
	NHS GG&C Diagnostics Division North Glasgow Sector, Department of Haematology Quality Manual			QM-ALL-ALL-001	
				Revision No: 27	
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QUALITY MANUAL

This Document together with any documents which it references, details the Quality Management System of the Department of Haematology, North Glasgow Division, NHS Greater Glasgow & Clyde. All policies and procedures described within are mandatory in the Department of Haematology, North Glasgow Sector.



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1 Abbreviations and Acronyms

ACH	Ambulatory Care Hospital
AGM	Assistant General Manager
AMR	Annual Management Review
BSQR	Blood Safety and Quality Regulations
CCS	Consultant Clinical Scientist
CHS	Clinical Head of Service (Laboratory Director)
CLNS	Clinical Lead North Sector
CS	Clinical Scientist
CSM	Clinical Services Manager
CPD	Continuing Professional Development
EQA	External Quality Assessment
GGH	Gartnavel General Hospital
GM	General Manager (Laboratory Medicine)
GRI	Glasgow Royal Infirmary
HCPC	Health and Care Professions Council
HSE	Health and Safety Executive
H&SO	Health and Safety Officer
IBMS	Institute of Biomedical Science
IQC	Internal Quality Control
ISO	International Organization for Standardisation
JD	Job Description
LIMS	Laboratory Information System
MHRA	Medicines and Healthcare Products Regulatory Authority
MSC	Managed Service Contract
NHS	National Health Service
NHSGGC	NHS Greater Glasgow and Clyde
QM	Quality Manual
QMS	Quality Management System
QTPM	Quality, Training and POCT Manager
RCA	Root Cause Analysis
RF	Radio Frequency
SLA	Service Level Agreement
SLM	Sector Laboratory Manager
SNBTS	Scottish National Blood Transfusion Service
SOP(s)	Standard Operating Procedure(s)
STB	Stobhill ACH
TL	Technical Lead
TP	Transfusion Practitioner
TSM	Technical Services Manager
UKAS	United Kingdom Accreditation Service
UoM	Uncertainty of Measurement

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2 Introduction

This Quality Manual describes the Quality Management System (QMS) of the North Glasgow Sector Haematology Department. This Quality Manual can be regarded as the index to the separate documentation of management, laboratory, clinical and quality procedures.

The sections of the Quality Manual are arranged so that in the title of each section or sub section the relevant standard of the ISO15189-2022 standards is referenced. Please note that standards may be referenced in more than one section. Reference to other standards or Legislation will be included where relevant. In each section there is a brief description of the way in which the Department seeks to comply with the particular standard and/or legislation and references are given to appropriate documents using their QMS reference number [ABC-ABC-ABC-XXX]. The full title of the document can be found in the appendices, [see Appendix 1](#). Publications relative to Accreditation and Regulatory bodies can also be found in the appendices, [see Appendix 2](#). All referenced documents can be found on the department's QMS system; Q-Pulse.

3 Overview of the organisation

As part of the diagnostic services of NHS Greater Glasgow and Clyde (NHSGGC), the Department of Haematology, North Glasgow Sector, provides Haematology, Haemostasis, Blood transfusion and Diagnostic Haemato-oncology services from three sites (Glasgow Royal Infirmary, Gartnavel General Hospital and Stobhill ACH) to service users for the benefit of the patient and population. Additionally the department provides blood for transfusion to the Nuffield Hospital (Glasgow), Lightburn Hospital (NHSGGC) and the Marie Curie Hospice (Glasgow). Details of the services provided on each NHSGGC North Sector site can be found in the Departmental User Handbook [MAI-ALL-ALL-009]. With the exception of the Diagnostic Haemato-Oncology service all locations are staffed from a pool of staff based at the Glasgow Royal Infirmary.



The laboratory has adopted a quality management system for the effective and efficient use of its resources. All employees are committed to the culture of quality. All staff share responsibility for identifying nonconformities or opportunities for improvement and recording these instances so that corrective or preventive actions can be taken to ensure the laboratory meets the needs of its customers. All aspects of the quality management system; including (but not exclusive to) organisation, reporting structures, internal audit, incident reporting, training and competency are applied equally across all the laboratory sites and processes within the North Glasgow Sector in accordance with the relevant regulatory and accreditation standards [ECD-ALL-GDL-027, ECD-ALL-GDL-028, ECD-ALL-GDL-065, ECD-ALL-GDL-092, ECD-ALL-MAN-002] and any subsidiary documentation [see appendix 2](#).

3.1 NHSGGC Mission statement

"Deliver effective and high quality health services, to act to improve the health of our population and to do everything we can to address the wider social detriments of health which cause health inequalities".

3.2 Objectives

The objectives of the laboratory are to produce accurate, reliable and timely analyses' results that meet the needs and requirements of its patients and users. To maintain an effective quality

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management system that retains its integrity when changes to the management system are planned and implemented. To ensure compliance with all relevant statutory requirements. To comply with all health and safety requirements.

The department senior management through the Quality Manager contribute to the implementation of the quality management system to achieve the defined objectives.

3.3 Scope

This Quality Manual describes the quality management system (QMS) of the Department of Haematology, North Glasgow Sector.

References to supporting policies and procedures described in this document are available on the departments QMS system, Q-Pulse and listed in the appendices of this manual.

This document's scope is:

3.3.1 Internal use:

To communicate to staff the laboratory's quality policies and quality objectives. To make the staff familiar with the processes used to achieve compliance with any requirements. This facilitates the implementation of the quality management system as well as ensuring its maintenance and required updates during altering circumstances. This allows effective communication and the control of quality related activities and a documented base for quality system audits.

3.3.2 External use



To inform the service users about its quality policies as well as its implemented quality management system and of compliance.

3.4 Quality Policy Statement

Senior management is dedicated to providing ALL the resources necessary to maintain the laboratory quality management system.

The laboratory is committed to continual improvement, meeting patient and service user requirements and providing a basis for the establishment and review of the quality objectives.

Quality practices are communicated within the organisation and are understood and adhered to by all employees. The laboratory ensures a competent workforce to deliver quality results in a timely manner according to the Blood Safety and Quality Regulations 2005 (amended 2007) [ECD-ALL-GDL-028] and The Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2005 and 2006) [ECD-ALL-GDL-065] as regulated by the MHRA. Also ISO15189-2022 [ECD-ALL-GDL-027] as assessed for compliance by The United Kingdom Accreditation Service (UKAS) in all the locations it operates from. The laboratory ensures that each section partakes in and documents internal quality assurance activity. The laboratory ensures that each department belongs to and participates in, appropriate External Quality Assurance schemes with evidence of performance review. The laboratory ensures that each department is routinely active in addressing Health AND Safety, Staff training and development, appropriate equipment maintenance and internal audit.

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4 Organisation and Management General Requirements

The laboratory ensures to deliver quality results in a timely manner according to the Blood Safety and Quality Regulations 2005 (amended 2007) [ECD-ALL-GDL-028], The Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2005 and 2006) [ECD-ALL-GDL-065] and ISO15189-2012.

4.1 Impartiality

The Department of Haematology, North Glasgow Sector, NHS Greater Glasgow & Clyde is committed to impartiality in all laboratory activities. The laboratory is structured and managed to safeguard impartiality and ensure that technical and clinical judgements are not influenced by commercial, financial, or other pressures.

The laboratory is not engaged in any activity that could compromise impartiality or technical judgement.

All staff are required to declare any potential conflicts of interest to their line manager(s), The laboratory management regularly reviews relationships and activities to identify and mitigate threats to impartiality, including those arising from ownership, governance, management, personnel, shared resources, finances, contracts, or marketing.

The Laboratory Management are designated to oversee impartiality and independence. The TSM will report any threats to impartiality to the Senior Staff Meeting.

Roles and responsibilities are clearly defined in job descriptions and departmental policies.

Any identified threats to impartiality are documented and actions taken to eliminate or minimise their effect.

Equipment, Reagents, consumables and other services (i.e. calibration) are managed through the Managed Service Contract (MSC). When the contract is out for renewal all staff involved in the assessment of the renewal must complete a declaration of any interests that may affect their decisions in line with NHSGGC and NHS Scotland policy. This declaration applies also to the procurement of any major IT system (i.e. LIMS) that is not provided by either NHSGGC eHealth or NHS Scotland.



4.2 Confidentiality

4.2.1 Management of information

The laboratory is responsible, through legally enforceable agreements, legislation, regulation and internal policies for the management of all patient information obtained or created during any of the laboratories activities. This includes ensuring privacy and confidentiality at all times.

4.2.2 Release of information

All staff, including committee members, contractors, and external parties acting on behalf of the laboratory, are required to keep confidential all information obtained or created during the performance of the laboratories activities.

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Patient information is only released in accordance with legal or contractual requirements, and patients are notified of any such disclosures unless prohibited by law.

Access to patient data is restricted to authorised personnel only, controlled by access levels in the Laboratory Information Management System (LIMS) laboratory and other patient IT systems.

Procedures are in place for the release of information, including notification to patients and the documentation of disclosure [ECD-ALL-POL-011, ECD-ALL-POL-013, MAP-ALL-ALL-002, MAF-ALL-ALL-011].

4.2.3 Personnel responsibility

Confidentiality agreements are signed by all staff as part of their work contract, LIMS systems access and is required before being allowed access to any Health board data systems.

Data protection and confidentiality are included in all staff induction via Statutory and Mandatory training (Safe Information Handling).

Procedures are in place for the maintenance of confidentiality and data protection: [MAP-ALL-ALL-002, MAP-ALL-ALL-018, ECD-ALL-GDL-090, ECD-ALL-POL-006, ECD-ALL-POL-011, ECD-ALL-POL-013].

4.3 Requirements Regarding Patients

The laboratory management ensures that the well-being, safety, and rights of patients are the primary considerations in all activities.

4.3.1 Patient Involvement:

Patients and laboratory users are provided with opportunities to contribute information that aids in the selection of assay methods and interpretation of results. The process for this is available on the department's webpages [Map-ALL-ALL-008].

Feedback from patients and users is actively sought and reviewed.

4.3.2 Information Provision:

Information about assay processes, including expected result times and, where applicable, costs, is made publicly available via the Service User Handbook and departmental webpages on the NHSGGC website [MAI-ALL-ALL-009]

The laboratory provides clear instructions for sample collection, consent, and result interpretation [MAI-ALL-ALL-009]



4.3.3 Review of Assays and Processes:

The range of assays and processes offered is periodically reviewed to ensure clinical appropriateness and necessity [MAP-ALL-ALL-013, LAF-ALL-ALL-020].

Any changes to the scope of services are communicated to users and documented.

4.3.4 Incident Disclosure:

Incidents that resulted or could have resulted in patient harm are disclosed to patients, users, and relevant authorities, and actions taken to mitigate such harms are recorded in line with the

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department [MAP-ALL-ALL-007], Health Board Risk management policies [ECD-ALL-POL-004] and NHSGGC's Duty of Candor policy [ECD-ALL-GDL-094]

4.3.5 Respect and Dignity:

All patient samples are treated with due care and respect, in accordance with the relevant legislation, NHSGGC and departmental policies [MAP-ALL-ALL-002].

