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QUALITY MANUAL

Incorporating Quality Policy (QDH&I002)

This Quality Manual, together with specified documents, represents the Quality Management System of the Histocompatibility and Immunogenetics (H&I) laboratory. The Quality Manual has been compiled to meet the requirements of the United Kingdom Accreditation Service (UKAS) system and appropriate national and international standards including those of the European Federation for Immunogenetics (EFI). All procedures specified herein are mandatory within the H&I laboratory.

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Abbreviations

AMR	Annual Management Review
BSc	Bachelor of Science degree
BSHI	British Society for Histocompatibility and Immunogenetics
BSHI dip	BSHI diploma
BMS	Biomedical Scientist
CCS	Consultant Clinical Scientist
CMV	Cytomegalovirus
CS	Clinical Scientist
CPD	Continuing Professional Development
eQMS	electronic QMS
EFI	European Federation for Immunogenetics
EPT	External Proficiency Testing
FCXM	Flow Cytometry Crossmatch
FIBMS	Fellow Institute of Biomedical Science
FRCPath	Fellow of the Royal College of Pathologists
GGH	Gartnavel General Hospital
H&I	Histocompatibility and Immunogenetics
H&S	Health and Safety
HCPC	Health and Care Professions Council
HLA	Human Leucocyte Antigen
HMT	Haematology Management Team
HPCT	Haematopoietic progenitor cell transplantation
IBMS	Institute of Biomedical Science
IQC	Internal Quality Control
ISO	International Organisation for Standardisation
KPI	Key Performance Indicator
LMT	H&I Lab Management Team
LIMS	Laboratory Information Management System
MDT	Multi-Disciplinary Team
MSC	Managed Service Contract
MU	Measurement Uncertainty
NIBSC	National Institute of Biological Standards and Controls

NHS GG&C	National Health Service Greater Glasgow and Clyde
NHSBT	NHS Blood and Transplant
ODT	Organ Donation and Transplantation
PCR	Polymerase Chain Reaction
PCS	Principal Clinical Scientist
PDP	Personal development plan
PhD	Doctor of Philosophy degree
POCT	Point of Care Testing
PPE	Personal Protective Equipment
QC	Quality Control
QEUH	Queen Elizabeth University Hospital
QMR	Quarterly Management Review
QMS	Quality Management System
RHC	Royal Hospital for Children
RMS	Reagent Management System
SNBTS	Scottish National Blood Transfusion Service
SOP	Standard Operating Procedure
UKAS	United Kingdom Accreditation Service
VUD	Volunteer Unrelated Donor

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1. Introduction

1.1. The Quality Manual

This Quality Manual describes the Quality Management System (QMS) of the Histocompatibility & Immunogenetics (H&I) laboratory. A QMS integrates the organisational structure, processes, procedures and resources needed to fulfil a quality policy and thus meet the needs and requirements of the user. QMS are frameworks of quality standards against which organisations can be assessed (internally or externally) to lead to continuous quality improvement and achieve accreditation status.

The QMS ensures that:

- Laboratory management establishes written quality objectives that are consistent with the quality policy and are regularly reviewed.
- The Quality Manual is established, reviewed and updated as required with changes communicated to all personnel concerned.
- There is a Quality Manager who has responsibility for the implementation and maintenance of the quality management system.
- There is a process of document control enforced.
- The control of process and quality records is according to current legislation, regulations and guidelines.
- The control of clinical material is according to current legislation, regulations and guidelines.
- Laboratory management conducts an annual review of the laboratory's QMS and all its services.
- Laboratory management reviews performance targets such as turnaround time, repeat rate, cost effectiveness and the efficacy of processes.

The Quality Manual is an indexed document to separate management, laboratory, clinical and quality procedures. Throughout the text there are references to International Organisation for Standardisation (ISO) standards allied to the procedures. The layout of this Quality Manual follows that of the BS EN ISO 15189:2022 Medical Laboratories – Requirements for quality and competence. The sections have been mapped to the correspondent ISO 15189 standards (from section 4). The Quality Manual undergoes annual review.

Laboratory staff are informed of the content of the Quality Manual by the following processes:

- The Quality Manual forms part of new staff local induction.
- The Quality Manual is referred to at staff annual Personal Development Plan (PDP) meetings.
- Amendments and updates to Quality Manual are reported at laboratory staff meetings.
- The review of the Quality Manual forms part of the annual management review.
- Distribution via eQMS of "acknowledgment" e-mails prompting staff to read the

Quality Manual.

