QUALITY MANUAL

(UKAS)

REPRESENTING THE

CLINICAL BIOCHEMISTRY

QUALITY MANAGEMENT SYSTEM

CONTENTS PAGE

1. Introduction

1.1 Scope and Purpose

This Quality Manual, together with Policy and Procedure documents to which it refers, serves to define the Quality Management System (QMS) of the Department of Clinical Biochemistry, Clyde Sector, NHSGGC.
The document has been compiled principally to meet with requirements of the United Kingdom Accreditation Service (UKAS), and, other relevant National and International Quality Standards.
All policies and procedures specified herein are mandatory within the Department of Clinical Biochemistry, Clyde Sector, NHSGGC.
The Quality Manual aims to fulfil two principle functions:

1. Describes the Quality Management System for the benefit of Departmental Staff,
2. Provides insight into the organisation for interested parties outside NHS GG&C.

Clyde Clinical Biochemistry is UKAS accredited to ISO 15189:2012E. A full breakdown of the departmental schedule of accreditation can be found on the UKAS website. Certificate number 9353.

2.0 Organisation and Management Responsibility

2.1 Organisation

The organisation - NHS Greater Glasgow & Clyde (NHS GG&C), is the legal entity for all NHS GGC Laboratories.
This is evidenced by the following links:

Staffnet site:
https://www.nhsggc.org.uk/
Lists all the hospitals within NHS GG&C.

NHS Scotland Recruitment website:
https://jobs.scot.nhs.uk/_results.aspx?catID=15&regionID=9&orgID=&word=
Shows jobs by 'Region - where NHS GGC is one of them.

Scottish Government
https://www2.gov.scot/Topics/Health/NHS-Workforce/NHS-Boards
Public bodies in Scotland includes Health Bodies – NHS Scotland is comprised of 14 Regional NHS Boards – NHS GGC is one of them.

NHS GGC delivers clinical laboratory services across North, South and Clyde sectors of Glasgow. Clyde Clinical Biochemistry is part of the Clyde Sector of NHS Greater Glasgow & Clyde (GG&C).

The Clyde Clinical Biochemistry department aims to fulfil the requirements of ISO 15189: 2012 (E) when providing quick and accurate biochemistry results on a variety of sample types. This service aids hospital clinicians and general practitioners in the speedy diagnosis of disease or in the monitoring of treatment.
The Clyde Clinical Biochemistry Department provides a service across 3 hospital sites:

Inverclyde Royal Hospital (IRH)
Level C
Dept of Clinical Biochemistry
Larkfield Road
Greenock
PA16 0XN

Tel: 01475 633 777 (Switchboard)
Tel: 01475 504 319 (Biochemistry)
Fax: 01475 635 486 (Lab Office)

Royal Alexandra Hospital (RAH)
Dept of Clinical Biochemistry
Corsebar Road
Paisley
PA2 9PN

Tel: 0141 887 9111 (Switchboard)
Tel: 0141 314 6658 (Biochemistry)
Fax: 0141 314 6604 (Lab Office)

Vale of Leven (VOL) Hospital
Dept of Clinical Biochemistry
Main Street
Alexandria
G83 0UA

Tel: 01389 754 121(Switchboard)
Tel: 01389 817 568 (Biochemistry)
Fax: 01389 755 948 (Biochemistry)

Laboratory management within Clyde Clinical Biochemistry ensure:

- Laboratory competence, impartiality, judgement & operational integrity are maintained to the levels set by GG&C and no activities will diminish confidence in these attributes.
- The quality of the service is not influenced by commercial, financial or other pressures.
- Declare any competing services, where conflicts of interest may exist.
- Procedures are in place to ensure staff handle Biochemistry samples in accordance with relevant legal requirements.
- Information is kept confidential.

Policies supporting this are listed below.

Document Number	Title
Staffnet	http://www.staffnet.ggc.scot.nhs.uk/Corporate%20Services/Finance/Pages/FinancialGovernance-New!.aspx http://www.nhsggc.org.uk/working-with-us/hr-connect/policies-

and-staff-governance/policies/code-of-conduct-for-staff/

The laboratory ensures ethical conduct of the staff is maintained by auditing HCPC registration of all qualified Biomedical and Clinical Scientific staff; GMC registration for all Medical staff and ensuring completion of the Health Care Support Worker Workbook for all new Health Care Support workers. For existing Associate Practioners and Health Care Support workers LearnPro module Code of Conduct is required and checked at annual review. In addition, there are a number of mandatory Learnpro modules, such as Clinical Governance and Finance, also reviewed annually, during staff appraisal. Ethical conduct is also discussed and evidenced during the appraisal. All supporting evidence is held within the competence files in the Technical Services Managers office with an overview within the Clyde Biochemistry shared drive:

xggc-fsrv-04>GGC Biochemistry>Clyde>Competence>Competence Overview

Greater Glasgow and Clyde policies on Code of Conduct, Standing Financial Instruction and Fraud are also distributed via the Quality Management System for staff review and acknowledgement.

2.2 Laboratory Director (ISO 4.1.1.4)

Clyde Clinical Biochemistry is directed by the Sector Lead Clinician, who has executive accountability and the competence to take responsibility for the service provided.

Duty	Responsibility	Deputy	Comment
a) Provide effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.	1) Lead clinician, 2) TSM and 3) lab management team.	1)TSM 2) Lab management team	Through BIMT and MSC budget meetings.
b) Relate and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.	1) Lead clinician, 2) TSM and 3) Sector manager.	1) TSM and 2) Sector manager.	Senior lab staff will deal directly with UKAS. Lab issues user surveys, newsletters and has SLA's with all outside service users.
c) Ensure that there are appropriate numbers of	Training Manager	1)TSM 2)Training Lead	Training and education records

staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users			kept of all staff.
d) Ensure the implementation of the quality policy.	Quality Manager	Sector Manager	Controlled document in QMS.
e) Implement a safe laboratory environment in compliance with good practice and applicable requirements.	Health & safety manager	Sector manager	H&S committee meet every 3 months and is a standing item on monthly staff meetings.
f) Serve as a contributing member of the medical staff for these facilities served, if applicable and appropriate.	Lead Clinician	Consultant Clinical Scientists	
g) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.	Consultant Clinical Scientists	Principle Clinical Scientists	24/7 on call consultant cover is provided by one adult rota and one metabolic rota. Both of these are staffed by consultants from Clyde and QEUH Biochemistry
h) Select and monitor laboratory suppliers	TSM	Sector manager	Controlled through managed service contract.
i) Select referral laboratories and monitor the quality of their service.	Cross sector Clinical and Scientific Forum	Cross sector Quality Managers	All referral labs are asked to complete an evaluation form annually, see audit AUD65.
j) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations.	CPD Officer	1).TSM 2).Consultant Clinical Scientist	All staff complete mandatory training, NEQAS, CPD, attend scientific meetings and lunchtime educational presentations.
k) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service and services.	Quality Manager	1).Clinical Lead TSM 1) BMS Audit Lead	Defined through quality manual and quality objectives and plans – QP-CBIO-004. Monitored via

			balanced scorecard monthly at BIMT.
l) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated.	1) Lead clinician, 2) TSM and 3) sector manager.	1)TSM 2) sector manager.	Use audit module in QMS, incident reporting tools Datix and reporting meetings.
m) Address any complaint, request or suggestion from staff and/or users of laboratory services.	Consultant clinical scientists	Quality manager	Managed via QMS system, staff meetings and BIMT.
n) Design and implement a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.	1) Lead clinician, 2)TSM and 3) sector manager.	1)TSM and 2) sector manager.	Contingency protocol within Q-Pulse, MI-CBIO-003 and GG&C policies within Staffnet.
o) Plan and direct research and development, where appropriate.	1) Lead clinician, 2) Consultant Clinical scientists 3) TSM and sector manager.	1) TSM and 2) sector manager.	

The Laboratory Director professionally delegates some clinical, scientific, professional, consultative, advisory, organisational, administrative and educational activities to qualified staff, as appropriate. The duties of the Laboratory Director and all delegated staff are described within their relevant job descriptions, located within the Turas database.

Key Personnel, including the Technical Services Manager, Laboratory Sector Manager and Quality/H&S/Training Manager are professionally responsible and managerially accountable to the Sector Lead Clinician, and to the General Manager (Diagnostics Directorate, NHSGGC).
The Sector Lead Clinician & General Manager would be responsible for ensuring there is no conflict of interest, if the other managers are deputising in more senior roles. This would be recognised & addressed through regular meetings & the approval process of laboratory resources.

2.3 Management responsibility (ISO 4.1.2)

Management commitment

Laboratory management, within Clyde Clinical Biochemistry continuously improve and develop the Quality Management System and monitor its effectiveness by:

- Communicating changes to laboratory staff & highlighting regulatory & accreditation requirements
- Reviewing the Quality Policy annually
- Developing Quality Objectives & plans annually
- Reviewing Clinical Governance & Staff organisation charts
- Implementing communication processes with laboratory staff
- Appointing a Quality, Training, Health & Safety Manager
- Conducting an Annual Management Review (AMR)
- Assessing staff competence
- Ensuring appropriate resources are available for pre-examination, examination & post-examination procedures

The Department Management Team have cross site (Clyde-wide) responsibility. Technical staff are based at RAH but are trained to work during core hours across the Clyde Sector. Hospital Site specific shift rotas operate out with core hours and are staffed by dedicated out of hours teams familiar with the specific operation of each site. The repertoire of testing is located within, Clyde Biochemistry Test Repertoire LF-CBIO-027.

2.4 Needs of Users (ISO 4.1.2.2)

Laboratory management, within Clyde Clinical Biochemistry, ensure Biochemistry advice, examination & reporting procedures meet the needs & requirements of users through the following processes:

The Clyde Clinical Biochemistry provide a Laboratory Handbook and a GP Handbook, to inform users on laboratory services. These documents are available on Staffnet and the NHS GG&C internet site. These documents are listed below.

