCPC Registration certificates are kept in the TSM’s office.

5.1.3. Job descriptions
(held by individuals and by TSM)
To allow each member of staff to know their duties, responsibilities and rights, they are given a written job description. Job descriptions include:
- Job title
- The location within the organisation
- Accountability
- Main purpose of the job
- Main duties and responsibilities
- Staff annual joint review
- All staff have a contract of employment, which is in compliance with current legislation and provides clear terms and conditions of service

5.1.4. Personnel introduction to the organizational environment
GG&C Health Board has a comprehensive staff orientation and induction programme. An induction pack is issued on or before a new employee's starting date and local induction training is carried out on the first day of work. Details for induction are located within MP_HR_003 Orientation and Induction. New staff have 3 months to complete induction and must be signed off by the training manager.

This local induction training covers such areas as:
- Department/Division information
- Working environment
- Terms and conditions of employment
• Staff facilities
• Healthcare Support Workers code of conduct (from non registered staff)

Records of staff orientation and induction are kept in individuals personal files.

5.1.5. Training
A training and education programme exists for all staff, which is in accordance with guidelines from the relevant professional and registration bodies.

The following are covered under induction:
• Job description including an organisational chart
• Patient confidentiality, data protection and ethical conduct
• Health & Safety
• Equality and Diversity
• Quality Management Introduction
• Q-pulse Introduction

Personnel undergoing training have regular meetings with the training manager and training officer to review the effectiveness of the training programme.

5.1.6. Competence assessment
Competence records are held by the training manager for all processes in the department and individual records are kept by all staff members. Competence is evidence based and for technical staff can include:
• Direct observation of staff carrying out routine work processes and procedures such as routine testing, health and safety checks, equipment maintenance and result entry/ validation.
• Review of work records
• Assessment of problem solving skills and theoretical knowledge of test procedures
• Repeatability of results gathered during set processes such as pipetting specific amounts of liquid accurately.

Management and Clinical staff require to complete evidence based competencies such as:
• Attendance and participation at meetings
• Quality and Key performance indicators being met
• Peer review of case reports
• Production of quality/ management reports

5.1.7. Review of staff performance
All staff participate in an annual joint review (e-KSF for Technical and Clinical Scientist staff and Annual appraisal for Consultant staff) that includes consideration of:
• e-KSF outline for the job role if appropriate.
• The quality objectives and plans of the laboratory.
• The current job content.
• Documentation of training needs and agreed personal objectives with the appraiser.
• Evidence that management has recognised the agreed development needs of individual staff members.

All staff performing e-KSF and appraisals have had training and records of all staff reviews are kept.

5.1.8. Continuing education and professional development
All staff are encouraged to participate in "Continuing Professional Development" (CPD), which is mandatory for continuing registration with HCPC and the Royal College. This is outlined in the training Policy.

Opportunities for further education and training are available in relation to the requirements of the service and individual personal development as outlined in the training policy. The Department provides resources for such education that includes:
• Access to library and information services.
• Suitable accommodation for private study.
• Opportunity to attend meetings, seminars and conferences.
• Financial support.

Records of training and education are kept for each member of staff.

5.1.9. Personnel records
The Human Resources Department of the Diagnostic Directorate of the Acute Division of NHS Greater Glasgow and Clyde holds the complete staff record. The Occupational Health Department holds vaccination records and the Pay Department holds records of payments.
In addition, confidential staff records are kept including:

- Personal details.
- Employment details.
- Job description.
- Terms and conditions of employment.
- A record of staff induction and orientation.
- A record of attendance at fire lectures.
- A record of attendance at manual handling courses.
- A record of education and training.
- Relevant educational and professional qualifications.
- Certificate of registration with the Health & Care Professions Council (HCPC).
- Absence record.
- Accident record.
- Record of annual joint review.
- Occupational health record.
- A record of disciplinary action.

All of the above paperwork is held with either the TSM or the Training Manager.