2. References

External quality documents are stored within eQMS and distributed to all staff for acknowledgement. Reference is made to the undernoted documents to ensure compliance with required standards for accreditation. Additional United Kingdom Accreditation Service (UKAS) publications are also available via eQMS to describe methods of application for accreditation and for guidance within specific areas of the accreditation process.

EXTREFDOC204: ISO 15189 2022 Medical Laboratory Standards

QDH&I072 European Federation for Immunogenetics (EFI) Standards for Histocompatibility and Immunogenetics Testing

2.1. Accreditation and display of reference to accreditation

The laboratory is both a UKAS accredited laboratory (No: 9010) and EFI accredited laboratory (No: 03-SC-001.999).

The department will display the logo and reference number for both accrediting bodies on all reports where test results are reported, and any opinions and interpretations included within the report are within the accredited scope of the laboratory (EXTREFDOC197).

3. General Information

3.1. The H&I laboratory

The National Health Service Greater Glasgow and Clyde (NHS GG&C) H&I laboratory is located on the grounds of Gartnavel General Hospital Glasgow (GGH) and forms part of the NHS GG&C Diagnostics Directorate which sub divides into Laboratory Medicine Division.

Postal address:
Histocompatibility and Immunogenetics Laboratory
Level 1, Laboratory Medicine Building
Gartnavel General Hospital
21 Shelley Road
Glasgow G12 0ZD
Telephone: 0141 301 7755

3.2. Laboratory Scope

The H&I laboratory performs a comprehensive range of serological and molecular techniques. These techniques allow identification of human leukocyte antigens (HLA) and permit the detection of immunological sensitisation to HLA. The tests are carried out in support of:

- solid organ transplantation programmes:
    - adult kidney transplantation for the west of Scotland at the Queen Elizabeth University Hospital, Glasgow
    - paediatric kidney transplantation for all Scotland at the Royal Hospital for Children, Glasgow
    - adult cardiac transplantation for all Scotland at the Golden Jubilee Hospital, Clydebank
- haematopoietic progenitor cell transplantation (HPCT)
    - adult HPCT for all Scotland at the Queen Elizabeth University Hospital, Glasgow
    - paediatric HPCT for all Scotland at the Royal Hospital for Children, Glasgow
- disease diagnosis, (including narcolepsy, ankylosing spondylitis, coeliac disease, Behçet's disease)
- pharmacogenomics e.g. B*57:01 and abacavir sensitivity
- UK national deceased organ donor allocation covering the west of Scotland

The laboratory provides an on-call service operating 365 days per year. Healthcare Scientists: Biomedical Scientists (BMS) and Clinical Scientists (CS) are Health and Care Professions Council (HCPC) registered and are active participants in a recognised Continuing Professional Development (CPD) schemes run by the British Society of Histocompatibility and Immunogenetics (BSHI), Institute of Biomedical Science (IBMS) or the Royal College of Pathologists.

No point of care testing is undertaken by the H&I service (POCT)

3.3. The User Manual

A full list of H&I services is available in the H&I User Manual (QDH&I014). An electronic copy is posted on the staff intranet H&I laboratory page and web page

Staff net (NHS GG&C – NHS Staff access only)

http://www.staffnet.ggc.scot.nhs.uk/Acute/Diagnostics/All%20Laboratory%20Medicine/Tissue%20Typing/Pages/default.aspx

Webpage

https://www.nhsggc.scot/downloads/histocompatibility-and-immunogenetics-user-manual/

4. General requirements

4.1. Impartiality

All NHS GG&C staff are required to adhere to the NHS GG&C Code of Conduct Policies. Code of Conduct for staff is based around the *Standards of Business Conduct* (QDH&I122) for NHS Staff. The key elements of the Code of Conduct for Staff are that the employees of NHS GG&C are expected to:

- ensure that the interest of patients remain paramount at all times
- be impartial and honest in the conduct of their business
- use the public funds entrusted to them to the best advantage of the service, always ensuring best value for money

Employees should not:

- abuse their official position for personal gain or to benefit their family and/or friends
- seek to advantage or further their private business or other interests, in the course of their official duties

All HCPC registered biomedical and clinical scientists must also adhere to the *'HCPC Standards of conduct, performance and ethics'* (EXTREFDOC32).