Document Number	**Title**
PD-CBIO-001	Biochemistry Laboratory Handbook
PD-GGC-003	Biochemistry Handbook for Primary Care Users

The Annual Management Review establishes Quality Objectives (see 4.1.2.4) and a process of quality planning is agreed in order to achieve and maintain these objectives.
Quality planning is based around the International Standard, EN ISO 15189:2012(E), published by the British Standards Institution (BSI) Limited 2012. Laboratory management evaluate laboratory processes in conformity with this accreditation standard and with the needs and requirements of users.

There is a new legal requirement, termed Duty of Candour, where there is an ethical and professional statutory requirement for health care professionals to inform patients of any safety incident, caused by the organisation that has resulted in harm.
This is included in the health professional's 'Code of Conduct'- instructing staff to be honest with patients concerning their care and treatment.

Document Number	Title
QP-CBIO-009	Evaluation, Quality Assurance & Quality Improvement SOP
QP-CBIO-015	Handling of Complaints SOP
MP-GGC-013	Duty of Candour Policy
PD-GGC-013	GGC Board Code of Conduct Policy
PD-GGC-013	IBMS Code of Conduct
MF-CBIO-028	User Feedback
STAFFNET	GG&C Complaints Procedure

2.5 Quality Policy (ISO 4.1.2.3)

Laboratory management, within Clyde Clinical Biochemistry, have established a Quality Policy for the provision of service
Clyde Clinical Biochemistry is dedicated to providing a high Quality service to users. Management of resources, pre-examination, examination & post-examination processes are reviewed and Quality Indicators and Objectives established on a yearly basis, during the Annual Management Review (AMR).

The needs and requirements of the service users are priority. Therefore Clyde Clinical Biochemistry will:

- Uphold professional values and follow good professional guidelines.
- Comply with all NHS policies
- Perform a repertoire of tests that meets the requirements of our users
- Comply with International Quality Standards, such as ISO:15189
- Retain Quality accreditation with the United Kingdom Accreditation Service (UKAS)
- Ensure that all personnel are familiar with the Quality Management System by distributing and acknowledging the Quality Manual and all procedures relevant to their work.
- Commit to the health, safety and welfare of all staff and compliance with relevant environmental legislation. Visitors to every department will be treated with respect and due consideration will be given to their safety while on site
- Continue to assess user satisfaction, internal and external quality assurance and corrective actions as part of continual quality service improvement.

Clyde Clinical Biochemistry commit to:

- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
- Procurement and maintenance of equipment and other resources as are needed for provision of the service

- Collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- Use of examination procedures, which ensure the highest achievable quality of all tests performed
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful

Authorised signature: 

Document Number	Title
QP-CBIO-003	Quality Policy

2.6 Quality Objectives and Planning (ISO 4.1.2.4)

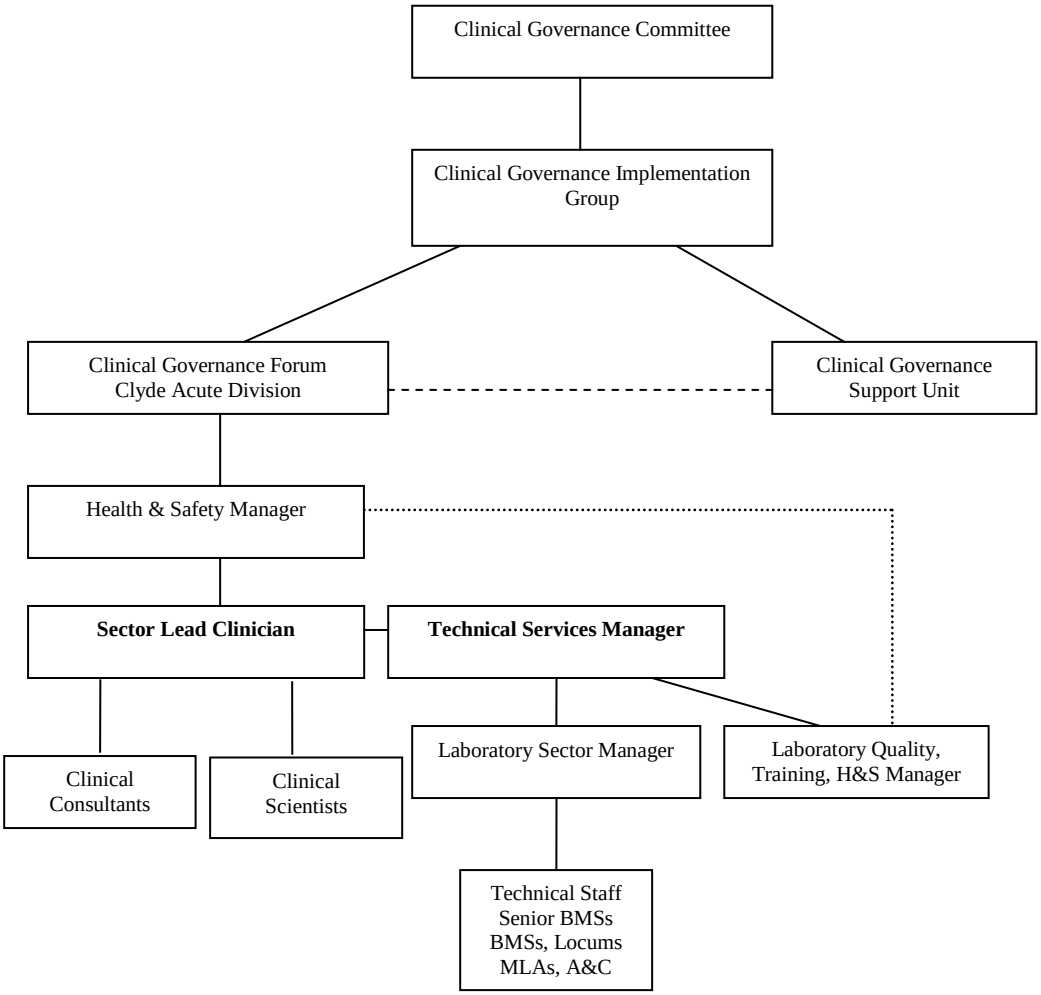
Clyde Clinical Biochemistry department develop quality objectives and plans on an annual basis. Quality planning is based around the International Standard, EN ISO 15189:2012(E), published by the British Standards Institution (BSI) Limited 2012. Laboratory management evaluate laboratory processes in conformity with this accreditation standard and with the needs and requirements of users.
Clyde Clinical Biochemistry Quality Objectives & Plans are listed in the document below.

Document Number	Title
QP-CBIO-004	Quality Objectives & Plans
LFD-CBIO-033	Annual Management Review (AMR)
AUD163	Horiz: ISO 4.2 + 4.3 QMS + Document Control

2.7 Responsibility, Authority & Interrelationships (ISO 4.1.2.5)

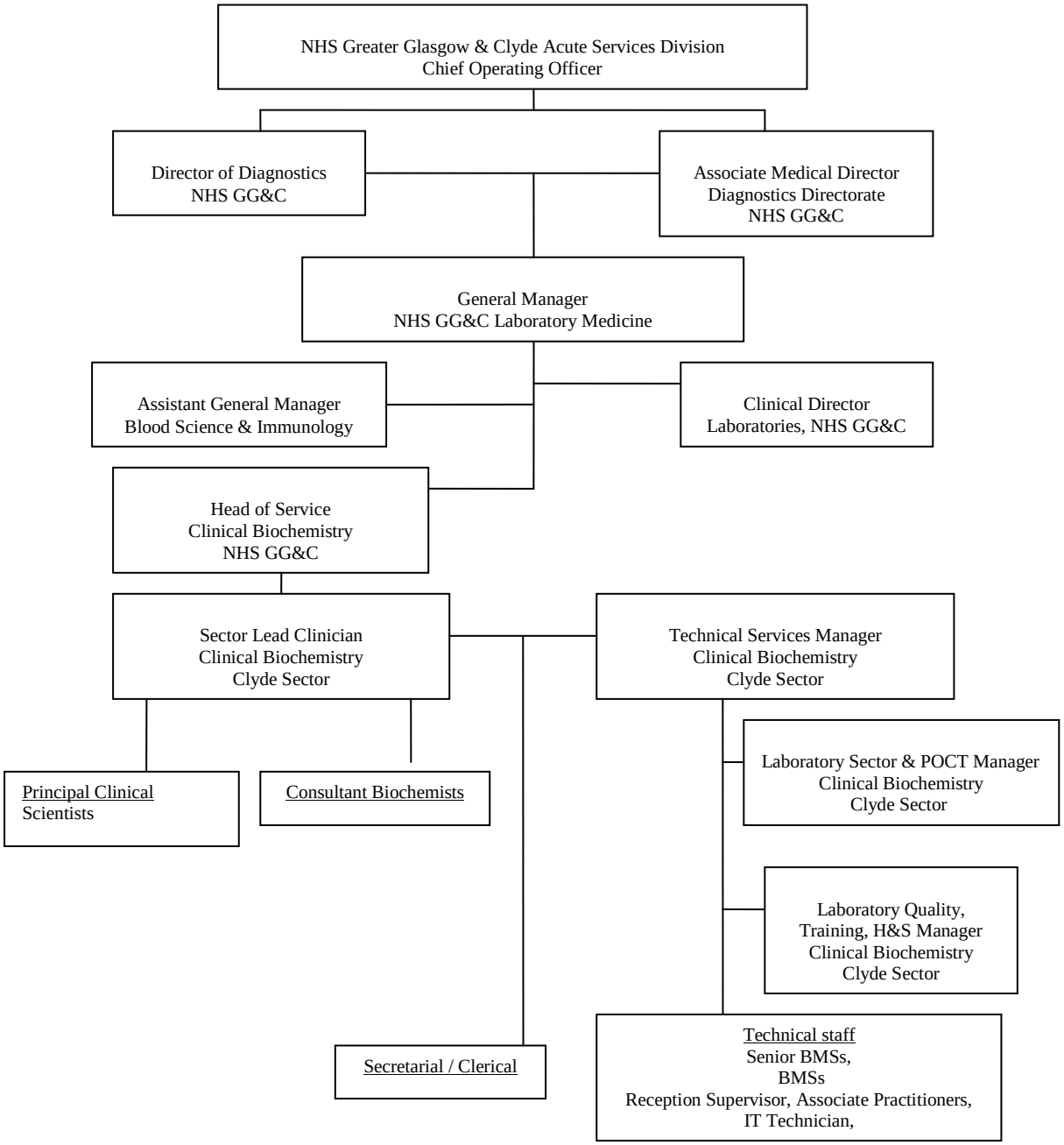
The Clinical Governance Chart below to shows the organisation of Clyde Clinical Biochemistry. The Staff Organisation Chart shows the authority and inter-relationships of laboratory personnel.
The duties & responsibilities of all staff are described within their relevant job descriptions (located within individual Turas records).