5.2. Accommodation and environmental conditions

5.2.1. General
We aim to ensure there is a working environment in which staff can perform required functions in accordance with national legislation and guidelines. The premises are a state-of-the-art building which meets all current regulations for medical laboratory accommodation.

The premises have space for:

- Specimen reception.
- The functioning and use of all equipment.
- Separation of incompatible activities (e.g. Office and laboratory).
- Storage facilities.
- Access to the premises is by swipe card entry via locked doors.
- All walk in Fridges and Freezers are fitted with an alarm and emergency release switch and these are checked during the Quarterly workplace inspection.
5.2.2. Laboratory and office facilities
These are well separated / demarcated.

5.2.3. Storage facilities
Paper-light systems operate with regards to reports and storage of paper records. Scanning options are available. Consumables and reagent storage is appropriate with large functional areas (Frozen, cold and ambient).

5.2.4. Staff facilities
Common room refectory, with cooking, eating and drinking facilities are provided at both the main laboratory and the VIC ACH laboratory. Toilets, including disabled, and shower facilities are provided.

5.2.5. Patient sample collection facilities
(N/A)

5.2.6. Facility maintenance and environmental conditions
The premise is a recently refurbished building with new temperature and air management systems in place. Quarterly workplace inspections are carried out and reported to facilities in addition to monthly fire and waste audits. All non conformances are recorded in the CA/PA module on Q-pulse.

Laboratory management’s safety responsibilities are defined in the Health & Safety Manual and in the trusts H&S Policy. A hard copy of this manual is kept in the OM office.

5.3. Laboratory equipment, reagents and consumables

5.3.1. Equipment
The laboratory aim to ensure that sufficient & appropriate equipment is available to ensure the quality of examination results.

Procedures are established for the management of equipment. Refer to MP_005 Procurement and Management of Equipment.

This includes:
- Selection, purchasing and ordering
- Assessment of suppliers
- Receipt and verification of identity and condition
- Acceptance testing
- Issue and inventory management
- Maintenance and repair
- Safe disposal

All equipment is operated by trained and authorised personnel and this is proven by competence records (see 5.1 above). All manuals are stored as either hardcopies or in Q-pulse.

Equipment calibration is set out in MP_010 Equipment calibration and metrological traceability.

All adverse incidents involving equipment are logged on Q-pulse, investigated and reported to the manufacturer.

5.3.2. Reagents and Consumables
Laboratory management ensures the availability of the reagents, calibration material and quality control material required to provide a service which meets the needs and requirements of users. Refer to M_MM_009 Policy and Procedures for the Management of Materials.

Control of Substances Hazardous to Health files (Risk Assessment and COSHH sheets) are maintained for all hazardous materials, and manufacturers’ safety data sheets (MSDS) are held where available.

Materials in use are correctly identified with date of receipt, lot numbers and expiry.

All reagents and consumables affecting the quality of examination results are pre-accepted before being brought into routine use using LI_G_003 Reagent delivery and pre acceptance of new lots. Any lots that are do not meet this criteria or have been involved in an adverse incident and recorded on Q-pulse and reported to the manufacturer.
All records for reagents and consumables are held in the Abbott Reagent Management System (RMS) (see MP_GBIO_009 for operating details) or in the telepath reagent diary (see LI_M_001).

5.4. **Pre-examination processes**

We aim to ensure that our users are fully aware of our service in order that they can make the best use of it. The information includes how to contact us, how to correctly send specimens for analysis, and how to obtain clinical advice. This is available in the lab handbook MP_006 and GP handbook which can be accessed on our website.