All staff maintain public confidence in the NHS GG&C service by always adhering to public service values and ensuring that the interests of patients are put before personal gain. This can be demonstrated by ensuring that all potential conflicts of interest are openly declared, and staff play no part in decisions that may benefit themselves, their family, friends, or close associates. It is also important that staff do not accept gifts or hospitality, which could be viewed as potentially influencing their actions. NHS GG&C have an online Register of Interests System, which allows staff the opportunity to register any potential conflict of interests or offers of gifts and hospitality. What constitutes an "interest" is quite wide and can include other employments, consultancies, outside business interests, directorships, trusteeships and even a position of responsibility with a charity Code of Conduct for Staff and Declarations of Interests, Gifts and Hospitality (scot.nhs.uk).

Staff are asked at their annual competency review if they have declared any impartiality / conflict of interests following GGC protocol as described above (Recorded in forms LFTR29, 30, 32, 39 and 56)

4.2. Confidentiality

4.2.1. Management of information

The laboratory is responsible for the management of all patient information obtained or created during the performance of laboratory activities. Management of patient information includes privacy and confidentiality. All patient information is regarded as

confidential and maintained as described within *QDH&I109: Retention and Storage of Clinical Samples and Documentation*.

4.2.2. Release of information

The release of patient information to requesting medical and nursing staff is described within reporting procedures. Patient information that is shared with external organisations is referred to within *QDH&I109: Retention and Storage of Clinical Samples and Documentation*. Routinely patient information is shared with the unrelated bone marrow donor registries (*LPRA008: Performing an unrelated donor search and requesting blood samples from unrelated donors*) and when registering a renal transplant patient with NHS Blood and Transplant Organ Donation and Transplantation (NHSBT ODT) (*LPXM075: Registering or changing a patient status on the national transplant waiting list*).

If a patient or their legal representative wishes access to records regarding their treatment and tests performed, then this request must be made via the "Legal Aspects Team" following guidance available on NHS GG&C website and the laboratory will only deal directly with this team and not the person making the enquiry. https://www.nhsggc.scot/patient-visitor-faqs/health-rights/access-to-records/.

4.2.3. Personnel responsibility

NHS GG&C have produced the following documents for all staff:

EXTREFDOC37: Guidance on handling personal identifiable data; this describes steps that must be followed when sending or receiving confidential and sensitive information.

EXTREFDOC30: Internet Acceptable Use Policy; this must be read by all members of staff with access to information systems and applications.

Staff training around confidentiality forms part of NHS GG&C mandatory training and is fulfilled by completion of the LearnPro module: GGC: 009 Safe Information Handling (Statutory and Mandatory Training - NHSGGC)

QDH&I 021 H&S guide for visitors is available for all visitors (including contractors) to the laboratory and office area.

4.3. Requirements regarding patients

a) The laboratory has various opportunities to receive feedback from its users via meetings and regular communication via telephone, email and 'MS Teams'.
b) The Laboratory user manual is available (to users and patients) on the NHS GG&C website and contains information on how to contact the laboratory (see section 3).
c) All examination methods are reviewed to ensure that they are clinically appropriate and necessary at the laboratory management review (QMR) meetings (QDH&I239).
d) The laboratory's procedure for reporting incidents that have or could have resulted in patient harm is described within QDH&I116. This includes informing UKAS of any

significant event that affects patient safety. Incident reporting on DATIX includes the opportunity to disclose to patient, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm. Records of actions taken to mitigate these incidents can also be recorded on DATIX, and locally using the eQMS non-conformance module. NHS GG&C Policy and Procedure on Duty of Candour Compliance aims "to improve the support, timeliness, quality and consistency of communication with patients and / or relevant persons when an unexpected or unintended incident occurs; and to provide clear information to staff on what they should do when they are involved in an incident and the support available to them." Duty of Candour Policy and Guidance (sharepoint.com) https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Duty-of-Candour-Policy.aspx

e) All patient samples, results, personal data are treated with due care and respect (*QDH&I109: Retention and Storage of Clinical Samples and Documentation*).
f) NHS GG&C operates a comprehensive consent policy; https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Consent-to-Treatment-Policy.aspx. Consent is inferred when submitting a specimen request to the laboratory. Specific consent is obtained when patient details are shared with external organisations e.g. bone marrow donor and organ donation registries.
g) The laboratory ensures the ongoing availability and integrity of retained patient samples and records in the event of closure, acquisition or merger (*QDH&I109: Retention and Storage of Clinical Samples and Documentation*).
h) The laboratory will make relevant information available to a patient and other health service providers as requested in line with section 4.2.2. above.
i) The rights of patient to have care that is free from discrimination is upheld by NHS GG&C and is described on their website: NHSGGC - Equalities in Health https://www.nhsggc.scot/your-health/equalities-in-health/

5. Structural and governance requirements

5.1. Legal entity

The H&I laboratory is located within NHS GG&C Health Board, which is the entity that can be held legally responsible for its activities.