Clyde Biochemistry - Clinical Governance Chart



There is a single Clinical Biochemistry Department in the Clyde Sector with service provision on 3 sites. Laboratory direction is as follows:
The Head of Service has overall responsibility for these departments. The Sector Lead Clinician is professionally responsible and managerially accountable to the Head of Service. All consultants and clinical scientists are professionally responsible and managerially accountable to the Sector Lead Clinician. A clinical consultant or scientist of equivalent standing is in daily charge of each department.

Clinical Biochemistry - Staff Organisation Chart



Document Number	Title
MI-CBIO-001	Clinical Governance Chart
MI-CBIO-002	Staff Organisation Chart

2.8 Communication (ISO 4.1.2.6)

Laboratory management, within Clyde Clinical Biochemistry have established various meetings for staff communication. The proceedings are conducted according to the local Meetings Procedure and records are kept within the Biochemistry document control system. Minutes from all meetings are emailed to relevant to staff. All meetings are listed below.

Biochemistry & Immunology Management Team (BIMT)
Meet monthly but may vary in frequency as necessary and as matters dictate.

NHS Greater Glasgow & Clyde, Clinical Scientific Forum
Meet monthly but may vary in frequency as necessary and as matters dictate.

NHS Greater Glasgow & Clyde, Clyde Biochemistry Management Group
Meet monthly but may vary in frequency as necessary and as matters dictate.

The Clyde Clinical Biochemistry Annual Management Review Group
Meet on an annual basis in accordance with ISO 15189:2012(E), 4.15.2

Clyde Clinical Biochemistry Quality Control Group
Meet monthly but may vary in frequency as necessary and as matters dictate.

Clyde Clinical Biochemistry Reporting Group
Meet monthly but may vary in frequency as necessary and as matters dictate.

Clyde Health & Safety Committee
Meet quarterly but may vary in frequency as necessary and as matters dictate.

Clyde POCT Group
Meet twice per year but may vary in frequency as necessary and as matters dictate.

Clyde Clinical Biochemistry Senior Staff Group
Meet monthly but may vary in frequency as necessary and as matters dictate.

Clyde Clinical Biochemistry Lab Brief
Meet on a weekly basis at RAH & IRH.

RAH Reception Group
Meet on a weekly basis at RAH.

Document Number	Title
LFD-CBIO-001	Management Meetings
LFD-CBIO-002	Annual Management Review (AMR)
LFD-CBIO-003	QC Meetings
LFD-CBIO-004	Senior Staff Meetings
LFD-CBIO-015	Reporting Biochemist Meetings
LFD-CBIO-005	Reception Meetings
LFD-CGEN-001	Health & Safety Committee Meetings
LFD-CGEN-003	Clyde Point of Care Testing (POCT) Meetings
LFD-GGC-001	Biochemistry Immunology Management Team Meetings (BIMT)
LFD-GGC-003	Point of Care Testing (POCT) Meetings
LFD-GGC-004	Quality Management & Compliance Group
LFD-GGEN-001	Health, Safety & Security Meetings
LFD-GGC-007	NHS Greater Glasgow & Clyde, Clinical Scientific Forum
LFD-IBIO-001	IRH Lab Brief Meetings
LFD-RBIO-001	RAH Lab Brief Meetings
MP-CBIO-012	Staff Meetings Procedure

2.9 Quality Manager (ISO 4.1.2.7)

As fully defined in the Quality Manager Job Description (located in Turas), the Quality Manager has delegated responsibility and authority to include:

- Ensuring that processes needed for the Quality Management System are established, implemented, and maintained;
- Reporting to laboratory management, at the level at which decisions are made on laboratory policy, objectives, and resources, on the performance of the quality management system and any need for improvement;
- Ensuring the promotion of awareness of users' needs and requirements throughout the laboratory.

Accountable to the Technical Services Manager, the Quality Manager is responsible for the development and maintenance of the QMS.

2.10 Quality Management System (ISO 4.2)

Clyde Clinical Biochemistry Quality Management System (QMS) provides the structure; processes, documentation and resources needed to fulfil the departmental Quality Policy (see 4.1.2.3). The Quality Manager (see 4.1.2.7), under the direction of the Technical Services Manager, ensures the system is maintained and documented within a Quality Manual (see 4.2.2.2) and reports to laboratory management on the function, effectiveness and compliance of the Quality Management System with accreditation standards.

Document Number	Title
QP-CBIO-003	Quality Policy
QP-CBIO-004	Quality Objectives & Plans

2.11 Documentation requirements (ISO 4.2.2)

The Quality Manual includes:

a) The quality policy (ISO 4.1.2.3) or makes reference to it;
b) A description of the scope of the quality management system;
c) A presentation of the organisation and management structure of the laboratory and its place in any parent organisation;
d) A description of the roles and responsibilities of laboratory management (including the Laboratory Director and Quality Manager);
e) A description of the structure and relationships of the documentation used in the QMS;
f) The documented policies established for the quality management system and reference to the managerial and technical activities that support them.
g) All laboratory staff shall have access to and be instructed on the use and application of the Quality Manual and the referenced documents.

Document Number	Title
LFD-CBIO-033	Clyde AMR
LFD-GGC-004	Quality Management & Compliance Group
MF-CBIO-004	Storage & Retention of Records & Samples
MI-CBIO-001	Clinical Governance Chart
MI-CBIO-002	Staff Organisation Chart
MP-CBIO-003	Control of Clinical Material
QP-CBIO-002	Quality Manual (UKAS)
QP-CBIO-003	Quality Policy
QP-CBIO-004	Quality Objectives & Plans
QP-CBIO-006	Q-Pulse SOP
QP-CBIO-007	Document Control SOP
QP-CBIO-008	Control of Process & Quality Records
AUD89	Horiz: ISO 4.2 & 4.3

2.12 Document control (ISO 4.3)

Document control requirements are fulfilled by QP-CBIO-007.

QMS documentation is subject to strict management control, and subject to defined review and amendment, as appropriate.

- QMS documentation is approved for use by authorised personnel, prior to use,
- QMS documents are uniquely identified, paginated, and have traceability to the date of issue (active date), revision version, version history, and staff responsible for authorisation (activation),
- There is a readily accessible Master List that prevents the use of invalid, or obsolete, documents,
- QMS documents are legible, readily identifiable and retrievable,
- QMS documents are regularly reviewed and updated, as required,

- Only current document versions are available to staff,
- QMS access is restricted to authorised staff (Q-Pulse Password Control)

The Quality Management System (QMS), Q-Pulse is provided and supported by Gael Quality Ltd. Contact details are listed below:

Address: Ideagen Gael Ltd
Orion House
gael.com
S.E. Technology Park
East Kilbride
South Lanarkshire
G75 0RD
United Kingdom

Phone: 01355 593 400
Email: info@ideagen-

Further details on document control can be found within the documents listed below:

Document Number	Title
MF-CBIO-004	Storage & Retention of Records & Samples
QP-CBIO-006	Q-Pulse SOP

2.13 Service Agreements

The requirement to formally define service user requirements, inclusive where appropriate, of formal contract (SLA), is identified by the Department as an essential prerequisite of a quality service.
SLA is hence considered as part of the negotiation of a service contract, agreed between the Department and the user organisation, where the level of service is formally defined.
The Department acknowledges that:

- Each request accepted by the laboratory for examination(s) shall be considered an agreement.
- Agreements to provide medical laboratory services (as defined by Test Request / Order, either by Hard Copy Request Form, or by electronic requesting systems) shall take into account the request, the examination and the report. The agreement shall specify the information needed on the request to ensure appropriate examination and result interpretation.

The Department operates standardised protocol for the establishment, review, and administration of SLA's. These documents are listed below:

Document Number	Title
MP-CBIO-006	Service Level Agreements (SLAs) SOP
MP-GGC-004	IT Operational Service Level Agreement
PD-GGC-004	POCT Service Level Agreement Template
PD-GGC-005	MSC Clyde Sector Technical Specifications for Biochem/ Haem

2.14 Examination by Referral Laboratories (ISO 4.5)

The choice of referral laboratories has been agreed across all GG&C biochemistry sector laboratories. This is kept under review at the cross sector Clinical and Scientific Forum, where consensus is reach on the quality of referral laboratories in terms of cost, turnaround time and accreditation status. Clyde Biochemistry undertakes an annual referral laboratory audit to confirm continuing status of referral laboratories. All details of the procedure, including the provision of examination results are included in the documents listed below.

Document Number	Title
LI-RBIO-003	Priority Sendaway Samples
LP-CBIO-030	Sendaway Test SOP
MI-CBIO-004	Sendaway Tests Table
AUD113	Referral lab Survey

2.15 External Services and Supplies (ISO 4.6)

The Department facilitates procedure for the selection and purchasing of equipment, reagents, calibration, quality control materials, consumable supplies and services that have the capacity to affect the quality of the service. These procedures are listed below.