4.3.6 Consent:

Informed consent is obtained for all procedures as required, following the NHSGGC Consent Policy [ECD-ALL-GDL-089].

Special procedures requiring explicit consent including Family Origin Questionnaires are clearly identified and documented.

4.3.7 Sample and Record Integrity:

The ongoing availability and integrity of retained patient samples and records are ensured. Retention and disposal of samples and records follow the department's policy [MAP-ALL-ALL-002] Scottish Government. Health and social care - records management: code of practice [ECD-ALL-GDL-090] and all relevant legislation, the Blood Safety and Quality Regulations 2005 (amended 2007) [ECD-ALL-GDL-028], The Medicines for Human Use (Clinical Trials) Regulations 2004 (amended 2005 and 2006) [ECD-ALL-GDL-065], Human Tissue Act – 2004 [ECD-ALL-MAN-002]

4.3.8 Information Access:

Relevant information is made available to patients and healthcare providers upon request, in accordance with data protection and confidentiality policies [MAP-ALL-ALL-002, MAP-ALL-ALL-018, ECD-ALL-GDL-090, ECD-ALL-POL-006, ECD-ALL-POL-011, ECD-ALL-POL-013].



4.3.9 Non-Discrimination:

The laboratory upholds the rights of patients to care that is free from discrimination, in line with the Equality and Diversity Policy [ECD-ALL-POL-012] and is included in staff induction and Statutory and Mandatory training.

5 Structure and Governance

5.1 Legal Entity

The Department of Haematology, North Glasgow Sector, is a constituent of the Diagnostics Division within the Acute Services of NHS Greater Glasgow and Clyde. The laboratory is a legally recognised entity, accountable for its activities and compliance with statutory and regulatory requirements. The department provides routine and specialised haematology services from four sites: Glasgow Royal Infirmary, Gartnavel General Hospital, Stobhill ACH, and West Glasgow ACH. Blood transfusion services are provided from Glasgow Royal Infirmary (24-hour service) and Gartnavel General Hospital (Monday–Friday, 08:00–18:00). Details of services provided at each site are available in the Departmental User Handbook [MAI-ALL-ALL-009].

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5.2 Laboratory Director

The Clinical Head of Service serves as the Laboratory Director and is responsible for the implementation and maintenance of the management system, including risk management across all laboratory operations. The Laboratory Director is supported by the North Sector Haematology Consultants, Technical Services Manager, Sector Laboratory Manager, Quality Training and POCT Manager, Technical Leads and other senior staff as detailed in the organisational structure.



5.2.1 Competence

The Laboratory Director's qualifications, delegated authority, and resources are documented and reviewed regularly.

5.2.2 Duties and Responsibilities

The Laboratory Director's duties and responsibilities include:

- a) Providing effective leadership of the medical laboratory service, including budget planning and financial management, in accordance with Health Board assignment of such responsibilities
- b) Relate and function effectively with applicable accrediting and regulatory agencies and authorities, appropriate administrative officials, the healthcare community, the patient population served and providers of formal agreements, when required
- c) Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users
- d) Ensure the implementation of the quality policy
- e) Implement a safe laboratory environment in compliance with good practice and applicable requirements
- f) Implementation of the Incident and risk management procedure in all laboratory operations to prevent patient harm and to identify opportunities for improvement that are evaluated and modified when identified as being ineffective.
- g) Serve as a contributing member of the medical staff for those facilities served when applicable and appropriate
- h) Ensure the provision of clinical advice with respect to the choice of assays, use of the service and interpretation of assay results
- i) Advise and engage in the selection and monitoring of laboratory suppliers
- j) Advise and engage in the selection and monitoring of referral laboratories

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- k) Advise and engage in the selection of professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations
- l) Advise and engage in the implementation and monitoring of standards of performance and quality improvement of the medical laboratory service(s)
- m) Advise and engage in the monitoring of all work performed in the laboratory to determine that clinically relevant information is being generated
- n) Address any complaint, request or suggestion from staff and/or users of laboratory services
- o) Advise and engage in the design and implement of a contingency plan to ensure that essential services are available during emergency situations and/or other situations when laboratory services are limited or unavailable
- p) Plan and direct research and development where appropriate.

5.2.3 Delegation of duties

Duties may be delegated to qualified and competent personnel when the Laboratory Director is not available, but the ultimate responsibility for the laboratory's operation remains with the Laboratory Director. Some duties may be delegated or have responsibility shared between more than one competent individual

Duties are delegated to the clinical lead for Haematology in the North Sector, in their absence they are delegated to the most senior Haematology Consultant on that site.

Duties are delegated to the TSM, in their absence the most senior member of the management staff on that site

The following table (abbreviated descriptions) shows the delegation of the above duties to other members of the department

	Description (abbreviated)	Delegation
a	budget planning and financial management	TSM, Clinical Lead (North Sector), CCS
b	accrediting and regulatory agencies and authorities,	TSM, Clinical Lead (North Sector), QTPM, CCS
c	appropriate numbers of staff with the required education,	TSM, QTPM
d	implementation of the quality policy	TSM, Clinical Lead (North Sector), CCS, QTPM

	Description (abbreviated)	Delegation
e	safe laboratory environment	TSM, H&SO
f	Incident and risk management procedure	QTMP
g	contributing member of the medical staff	All Haematology Consultants
h	provision of clinical advice	Clinical Lead (North Sector), CCS,CS
i	selection and monitoring of laboratory suppliers	TSM, Clinical Lead (North Sector), CCS, QTPM, SLM, TL
j	selection and monitoring of referral laboratories	TSM, Clinical Lead (North Sector), CCS, QTPM, SLM, TL
k	professional development programmes	QTMP, CS
l	monitoring of standards of performance	TSM, QTPM
m	clinically relevant information	TSM, Clinical Lead (North Sector), CCS, CS, QTPM, SLM, TL
n	any complaint, request or suggestion	TSM, Clinical Lead (North Sector), QTPM, CCS
o	implement of a contingency plan	TSM, Clinical Lead (North Sector), CCS, QTPM, SLM, TL
p	direct research and development	CCS, CS



5.3 Laboratory Activities

5.3.1 General Requirements

The laboratory describes and documents the range of activities for which it conforms to ISO 15189:2022, including all laboratory services provided at the main and satellite locations as stated in the Department's user handbook [MAI-ALL-ALL-009]. The laboratory only claims conformity with ISO 15189:2022 for activities directly under its control and as stated in the Department's user handbook [MAI-ALL-ALL-009]

5.3.2 Conformance with Requirements

The laboratory performs all activities on all sites in conformance with all regulatory, statutory and accrediting bodies for those activities under its direct control the range of activities carried out on each site is stated in the Department's user handbook [MAI-ALL-ALL-009].

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5.3.3 Advisory Activities

Appropriate laboratory advice and interpretation is available to meet the needs of patients and users [\[MAI-ALL-ALL-009\]](#)

This includes arrangements for communicating with laboratory users on the following when applicable:

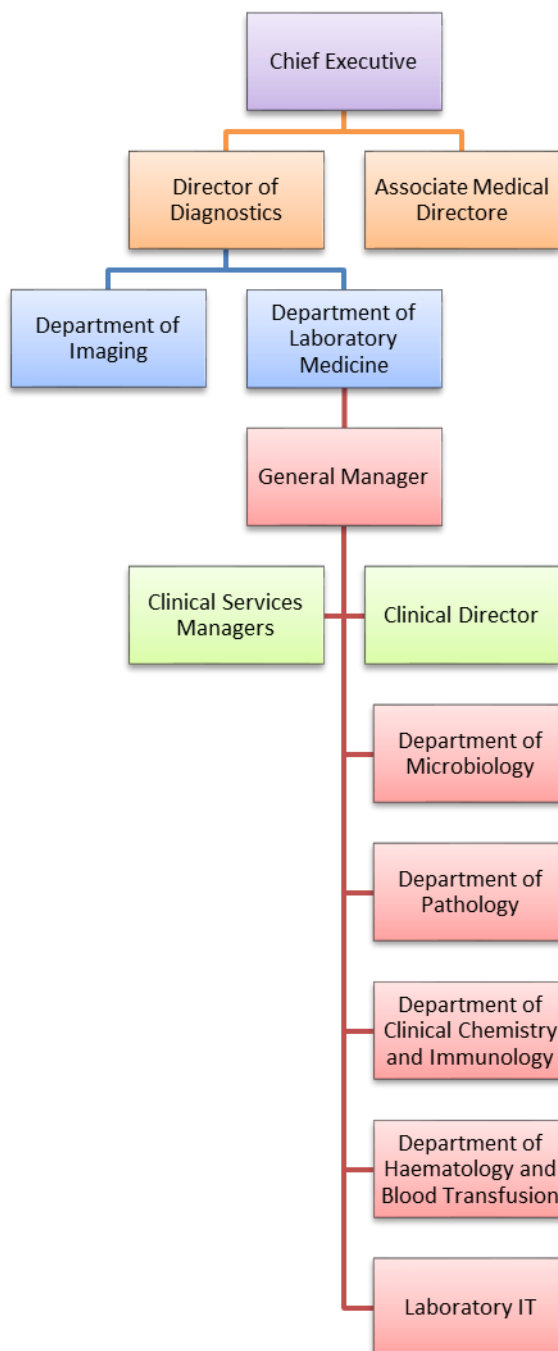
- Advising on the choice and use of any assays and processes including the required type of sample and clinical indications.
- The limitations of any assays and processes and the frequency of requesting the assays or process.
- Professional advice on the interpretation of the results of assays or processes
- Advice on the effective use of any assays and processes
- Communication and information on assays and processes in instances such as the failure of a sample(s) to meet the stated acceptability criteria.