NHS Greater Glasgow & Clyde,
Corporate Headquarters,
J B Russell House,
Gartnavel Royal Hospital,
1055 Great Western Road,
Glasgow,
G12 0XH

5.2. Laboratory director

5.2.1. Laboratory director competence

The laboratory is directed by Mrs Catherine Hastie, has the required qualifications, Fellow of the Royal College of Pathologists (FRCPath) and is deemed competent (annual TURAS review). The Laboratory Director has the responsibility and resources (as defined in 5.2.2) to fulfil the requirements of the QMS.

5.2.2. Laboratory director responsibilities

The Laboratory Director is responsible for the professional direction of the H&I laboratory ensuring that the laboratory operates in accordance with the best evidence-based clinical, scientific and technical practices. The duties and responsibilities of the laboratory director are given in *Job Description* (QDH&I210). The term Laboratory Director is synonymous with "Head of H&I Department" and "Consultant in Charge". The Laboratory Director reports to the General Manager (via the Clinical Services Manager) and the Clinical Director of Laboratory Medicine within the Diagnostics Division of NHS GG&C.
Responsibilities include:

- monitoring budget, resources, workforce planning, training and education
- attending Multi-Disciplinary Team (MDTs) meetings with clinicians in support of solid organ and haematopoietic progenitor cell transplantation
- providing 24/7 consultancy support to Scottish renal and cardiac units (in conjunction with other members of the Scottish Consultant Clinical Scientist (CCS) H&I network) to ensure the provision of appropriate clinical advice
- monitoring all laboratory process activity and performance activity to determine that clinically relevant information is generated
- application of risk management to all aspect of laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed
- overseeing participation in external accreditation schemes and interaction

with regulatory and accrediting bodies
- ensuring appropriate staffing levels, training and competence
- implementing Quality Policy
- defining and implementing quality objectives
- overseeing and ensuring implementation of all components of the QMS as recorded within eQMS software – i.e. documentation, audits, health and safety (H&S), user feedback, training, corrective action preventative action, and is responsible for continual quality improvement
- planning and overseeing research projects and professional development programmes within the department
- addressing complaints or suggestions for improvement
- establishing a contingency plan to ensure delivery of essential services during emergency situations

5.2.3. Delegation of duties

Whilst the Laboratory Director is accountable for the overall operation and administration of activities within the laboratory, key activities are delegated to assigned individuals (named individuals given in 6.2.1, Table 1.)

1. Deputy to the Laboratory Director
2. Laboratory Manager
3. Quality Manager/Deputy
4. Health and Safety
5. Training

In the absence of any of these individuals, the responsibilities are delegated upwards and tasks assigned to other appropriately trained staff.

5.3. Laboratory activities

5.3.1. General

The Department provides a comprehensive routine and specialised H&I service from its location at Gartnavel General Hospital (GGH) as defined in the user manual (see Section 3). No POCT is undertaken within this service.

5.3.2. Conformance with requirements

Laboratory activities are undertaken as described within this Quality Manual and associated Quality Policy. The laboratory adheres to the standards of UKAS (ISO 15189:2022) and EFI.

5.3.3. Advisory activities

Advice on and interpretation of laboratory tests and results is available during laboratory operating hours. An out of hours (24/7) on call service is available to support deceased donor solid organ transplantation including Consultant/ Principal Clinical Scientist (C/PCS) advice.

The laboratory undertakes a quarterly review of its activities and performance (QMR) and within this the examinations undertaken, types of samples received, inappropriate samples (e.g. excess samples not required, or incorrect samples) are reviewed and users are notified of any findings that may impact on the requests that are made.

Users are informed when samples received are rejected (see *LPMOL091 Sample reception, acceptance and rejection*).