Document Number	Title
MP-CBIO-004	Procurement, Management & Validation of Equipment.
MP-CBIO-026	Management of reagents, calibration and QC Material
LI-CBIO-067	Evaluation and selection of service providers

NHSGGC operates a system of strict budgetary control, as detailed within NHSGGC Standing Financial Instructions. In accordance with this system, the purchasing of supplies, by the Department, is controlled through authorised staff use (password controlled) of the software-based purchasing systems – "PECOS".

In addition to this, a system for Internal Supplies Ordering, used for the indenting of general and office supplies from the Hospital Stores and Pharmacy Department operates. The policies and procedures for use of this

system, facilitated through on-line requisition forms, are again outlined within the aforementioned Standing Financial Instructions.
Many laboratory supplies, including reagents, calibration and quality control material, are purchased through standing order contract (e.g. Managed Service Contract) with the supplier company.
The Department:

- Satisfactorily selects and approves suppliers based on their ability to supply services, equipment, reagents and consumable supplies, in accordance with contracted requirements,
- Compliant with NHSGGC Policy, operates strict purchasing control procedures,
- Shall purchase goods, services, equipment and materials only from a list of selected and approved suppliers,
- Shall monitor the performance of suppliers to ensure that purchased services or items consistently meet contracted criteria.

An inventory of all equipment is documented in the Equipment module of Q-Pulse.

2.16 Advisory services (ISO 4.7)

Laboratory management, within Clyde Clinical Biochemistry, have established procedures for communicating with users, which include:

- Advice on the choice of examinations/services/sample type/frequency of testing
- Clinical advice on individual patients
- Advice on interpretation of Biochemistry results
- Promoting laboratory services
- Advice on sample acceptance / rejection criteria

The Laboratory Handbook and GP Handbook provide users with up-to-date information to facilitate proper use of the service. It is available to all registered NHS staff via the intranet site, 'Staffnet' as shown by the link below. A link to the GP Handbook is also available on the Integrated Clinical Environment (ICE) for GPs.

Staffnet > Acute > Diagnostics > All Laboratory Medicine > Clyde Laboratory Medicine > Laboratory Manuals

Document Number	Title
MP-CBIO-009	Clinical Advice and Interpretation
PD-CBIO-001	Clyde Biochemistry Laboratory Handbook
PD-GGC-003	Clyde Biochemistry GP Handbook

2.17 Complaints and Comments (ISO 4.8)

Clyde Clinical Biochemistry have established a procedure for the management of complaints, based on the NHS GG&C Complaints Policy.

There is a new legal requirement, termed Duty of Candour, where there is an ethical and professional statutory requirement for health care professionals to inform patients of any safety incident, caused by the organisation that has resulted in harm.
This is included in the health professional's 'Code of Conduct'- instructing staff to be honest with patients concerning their care and treatment.

The procedures are listed below.

Document Number	Title
QP-CBIO-009	Evaluation, Quality Assurance & Quality Improvement SOP
QP-CBIO-015	Handling of Complaints SOP
MF-CBIO-028	User Feedback
MP-GGC-013	Duty of Candour Policy
PD-GGC-013	GGC Board Code of Conduct Policy
PD-GGC-013	IBMS Code of Conduct
STAFFNET	GG&C Complaints Policy

2.18 Identification & control of nonconformities (ISO 4.9)

The comprehensive and systematic approach towards corrective, and or preventative action (CAPA), is detailed in the document listed below. This document serves to define procedures and responsibilities for the reporting of non-conformance, corrective actions, implementation of process change, where appropriate, and subsequent review/audit, using the Q-Pulse Audit and Non-Conformance Modules. All non-conformities are reviewed at the monthly Clyde Biochemistry Management Meetings.

Document Number	Title
QP-CBIO-014	Identification & Control of Non-conformities

2.19 Corrective and Preventative Action (ISO 4.10, 4.11)

Departmental procedures for the reporting and administration of CAPA, using the CAPA module of Q-Pulse are defined in QP-CBIO-014, Identification & Control of Non-conformities.

Corrective actions are logged in the CAPA module of Q-Pulse with the aim of preventing a re-occurrence. Preventative action is also logged in the CAPA module and aims to remove potential cause(s) of nonconformities, to prevent them from ever occurring. This is a proactive, Quality Improvement process. Preventative actions include:

- Audits
- Potential non-conformities arising from actual non-conformities
- Reviews of laboratory data i.e. IQC trend analysis or External Quality Assurance (EQA) reports.

2.20 Continual Improvement (ISO 4.12)

Clyde Biochemistry is committed to continual quality improvement. Improvement processes include:

- User Satisfaction Surveys
- Audits of the Quality Management System
- Scope Audits
- External Quality Assessment (EQA)
- Identification & control of nonconformities
- CAPA monitoring & review.
- Accreditation visits

These aspects are reviewed monthly at Clyde Biochemistry Management meetings and Clyde Biochemistry Quality Control meetings and annually at the Annual Management Review. Documents relating to this are listed below.

Document Number	Title
LFD-CBIO-001	Clyde Management Group
LFD-CBIO-033	Clyde AMR
LFD-CBIO-003	Clyde QC Meeting
QP-CBIO-004	Quality Objectives & Plans
QP-CBIO-005	Quality Indicators SOP
QP-CBIO-009	Evaluation, Quality Assurance & Quality Improvement SOP

2.21 Control of records (ISO 4.13)

The Clyde Clinical Biochemistry processes and quality records are documented and stored by Q-Pulse, the Laboratory Information Management System, LIMS, (Telepath) or hardcopies stored in folders. These are managed according to current legislation, regulations and guidelines.

Document Number	Title
MP-CBIO-004	Procurement, Management and Validation of Equipment
MF-CBIO-004	Storage & Retention of Records & Samples
PD-GGC-007	RCPath Retention & Storage of Pathological Records & Specimens
QP-CBIO-006	Q-Pulse SOP
QP-CBIO-007	Document Control SOP
QP-CBIO-008	Control of Process & Quality Records

2.22 Evaluation and Audits (ISO 4.14)

Clyde Biochemistry continually audit and evaluate all internal and supporting processes to meet the requirements of the users.

Consultant Clinical Scientists, within Clyde Clinical Biochemistry regularly review the departmental Laboratory Handbook to ensure:

- examinations are appropriate for requests
- sample specifications i.e. type, volume, transport are appropriate for testing requirements.

Document Number	Title
PD-CBIO-001 PD-GGC-003	Biochemistry Laboratory Handbook Biochemistry Handbook for Primary Care Users

2.23 Assessment of user feedback (4.14.3)

Clyde Clinical Biochemistry & Clyde Haematology work together, to conduct annual User Satisfaction Surveys. User Satisfaction Surveys are reviewed annually by the NHS GG&C Quality Managers and based on performance target areas. The surveys alternate annually between hospital and GPs. A summary of results is published on the staff intranet site.

Document Number	Title
AUD142 AUD114	User Satisfaction Audit - Wards User Satisfaction Audit - GPs

2.24 Staff suggestions (ISO 4.14.4)

Laboratory management within Clyde Clinical Biochemistry encourage staff to make improvement suggestions on any part of the laboratory service, by providing a suggestions box within the laboratory areas. These suggestions are evaluated & communicated at weekly (RAH) or Monthly (IRH) staff meetings, where feedback is sought. Suggestions also tend to arise during the course of various staff meetings (see 4.1.2.6).If feedback is not available at the time, the suggestion is taken forward to the appropriate personnel.

Staff suggestions can be recorded in QPulse, under the CAPA module and are in the minutes of meetings. A summary of these is included in the Quality report, as part of the annual management review meeting.

2.25 Internal audit (ISO 4.14.5)

The Clyde Clinical Biochemistry audit schedule and associated processes are detailed within QP-CBIO-013, Internal Audit SOP. Supporting documents are listed below.

Document Number	Title
LFD-CBIO-033 QF-CBIO-018	Clyde AMR Audit schedules
QP-CBIO-007 QP-CBIO-006	Document Control – Clinical Biochemistry Q-Pulse Procedure – Clyde Biochemistry
QP-CBIO-013	Internal Audit SOP
AUD89	Horiz: ISO 4.2 & 4.3

2.26 Risk Management (ISO 4.14.6)

Risk management, an identified key component of effective Clinical Governance, incorporates a systematic approach to:

- Identifying risks (to staff, service users, patients, and fellow health care professionals),
- Identifying risks to the service
- Analysis of adverse clinical incidents, indemnity claims, and complaints,
- Control of risks by use of systems and checking procedures.

The Department operates a Health and Safety Procedure and Policy HSP-CBIO-001, HSP-CBIO-002 that includes a systematic process (including audit of Premises and Environment and Health and Safety) whereby risks to staff, service users, patients, and fellow health care professionals are reported, investigated and acted upon appropriately and promptly. As stipulated in the Departmental Policy, incidents and risks, inclusive of complaints, Quality Deviations, and service quality improvement, are reported and reviewed at the Clyde Biochemistry Management Meeting. All identified risks are embedded within the Q-Pulse document module.

The Department has a local business continuity plan which is linked to the cross-sector, NHSGGC Biochemistry Business Continuity Plan. These plans cover all eventualities from loss of part of the service to complete loss of service which may be caused by but not restricted to, loss of power, loss of water supply, loss of staff, complete loss of a site or sites for any other reason.

The department has a risk register MF-CBIO-002 which is discussed at the Annual Management Review and reviewed quarterly at the Clyde Management Meeting. Issues which cannot be resolved locally are escalated to the NHSGGC Biochemistry Risk Register which is held in DATIX and reviewed quarterly at BIMT.
The MSC provider produces a monthly report (based on a 3 month rolling window) detailing analyser downtime, tickets opened/closed and Preventative maintenance status. This information is shared with all senior technical staff and any anomalies discussed with the service engineer and a solution agreed. Ongoing issues are escalated to the Biochemistry MSC Group by the TSM.

The TSM's meet with the managed service provider on a monthly basis when these reports are further discussed along with other pertinent matters. All of this is minuted and actions and timescales agreed. Any failures to meet targets are discussed at this meeting and escalated where appropriate.