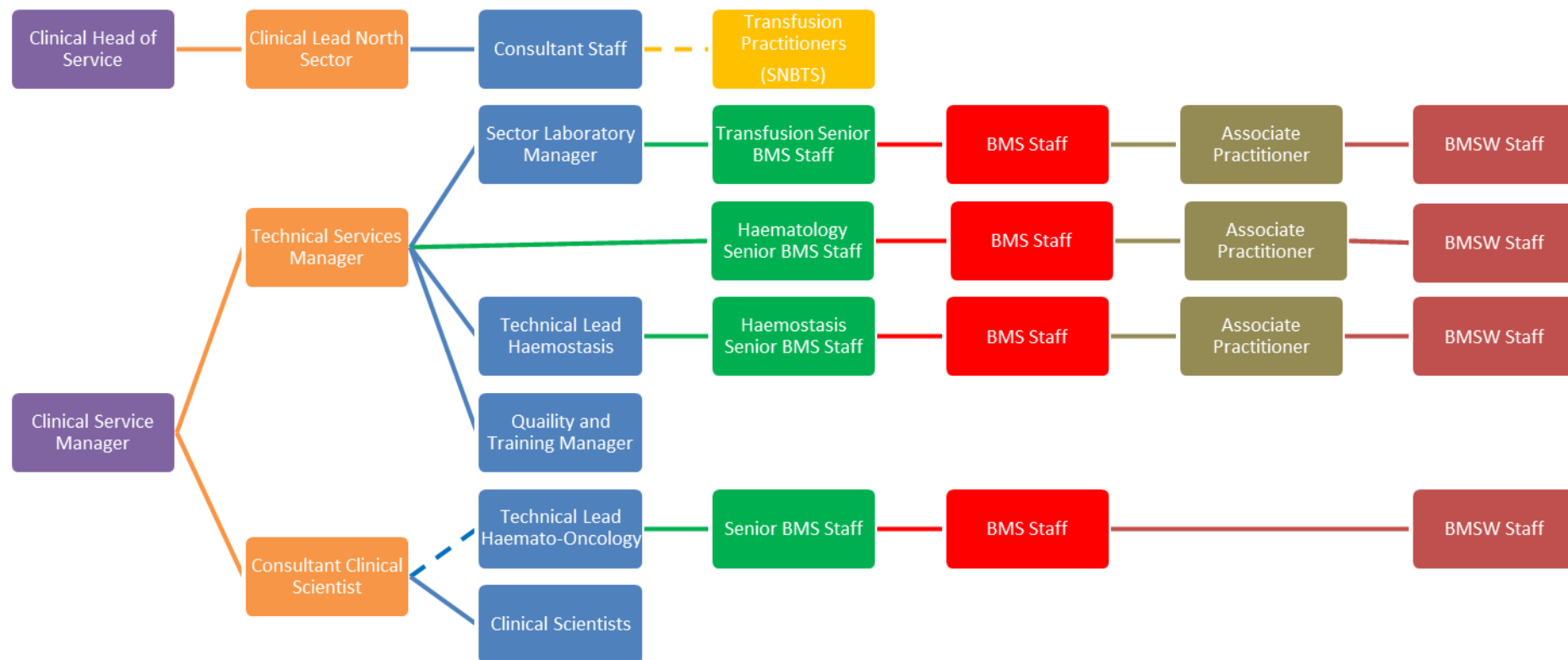
5.4 Structure and Authority



The organisational structure of the Department of Haematology is clearly defined and documented. The structure includes the Clinical Head of Service, General Manager, Clinical Services Manager, Lead Clinician North Sector, Technical Services Manager, Sector Laboratory Manager, Quality and Training Manager, Consultant Clinical Scientist, and other key roles. Organisational charts are maintained and show lines of accountability and reporting relationships. The responsibilities, authority, and interrelationships of all personnel who manage, perform, or verify work affecting laboratory results are specified in job descriptions and departmental policies.

See following organisational charts

5.4.1 Organisational Structure





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The department collaborates with other departments within NHSGGC, including Human Resources, e Health, Laboratory IT, Education and Learning, Finance, Procurement, and Facilities, as well as other support services.

The laboratory and Diagnostics Division organisational structures are shown in the charts included in this manual.

The senior Biomedical Scientist (BMS) staff are the primary point of contact for each site and are responsible for monitoring service delivery, quality control, quality assurance, equipment, stock, and performance.

5.4.2 Quality Management

The Quality Manager is delegated responsibility and authority to:

- Ensure that processes needed for the Quality Management System are established, implemented, improved, and maintained.
- Report to the laboratory management on the performance of the QMS and any requirements or actions for improvement.
- Identify and report deviations from the management system or procedures for performing laboratory activities.
- Initiate actions to prevent or minimise deviations and their effects.
- Promote awareness of patient and user needs and requirements throughout the laboratory.
- Ensure that the laboratories activities are carried out effectively.



5.5 Objectives and Policies

The laboratory's quality policy [MAP-ALL-ALL-014] and objectives [MAI-ALL-ALL-073] are established, documented, and maintained. These are reviewed annually at the Management Review meeting and are communicated to all staff. The Quality Objectives [MAI-ALL-ALL-073] are additionally regularly reviewed at the Quality Meeting and are completed or amended as required.

The quality policy and objectives are designed to meet the needs and requirements of the patients and users of the department, to provide assays and processes that meet the needs of its users, commit to good professional practice and ensure conformity with ISO 15189, BSQR, HTA, JACIE and GCP.

Quality indicators have been established to evaluate performance of the laboratories activities throughout key aspects of pre-analytical, analytical, and post-analytical processes.

Any changes to the management system must be made in conjunction with the departments change control process [MAP-ALL-ALL-030]

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5.6 Risk Management

Laboratory management establishes, implements, and maintains processes for identifying risks of harm to patients and opportunities for improved patient care associated with its assays, processes and activities [MAP-ALL-ALL-007].

Actions and initiatives are developed to address risks and provide opportunities for improvement. The effectiveness of these processes is regularly evaluated and modified as necessary.

Incident and risk management is documented and discussed at the relevant departmental meetings, including the Quality Meeting, Incident Meeting and Senior Staff Meeting.

A review is undertaken annually as part of the AMR [MAP-ALL-ALL-013] where it forms a standing item in the Quality, Training and POCT Managers report.

The Laboratory Director delegates (when not available) the review, evaluation of actions and processes, modification of actions and processes for the identification and evaluation of clinical harm/impact to patients to the Haematology Consultants and the Clinical Scientists on all sites in the Haematology and Blood Transfusion department of the North Sector of NHSGGC

6 Resource Requirements

6.1 General Requirements

The Department of Haematology ensures that sufficient and appropriate resources, including personnel, facilities, equipment, reagents, consumables, and support services are available to support all the laboratories activities and to maintain compliance with the requirements of any relevant statutory, regulatory, accreditation body or authority.

Resource requirements are reviewed annually as part of the management review [MAP-ALL-ALL-013] and whenever significant changes occur in workload, scope, or technology.

The laboratory maintains contingency plans to address resource shortages or emergencies [LAP-ALL-ALL-033, ECD-ALL-POL-038].

6.2 Personnel

6.2.1 General Requirements



The laboratory employs a sufficient number of competent staff to perform all its activities.

All personnel, including temporary and external staff, are required to act impartially, ethically, and in accordance with the laboratory's management system.

6.2.2 Competence Requirements

Requirements for each activity or function of the laboratory are specified in the available job descriptions and departmental policies.

Recruitment and selection is performed based on qualifications, experience and technical knowledge relevant to the role for which the applicant has applied.

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Training and where appropriate retraining is provided for all staff, including induction, statutory and mandatory training and ongoing CPD [MAP-ALL-ALL-026]. The levels of training and competence are monitored regularly.

Competence is assessed through direct observation, review of work activities, knowledge assessments, participation in EQA/IQC and the completion of reflection on what the staff member has learnt and how they will apply it for best practice [MAP-ALL-ALL-026].

All training and Competency records are maintained on the Laboratories QMS which allows for the monitoring of the status of competency including the requirement for periodic reassessment [MAP-ALL-ALL-026, LAP-ALL-ALL-008].

6.2.3 Authorisation

Following the successful completion of the departments relevant Training and Competency documentation [MAP-ALL-ALL-026] required for that process personnel are authorised to perform specific laboratory activities including:

- The selection, development and modification of processes
- The validation and verification of methods, assays and processes
- The review, release and reporting of results

The use of laboratory information systems including

- The accessing of patient data and information
- The entering of patient data
- The modification of patient data
- The entering of assay results
- The modifying of assay results.





Training
Documents List.xlsx



The following is a table of the activities that a staff member is authorised to perform by band. Note that Individual staff members may after training and assessment be able to perform certain tasks attributed to another band within this table.

Process	Band 3	Band 4	Band 6	Band 7	Band 8
Selection, development and modification of laboratory processes	No	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes Laboratory and budget holder authorisation required by Health Board SFI's

Process	Band 3	Band 4	Band 6	Band 7	Band 8
Validation and verification of methods, assays and processes	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes
Review, release and reporting of results using the LIMS	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Accessing patient data and information using the appropriate system	Yes: Following completion of the appropriate departmental training and competency assessment, or health board training	Yes: Following completion of the appropriate departmental training and competency assessment, or health board training	Yes: Following completion of the appropriate departmental training and competency assessment, or health board training	Yes: Following completion of the appropriate departmental training and competency assessment, or health board training	Yes: Following completion of the appropriate departmental training and competency assessment, or health board training
Entering patient data onto the LIMS	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.

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Process	Band 3	Band 4	Band 6	Band 7	Band 8
Modification of patient data on the LIMS	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Entering assay results onto the LIMS	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Modifying of assay results on the LIMS	No	no	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Perform appraisals and set PDP's	No	Yes: Following completion of the appropriate Health Board training.	No	Yes: Following completion of the appropriate Health Board training.	Yes: Following completion of the appropriate Health Board training.

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Process	Band 3	Band 4	Band 6	Band 7	Band 8
Training staff on non-analytical laboratory processes	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Training staff on analytical methods, assays and processes	No	No	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.	Yes: Following completion of the appropriate departmental training and competency assessment.
Creation of laboratory documents	No	Yes: Using the laboratory templates and as guided by the appropriate Band 7 or Band 8	Yes: Using the laboratory templates and as guided by the appropriate Band 7 or Band 8	Yes: Using the laboratory templates	Yes: Using the laboratory templates
Review and modification of laboratory documents	No	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following the assignment of appropriate access within the QMS.

Process	Band 3	Band 4	Band 6	Band 7	Band 8
Approval of Laboratory documents	No	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	No	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following the assignment of appropriate access within the QMS.
Audit	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.	Yes: Following completion of the appropriate departmental training and assignment of appropriate access within the QMS.



Note the appropriate training documents are embed above this table.

Creation, review and approval of laboratory documentation is also dependent upon the section of the laboratory and the roles of the individual staff bands within that section. The creation and review of documentation is assigned to those staff who will have knowledge of the process within that laboratory section. Document approval is undertaken by staff grades that have a supervisory element within their role. Their must always be a separate author and approver for a given document [\[MAP-ALL-ALL-003, LAP-ALL-ALL-023\]](#).

6.2.4 Continuing Education and Professional Development

All staff are encouraged to participate in a continuing education programme, for registered Biomedical Scientist and Clinical Scientists this is a requirement to maintain their entry on the statutory registers. This may include in-house training, seminars, external courses, conferences and webinars, all staff are also encouraged to take part in external CPD schemes [\[MAP-ALL-ALL-026\]](#).

The provision, suitability and availability of Continuing Professional Development training programmes is reviewed annually at the management review where it is a standing element of

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the Quality, Training and POCT Managers report [\[MAP-ALL-ALL-013\]](#) and at the departments training meetings.