5.4. Structure and authority

5.4.1. General

The H&I Service is within the Laboratory Medicine division of the Diagnostics Directorate of the NHS GG&C Health Board. The organisation and management structure for the H&I laboratory within NHS GG&C is shown in figure 1. A more detailed organogram for the Acute Services Division is available *EXTREFDOC216: Acute Services Structure*, which shows the relationship between Diagnostics Directorate, Human Resources, Finance and Medicine.

The organisation and management structure within the H&I laboratory is shown in figure 2, which also highlights relationship with other NHS GG&C services supporting the laboratory.

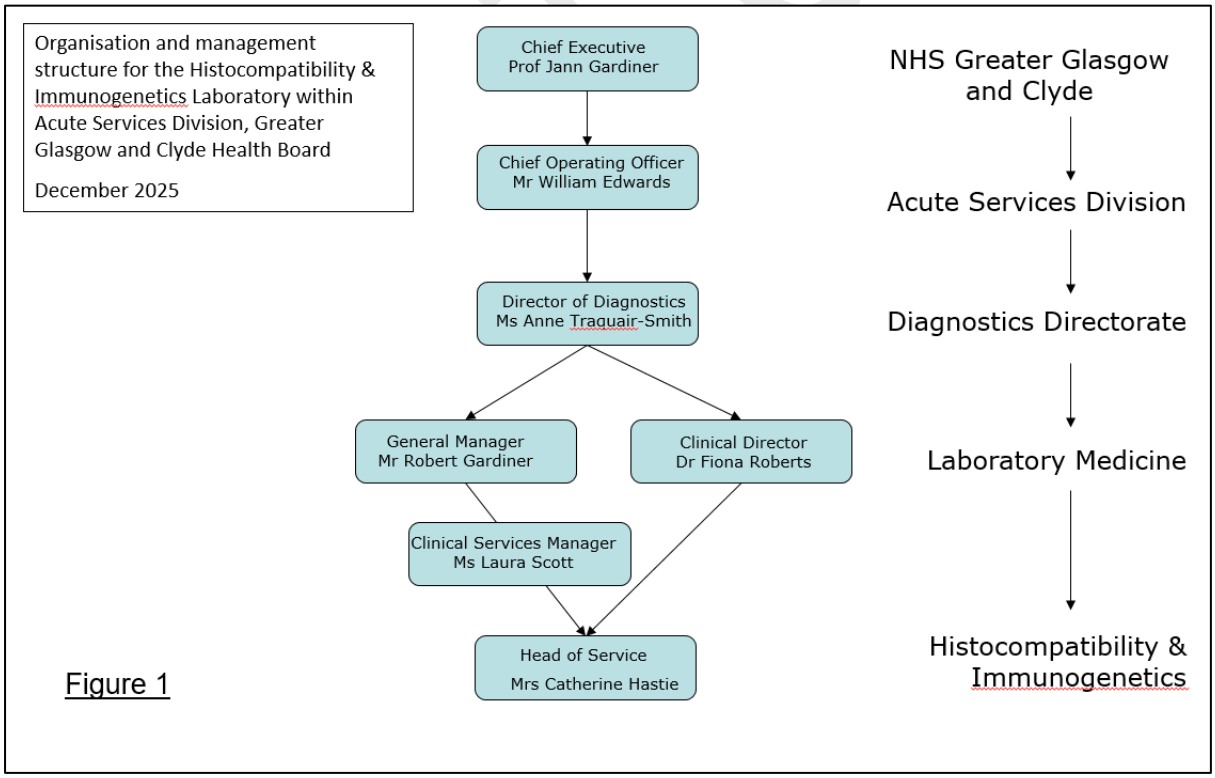


Figure 1

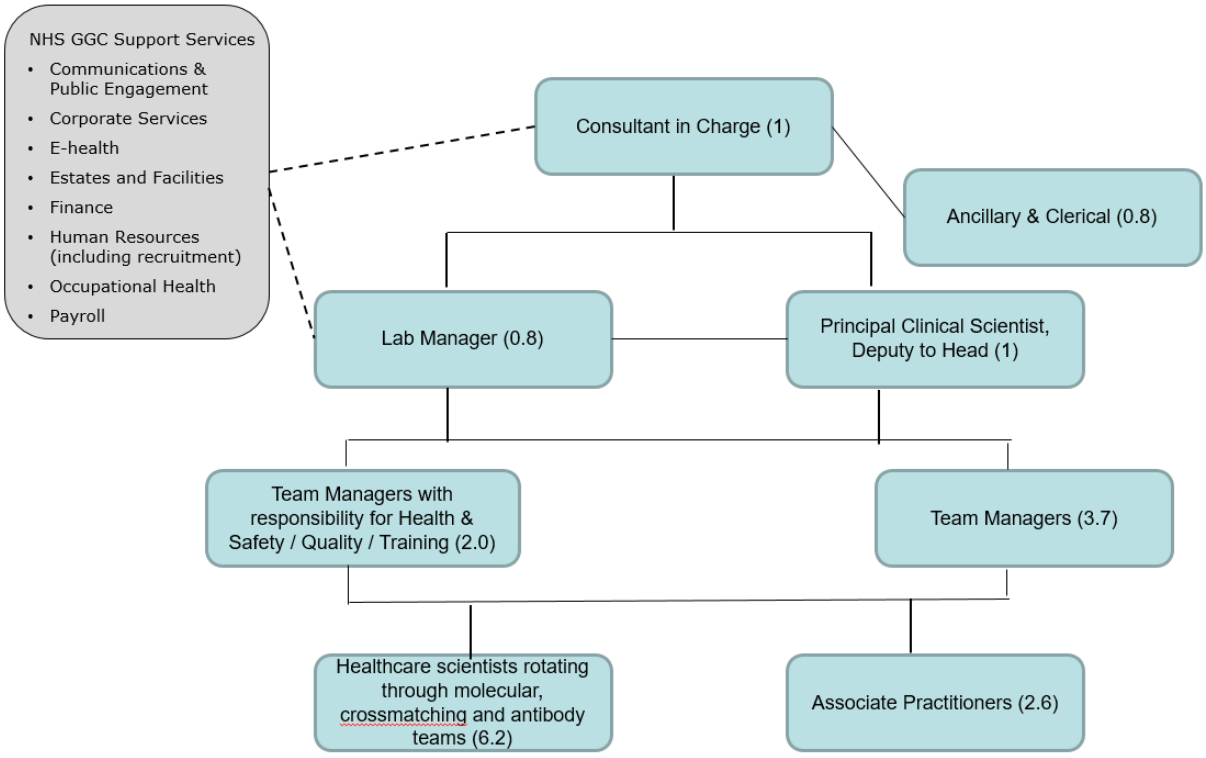


Figure 2 Histocompatibility & Immunogenetics Laboratory Organisation chart December 2025 (WTE)

Figures 1 and 2 shows the lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities.

A consistent application of laboratory activities and validity of results generated takes place by

- the careful selection, induction and training of appropriately (e.g. HCPC registered) qualified staff. NHS GG&C recruitment documents and policies can be accessed at: https://www.nhsggc.scot/staff-recruitment/hrconnect/the-recruitment-service/.
- providing equipment and consumables that are procured and maintained using The Managed Service Contract (MSC), Reagent Management System, (RMS) and NHS "Pecos" request systems. Associated procedures include *QDH&I028: Guidelines for selection and validation /verification of examination procedures* and *LPRA048: Laboratory Ordering and Stock management system*.
- ensuring examination processes are verified and validated before use. Processes are continuously monitored using internal quality control and external quality assurance checks. *QDH&I028* describes guidelines for selection and validation /verification of examination procedures.