5.4.1. **Information for users and patients**

The information for users includes:
- Contact details of key staff
- Location of the laboratory
- Opening hours
- Details of the out of hours service
- Instructions for specimen transport
- Availability of clinical advice and interpretation
- The repertoire of tests offered, specimen type required and turnaround time
- Key factors which are known to affect the validity of results

5.4.2. **Request form**

The request forms are designed to include:
- Sufficient information to allow unique identification of the patient
- The source of the request
- The requesting individual
- The date and time of specimen collection
- Specimen type and where appropriate the anatomical site of origin
- The investigation required
- Relevant clinical information
- Location to which report should be sent (including copy report)
- The unique laboratory accession number

The date & time of receipt at the laboratory is recorded in the LIMS at computer entry (PID).
The department encourages proper completion of the request form.

5.4.3. Specimen collection and handling
The laboratory handbook MP_006 details the procedures for the proper collection and primary handling of samples. Any samples deviating from this should be recorded. Advice in the lab handbook to minimise specimen collection errors includes:

- Checking the completion of the request form and confirming the identity of the patient
- Checking that the specimen container is correctly labelled
- Ensuring that the specimen is correctly collected
- Minimising the risk of interchange of samples and sub samples
- Ensuring that environmental and storage conditions are fulfilled
- Ensuring the safe disposal of all materials used in specimen collection
- Ensuring that high risk specimens are identified and processed correctly
- Ensuring that all spillages and breakages are dealt with correctly
- Minimising the risk to ensure the safety of the specimen collector carrier, the general public and the receiving laboratory

5.4.4. Specimen transportation
The GG&C Specimen Transport Policy fulfils this standard. This includes:

- Measures to ensure the safety of the courier the general public and the receiving laboratory
- Measures to ensure the confidentiality of patients' samples whilst in transit
- Measures to minimise delay in delivery
- Disinfection protocol following spillage
- Model rules on the type of outer container used to transport specimens

5.4.5. Sample reception
The Specimen Reception procedure LP_GBIO_SR_031 includes instructions on:

- Accurate matching of request form and specimen
- Recording date of receipt
- Assigning a unique laboratory accession number
- Handling urgent samples
- Spillage protocol
- Staff safety
Specimen Acceptance and Rejection Criteria LI_SR_012 has instructions for the rejection of specimens that includes:

- The criteria for rejection of specimens.
- The recording of rejected samples.
- Notification of the user concerning rejected specimens.

5.5. Examination processes
We aim to use procedures that are selected to meet the needs and requirements of the users in order to make them confident that our test repertoire is designed for the maximum benefit of their patients.

5.5.1. Selection, verification and validation of examination procedures
Prior to introduction, all examination procedures are validated and verified for their intended use (MP_G_007 Procedure for the Selection, Validation & Verification of Examination Procedures) and the methods used and results obtained are recorded using forms QF_G_001 and QF_G_003.

When examination procedures are changed so that results or their interpretation may be significantly different, the changes are explained to users prior to the introduction of the new procedure.

Refer to QP_GBIO_003 for Measurement of Uncertainty and Traceability protocol.

5.5.2. Biological Reference Intervals or Clinical Decision Values
All results that breach the clinical decision values set by the laboratory are telephoned to users as per protocol LP_R_005 Procedure for Telephoning Results (appendix A). This information is also in our laboratory handbooks.

5.5.3. Documentation of Examination procedures
The standard operating procedures (SOPs) for the conduct of all examinations are prepared according to the Document Control procedure QP_G_002 and templates QP_G_012 and QP_G_006.

Procedures for the conduct of all laboratory procedures include the following:

- The purpose and scope of the examination.
- Principle of procedures
- Responsibility.
- References and associated documents (e.g. cross reference to).
- Safety considerations.
5.6. Ensuring quality of examination results

The laboratory uses a wide range of procedures in order to detect errors and prevent release of erroneous results including IQC and inter-laboratory comparisons (EQA). The materials used are as close as possible to patient samples in their reaction to the examining systems and the systems are designed to check the entire process (pre examination, examination and post examination).

IQC

There is a comprehensive range of procedures for internal quality control (IQC) of all examinations, which verify that the intended quality is achieved. The laboratory has procedures in place for preventing the release of results in the event of quality control failure- see QP_M_001, QI_C_001 and QP_T_001.