2.27 Quality Indicators (ISO 4.14.7)

Quality indicators can be used to measure aspects of Quality within a laboratory. Quality Indicators are discussed and reviewed at the AMR. Further details on quality indicators are within the document listed below. Additional quality indicators, such as turn around time and percentage of staff who have completed their annual appraisal, is available within the NHS GG&C, Laboratory Balanced Scorecard, which is discussed and reviewed at the Biochemistry and Immunology Management Team meeting. This is available for all staff to view within the GGC Biochemistry folder on all Biochemistry desktop PCs.

Document Number	Title
QP-CBIO-005	Quality Indicators SOP

2.28 Reviews by external organisations (ISO 4.14.8)

Full details of the UKAS assessment process, the requirements of ISO 15189, and scheme participants, can be accessed via http://www.ukas.com. The Accreditation and Process is essentially defined by the following UKAS publications:

UKAS LAB 3 - The conduct of UKAS Laboratory Assessments. This defines the 4 year cycle, assessment process & assessor roles in the conduct of UKAS laboratory accreditation assessments. All of this is organised & led by a consistent assessment manager.

UKAS TPS 51 – Accreditation of Multi-Site Laboratories. This provides guidance on the assessment and accreditation of multi-site laboratories and describes how UKAS will assess and make reference to multi-site laboratory accreditations. Clyde Clinical Biochemistry compliance with TPS 51 is detailed in MI-CBIO-005.

UKAS TPS 53 – Management system requirements of laboratories & inspection bodies – statement for use on test, examination, calibration & inspection reports/certificates. This states the terminology used by UKAS assessors in establishing Technical competence & a Quality Management System that fulfils ISO Standard requirements, to consistently deliver valid patient results.

UKAS LAB 1 – Reference to Accreditation for Laboratories. When the tests & service of a laboratory are accredited by UKAS, this should be promoted to our users - to provide confidence that the service is assessed & maintained to International Quality standards. Clyde Clinical Biochemistry promotes our UKAS accreditation status on our website, where we have a link to our UKAS Scope of Accreditation – showing users exactly what tests are UKAS accredited. We choose not to use the 'UKAS logo' on sample reports as some tests in a multi-test report, may not be UKAS accredited. We also choose not to use 'comments' on sample reports due to a risk this could detract from clinically significant comments.

2.29 Management Review (ISO 4.15)

Laboratory management within Clyde Clinical Biochemistry, very year, replace 1 of their monthly Management Meetings with an Annual Management Review (AMR) meeting. This enables review of:

- The Quality Management System
- Health & Safety
- Information Technology
- Point of Care Testing

Annual Summary Reports for each topic, are submitted in advance of the meeting & circulated to all attendees. This allows the management team to focus discussion on future tasks & improvements.

Document Number	Title
LFD-CBIO-033	Annual Management Review (AMR)
MF-CBIO-001	AMR Form
MP-CBIO-001	Conducting the AMR Meeting

The minutes from the Clyde Clinical Biochemistry AMR, including agreed actions & timelines, are stored in Q-Pulse, in the documents module. This is distributed to staff, who are asked to read and acknowledge the contents.

3.0 Personnel, Training and Facilities

3.1 Personnel General (ISO 5.1.1, 5.1.2, 5.1.3)

Laboratory management within Clyde Clinical Biochemistry are aware that staff are their most important asset and have established a procedure for personnel management. All staff are given the opportunity to contribute fully to the Biochemistry service and are treated fairly by laboratory management. Hard copies of personnel records including qualifications/registrations are securely retained by the TSM for technical staff and clinical sector lead for scientific/medical staff.

Document Number	Title

MF-CBIO-006	Personal Staff Details
MP-CBIO-002	Personnel Procedure
STAFFNET	NHS GG&C Resourcing & Recruitment Page
STAFFNET	NHS GG&C Code of Conduct for staff (includes whistleblowing)
STAFFNET	NHS GG&C Grievance Policy & Procedure
STAFFNET	NHS GG&C Disciplinary Policy & Procedure
MF-CBIO-018	Staff List – Clyde Biochemistry
Health Care Professions Council (HCPC)	http://www.hpc-uk.org/
General Medical Council (GMC)	http://www.gmc-uk.org/
Job Descriptions	Turas NHS Education for Scotland (NES)

3.2 Personnel induction and training (ISO 5.1.4, 5.1.5)

Clyde Clinical Biochemistry have procedures in place to ensure that members of staff are fully inducted into the workplace and receive all relevant training to allow them to perform their role. In addition to this, the department have procedures in place for staff members returning to work from long term absence. The induction and training process is recorded and records retained by the staff member in their individual portfolio.

Document Number	Document Title
TF-CBIO-001	Biochemistry Induction Checklist
TF-CBIO-059	New BMS Training Plan
TF-CBIO-060	Return to Work Training Plan
TP-CBIO-002	Induction Policy
TP-CBIO-001	Training Policy
TP-CBIO-003	Training Manual

3.3 Training

Clyde sector, Clinical Biochemistry has a positive training culture. There is 1 training manager & 1 training officer, who work with laboratory management to organise enjoyable comprehensive training programmes.
Clinical Biochemistry promote opportunities for personal development & some staff have participated in the following:

- Modern Apprentiship Cohort 2017-2019
- IBMS Registration Portfolio completion
- IBMS Specialist Portfolio completion
- Masters in Biomedical Science completion
- IBMS Higher Specialist Portfolio completion
- IBMS Certificate of Extended Practice in Quality Management
- IBMS Certificate of Extended Practice in Training

All staff are expected to show evidence of their training experiences, by maintaining a personal evidence portfolio. This is reviewed by Laboratory management & the individual during Annual Joint Reviews (CPA Standard B7) & may be verified by IBMS representatives or audited by Health Care Professions Council (HCPC) committees.

3.4 Competence assessment (ISO 5.1.6)

Clyde Clinical Biochemistry ensure that all members of staff are certified as competent in the processes which they carry out. As such, competence assessments are carried out by suitably qualified members of staff and records of competence are retained in a filing cabinet, within a locked office. Competence assessments must be renewed every two years.

Document Number	Title
LP-CBIO-025	SOP: Competence
TF-CBIO-058	Competence: Overview Spreadsheet
TF-CBIO-179	Competence: Abbott Alinity Observation
TF-CBIO-099	Competence: Abbott Architect (Assistant Practitioner) Observation
TF-CBIO-012	Competence: Abbott Architect Observation
TF-CBIO-180	Competence: Abbott Architect Q&A
TF-CBIO-123	Competence: Abbott Freestyle Precision Pro Glucose Meter Observation
TF-CBIO-128	Competence: Alere Urine Pregnancy Testing Q&A
TF-CBIO-116	Competence: Balances Observation
TF-CBIO-117	Competence: Centrifuge Observation
TF-CBIO-108	Competence: Cryoglobulins & Cryofibrinogens Observation
TF-CBIO-178	Competence: Cryoglobulins & Cryofibrinogens Q&A
LI-CBIO-079	Competence: Dilutions Q&A
TF-CBIO-062	Competence: Duty Biochemist Observation
TF-CBIO-101	Competence: Flexlab Track (Assistant Practitioner) Observation
TF-CBIO-061	Competence: Flexlab Track Observation
TF-CBIO-188	Competence: Flexlab Track Q&A
TF-GGC-002	Competence: Formalin spillages Observation
TF-CBIO-145	Competence: Health & Safety Evidence
TF-CBIO-181	Competence: Health & Safety Observation
TF-CBIO-182	Competence: Health & Safety Q&A
TF-CBIO-104	Competence: IT Failure Q&A
TF-CBIO-105	Competence: IT Failure Certificate
TF-CBIO-014	Competence: Laboratory Information Management Systems (LIMS) Observation
TF-CBIO-177	Competence: LIMS / Technical Reporting Q&A
TF-CBIO-112	Competence: Macroprolactin PEG Precipitation Observation

TF-CBIO-183	Competence: Macroprolactin Q&A
TF-CBIO-146	Competence: Management Case Study 1 Evidence
TF-CBIO-147	Competence: Management Case Study 2 Evidence
TF-CBIO-148	Competence: Management Case Study 3 Evidence
TF-CBIO-109	Competence: Management evidence
TF-CBIO-111	Competence: Menarini (Assistant Practitioner) Observation
TF-CBIO-184	Competence: Menarini HA-8180 Q&A
TF-CBIO-110	Competence: Menarini HA-8180 Observation
TF-CBIO-015	Competence: Osmometer 3320 Observation
TF-CBIO-185	Competence: Osmometer 3320 Q&A
TF-CBIO-019	Competence: Precision web Observation
TF-CBIO-102	Competence: Protein Electrophoresis Reporting Observation
TF-CBIO-022	Competence: Q-Pulse Observation
TF-CBIO-187	Competence: Q-Pulse Q&A
TF-CBIO-144	Competence: Quality Management Evidence
TF-CBIO-107	Competence: Reception EQA Observation
TF-CBIO-017	Competence: Sebia Electrophoresis & Immunofixation Observation
TF-CBIO-186	Competence: Sebia Electrophoresis & Immunofixation Q&A
TF-CBIO-113	Competence: Sendaways Observation + Q&A
TF-CBIO-178	Competence: Siemens Centaur Observation
TF-CBIO-011	Competence: Specimen reception Observation + Q&A
TF-CBIO-142	Competence: Sweat tests [Wescor] Observation
TF-CBIO-118	Competence: Thermometers Observation

3.5 Staff performance reviews (ISO 5.1.7)

In Clyde Clinical Biochemistry, each member of staff participates in annual appraisal meetings, known as Turas joint reviews. The meetings are confidential but all aspects are recorded for training and monitoring purposes and include aspects such as, review of performance and objectives for the forthcoming year.