6.2.5 Personnel Records

The laboratory in conjunction with the Health Board's Human Resources and Recruitment departments maintains comprehensive personnel records, including:

- Qualifications
- References
- Job descriptions
- Training and competence assessments
- Authorisations
- Appraisals
- CPD records
 - Where the CPD training has been provided by the department.
- Absence
 - Long and Short Term
- Annual Leave

Records are stored securely in Q-Pulse, TURAS, and electronic and manual personnel files, with access restricted to authorised staff.

6.3 Facilities and Environmental Conditions

6.3.1 General Requirements

The laboratory is housed in facilities that are suitable for all its activities and maintained to ensure safety, functionality, and compliance.

Environmental conditions are monitored and recorded as required.

6.3.2 Facility Controls

Access to the laboratory building is controlled by RF-chipped identity cards.

There are measures in place to prevent contamination, cross-contamination between reagents, consumables and samples. (separate storage, cleaning schedules).



Health and Safety facilities (eyewash stations, alarms) are provided and regularly checked and are included in NHSGGC's Safety, Health and Wellbeing (SHAW) calendar.

6.3.3 Storage Facilities

Secure storage space is provided, temperature controlled where required, for samples, equipment, reagents, consumables, documents, and records.

Temperature-controlled storage (cold rooms, fridges, freezers, blood fridges) is monitored and maintained in compliance with BSQR, GCP, HTA and ISO 17025.

Hazardous materials and waste are stored and disposed of according to NHSGGC policy and the relevant Health and Safety Legislation.

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6.3.4 Personnel Facilities

All Staff have access to toilets, washrooms, staff rooms, catering facilities, secure lockers and storage for personal and protective clothing (PPE).

Study rooms and seminar rooms are available for training and professional development.

6.3.5 Sample Collection Facilities

Patient samples are collected in wards, clinics, and primary care settings, obtaining, collection and transportation of these samples is not managed or under direct control of the laboratory.

The laboratory provides guidance on sample types, labelling, collection and transportation requirements in the Service User Handbook [\[MAI-ALL-ALL-009\]](#).

6.4 Equipment

6.4.1 General Requirements

Equipment is selected, procured, installed, accepted, maintained, and decommissioned according to departmental policies [\[MAP-ALL-ALL-010, MAP-ALL-ALL-030, MAP-ALL-ALL-007, LAP-ALL-ALL-023\]](#) to prevent any loss of performance and ensure ongoing fitness for purpose. Equipment, reagents and consumables are supplied under a managed service Contract.

6.4.2 Equipment Requirements

All equipment that can that is used for laboratory activities is labelled with the department's unique asset number and recorded in the Q-Pulse asset register [\[LAP-ALL-ALL-023\]](#).

Equipment is maintained and replaced as needed to ensure quality of results [\[MAP-ALL-ALL-010, MAP-ALL-ALL-030\]](#) and continuing to maintain the performance of the laboratory service. Equipment is supplied under a Managed Service Contract (MSC) should a replacement be required it is the MSC providers responsibility to provide this.

6.4.3 Equipment Acceptance Procedure

All the laboratory equipment is verified for fitness of purpose with specified acceptability criteria before being placed or returned into service.



Acceptance testing is documented in Q-Pulse [\[MAP-ALL-ALL-030, LAP-ALL-ALL-023\]](#)

6.4.4 Equipment Instructions for Use

Manufacturer's manuals, package inserts and SOPs are all available at the point of use either as a hardcopy or on the departments QMS

Only trained, competency assessed and authorised personnel are allowed to operate the equipment used for the laboratory service.

All equipment within the department is used in accordance within the specifications stipulated by the manufacturer(s) and supplier(s).

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6.4.5 Equipment Maintenance and Repair

Preventive maintenance is scheduled according to manufacturer's instructions and documented in Q-Pulse [LAP-ALL-ALL-023, LAF-ALL-ALL-004] on the equipment's asset record.

Any defective equipment is withdrawn from service, labelled and decontaminated to allow the service personnel to safely work on the equipment.

Equipment is only returned to use after verification has indicated its ongoing fitness for purpose [MAP-ALL-ALL-007, LAF-ALL-ALL-004, LAF-ALL-ALL-046].

Maintenance contracts are reviewed annually as part of the Laboratory Medicine MSC contract.

6.4.6 Equipment Adverse Incident Reporting



All adverse incidents are reported as non-conformities in Q-Pulse [LAP-ALL-ALL-023, MAP-ALL-ALL-007] and where appropriate reported to the manufacturer, MHRA, or HSE. The performance of the equipment is reviewed at the quality meetings and at the Annual Management review [MAP-ALL-ALL-013].

Field Safety notices and other notifications about the performance of equipment are recorded as non-conformances within Q-Pulse in accordance with the departments Incident and risk management policy [MAP-ALL-ALL-007].

6.4.7 Equipment Records

Records for each item of equipment are maintained on Q-Pulse [LAP-ALL-ALL-023, MAP-ALL-ALL-010, LAF-ALL-ALL-020] these include:

- The manufacturer
- Supplier details (where different)
- The department's unique asset number
- The equipment's location
- The equipment's serial number
- The record of acceptance testing
 - Further Acceptance testing when required
- The record of any modification
 - Further Acceptance testing when required
- Calibration certificates and records where appropriate
- Maintenance records
 - Preventative Maintenance
 - Unscheduled service visits
 - Damage
- The Annual Performance Review [LAF-ALL-ALL-020]
 - Reported to the Annual Management Review [MAP-ALL-ALL-013]
- The current status of any past or present equipment
- Any incidents Involving the equipment [MAP-ALL-ALL-007]
 - Corrective action(s)

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All records are retained in line with the department's policy and in conjunction with the RcPath/IBMS Guidelines [\[MAP-ALL-ALL-002\]](#).

6.5 Equipment Calibration and Metrological Traceability

6.5.1 General requirements

Calibration (where required) and metrological traceability requirements is detailed for all equipment used in the performing of quantitative methods.

Calibration certificates are retained in the equipment's asset record within Q-Pulse. Information on metrological traceability including package inserts or other information and documentation supplied by the manufacturer(s) or supplier(s) is also stored on the departments QMS.

6.5.2 Equipment Calibration

Calibration of equipment is performed by external providers accredited to ISO: 17025, Calibration certificates are stored in the equipment's record with the departments QMS.

Where the accuracy or viability of the calibration of a piece of equipment is in doubt this is considered an adverse incident and the situation managed via the departments Incident and Risk Management Procedure [\[MAP-ALL-ALL-007\]](#) as described in 6.4.5 and 6.4.6

6.5.3 Metrological Traceability

Metrological traceability documentation, including package inserts or other information supplied by the manufacturer(s) or supplier(s) is retained within Q-Pulse.

Where SI traceability is not possible, alternative means (reference methods, consensus standards) are used and this is documented within Q-Pulse.

6.6 Reagents and Consumables

6.6.1 General Requirements



The selection, procurement, reception, storage, acceptance testing, and inventory management of reagents and consumables are controlled by the appropriate departmental policies [\[MAP-ALL-ALL-011, MAP-ALL-ALL-030\]](#). Equipment, reagents and consumables are supplied under a managed service Contract.

6.6.2 Receipt and Storage

Reagents and consumables are checked on receipt, stored according to manufacturer's instructions and the environmental conditions monitored on all sites [\[LAF-ALL-COA-004, LAF-ALL-HAE-007, LAF-ALL-HAE-044, LAF-GGH-ONC-051, LAF-GRI-BTS-008, LAF-GRI-COA-075, LAF-GRI-COA-078, LAF-GRI-COA-079, LAF-GRI-COA-081, LAF-GRI-COA-082, LAF-GRI-COA-084, LAP-ALL-COA-006 LAP-ALL-HAE-012, LAP-ALL-HAE-012, LAP-GRI-BTS-039, LAP-GGH-ONC-027\]](#).

6.6.3 Acceptance Testing

All new batches or lots are verified for acceptable performance before being put into use.

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All acceptance testing is documented and reviewed [[LAF-ALL-COA-004](#), [LAF-ALL-HAE-007](#), [LAF-ALL-HAE-044](#), [LAF-GGH-ONC-051](#), [LAF-GRI-BTS-008](#), [LAF-GRI-COA-075](#), [LAF-GRI-COA-078](#), [LAF-GRI-COA-079](#), [LAF-GRI-COA-081](#), [LAF-GRI-COA-082](#), [LAF-GRI-COA-084](#)]. Reagents and consumables that are received on one site before being transported to a different site within the department undergo further acceptance testing on that site to ensure that there has been no loss of fitness for purpose during transportation.

6.6.4 Inventory Management

There is a stock segregation policy to keep those reagents and consumables that have had their acceptance testing completed from those that are awaiting the commencement and/or completion of their acceptance testing [[LAP-ALL-COA-006](#), [LAP-ALL-HAE-012](#), [LAP-ALL-HAE-012](#), [LAP-GRI-BTS-039](#), [LAP-GGH-ONC-027](#)]

Reagent and consumable stock levels are monitored regularly on all sites to prevent any situation in which there may be a shortage of reagents or consumables.

6.6.5 Instructions for Use

Manufacturer's package inserts, other documentation provided by the manufacturer or supplier and SOPs are available at the point of use either as hardcopies or as records on the departments QMS.



6.6.6 Adverse Incident Reporting

Incidents involving reagents or consumables are reported as non-conformities [[MAP-ALL-ALL-007](#), [LAP-ALL-ALL-023](#)] and where appropriate, to the manufacturer, MHRA, or HSE all such incidents are reviewed at quality meetings.

6.6.7 Records

Records for reagents and consumables are held as hardcopies [[LAF-ALL-COA-004](#), [LAF-ALL-HAE-007](#), [LAF-ALL-HAE-044](#), [LAF-GGH-ONC-051](#), [LAF-GRI-BTS-008](#), [LAF-GRI-COA-075](#), [LAF-GRI-COA-078](#), [LAF-GRI-COA-079](#), [LAF-GRI-COA-081](#), [LAF-GRI-COA-082](#), [LAF-GRI-COA-084](#)]. within the laboratory and on the operating software of the analyser this information includes

- The name and/or type of the reagent or consumable
- The batch or lot number of the reagent or consumable
- The date of receipt of the reagent or consumable
- The expiry date of the reagent or consumable
- A record of the acceptance testing of the reagent or consumable
- The final use of the reagent or consumable.

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6.7 Service Agreements

6.7.1 Agreements with Laboratory Users

Service Level Agreements (SLAs) are established with users. These specify the requirements, responsibilities, and review processes [MAP-ALL-ALL-024] of both the department and the department's users.

Agreements are reviewed periodically and updated as necessary with the review period and any modifications to the agreement agreed by both parties.

Users are informed of any by the department of any changes that may affect assay results and any modifications of the agreement that may be required as a consequence.

6.7.2 Agreements with POCT operators

The laboratory currently does not have any agreements with POCT operators.

There is no POCT performed or planned by the department.

6.8 Externally Provided Products and Services

6.8.1 General Requirements

Requirements for externally provided products and services are reviewed, defined and approved.