5.4.2. Quality Management

The H&I laboratory has personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out the duties of a Quality Manager and deputy. The

job descriptions are *QDH&I254: Team Manager / Quality Manager* and *QDH&I255: Team Manager / Deputy Quality Manager.*

a) The Quality Management team, working together with all laboratory personnel is committed to the implementation, maintenance and improvement of the management system by:

- ensuring laboratory personnel are aware of the importance of satisfying the needs and requirements of the users whilst complying with the relevant regulatory requirements
- establishing a *quality policy* (QDH&I002)-the quality policy is reviewed at the Annual Management Review (AMR), QDH&I256.
- establishing *quality objectives* - these objectives and plans are reviewed and updated at QMR meetings QDH&I239.
- defining responsibilities, authorities and interrelationships of all personnel as detailed within this document and within job descriptions available on eQMS
- performing a QMR see *QDH&I238: Management Quarterly Review Agenda* and *QDH&I239: Management Quarterly Review Report* ()
- performing an AMR within one of the four QMR, which is reported on eQMS (QDH&I256)
- performing competency assessments that form a key component of the laboratory training programme. Competency is assessed and reviewed according to criteria set down in *LPTR001: Laboratory training policy* and *LPTR002: Training programme for the IBMS Specialist Diploma.*

b) All deviations arising from the management system or from the procedures for performing laboratory activities are recorded as a non-conformance on eQMS and have actions generated to prevent or minimise future deviations. All members of staff are encouraged to raise a non-conformance based on a deviation.