Document Number	Title
MF-CBIO-007	Turas Preparation Form
MI-GGC-011	Turas – Managers & Reviewers
MP-GGC-017	Turas Appraisal

3.6 Continuing education & professional development (ISO 5.1.8)

The Health Care Professions Council (HCPC) would define CPD as "*Any Activity from which you learn or develop professionally*". Since 2005, every registrant must sign a disclaimer to say they have & will continue to have, CPD records, every 2 years. If this is found to be untrue, the registrant may be removed from the HCPC register.

Continuing Professional Development (CPD) incorporates a range of activities i.e. work-based, professional, educational, self-directed. All professionals must participate in CPD to learn and develop skills that allow them to practice safely, effectively and legally by keeping their knowledge up-to-date.

Whilst it is the responsibility of the individual staff member to maintain their CPD folder Clyde Clinical Biochemistry are fully supportive in assisting staff through providing in house opportunities to accrue CPD points.

In line with ISO 15189:2012(E), Clyde Clinical Biochemistry provide a Lunchtime Education Schedule, involving monthly presentations on relevant topics, for the purpose of CPD. Staff are encouraged to attend and posters advertising event are provided.
Each member of staff is responsible for up-dating their own CPD portfolio and CPD activities are checked during Turas joint reviews.

Document Number	Document
TF-CBIO-007	Lunchtime Education Schedule
TF-CBIO-008	CPD Attendance Form
TF-CBIO-009	Reflective Learning Sheet (RFL)
TF-CBIO-155	Scenario Based Training Certificate
TI-CBIO-001	NHS LearnPro Modules to complete
MF-CBIO-024	Course Attendance / Feedback Agreement
MF-CBIO-007	Turas Preparation Form
Personal Portfolios	Education & CPD
HCPC	Your Guide To Our Standards for Continuing Professional Development

3.7 Staff held personnel records (ISO 5.1.9)

Clyde Clinical Biochemistry staff must be able to show the following records, if requested:

- Educational Qualification Certificates
- State registration certificate
- Work Experience evidence
- Job description
- Induction records
- Training records
- Competence assessments
- CPD evidence
- Turas joint review details
- Personal accidents / exposure to hazard documents (if applicable)

- Immunisation evidence

3.8 General Facilities (ISO 5.2.1)

Clyde Clinical Biochemistry provides a working environment where staff can perform their daily duties safely and effectively. Access to all laboratories is restricted, as described in the local Health and Safety Procedure, to minimise exposure to danger of infection and provide security for staff and equipment. A biohazard sign is placed at the laboratory entrance to show why access is restricted.

Clyde Biochemistry believe authorised personnel should include all NHS GG&C employees, which come under one of the following descriptions:

- Laboratory office / secretarial staff
- Medical Laboratory Assistant
- Biomedical scientist
- Clinical Biochemist
- Laboratory Consultant
- Porter
- Infection Control Nurse
- Estates / Facilities worker
- Specimen Transport Driver

This list is not exhaustive and may include any employee who regularly enters the laboratory building, for good reason.

In compliance with NHS GG&C regulations, a quarterly Health and Safety audit is conducted on each site and the results are recorded in Q-pulse for all staff to see. Any environmental changes or non-conformances within the laboratory building are communicated to staff at various meetings. NHS GG&C operate a no smoking policy on all hospital grounds for the comfort and wellbeing of staff and patients.

Document Number	Title
HSF-GGC-002	Quarterly Workplace Inspection Checklist
HSI-CBIO-001	Containment Level 2
HSI-CBIO-002	Clean area
HSI-CBIO-005	Waste Disposal Storage Area
HSP-CBIO-001	Health & Safety Procedure
LP-CBSC-001	Blood Sciences Specimen Reception Procedure
MF-CBIO-004	Storage & Retention of Records & Samples

3.9 Working facilities (ISO 5.2.2)

Clyde Clinical Biochemistry ensure the following conditions are met:

- Controlled access to specimen testing areas – for safety, quality and confidentiality
- Information, samples and resources are secure

- Specimen testing areas have correct:
- energy back-up,
- lighting,
- ventilation,
- noise levels,
- water resources,
- waste disposal
- LIMS is appropriate size and complexity for efficient information transfer
- Health and Safety devices are available and maintained in good working order:
- emergency release locks
- intercom systems
- alarms
- eyewash stations

3.10 Storage Facilities (ISO 5.2.3)

In order to maintain the integrity and confidentiality of samples, equipment, supplies and records within the department, Clyde Clinical Biochemistry have the following facilities:

1). Cold room, refrigerators and freezers (for samples or reagents)
2) Waste Disposal Storage Area (clinical waste is separated from domestic or recycling waste where possible)
3) Office storage facilities (records and request forms)
4) Telepath, AMS, RMS, Dart Scanner, GEM Web and Precision Web computer software packages (data storage and retrieval)

Document Number	Title
HSI-CBIO-005	Waste Disposal Storage Area
HSP-CBIO-008	Waste Disposal Policy
LI-CBIO-031	Dart System
LP-CBIO-007	IL GEM Premier 4000
LP-CBIO-009	Precision Web
LP-CBIO-012	Abbott Analyser Management System (AMS)
LP-CBIO-027	Reagent Management System (RMS)
LP-CBIO-032	Telepath SOP
MF-CBIO-004	Storage & Retention of Records & Samples
MP-CBIO-003	Control of Clinical Material
PD-GGC-007	RCPath Retention & Storage of Pathological Records & Specimens
QP-CBIO-008	Control of Process & Quality Records
QP-CBIO-006	Q-Pulse SOP
QP-CBIO-007	Document Control SOP
QP-CBIO-008	Control of Process & Quality Records
LP-CBIO-017	Flexlab Track SOP
LI-CBIO-057	Receipt and Storage of Items

3.11 Staff facilities (ISO 5.2.4)

To ensure personal safety, comfort and hygiene, Clyde Clinical Biochemistry ensure that there is adequate provision of areas for rest/meals, study, personal storage, meetings and toilet facilities. All staff facilities are within secure areas with access via either key code entry or key fob activation.

Document Number	Document Title
HSP-CBIO-001	Health & Safety Procedure
HSP-GGC-001	Health & Safety Management Manual
STAFFNET	NHS GG&C Health & Safety Policy
STAFFNET	NHS GG&C Fire Safety Policy
STAFFNET	NHS GG&C Workplace Health, Safety & Welfare Policy
STAFFNET	NHS GG&C Policy on the Provision & Use of Work Equipment
STAFFNET	NHS GG&C Waste Management Policy
STAFFNET	NHS GG&C Display Screen Equipment Policy
STAFFNET	NHS GG&C Incident Management Policy
STAFFNET	NHS GG&C SmokeFree Policy
STAFFNET	NHS GG&C Policy on the Provision & Use of Personal Protective Equipment

3.12 Patient Facilities (ISO 5.2.5)

In Clyde Clinical Biochemistry, there are no patient sample collection facilities within the laboratory areas. Patient samples are collected in wards or clinics within the hospital.

3.13 Facility Maintenance & Environmental Conditions (ISO 5.26)

Clyde Sector Clinical Biochemistry Departments are committed to ensuring all staff and visitors are protected from harm by providing a safe environment and personal protective equipment in accordance with current legislation and safety guidelines.

The organisation and management of Health and Safety in each department is detailed in the Biochemistry Health & Safety Procedure. This procedure contains all local health & safety policies including:

a) Fire policy

b) Spillage policy

c) Incident policy

d) Incident Management Plan

e) COSHH / Risk assessment

f) Disinfection policy

g) Decontamination policy

h) Waste Disposal Policy

i) Specimen transportation.

j) First Aid Policy

The Health & Safety Executive (HSE), Advisory Committee on Dangerous Pathogens (ACDP), "*The Approved List of Biological Agents*" 2004, assigns biological agents into relevant hazard groups. COSHH defines levels of containment when working with these groups. All work in Clyde Biochemistry laboratories must be carried out at a minimum of containment level 2 (CL2), designed to protect against hazard group 2 biological agents. However, Biochemistry also receive some 'High Risk' specimens, containing hazard group 3 agents. These must be identified by the user, who should highlight this to laboratory staff. Due to the nature of biochemical analysis, hazard group 3 specimens can be processed, with caution, in a CL2 laboratory. However, any propagation of hazard group 3 or 4 specimens (such as in Microbiology processes) would require a higher containment level.

Model rules for porters, couriers, uplift of specimens, visitors and medical laboratory staff are displayed in each of the Clyde Clinical Biochemistry sites.

Document Number	**Title**
HSF-IBIO-001	IRH Health & Safety Contacts Sheet
HSF-IBIO-003	IRH Fire Action Plan
HSF-RBIO-001	RAH Health & Safety Contacts Sheet
HSF-RBIO-003	RAH Fire Action Plan
HSF-VBIO-001	VOL Health & Safety Contacts Sheet
HSF-VBIO-002	VOL Fire Action Plan
HSI-CBIO-003	Model Rules for Laboratory Staff
HSI-CBIO-004	Incident Management Plan
HSP-CBIO-001	Health & Safety Procedure
HSP-CBIO-002	Health & Safety Policy
HSP-CBIO-003	Fire Safety Policy
HSP-CBIO-004	Spillage Policy
HSP-CBIO-007	Incident Control Policy
HSP-CBIO-008	Waste Disposal Policy
HSP-GGC-001	Health & Safety Management Manual
HSP-RBSC-001	RAH First Aider Policy
LF-CBIO-001	Bench Cleaning Diary
MF-CBIO-005	Specimen Release Form (to Police)
MF-IBIO-002	IRH Fire Evacuation staff list
MF-RBIO-014	RAH Fire Evacuation staff list
MI-GGC-004	Model Rules for Laboratory Porters
MI-GGC-005	Model Rules for Laboratory Couriers
MI-GGC-006	Model Rules for Uplift of Specimens
MI-GGC-007	Model Rules for Visitors Or Others Delivering to Laboratories
MP-GGC-006	Transport & Disposal of Specimen Containers & Specimens

	Policy
STAFFNET STAFFNET STAFFNET STAFFNET STAFFNET	NHS GG&C Management of Needlestick Injuries & Exposure to Blood & High Risk Body Fluids NHS GG&C Waste Management Policy NHS GG&C, Clyde Sector, Management of Waste Operational Procedures NHS GG&C Incident Management Policy NHS GG&C Policy on the Provision & Use of Personal Protective Equipment
Consultant Microbiologist for Infection Control	Dr Craig Williams Contact via switchboard
HSE Advisory Committee on Dangerous Pathogens	The Approved List of Biological Agents **http://www.hse.gov.uk/pubns/misc208.pdf**

4.0 Laboratory Equipment, Reagents & Consumables

4.1 Equipment (ISO 5.3.1.1 – 5.3.1.7)

Clyde Clinical Biochemistry, is involved in the NHS GG&C Managed Service Contract (MSC) for procuring equipment & supplies.