6.8.2 Referral laboratories and consultants

All referral laboratories and consultants are selected, evaluated, and monitored according to departmental policies [MAP-ALL-ALL-017, MAP-ALL-ALL-024].

A list of all referral laboratories and consultants is maintained and available to staff and users [MAI-ALL-ALL-009].



6.8.3 Review and Approval of Externally Provided Products and Services

Performance of external providers is reviewed regularly and records are retained within the Laboratory Management QMS or within the departments QMS.

There are defined criteria for the selection, evaluation of performance and re-evaluation of External providers these are designated under the Laboratory Medicine MSC contract. A list of all suppliers to the department and including a date of review of the suppliers can be found the departments QMS [LAP-ALL-ALL-023].

The department has a defined procedure for the referral of samples and transportation of samples [MAP-ALL-ALL-017]

There are procedures in place ensuring that externally provided products and services conform to the laboratory's established requirements under the Laboratory Medicine MSC contract and the departments own policy [MAP-ALL-ALL-024].

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Should there be a requirement to take any action(s) following unsatisfactory of performance of external suppliers this taken using the department's Incident and Risk Management policy and raised as a non-conformance on Q-Pulse [\[MAP-ALL-ALL-007, LAP-ALL-ALL-023\]](#).

7 Process Requirements

7.1 General Requirements

The Department of Haematology, North Glasgow Sector, NHS Greater Glasgow & Clyde, identifies and manages risks to patient care across pre-analytical, analytical, and post- analytical processes. Risks are assessed and mitigated to the extent possible, with residual risks communicated to users as appropriate. Opportunities for improvement are identified and managed within the QMS framework, with effectiveness monitored and evaluated according to potential patient harm.

7.2 Pre- analytical Processes

7.2.1 General Requirements

Procedures for all pre-analytical activities are available in the User Handbook [\[MAI-ALL-ALL-009\]](#) located on the department's webpages. These processes are regularly reviewed to ensure they support the intended examination outcomes and comply with BSQR [\[ECD-ALL-GDL-028\]](#), HTA [\[ECD-ALL-MAN-002\]](#), ISO 15189:2022 and GCP [\[ECD-ALL-GDL-065\]](#). Further advice is available by contacting the department.

7.2.2 Laboratory Information for Patients and Users

Comprehensive information is provided to users and patients via the Departmental Service User Handbook [\[MAI-ALL-ALL-009\]](#) and department's webpages including:



- The location of the department's laboratories.
- The department's operating hours
- The contact details for the department
- Sample collection procedures and requirements
- The scope of the department's activities
- Assay Turnaround Times
- The advisory services available
- Any consent requirements
- Any factors that affect assay performance or interpretation
- Uncertainty of Measurement associated with assays
- The feedback and complaints process

7.2.3 Requests for Providing Laboratory Assays

All requests for assays and processes are considered to be formal agreements between the department and the user and/or requester.

Requests for assays or processes must provide:

- Patient identification (full name, CHI number, DOB)

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- Requestor identification
- Requestor location
- Assay(s) requested
- Any relevant clinical information
- The Date/time of specimen collection
- The request's priority status (if applicable)

Further assays or processes received as an oral request may require documented confirmation: for example a request for blood components and/or products after the receipt and processing of a Group and Antibody screening request.

7.2.4 Primary Sample Collection and Handling

7.2.4.1 General Requirements

Procedures for all pre-analytical activities are available in the User Handbook located on the department's webpages. These processes are regularly reviewed to ensure they support the intended assay outcomes and comply with BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], ISO 15189:2022 and GCP [ECD-ALL-GDL-065]. Further advice is available by contacting the department.

Any deviations resulting in rejection of a request is recorded and any risk or impact on patient's and user will be assessed. Where this involves a sample for Blood Transfusion there is a legal requirement to report this to the MHRA under some circumstances.

7.2.4.2 Information for Pre-collection Activities



Instructions for pre-collection activities are provided in the User Handbook located on the department's webpages. Further advice is available by contacting the department.

These cover:

- Requirements with regard to patient preparation where appropriate
- Sample type,
- Sample volume
- Appropriate sample containers
- Clinical information
- Minimum required data set on the samples
- Minimum required data set on the forms
- Minimum required data set for Blood Transfusion samples for compliance with BSQR
- Additional requirements for Blood Transfusion samples for compliance with BSQR

NHSGGC policies on Waste Management and Disposal of Sharps control the disposal of material used in sample collection [ECD-ALL-POL-039].

7.2.4.3 Patient Consent

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Consent for all laboratory activities is performed in line with [\[ECD-ALL-GDL-089\] NHSGGC Consent policy](#). Informed consent is obtained for all procedures.

Certain procedures require explicit consent to comply with legal obligations under BSQR [\[ECD-ALL-GDL-028\]](#), HTA [\[ECD-ALL-MAN-002\]](#), and GCP [\[ECD-ALL-GDL-065\]](#). Further advice is available by contacting the department.

Emergency situations are managed in the patient's best interest

7.2.4.4 Instructions for Collection Activities

Information for service users for the completion of requests (manual or electronic) including sample type and volume is provided in the service user handbook for the department of haematology [\[MAI-ALL-ALL-009\]](#). Information is also displayed on the Trakcare and GP ICE systems. Further advice is available from the laboratory.

The Electronic requesting systems automatically capture all the required patient demographics and sample requirements.

NHSGGC policies on Waste Management and Disposal of Sharps control the disposal of material used in sample collection [\[ECD-ALL-POL-039\]](#).

Instructions include:

- Patient identity confirmation
- Pre- analytical requirements (e.g. fasting)
- Sample collection
- Sample labelling
 - Including Additional requirements for Blood Transfusion samples for compliance with BSQR
- Collector identity and collection date/time
 - Including additional requirements for Blood Transfusion samples for compliance with BSQR



7.2.4.5 Sample Transportation

There is an established NHSGGC policy for the transportation of specimens by porters and couriers [\[ECD-ALL-POL-031\]](#) in compliance with regulatory requirements and includes:

- The effective use of the pneumatic tube system
- Ensuring the safety of:
 - The courier
 - NHSGGC Staff
 - The general public
 - The receiving Laboratory

There are Instructions for:

- Packaging
- Labelling
- Dispatch

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- Time and temperature constraints

Reporting incidents during transportation that may:

- Affect quality of the specimen
- Affect the safety of personnel

7.2.5 Sample Receipt

7.2.5.1 Sample Receipt Procedure

The department follows procedures for specimen reception [LAP-GRI-ALL-002] [LAP-GRI-BTS-031] [LWI-GGH-ONC-001] that includes:

- The traceability of samples to patients
- Acceptance criteria
- Rejection criteria
- Recording the receipt date and time
- The handling of urgent samples

The department has a procedure for the reporting of problems with samples [MAP-ALL-ALL-020]

7.2.5.2 Sample Acceptance Exceptions

Compromised but clinically critical samples are managed with risk assessment by a clinical staff member and recorded [LAF-ALL-ALL-026], reports indicate any limitations or considerations that require to be taken into account.

7.2.5.3 Pre- analytical Handling, Preparation, and Storage



The department follows procedures for specimen reception [LAP-GRI-ALL-002] [LAP-GRI-BTS-031] [LWI-GGH-ONC-001] that ensure sample integrity and prevent loss or damage.

Time limits for additional assay requests and sample stability are specified. Further advice is available from the laboratory.

7.3 Analytical Processes

7.3.1 General requirements

Validated and verified analytical methods are selected and used to assure clinical accuracy. All procedures and supporting documentation are controlled and available to personnel. Periodic evaluation ensures clinical appropriateness. The Departmental Change Control and Verification Policy [MAP-ALL-ALL-030] and associated documents describe the procedures and requirements for Change Control and the evaluation and performance of validation and/or verification of processes.

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7.3.2 Verification of analytical Methods

The Departmental Change Control and Verification Policy [\[MAP-ALL-ALL-030\]](#) and associated documents describe the procedures and requirements for Change Control, evaluation and performance of the verification of processes.

This includes:

- Any specimen requirements
- The appropriate equipment and supplies
- Any required reagents, standard(s) and/or calibrators
- IQC
- EQA
- Calibration requirements
- Instructions for use
- Any limitations of the process
- Any interference with the process.
- Any Cross reactions with the process.
- The reportable intervals of the assay.
- The recording and calculation of results (if appropriate).
- The Reference limits (reference range).
- Any Hazards and safety precautions (risk assessment).
- The performance criteria.
- The Uncertainty of Measurement estimation.



7.3.3 Validation of analytical Methods

Validation is performed for:

- Laboratory-developed methods
- Methods used outside intended scope
- Modified validated methods
- Validation confirms fitness for intended use all records are kept on the departments QMS records

7.3.4 Evaluation of Measurement Uncertainty (MU)

Uncertainty of measurement estimations have been determined [\[MAP-ALL-ALL-012\]](#). Using the methodology in the UKAS publication UKAS 3003: The Expression of Uncertainty and Confidence in Measurement [\[ECD-ALL-GDL-059\]](#). These are calculated using a spreadsheet showing bias and targets. They are stored in Q-Pulse and for quantitative assays are recorded in the service user handbook for the Department of Haematology [\[MAI-ALL-ALL-009\]](#) located on the departments [webpages](#), to be available to service users. The estimation of uncertainty of measurement estimation is considered fit for purpose following final review by a clinical member of the Haematology staff to indicate that the uncertainty of measurement estimation would not affect the decision by a service user at any clinical decision value or level, or the advice given by a Clinical member of the Haematology staff. This is because the clinical decision level/value can vary on an

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individual basis for all but a few assays. The Uncertainty of measurement for qualitative assays is stored in Q-Pulse and is available on request to the Quality Manager.

7.3.5 Biological Reference Intervals and Clinical Decision Limits

The reference ranges are included in the standard operating procedures and in the service user handbook for the department of haematology [MAI-ALL-ALL-009] to be available to service users. These are reviewed at the annual management review [MAF-ALL-ALL-013].

7.3.6 Documentation of analytical Procedures

All methods and equipment have standard operating procedures these and any associated work instructions are stored in Q Pulse. These are all controlled documents which are reviewed biennially or sooner as stated on the document. The requirements are described in the policy document [MAP-ALL-ALL-003] the process in [LAP-ALL-ALL-008]. Changes affecting interpretation are communicated to users.

7.3.7 Ensuring the Validity of Assay Results

7.3.7.1 General requirements

The Departmental Quality Assurance Policy [MAP-ALL-ALL-012] outlines the department's procedures for quality Assurance.

7.3.7.2 Internal Quality Control (IQC)

Instructions on the preparation for use, stability and storage are contained in the individual SOP's. Low, mid and high value controls are used at all locations where available. The levels are selected to check the assay for linearity, to test the functional limit of detection and to check the assay at the most frequently measured interface between normal and pathological values. The Frequency of performing of IQC is dependent on analyser, risk and/or method stability as well as continuous processing or batch analysis.