EQA

The laboratory participates fully in the available External Quality Assessment schemes appropriate to the examinations and interpretations provided. EQA samples are integrated into the routine work flow of the lab as much as possible in order to mimic the handling of actual patient samples. The laboratory does not communicate the results of EQA samples with other participants until after the submission of data.

EQA samples are run on every analyser to show comparability of results (see QP_G_014 Comparability of patient results).
A record of results against agreed performance criteria of the EQA scheme is maintained and any non conformance recorded on Q-pulse and investigated (see Q_006 External Quality Assessment Policy). EQA performance results are reviewed at the section quality meetings and any poor performance escalated to the Quality team and Executive groups. All EQA reports form part of the minutes taken at the quality meetings and are available to all staff on Q-pulse.

5.7. Post-examination processes

5.7.1. Review of results
Authorised personnel review the results of laboratory examinations in order to ensure that patient safety is not compromised. The scrutiny and reporting of results by reporting biochemists and auto selection of results is detailed in LP_R_002. The computerised selection of severely abnormal results is detailed in LP_R_003.

5.7.2. Storage, retention & disposal of clinical samples
The laboratory has a documented procedure for the identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. This is described in procedure QP_G_003 Control of clinical material. This document also describes the storage of paediatric samples which require to be stored for different time periods than adult samples. Samples are disposed of in accordance with GG&C policy and M_HS_001 Disposal of Clinical waste.

5.8. Reporting of results

5.8.1. The report
The laboratory produces reports which are clear and unambiguous and which contain sufficient information to enable our users to interpret the results for accurate treatment of their patients. The majority of reports are returned by electronic means via Track care and GP ICE but paper reports are also sent to areas that do not have access to these systems. All manual transcriptions are checked for accuracy.

Samples which have been delayed and the results could compromise patient care are handled as per LI_SR_002 Delayed Receipt Samples. Reports include the following information:

- Identification of the examination(s) performed
- The laboratory name and contact phone number
• Any examinations performed by a referral laboratory
• The name, date of birth and CHI number of the patient (on each page)
• The requesting individual and the source to which reports are returned (on each page)
• The specimen type and date of collection.
• Date of report
• Examination result and units
• Biological reference intervals (this is also in the laboratory handbook)
• Interpretive comments as appropriate
• Highlighting of abnormal results
• Identification of the person (or system) reviewing the results and authorising release of the report
• Page number and total of pages

5.9. Release of results
The laboratory has documented procedures for the release of examination results including details of the authorised staff who may release results and to whom they may release them. The standard is covered in:
• LP_R_003 Computerised selection of severely abnormal results
• LP_R_005 Procedure for telephoning results
• LP_R_002 Scrutiny and Reporting of Results by Reporting Biochemists and Auto selection of Results

5.9.3. Revised reports
The procedure SOP_GEN_0016 for issuing an amended report includes:
• The criteria for issuing amended reports.
• Authorisation level of staff able to amend reports.
• The identification of amended reports to the user.
• A process of recording the issue of an amended report.
• The reason for issuing an amended report.
• Instigation of corrective and/or preventive action, if required.
• A process for archiving amended results.

5.10. Laboratory information management
The laboratory ensures that access to data and information is given to authorised staff to enable them to provide a service which meets the needs and requirements
of our users. The confidentiality of patient information is governed by the Data Protection Act, NHSGG&C I.T. Policy and local policy M_008 Management of Data and information. The local policy is distributed to all staff for acknowledgment via Q-pulse.

The laboratory information system (LIMS) is TelePath, supported by other IT for specialised tasks such as electronic ordering and reporting systems. These systems are accessed by authorised CSW, Biomedical Scientist, Clinical Scientist, Medical and Administrative staff who are given passwords for each system. All systems are supported by the IT Department of NHSGG&C.