Laboratory management within Clyde Clinical Biochemistry have established a procedure for the selection, purchasing and management of equipment.

All equipment within the department is logged under the Equipment module of Q-Pulse including serial number, service reports and other pertinent information. All equipment is verified for use before entering service and records retained. Comprehensive operating instructions are provided which include information on calibration, metrological traceability, incident reporting, maintenance and repair.

Document Number	Document Title
MP-CBIO-004	Procurement, Management & Validation of Equipment.
LP-CBIO-001	Architect SOP
LP-CBIO-004	Osmometer 3320 SOP
LP-CBIO-033	Menarini HA 8180 SOP
LP-CBIO-017	Flexlab track SOP
LP-CBIO-036	Pipette SOP
LP-CBIO-038	Centrifuge SOP
LP-CBIO-013	Sebia Capillarys and Hydrasis SOP
Q-Pulse Equipment Module	Pipette certificates
LF-CBIO-004	Sebia Hydrasis 2 Maintenance Record
LF-CBIO-005	Sebia Capilarys Maintenance Record
LF-CBIO-104	Menarini maintenance sheets

LFD-RBIO-046	Reception Centrifuge Maintenance Logs
QF-RBIO-005	Track maintenance sheet
LF-CBIO-021	Out Of Service Notice
HSF-CBIO-060	Decontamination Certificate
Q-Pulse	Equipment module
MI-GGC-002	Abbott Service & Equipment Faults
LFD-CBIO-006	Method Verification-Flexlab Track
LFD-CBIO-017	Method Verification for HA 8180
LFD-RBIO-003	Verification- Abbott Architect
LFD-CBIO-009	Method Verification- Osmometer 3320
LFD-CBIO-010	Method Verification- Sebia Electrophoresis
LP-CBIO-025	Staff Competence SOP
HSI-CBIO-004	Incident Management Plan
HSP-CBIO-007	Incident Control Policy
MP-GGC-003	Significant Clinical Incident (SCI) Procedure

4.2 Reagents and Consumables (ISO 5.3.2)

Clyde Biochemistry has documented procedures for the:

- Receipt
- Storage
- Acceptance testing
- Inventory Management

of all reagents and consumables.

All 3 Clyde Biochemistry Laboratories, IRH, RAH and VOL, order and store stock for that site. All stock is received and stored according to the manufacturer's instructions. Instructions for use, of stock received, are held on the equipment software or have reference to the location of a hardcopy folder in the equipment standard operating procedure (SOP). All reagents are QC assessed before going into use for patient examinations. Any adverse incidents must be reported using the procedure referred to in the evidence table. Records of all reagents and consumables are held in the Reagent Management System (RMS).

Document Number	**Title**
HSP-CBIO-007	Incident Control Policy
LI-CBIO-001	QC Acceptance Criteria
LI-CBIO-050	RMS Stock Check and Stock Adjust
LI-CBIO-057	Receipt and Storage of Non-MSC Items
LP-CBIO-027	Reagent Management System (RMS)
QP-CBIO-010	Internal Quality Control

5.0 The Examination Process

5.1 Information for patients and users(ISO 5.4.2)

Clyde Clinical Biochemistry ensure that information is made available to the service users and public regarding the services on offer from the department. This includes, where appropriate, information regarding making a request to the department, acceptance criteria, how to seek clinical advice and the procedure for making complaints. This information is available via the NHS GG&C internet page and via Staffnet.

There is a new legal requirement, termed Duty of Candour, where there is an ethical and professional statutory requirement for health care professionals to inform patients of any safety incident, caused by the organisation that has resulted in harm.
This is included in the health professional's 'Code of Conduct'- instructing staff to be honest with patients concerning their care and treatment.

Public information can be found at the following web address
http://www.nhsggc.org.uk/about-us/professional-support-sites/biochemistry/

Document Number	Document Name
PD-CBIO-001	Biochemistry Laboratory Handbook
PD-GGC-003	Biochemistry Handbook for Primary Care Users
MP-GGC-013	Duty of Candour Policy
PD-GGC-013	GGC Board Code of Conduct Policy
PD-GGC-013	IBMS Code of Conduct

5.2 Sample collection and transport (ISO 5.4.4 5.4.5)

Clyde Clinical Biochemistry provides instructions for service users in sample collection and transport. Including required request form information, sample volumes and type, any special sample collection requirements, acceptance/rejection criteria and method of transporting samples to the laboratory.

Document Number	Document Title
PD-CBIO-001	Biochemistry Laboratory Handbook
PD-GGC-003	Biochemistry Handbook For Primary Care Users
LP-CBSC-001	Blood Sciences Reception Procedure
QP-CBIO-014	Identification And Control Of Non-conformities
LI-CBIO-051	24 Hour Urine Collections
Greiner bio-one	Vacuette Selection Chart
Greiner bio-one	Paediatric Selection Chart
Greiner bio-one	Recommended Centrifugation Speed for Vacuette Blood Collection Tubes

5.3 Sample Reception (ISO 5.4.6 5.4.7)

Clyde Clinical Biochemistry has a combined blood sciences reception shared with the Clyde Haematology department. Procedures ensure that all relevant requirements regarding reception processes are suitable for departments, including but not limited to, priority samples, sample acceptance/rejection criteria, procedures for non conformance and procedure for booking samples into LIMS. All samples received by the laboratory are electronically entered into LIMS recording the time taken, received and the person booking in.

Processes are in place to ensure the integrity and security of samples prior to analysis. In such instances where samples are unable to be analysed that day they are stored in an appropriate manner to ensure their integrity. Information is also made available to users and staff regarding time limits for requesting additional tests.

Document Number	Title
LP-CBSC-001	Blood Sciences Reception Procedure
LP-CBIO-017	Flexlab Track SOP
LI-CBIO-029	Telepath Sample Archiving
PD-CBIO-001	Lab Handbook
MF-CBIO-004	Storage and Retention of Records and Samples

5.4 Examination Processes (ISO 5.5.1.2, 5.5.1.3)

The laboratory has selected examination procedures that have been validated for their intended use. Verified examination data is presented and validated by the laboratory at the Clyde Biochemistry Management meeting before being introduced into routine use. If examination procedures are changed the influence of that change will be documented at the Clyde Biochemistry Management meeting and the implications communicated to users. The document detailing this process is listed below.

Document Number	Title
MP-CBIO-014	Instrument and Method Verification SOP
QF-CBIO-016	Instrument/Method Verification Form

5.5 Measurement Uncertainty of measured quantity values (ISO 5.5.1.4)

The Uncertainty of Measurement Process is defined by the following UKAS publications:

LAB 12 – The Expression of Uncertainty in Testing. This describes why laboratories should express uncertainty of measurement as well as the reporting, evaluation & how to calculate expanded Uncertainty of Measurement.

M3003 – The Expression of Uncertainty & Confidence in Measurement. This amplifies guidance on requirements for expressing Uncertainty of Measurement.

TPS 41 – UKAS Policy on Metrological Traceability. This gives guidance on tracing the history of a result, through an unbroken chain of calibrations – each of which will contribute to the Uncertainty of Measurement, back to an original reference, recommended by the manufacturer.

ILAC-P10:01/2013 – ILAC Policy on the Traceability of Measurement Results. This states that all calibrations are traceable to an International System of Units (SI) & ILAC supports world-wide competence through recognition of accreditation bodies.

Clyde Biochemistry utilises multiple chemistry and immunoassay analysers to optimise throughput. Therefore, result analysis may be completed across different analyser platforms. The laboratory is required to estimate the Uncertainty of Measurement (UoM) for all quantitative analyses (ISO 15189). Consequently, the variation calculated must be for the Clyde Biochemistry network rather than an analyser coefficient of variation, (unless the assay is only performed on one analyser). Clyde Biochemistry UoM is reviewed at the Clyde Biochemistry Quality Control meetings and UoM data is available to users by contacting the Duty Biochemist, see Laboratory Handbook, PD-CBIO-001. Documents detailing the UoM process are detailed below.

Document Number	Title
LFD-GGC-006	Uncertainty of Measurement (UoM) Meetings
QP-CBIO-016	UoM Data Preparation
QP-CBIO-017	Clyde Biochemistry Uncertainty of Measurement Table
QP-CBIO-018	Uncertainty of Measurement and Traceability

5.6 Biological Reference Intervals or Clinical Decision Values (ISO 5.5.2)

Clinical advice and test result advice are available by contacting the Duty Biochemist, see Laboratory Handbook, PD-CBIO-001. Reference ranges are available on Staffnet and the NHS GG&C internet page.

5.7 Documentation of Examination Procedures (ISO 5.5.3)

Procedures and laboratory instructions are written by, and for laboratory staff to facilitate laboratory duties. All procedures and instructions are available on Q-Pulse and are subject to the same document control as all laboratory documents. Some copies of laboratory procedures are available as printed copies within the laboratory, although staff are aware that printed copies are only confirmed as up-to-date at the time of printing.

5.8 Quality of Examination Results (ISO 5.6)

Clyde Clinical Biochemistry ensures the quality of all examination results through a system of stringent quality control at all stages of the examination process. The laboratory strives to ensure that all results are produced accurately and to the highest possible standard.