IQC data is reviewed regularly, and patient results are withheld if IQC fails

IQC reports for all locations are discussed monthly at the quality meeting [SCM-MIN-QM-001 onwards]. There are procedures in place for the assessment of the impact and risk of IQC failure including, re-analysis of samples, amending reports and incident reporting.



7.3.7.3 External Quality Assessment (EQA)

The Departmental Quality Assurance Policy [MAP-ALL-ALL-012] outlines the department's procedures for quality Assurance.

Participation in EQA programmes is mandatory where these programmes are available. EQA samples are processed by the department staff whom routinely perform that assay and results are reviewed with corrective actions taken as needed

7.3.7.4 Comparability of Assay Results

Cross site analysis is performed for all those tests performed on more than one site as detailed in the Quality Assurance Policy [MAP-ALL-ALL-012]. This is discussed at the quality meeting [SCM-

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ALL-ALL-XXX] if required, reported to the annual management review and used in the annual review of processes. The data obtained is available on Q-Pulse.

7.4 Post- analytical Processes

7.4.1 Reporting of Results

7.4.1.1 General Requirements

Results are reported accurately, clearly, and unambiguously, including all necessary information for interpretation. Delays are notified to users as appropriate 2 1.

7.4.1.2 Result Review and Release

Results are reviewed and authorised prior to release, evaluated against clinical information. Responsibilities for release are specified. Staff are not authorised to review or release results until they have completed the appropriate training and competency documentation [MAP-ALL-ALL-026].

The departmental procedure [MAP-ALL-ALL-020] details the process to be followed. This procedure includes consideration of the following:

- The indication in the report if the quality of the primary sample received was unsuitable for analysis.
- The indication in the report if the quality of the primary sample received could have compromised the quality of the result generated.
- Any checks to ensure that results are without errors in transcription.

If results are communicated via telephone then they are only provided to suitably authorised personnel these are then followed up by the production of a formal report.

7.4.1.3 Critical Result Reports



if an assay result falls within established critical values a clinician or other authorised health professional is immediately notified.

The departmental procedure [MAP-ALL-ALL-020] details the process to be followed.

7.4.1.4 Special Considerations for Results

The departmental procedure [MAP-ALL-ALL-020] details the process to be followed. This procedure includes consideration of the following:

- That if a result has been communicated verbally the following is recorded:
 - The name of the person notified
 - Details of the results conveyed
 - Any difficulties encountered in making the notification
 - The name of the laboratory member who undertook the communication
 - The date and Time of communication

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- That checks are made to ensure that results are only made available to those authorised to receive them.

If results are communicated via telephone then they are only provided to suitably authorised personnel these are then followed up by the production of a formal report.

Simplified reporting and preliminary reports are available when agreed with users these are always followed by a final report.

Counselling is provided and managed by either NHSGGC or NHS Scotland and is available to patient's only after the relevant clinical area has been in receipt of any assay results.

Anonymised result reports are used for reporting to clinical trials and research in accordance with [MAP-ALL-ALL-002, MAP-ALL-ALL-018, ECD-ALL-GDL-090, ECD-ALL-POL-006, ECD-ALL-POL-011, ECD-ALL-POL-013, ECD-ALL-GDL-065].

7.4.1.5 Automated Selection, Review, Release, and Reporting



Automated selection and reporting of results is agreed by the reporting clinical staff and is defined at an individual test level as part of the change control and verification process [MAP-ALL-ALL-030]. The reference ranges, action limits and authorisation limits of tests are programmed into both the middleware and the LIMS. These are reviewed at the annual management review [MAP-ALL-ALL-013].

7.4.1.6 Requirements for Reports

The department issues electronic reports only, these are available for viewing on Track Care, SCI Store, GP ICE and Clinical portal

All reports include:

- Patient identification
- Laboratory Identification
- Requestor Identification
- Request date
- Sample details
- Sample type
 - Where transmitted by the LIMS
- Assay type
- Assay results
- Authoriser
 - Where this has been entered as a free text comment
- Reference ranges
- Alerts indicating critical/clinical decision limits
- Report status

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7.4.1.7 Additional Information for Reports

Reports will include where practicable

- The time of collection
- The time of the report's release,
- Any referral lab details,
- Any interpretive comments
- Any trends where practicable

7.4.1.8 Amendments to Reported Results

There is a departmental procedure [\[LAP-ALL-ALL-007\]](#) for revising and amending reports which includes:

- The criteria for issuing a revised and amended report.
- The identification to the user of issue of an amended or revised report.
- The process for recording the issue of revised and amended reports.
- The reasons for issuing an amended or revised report
- The instigation of corrective and preventive action (if required).
- The accurate recording of revised and amended reports.

Amended results are communicate using the departments policy [\[MAP-ALL-ALL-020\]](#)

7.4.1.9 Post- analytical Handling of Samples



The departments stores, retains and disposes of clinical samples in accordance with the requirements of the Human Tissue Act 2004 [\[ECD-ALL-MAN-002\]](#), guidelines from the Royal College of Pathologists and the Institute of Biomedical Science and NHSGGC policies regarding the retention, storage and disposal of clinical material [\[MAP-ALL-ALL-002\]](#), [ECD-ALL-GDL-018](#) and [ECD-ALL-POL-039](#), and guidance from the Royal College of Pathologists and the Institute of Biomedical Science regarding the Release of Specimens. Also in compliance with legal obligations under BSQR [\[ECD-ALL-GDL-028\]](#), HTA [\[ECD-ALL-MAN-002\]](#), and GCP [\[ECD-ALL-GDL-065\]](#).

7.5 Nonconforming Work

To provide a comprehensive and systematic approach towards corrective and preventative action (CAPA) [\[MAP-ALL-ALL-007\]](#) describes the procedures and responsibilities for the reporting of non-conformance, incidents and subsequent review using the Q-Pulse Audit and Non-Conformance Modules and the DATIX incident reporting application. Procedures specific to the use of the Q-Pulse non-conformance module are described in [\[LAP-ALL-ALL-023\]](#). All non-conformances for all locations are reviewed in the quality meeting. All clinical incidents for all locations are reported via the DATIX application and are reviewed at the incident meeting.

This process documents:

- Responsibilities and authorities
 - Including the cessation and recommencing of activities.
 - Including identified authorised staff

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- Immediate and long-term actions
- Evaluation of clinical significance/impact
- Revision and notification of results
 - Using [LAP-ALL-ALL-007 and MAP-ALL-ALL-020]
- Corrective action
- Preventative action
- Evaluation of effectiveness of actions
- Record retention

7.6 Control of Data and Information Management

The department has a documented procedure [MAP-ALL-ALL-019] to ensure that the confidentiality of patient information is maintained at all times this is also in compliance with BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], GCP [ECD-ALL-GDL-065] and NHSGGC policy [ECD-ALL-POL-013].

7.6.1 General requirements

The laboratory has access to multiple systems to allow it to perform its activities as described in NHS GGC Laboratory Systems Management [ECD-ALL-POL-067]

7.6.2 Authorities and responsibilities for information management



The laboratory has documented the authorities and responsibilities for the management of the information systems, [ECD-ALL-POL-067] including the maintenance and modification to the information systems that can affect patient care. The laboratory in conjunction with eHealth and the Laboratory IT department is ultimately responsible for the laboratory information systems.

7.6.3 Information systems management

There is a documented procedure for managing all systems used for the collection, processing, recording, reporting, storage or retrieval of assay data and information, [ECD-ALL-POL-067]

This ensures that

- All systems are validated by the supplier and verified for functionality by laboratory IT and the laboratory before introduction.
- Any changes to the system, including laboratory software configuration or modifications to commercial Off-the-shelf software, are be authorised, documented and validated by laboratory IT and the laboratory before implementation
- There is documentation readily available to authorised users
 - Including that for day to day functioning of the system.
 - This includes departmental SOP's
- Actions have been Implemented taking cybersecurity into account, to protect the system from unauthorised access and safeguards data against tampering or loss.
- All systems are operated in an environment that complies with supplier specifications or in the case of non-computerised systems provides conditions which safeguard the accuracy of manual recording and transcription.

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- All systems are maintained in a manner that ensures the integrity of the data and information and includes the
- Recording of system failures and the appropriate immediate and corrective actions
 - Using the eHealth reporting procedure and the departments Incident and Risk management procedure [MAP-ALL-ALL-007]

7.6.4 Downtime plans

There are documented processes [LAP-ALL-ALL-033, ECD-ALL-POL-067] to maintain operations in the event of failure or during downtime in information systems that affects the laboratory's activities. This includes automated selection and reporting of results.

7.6.5 Off site management

There is a documented process [ECD-ALL-POL-067] that details what systems are managed and maintained off-site or through an external provider, and ensures that the provider or operator of the system complies with ISO15189 and legal obligations under BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], and GCP [ECD-ALL-GDL-065].

7.7 Complaints

The departmental Policy for Feedback and Complaints [MAP-ALL-ALL-008] and the NHSGGC Complaints Policy [ECD-AL-POL-005] detail how complaints are handled, with the aim of satisfying the complainant whilst at the same time being fair and open with all those involved.

Service users unhappy with the Department's response to a complaint, or where they would prefer to discuss the matter with someone not directly involved with the department or issue raised should contact the NHSGGC Complaints Team by telephone, email or by writing to them. Details about this service are available on the NHSGGC website. If still not satisfied with the response or resolution they then have the opportunity to refer the issue to the Ombudsman.



These documents detail the process of dealing with a complaint;

Including:

- Receipt
- Investigation
- Resolution
- Tracking and recording actions
- Non-discriminatory resolution

7.8 Continuity and Emergency Preparedness Planning

The laboratory has procedures In place to ensure that any risks associated with emergency situations, when laboratory activities are limited or unavailable (planned or unplanned) have been identified and have a strategy that involves plans, procedures and other relevant actions to ensure the continuation of operations after a disruption.

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These plans are periodically challenged and the response/consequences reviewed for effectiveness.

The laboratory has:

- A planned response to emergency situations [LAP-ALL-ALL-033], that takes into account the needs and capabilities of all the laboratory personnel
- Provides information and training as appropriate to relevant laboratory personnel
- Can respond to emergency situations
- The ability to take action to prevent or to mitigate any consequences of emergency situations, appropriate to the nature of the emergency and its potential impact.

8 Management system requirements

8.1 General Requirements

8.1.1 General Requirements

The Department of Haematology, North Glasgow Sector, maintains a documented Quality Management System (QMS) that supports and demonstrates consistent fulfilment of ISO 15189:2022, BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], and GCP [ECD-ALL-GDL-065] requirements. The QMS is implemented, maintained, and continually improved across all sites and processes, and is accessible to all staff via Q-Pulse.

8.1.2 Fulfilment of Management System Requirements

The QMS supports and demonstrates fulfilment of ISO 15189:2022 clauses 4–7 and 8.2–8.9. All requirements are mapped to local policies, procedures and any relevant legislation.