c) Actions are initiated following a deviation to prevent or minimize future deviations.

d) The performance of the management system is presented and reviewed by senior management during the QMR and AMR meetings (*QDH&I239* and *QDH&I256*).

e) The effectiveness of laboratory activities is reviewed during QMR and AMR meetings (*QDH&I239* and *QDH&I256*).

5.5. Objectives and policies

a) The laboratory has a Quality Policy (QDH&I002) which describes the overarching objectives of the service. The Quality Policy includes objectives to:

- meet the needs and requirements of its patients and users. These are reviewed annually at the AMR. The H&I laboratory has representation at various clinical meetings and therefore receives regular feedback regarding the quality of the H&I

service. The laboratory director and other senior biomedical and clinical scientists are in daily contact with users to provide advice. There is no direct contact with patients. Any complaints received from patients and users are registered within eQMS (QDH&I022) and corrective action taken is documented (QDH&I116). User feedback is shared with all staff at full staff laboratory meetings. Actions taken as a result of the feedback are presented at the QMR meetings and reported within the Management QMR Reports (QDH&I239). The User Manual (QDH&I014) provides patients and users with contact telephone numbers, test sample and storage requirements, the minimum criteria for acceptance and processing of a sample, modes of sample handling, the repertoire of tests, and target turnaround times. The user manual also details the protocol for activation of patients on the renal deceased donor transplant list and the processes required for work-up in related and unrelated HPCT. The User Manual is accessible on Staffnet (NHS GG&C Staff) and the internet (see section 3).

- ensure all H&I staff are committed to good professional practice. HCPC registered Biomedical and Clinical Scientists adhere to the HCPC standards of conduct, performance and ethics Standards of conduct, performance and ethics | (hcpc-uk.org) https://www.hcpc-uk.org/standards/standards-of-conduct-performance-and-ethics/.
  Both HCPC and non HCPC registered staff must follow NHS GG&C Code of Conduct for Staff Conduct and Complaints - NHSGGC
  https://www.nhsggc.scot/staff-recruitment/hrconnect/policies-and-staff-governance/polices/conduct-and-complaints/#code-of-conduct-for-staff
- provide examinations that fulfil their intended use. All examinations (laboratory tests and services) are reviewed during the QMR and AMR meetings to ensure that they fulfil their intended use, and meet the quality requirements by reviewing repeat rates and non conformities raised involving an examination
- conform to the standards of ISO 15189:2022 and EFI.

b) The laboratory director, deputy director, laboratory manager, quality manager and team managers form the H&I laboratory management team (LMT) which defines the quality objectives of the laboratory and how they are to be measured. The LMT is responsible for ensuring that plans are made to meet these objectives (Quality Policy QDH&I002). Staff across all levels of the service acknowledge laboratory objectives using eQMS. (QDH&I146d)

c) The LMP ensures that the integrity of the management system is maintained when changes to the management system are planned and implemented, through regular review at QMR and AMR meetings.

d) Quality indicators, to monitor performance in relation to objectives, are planned and reviewed at QMR meetings with an overarching AMR.

5.6. Risk managment

a) All processes undergo a risk assessment, and these are managed within eQMS. *QDH&I243 Risk & Preventive Action*: This procedure outlines the laboratory's compliance with Medical Laboratories – Requirements for quality and competence

(ISO 15189:2022) 8.5 Actions to address risk and opportunities for improvement.

QDH&I247 Risk and Incident Management describes the processes undertaken for the identification and management of risks (and incidents) within the H&I laboratory.

EXTREFDOC74: Risk Register Policy and Guidance. This is NHS GG&C's policy on the use of a risk register

QDH&I313 Local risk register is a register of local risks and actions arising.

b) The laboratory director's responsibility for risk management is described in 5.2.2

6. Resource requirements

6.1. General

Laboratory management ensures that the laboratory has available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities. Any shortfall in resources can be highlighted initially internally by (any member of staff) informing a Team Manager and raising a nonconformity. If this cannot be resolved immediately, it will be escalated to the Laboratory Manager / Deputy / Head of Laboratory for action. If the shortfall cannot be resolved by the laboratory management, the matter will be taken to Laboratory Medicine Management via either the monthly haematology management team meeting (HMT) or MSC Meeting or direct communication depending on urgency.