The department have robust IQA/EQA procedures for all tests carried out. Quality control material is designed to mimic patient samples as close as possible, wherever practical. All quality control procedures are regularly reviewed and action is taken as and when appropriate, based on the outcome of reviews.

The Proficiency Testing / EQA Process is essentially defined by the following UKAS publication:

TPS 47 – UKAS Policy on Participation in Proficiency Testing Schemes. This describes how laboratories confirm they have confidence in their results by comparing their results with other laboratories. It is UKAS policy for all UKAS accredited laboratories to participate in EQA schemes, where the laboratory will justify the frequency of participation & acceptance criteria for results.

To ensure comparability of results across sites and platforms Clyde Clinical Biochemistry regularly monitors uncertainty of measurement data across all sites, this information is regularly reviewed and made available to service users on request.

Document Number	Document Title
QP-CBIO-010	Internal Quality Control
QF-CBIO-003	Osmometer Results Record
QF-RBIO-001-004	Architect RAH QC Tick sheets
QF-VBIO-001-002	Architect VOL QC Tick Sheets
QF-IBIO-001-002	Architect IRH QC Tick Sheets
QP-CBIO-009	Evaluation, Quality Assurance And Continual Improvement Procedure
MF-CBIO-004	Storage And Retention of Records And Samples
LP-CBIO-001	Abbott Architect Operating Procedure
LP-CBIO-013	Sebia Electrophoresis SOP
LP-CBIO-033	Menarini HA 8180 SOP
LP-CBIO-004	Osmometer 3320 SOP
LF-CBIO-103	Menarini QC Data
LF-CBIO-017	Osmometer QC Data
LFD-CBIO-003	QC meetings
QI-RBIO-001	RAH Reception guide for booking in EQA samples
QI-IBIO-001	IRH Reception guide for booking in EQA samples
QI-VBIO-001	VOL guide for booking in EQA specimens
LI-VBIO-005	Identification of EQA specimens in the computer
QP-CBIO-011	Management of external quality assurance
QF-CBIO-001	EQA statement

QP-CBIO-006	Qpulse SOP
LFD-CBIO-020	EQA correspondence
LI-VBIO-006	EQA Website instructions
LF-CBIO-015	EQA Log Template
Qpulse CAPA module	EQA Reports
QP-GGC-002	TPS 47: UKAS Policy on participation in proficiency testing
QP-GGC-003	EA-4/18 INF:2010 Guidance on the level and frequency of proficiency testing participation (2010)
LFD-GGC-006	Uncertainty of Measurement Meetings
QP-CBIO-016	UOM Data Preparation
QP-CBIO-017	Clyde Biochemistry Uncertainty of Measurement Table
QP-GGC-008	LAB 12 - The Expression of Uncertainty in Testing
QP-GGC-010	M3003 - The Expression of Uncertainty & Confidence in Measurement
QP-CBIO-018	Uncertainty Of Measurement And Traceability
QP-GGC-011	TPS 41 – UKAS Policy on Metrological Traceability
QP-GGC-013	ILAC P10:01/2013 Policy on the Traceability of Measurement Results
PD-CBIO-001	Biochemistry Laboratory Handbook
PD-GGC-003	Biochemistry Handbook For Primary Care Users
LI-CBIO-062	Interlaboratory Comparison Protocol

5.9 Post-examination processes (ISO 5.7)

The procedures used to ensure that authorised and competent personnel review and release test results, following examination of associated internal quality control, clinical information (when available) and previous test results are listed below.

Document Number	**Title**
LF-CBIO-019	Laboratory Coded Comments
LI-CBIO-001	IQC Acceptance Criteria
LI-CBIO-027	Telepath Result Authorisation
LI-CBIO-028	Telepath Result Authorisation Out of Hours
LI-CBIO-035	Ranges of Results to Telephone
LI-CBIO-036	Abnormal Results Checklist
LP-CBIO-010	Reporting Guidelines for Electrophoresis
LP-CBIO-011	Telephone Procedure
LP-CBIO-032	Telepath SOP
LP-CBIO-039	BMS Reporting Bench SOP
MP-CBIO-009	Clinical Advice and Interpretation
QP-CBIO-010	Internal Quality Control
TF-CBIO-062	Competence: Duty Biochemist
TF-CBIO-102	Competence: Protein Electrophoresis Reporting
TF-CBIO-014	Competence: Laboratory Information Management Systems (LIMS)

The laboratory procedures for the storage, retention and disposal of clinical specimens are listed below.

Document Number	Title
HSP-CBIO-008	Waste Disposal Policy
LI-CBIO-029	Telepath Sample Archiving
LP-CBIO-017	FlexLab Track SOP
MF-CBIO-004	Storage and Retention of Records and Samples
MP-GGC-006	Transport and Disposal of Specimen Containers and Specimens Policy
PD-GGC-007	RCPath Retention and Storage of Pathological Records and specimens

5.10 Reporting Results (ISO 5.8)

Clyde Clinical Biochemistry has procedures are in place to ensure that all patient results are reported in a timely and accurate manner. Reports in both electronic and hard copy format include all necessary information to allow accurate clinical interpretation. Information included in reports contains, but is not limited to, comments regarding sample integrity likely to have an impact on patient results, highlighting of critical results and any interpretive comments.

Document Number	Title
LI-CBIO-038	Amendment of Reports
LP-CBIO-037	Computerised Selection of Results for Validation and Reporting
MP-CBIO-009	Clinical advice & Interpretation
LP-CBIO-012	AMS SOP
LP-CBIO-032	Telepath SOP
LI-CBIO-027	Telepath Result Authorisation
LI-CBIO-028	Telepath Result Authorisation Out Of Hours
LP-CBIO-011	Telephone Procedure
LI-CBIO-035	Ranges Of Results To Telephone
LF-CBIO-019	Laboratory Coded Comments
PD-CBIO-001	Biochemistry Laboratory Handbook
PD-GGC-003	Biochemistry Handbook For Primary Care Users
LP-CBIO-039	Validation bench SOP
LI-CBIO-036	Abnormal Results Checklist

5.11 Reporting Results (ISO 5.9)

The procedures used for the release of examination results are listed below. Electronic patient reports are able to be reviewed in Clinical Portal, by clinical members of staff. All results released by the laboratory are followed by an electronic or paper report. The documentation includes:

- Who may release the results and to whom

- An indication on the report if a sample is unsuitable for analysis
- Telephoning protocol for sample results that fall outside critical intervals. Details on the date and time of documentation and the responsible person are logged in the Laboratory Information System (LIS), Telepath.
- Interim reports

Document Number	Title
LF-CBIO-019	Laboratory Coded Comments
LI-CBIO-027	Telepath Result Authorisation
LI-CBIO-028	Telepath Result Authorisation Out of Hours
LI-CBIO-038	Amended Report Procedure
LP-CBIO-011	Telephone Protocol
LP-CBIO-037	Computerised Selection of Results for Validation and Reporting
LP-CBIO-032	Telepath SOP

5.12 Automated Selection and Reporting of Results (ISO 5.9.2)

The procedures for the selection and reporting of patient results are documented below. The criteria for the correct functioning of this system and associated verification data is held by GG&C Information Technology (I.T.) department. All electronic results are identifiable using a unique laboratory barcode and include the date and time of review in the Analyser Management System (AMS). The documentation includes:

- Automated selection and reporting criteria
- Indicating the presence of sample interference
- Analytical warning messages from the analysers

Document Number	Title
LP-CBIO-012	Abbott Analyser Management System (AMS)
LP-CBIO-037	Computerised Selection of Results for Validation and Reporting

5.13 Revised Reports (ISO 5.9.3)

The procedure for amended reports is listed below. The login details and date/time of amendment is logged in LIS.

Document Number	Title
LI-CBIO-038	Amended Report Procedure

6.0 Information Technology (ISO 5.10)

Health Information and Technology (HI&T) NHS GG&C, is responsible for ensuring the availability and management of data and information. The procedures include:

- Security
- Access
- Confidentiality and data protection
- Backup systems
- Storage, archive and retrieval
- Secure disposal

All systems comply with current national legislation and regulations in relation to data protection.

The authorities and responsibilities of personnel who use the Laboratory Information System (LIMS), including the maintenance and modification of this system, include:

- Access to patient data and information;
- The entry of patient data and examination results;
- Those staff with responsibilities to change patient data or examination results;
- Those staff with the authority to validate and report (release) examination results and reports are limited to HCPC registered Biomedical Scientists and Medical staff.

Documents ensuring the safeguarding and protection to the laboratory I.T systems are listed below.

Document Number	Title
MI-CBIO-003	I.T. Contingency Flow diagram
LP-CBIO-012	Analyser Management System SOP
LP-CBIO-032	Telepath SOP
MP-GGC-004	IT Operational SLA

I.T. support for the NHS GG&C Network and the Laboratory Information Management System (LIMS),Telepath is agreed and provided by NHS GG&C Health Information and Technology (HI&T), as described in I.T. Operational Level Agreement, MP-GGC-004.

I.T. support for the Abbott Analyser Management System (AMS) is agreed and provided by Omnilab as part of the Abbott Diagnostics managed service contract. Procedure and contact details are included in the document listed below.

Document Number	Title
MM-GGC-001	MyLab Portal Guide and Summary

The Departmental Change Control Policy, MP-CBIO-005 applies to all departmental activities which have an impact, or potential impact, on the quality and/or safety of the laboratory service. This policy also applies to the installation and upgrading of equipment and services, including projects managed by external organisations. Change control will be required prior to the introduction of all new or modified activities. The HI&T Department, NHSGGC, operates an independent Policy and Validation/Change Report Form, specific to the change/validation of IT Systems - see MP-CBIO-016.

Document Number	**Title**
NHS Scotland	NHS Scotland Code of Practice: Protecting Patient Confidentiality
STAFFNET	NHS GG&C Guidance on the Handling of Personal Identifiable, Confidential & Sensitive Information
STAFFNET	NHS GG&C Information Governance & Information Technology Security Framework