8.1.3 Management System Awareness

All staff are made aware of relevant objectives and policies including their contribution to the effectiveness of the QMS, and the consequences of non-conformance. This is provided at departmental Induction and through ongoing training ensure staff understand their roles within the QMS [see MAP-ALL-ALL-026, MAF-ALL-ALL-004].



8.2 Management System Documentation

8.2.1 General Requirements

The QMS documentation includes the following documents (given as examples) maintain objectives and policies for the fulfilment of ISO 15189:2022, BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], and GCP [ECD-ALL-GDL-065] requirements.

- Quality Manual: [QM-ALL-ALL-001] (this document)
- Quality Policy: [MAP-ALL-ALL-014]
- Quality Objectives: [MAI-ALL-ALL-073]
- Departmental Service Users Guide: [MAI-ALL-ALL-009]
- Incident and Risk Management: [MAP-ALL-ALL-007]

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- Retention & Storage of Clinical Material, Records and Archives: [\[MAP-ALL-ALL-002\]](#)
- Document Control: [\[MAP-ALL-ALL-003\]](#)
- Quality Assurance: [\[MAP-ALL-ALL-012\]](#)
- Departmental Audit: [\[MAP-ALL-ALL-004\]](#)
- Annual Management Review: [\[MAP-ALL-ALL-013\]](#)

All documentation is controlled, regularly reviewed, distributed and accessible to staff via Q-Pulse

8.2.2 Competence and Quality

The department's objectives and policies address competence, quality and consistent operation of the laboratory. The QMS ensures all personnel are competent for their assigned roles, duties and responsibilities with training and competency records maintained on the department's QMS [\[MAP-ALL-ALL-026, LAP-ALL-ALL-008\]](#).

8.2.3 Evidence of Commitment

The department's management demonstrates its commitment to the QMS through communication, resource provision, the appointment of a Quality Manager and regular management reviews [\[MAP-ALL-ALL-013, SCM-MIN-AMR-XXX\]](#).

8.2.4 Documentation

The departments documentation, processes, systems, and records related to ISO 15189:2022, BSQR [\[ECD-ALL-GDL-028\]](#), HTA [\[ECD-ALL-MAN-002\]](#), and GCP [\[ECD-ALL-GDL-065\]](#) are included in or referenced from the QMS. Documentation is reviewed and updated as necessary to ensure ongoing compliance [\[MAP-ALL-ALL-003\]](#).

8.2.5 Personnel Access

All personnel have access to the parts of the QMS documentation relevant to their responsibilities via Q-Pulse [\[LAP-ALL-ALL-023\]](#)

8.3 Control of Management System Documents



8.3.1 General Requirements

The laboratory controls all documents (internal and external) related to the QMS {MAP-ALL-ALL-003} using the department's QMS system [\[LAP-ALL-ALL-023\]](#).

8.3.2 Control of Documents

The department's document control [policy \[MAP-ALL-ALL-003\]](#) ensures that documents are:

- Uniquely identified
- Approved before issue
- Periodically reviewed
- Updated as necessary
- Current versions are available at points of use

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- Controlled distribution.
- Changes to the document are identified
- The current version status is identified

Documents are protected from:

- Unauthorised changes#
- Deletion
- Removal.
- Obsolete documents are prevented from unintended use and retained within the department's QMS system for a specified period [MAP-ALL-ALL-003, LAP-ALL-ALL-001, MAP-ALL-ALL-001, ECD-ALL-POL-023, LAP-ALL-ALL-023].

8.4 Control of Records

8.4.1 Creation of Records

Procedures for identification, collection, indexing, access, storage, maintenance, amendment, and safe disposal of records are detailed in [MAP-ALL-ALL-002, MAP-ALL-ALL-019, and MAP-ALL-ALL-003]. Records are created concurrently with each activity affecting quality.

8.4.2 Amendment of Records

All amendments to records are traceable, with both the original and the amended data retained, including the date, time and the individual making alterations [MAP-ALL-ALL-002, MAP-ALL-ALL-003, LAP-ALL-ALL-023].

8.4.3 Retention of Records

The Retention times of records is specified in [MAP-ALL-ALL-002] and records are accessible and legible throughout the retention period.

All records are available for management review and audit.



Records are retained in compliance with relevant guidelines and to comply with the legislative requirements of BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], and GCP [ECD-ALL-GDL-065].

8.5 Actions to Address Risks and Opportunities for Improvement

8.5.1 Identification of Risks and Opportunities

The department evaluates the impact of work processes and potential failures on assay results and modifies processes to reduce or eliminate identified risks [MAP-ALL-ALL-007, MAF-ALL-ALL-05] and mitigate the risk/Impact upon patient care.

Incidents and non-conformances are monitored via DATIX and Q-Pulse, with regular review at Incident Meetings [SCM-MIN-INC-001 onwards] and Quality Meetings [SCM-MIN-QM-001 onwards] to ensure the laboratory management system and the department achieves its objectives.

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8.5.2 Acting on Risks and Opportunities

ALL actions taken are proportional to the potential impact on results and patient safety.
Any decisions and actions are recorded and integrated into the QMS, with their effectiveness evaluated [MAP-ALL-ALL-007, LAP-ALL-ALL-023].

8.6 Improvement

8.6.1 Continual Improvement

The department has Quality Indicators and Performance Assessments that are broken down into pre-analytic, analytic, and post-analytic phases as a framework for internal audit and continual improvement [MAP-ALL-ALL-004, MAP-ALL-ALL-007, MAP-ALL-ALL_008]

Any improvement activities are prioritised based on risk and identified opportunities from non-conforming work, feedback and complaints from staff and users amongst others.

Effectiveness of actions is evaluated and reviewed [MAP-ALL-ALL-007]

Improvement plans, actions and outcomes are communicated to personnel via various methods including:

- Staff meetings
- Huddles
- Memos
- Email
- Distribution of documentation on Q-Pulse

8.6.2 Laboratory, Patients, User, and Personnel Feedback

The department encourages feedback or suggestions from patients, users, and staff [MAP-ALL-ALL-008, LAP-ALL-ALL-023]. There is a form available on the department's webpages for those who do not work in the laboratory.

All information received is analysed, reviewed and used where possible to improve the QMS and the department's services.

Records of any feedback and actions taken are maintained on the department's QMS and communication is provided to staff on any resulting actions or outcomes.



All feedback including staff, patient and user needs and requirements are discussed at Quality Meetings [SCM-MIN-QM-001 onwards] where it is a standing item on the agenda and Management Reviews [SCM-MIN-AMR-XXX].

8.7 Nonconformities and Corrective Actions

8.7.1 Actions When Nonconformity Occurs

Nonconformities are managed through immediate action, root cause determination, corrective action, and evaluation of effectiveness [MAP-ALL-ALL-007, LAP-ALL-ALL-023].

All actions are evaluated for their ability to correct any non-conformity, reassessed for potential risk and impact and documented in Q-Pulse or DATIX and the QMS is then updated as necessary.

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Actions to correct non-conformance are viewed as an opportunity for improvement.
All actions are reviewed for effectiveness.

8.7.2 Corrective Action Effectiveness

ALL corrective actions are appropriate to the effects of nonconformities and mitigate identified causes. Effectiveness is reviewed at Quality Meetings and Incident Meetings [MAP-ALL-ALL-007, SCM-MIN-QM-001 onwards, SCM-MIN-INC-001 onwards].

8.7.3 Records of Nonconformities and Corrective Actions

All records of any nonconformities and corrective actions are retained as evidence in Q-Pulse and are available for audit and review [MAP-ALL-ALL-007, LAP-ALL-ALL-023]. All records are available to be viewed by all staff of the department

8.8 Evaluations

8.8.1 General Requirements

Evaluations are conducted at planned intervals to ensure the QMS and processes meet the needs of patients and users, and conform to ISO 15189:2022. All findings are documented and reviewed [MAP-ALL-ALL-004].

8.8.2 Quality Indicators

Quality indicators (KPIs) are established and monitored for key processes, with regular review at Quality Meetings [SCM-MIN-QM-001 onwards], Senior Staff Meetings [SCM-MIN-SSM-001 onwards], and Management Reviews [SCM-MIN-AMR-001 onwards].



8.8.3 Internal Audits

8.8.3.1 Audit

Internal audits are scheduled and coordinated by the Quality Manager, using standardised checklists [QAC-ALL-ALL-001, QAC-ALL-ALL-002, QAC-ALL-ALL-003, QAC-ALL-ALL-004, QAC-ALL-ALL-005, QAC-ALL-ALL-007, QAC-ALL-ALL-010, QAC-ALL-ALL-011, QAC-ALL-ALL-021, QAC-ALL-ALL-025, QAC-ALL-ALL-026, QAC-ALL-ALL-027, QAC-ALL-ALL-028, QAC-ALL-BTS-001, QAC-ALL-BTS-004, QAC-ALL-BTS-009, QAC-ALL-ALL-031, QAC-ALL-ALL-030, QAC-ALL-ALL-032, QAC-ALL-ALL-035, QAC-ALL-ALL-033].

Audits are chosen to cover the requirements of ISO 15189:2022, BSQR [ECD-ALL-GDL-028], HTA [ECD-ALL-MAN-002], and GCP [ECD-ALL-GDL-065]

Audit findings are reported, and corrective actions are implemented without undue delay [MAP-ALL-ALL-004].

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8.8.3.2 Audit

The laboratory maintains an internal audit programme that includes:

Prioritisation is given to the risk to patients resulting from the laboratory's activities.
A schedule is planned which takes into consideration identified risks

Including

- The outcomes of external evaluations
- Previous internal audits
- The occurrence of nonconformities and/or incidents
- complaints
- changes affecting the laboratory activities
- All audit objectives have
- Criteria
- Scope

The Laboratory uses a selection of auditors who are trained, qualified and authorized to assess the performance of the laboratory's management system and whenever resources permit, are independent of the activity being audited

This is to ensure

- Objectivity
- Impartiality

The results of the audits are reported to relevant personnel [MAP-ALL-ALL-004, MAP-ALL-ALL-007, LAP-ALL-ALL-023] so that the implementation of appropriate correction and corrective actions can proceed without any undue delay.

ALL records of the audit programme and audit results are recoded within the department's QMS [MAP-ALL-ALL-004, LAP-ALL-ALL-023]

8.9 Management Reviews



8.9.1 General Requirements

The management team conducts an annual review of the QMS and all laboratory services [QMS-ALL-ALL-001, SCM-MIN-AMR-XXX].

8.9.2 Review Input

The input for the Annual Management Review can be found in [MAP-ALL-ALL-013] and includes:

- Status of previous actions
- Changes to the QMS



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- Volume, and type of activities
- Fulfilment of objectives and policies
- Outcomes of evaluations,
- Audits
- Review of nonconformities
- Corrective actions
- External assessments
- Feedback, suggestions and complaints
- Quality assurance
- Supplier performance,
- EQA results
- Training
- Review of equipment

8.9.3 Review Output

Outputs include decisions and actions on the effectiveness of the QMS.
The improvement of laboratory activities and services for users and patients.
Resource needs and any required changes. To systems.



Actions are implemented within agreed timescales, and results are communicated to staff and users [\[QMS-ALL-ALL-001, SCM-MIN-AMR-XXX\]](#).

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9 Appendices

9.1 Appendix 1: Referenced Documents



ECD-ALL-GDL-089: NHSGGC Consent policy.
 ECD-ALL-GDL-090: Scottish Government. Health and social care - records management: code of practice
 ECD-ALL-GDL-094: NHSGGC Duty of Candor Policy
 ECD-ALL-POL-005: NHSGGC Complaints Policy
 ECD-ALL-POL-006: NHSGGC Confidentiality Policy
 ECD-ALL-POL-010: NHSGGC Corporate Induction
 ECD-ALL-POL-011: NHSGGC Code of Conduct for Staff
 ECD-ALL-POL-012: NHSGGC Equality and Diversity Policy
 ECD-ALL-POL-013: NHSGGC Confidentiality and Data Protection Policy
 ECD-ALL-POL-015: NHSGGC Attendance Management Policy
 ECD-ALL-POL-01: NHSGGC Employment or Statutory regulated Professionals
 ECD-ALL-POL-017: NHSGGC Grievance Policy and Procedure
 ECD-ALL-POL-022: NHSGGC Disciplinary Policy
 ECD-ALL-POL-023: Header and Footer
 ECD-ALL-POL-031: NHSGGC Transport and Disposal of Specimens Containers and Specimens Policy
 ECD-ALL-POL-033: Healthcare Support Workers Code of Conduct
 ECD-ALL-POL-038: Business Continuity, Haematology GG&C
 ECD-ALL-POL-039: NHSGGC Waste Management Policy
 ECD-ALL-POL-040: NHSGGC Standing Financial Instructions
 HCP-ALL-ALL-001: Health and Safety Code of Practice
 LAF-ALL-ALL-004: Service/Maintenance Engineer - authorisation (permit) to work form
 LAF-ALL-ALL-020: Equipment and Process Review form
 LAF-ALL-ALL-021: Incident Investigation form
 LAF-ALL-ALL-026: Concessionary Release Form for Blood Sample Processing (non BT)
 LAF-ALL-ALL-046: Analyser Problem: FBC comparison form.
 LAF-ALL-COA-004: Haemostasis Routine Reagents Delivery and Batch Acceptance Log
 LAF-ALL-HAE-007: Haemoglobinopathy - Batch Acceptance Report
 LAF-ALL-HAE-044: Routine Haematology Batch Acceptance Log
 LAF-GGH-ONC-051: Haemato-oncology reagents acceptance log
 LAF-GRI-BTS-008: Batch Testing - Log Form
 LAF-GRI-COA-075: Molecular Haemostasis Batch Acceptance Log Form
 LAF-GRI-COA-078: Thrombophilia and Lupus Screen Reagents Delivery and Batch Acceptance Log
 LAF-GRI-COA-079: Anti Xa reagent delivery and batch acceptance log
 LAF-GRI-COA-081: Other Haemostasis Controls and Calibrators Delivery and Batch Acceptance Log
 LAF-GRI-COA-082: Other Haemostasis Reagents Delivery and Batch Acceptance Log
 LAF-GRI-COA-084: Platelet Agg delivery and batch acceptance log
 LAP-ALL-ALL-001: SOP Template
 LAP-ALL-ALL-007: Amending and Revising Reports
 LAP-ALL-ALL-008: Use of the Q-Pulse People and Training Course Module
 LAP-ALL-ALL-023: Q-Pulse
 LAP-ALL-ALL-033: Contingency plan
 LAP-ALL-COA-006: Haemostasis Batch Acceptance Procedure

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LAP-ALL-HAE-012: Batch Acceptance of Routine Haematology Reagents
 LAP-GGH-ONC-027: Batch acceptance procedure for Haemato-Oncology
 LAP-GRI-BTS-031: Blood Transfusion Reception
 LAP-GRI-BTS-039: Batch Acceptance
 LWI-ALL-ALL-031: Model Rules for Visitors
 LWI-ALL-HAE-010: Routine Haematology Batch Acceptance Procedure
 LWI-GGH-ONC-001: Sample Receipt and Booking In for Cell Markers
 LWI-GGH-ONC-034: Cell Markers Batch Acceptance
 LWI-GRI-BTS-044: Product Batch Acceptance
 MAF-ALL-ALL-004: Departmental Induction Form
 MAF-ALL-ALL-011: Disclaimer Form - Authorisation for the Release of Test Data and Specimens to the Police
 MAF-ALL-ALL-051: Local risk register
 MAI-ALL-ALL-009: Departmental Service User Guide
 MAI-ALL-ALL-073: Departmental Quality Objectives
 MAI-ALL-ALL-093: JD Haemato-oncology Manager
 MAI-ALL-ALL-094: JD Haemostasis Manager
 MAI-ALL-ALL-095: JD Sector Laboratory Manager
 MAI-ALL-ALL-096: JD Quality, Training and POCT Manager
 MAI-ALL-ALL-097: JD Biomedical Support Worker - Higher Level
 MAI-ALL-ALL-098: JD Senior Specialist BMS
 MAI-ALL-ALL-099: JD Specialist BMS
 MAI-ALL-ALL-100: JD Technical Manager
 MAI-ALL-ALL-119: JD Technical Services Manager
 MAI-ALL-ALL-120: JD Associate Practitioner (band 4)
 MAI-ALL-ALL-124: JD Consultant Clinical Scientist
 MAI-ALL-ALL-131: Laboratory major Incident Procedure (GRI)
 MAP-ALL-ALL-001: Management Policy Template
 MAP-ALL-ALL-002: The Retention & Storage of Clinical Material, QMS & Pathological Records, Specimens and Archives
 MAP-ALL-ALL-003: Document Control
 MAP-ALL-ALL-004: Departmental Audit
 MAP-ALL-ALL-007: Incident reporting and Risk Management
 MAP-ALL-ALL-008: Feedback Complaints Policy
 MAP-ALL-ALL-010: Management of Laboratory Equipment
 MAP-ALL-ALL-011: Management of Supplies, Reagents, Calibration and Quality Control Material
 MAP-ALL-ALL-012: Quality Assurance
 MAP-ALL-ALL-013: Procedure for the Annual Management Review
 MAP-ALL-ALL-014: Departmental Quality Policy
 MAP-ALL-ALL-017: Specimen Referral, Transportation and Packaging Requirements
 MAP-ALL-ALL-018: Personnel Management
 MAP-ALL-ALL-020: Reporting and Communicating of Results
 MAP-ALL-ALL-024: Service Level Agreement (SLA)
 MAP-ALL-ALL-026: Staff education and Training Policy
 MAP-ALL-ALL-030: Change Control and Verification Policy
 QAC-ALL-ALL-001: Organisation and QMS Audit
 QAC-ALL-ALL-002: Document Audit
 QAC-ALL-ALL-003: Pre-Analytical Process Audit
 QAC-ALL-ALL-004: Post Analytical Process Audit

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QAC-ALL-ALL-005: Equipment, Reagents and Consumables Audit
 QAC-ALL-ALL-007: Quality Control/Assurance Audit
 QAC-ALL-ALL-010: Accommodation and Environment Audit
 QAC-ALL-ALL-011: Training and Competency Audit
 QAC-ALL-ALL-020: 5 Whys Checklist
 QAC-ALL-ALL-021: Monthly Fire Audit
 QAC-ALL-ALL-025: CA/PA, Validation and Verification Audit
 QAC-ALL-ALL-026: Laboratory Information Systems Audit
 QAC-ALL-ALL-027: Evaluation, Audit and Review Audit
 QAC-ALL-ALL-028: Control of Records Audit
 QAC-ALL-ALL-030: Vertical Audit Form
 QAC-ALL-ALL-031: Horizontal Audit Form
 QAC-ALL-ALL-032: Process Audit
 QAC-ALL-ALL-033: TAT Audit form
 QAC-ALL-ALL-035: Non Conformance Follow up Audit Form
 QAC-ALL-BTS-001: Satellite Blood Fridges Audit
 QAC-ALL-BTS-004: Traceability of Blood and Blood Products Audit
 QAC-ALL-BTS-009: Cold Chain Storage (Satellite) Audit
 QAC-ALL-ALL-048: Referral Laboratory Checklist
 QM-ALL-ALL-001: Quality Manual
 SCM-MIN-AMR-XXX: AMR Minutes
 SCM-MIN-GGH-XXX: Haemato-Oncology Meeting Minutes
 SCM-MIN-GSM-XXX: General Staff Meeting Minutes
 SCM-MIN-HMT-XXX: Haematology Management Team Meeting Minutes
 SCM-MIN-HTM-XXX: Haemostasis Team Meeting Minutes
 SCM-MIN-HTT-XXX: Hospital Transfusion Team Meeting Minutes
 SCM-MIN-INC-XXX: Incident Meeting Minutes
 SCM-MIN-QM-XXX: Quality Meeting Minutes
 SCM-MIN-SSM-XXX: Senior Staff Meeting Minutes
 TD-NGS-ALL-0065: Health care support worker workbook

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9.2 Appendix 2: Regulatory and Accreditation Body Publications

ECD-ALL-GDL-028 Blood Safety and Quality Regulations 2005 and Amendment 2007

ECD-ALL-GDL-029: The National Accreditation Logo & Symbols: Conditions for use by UKAS and UKAS accredited organisations (URN BIS 14/902)

ECD-ALL-GDL-031: UKAS Lab 1: reference to Accreditation for Laboratories

ECD-ALL-GDL-032: UKAS Lab 3: The Conduct of UKAS Laboratory Assessments

ECD-ALL-GDL-034: UKAS Lab 12: The Expression of Uncertainty in Testing

ECD-ALL-GDL-036: UKAS Lab 39: UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation Within Laboratories

ECD-ALL-GDL-038: UKAS TPS 41: UKAS Policy on Metrological Traceability

ECD-ALL-GDL-039: UKAS TPS 47: UKAS Policy on Participation in Proficiency Testing

ECD-ALL-GDL-042: UKAS TPS 51: Accreditation of Multi-Site/Group Laboratories

ECD-ALL-GDL-044: UKAS TPS 57: Guidance and Policy on the Selection and Use of Reference Materials

ECD-ALL-GDL-046: UKAS TPS 63: UKAS Policy on Deviating Samples

ECD-ALL-GDL-059: UKAS 3003: The Expression of Uncertainty and Confidence in Measurement

ECD-ALL-GDL-065: The Medicines for Human Use (Clinical Trials) Regulations 2004 and amendments 2005 and 2006

ECD-ALL-GDL-071: JACIE Standards

ECD-ALL-GDL-073: Data Protection Act 2018

ECD-BTS-GDL-013: MHRA Rules and Guidance for Pharmaceutical Manufacturers and Distributors

ECD-ALL-MAN-002: Human Tissue Act – 2004