NHS GG&C provides all support services including e-health; Estates and Facilities; Human Resources; and Recruitment teams. There is also a robust Diagnostic Management structure to support labs (Figure 1 and 2).

6.2. Personnel

6.2.1. General

a) The laboratory has access to a sufficient number of competent persons to perform its activities. Workforce planning is reviewed and presented at the monthly HMT meeting. A list of current (March 2025) staff and their worktime equivalent (WTE) is given in Table 1.

Table 1

Head of Service/ Consultant Clinical Scientist (1.0)	Catherine Hastie, BSc, BSHI Dip, FRCPath
Principal Clinical Scientist (Deputy to Head) (1.0)	Claire Walker, BSc, PhD, BSHI Dip, DipRCPath
Laboratory Manager (0.8)	Alayna McDade, BSc, PhD (maternity cover) Ashleigh McBride, BSc, MSc (maternity leave)
Quality Manager/Team Manager (1.0)	Angela Richardson, BSc, MSc, BSHI Dip (1 year secondment)

Training Manger/Team Manager (1.0)	David McKenzie, BSc, MSc, BSHI Dip
Health & Safety Manager	Claire Walker, BSc, PhD, BSHI Dip, DipRCPath
Project Manager/ Team Manager (1.0)	Andrew Hamilton-Blair, BSc, MSc, BSHI Dip
Team Managers (1x 0.4, 1 x 1.0, 1 x 0.8, 1 x 0.5)	Claire Baird, BSc, PhD Katy Harrison, BSc (1 year secondment) Stacey Malone, FIBMS, BSc, MSc Michelle Thomson, BSc, MSc
Healthcare Scientists (1x 0.2, 6x 1.0)	Laura Barr, BSc CJ Dick, BSc Caitlin McColl, BSc Elaine Paterson, BSc Diane Young, HNC Amy MacLeod, BSc Kerry Liney, BSc, BSHI Dip
Associate Practitioners (1x 0.6, 2x 1.0)	Alistair Houston Nicola Immel Patricia Rigmond

b) All personnel within the department have a job description and a job profile that indicates the minimum qualifications required for the post. All Biomedical Scientists and Clinical Scientists are registered with the HCPC. Qualifications and competencies obtained are recorded within training records. Job descriptions

describe the responsibilities, authorities and tasks for personnel and are located for each grade in eQMS . Staff training requirements are detailed in the *Laboratory training policy* (LPTR001) and the *Training programme for the IBMS Specialist Diploma* (LPTR002). All staff complete GG&C Statutory and Mandatory training via e-learning "LearnPro" (http://nhs.learnprouk.com). An electronic copy of training activities is recorded in the training module of eQMS. The effectiveness of the training programme is audited annually and recorded in eQMS. Training covers:

- QMS
- Laboratory work processes
- Manzen (laboratory information management system, LIMS)
- Health and Safety
- Ethics including:
  - *HCPC Standards of conduct, performance and ethics.* (EXTREFDOC32)
  - *NHS GG&C Code of conduct for staff* (QDH&I122]
  - Confidentiality: *Management of Data and information* (QDH&I110)

c) Laboratory personnel are made aware, during their induction and annual review (TURAS) of the importance of meeting the needs and requirements of users as well as the requirements of quality standards including ISO15189:2022 and those of EFI (*LPRA014 Laboratory Personnel Management, LPTR001 Laboratory Training Policy*)

d) The Human Resources Department of NHS GG&C has a comprehensive staff induction programme. This is managed by the NHSGGC with an online (staffnet) induction form that is completed for all new staff together with the *LFTR14: H&I Departmental Induction Checklist*. All new staff undertake an orientation and induction programme described within Standard Operating Procedure (SOP) *LPRA014: Laboratory Personnel Management*. Records of laboratory induction are retained by the Laboratory Manager/Training Manager. This programme covers terms and conditions of employment, staff facilities, health and safety requirements, and occupational health services.

6.2.2. Competence requirements

a) All laboratory staff have their competence requirements, including education, qualification, training, retraining, technical knowledge, skills and experience assessed at least annually as described within *LPTR001: Laboratory Training Policy***.** Competence is specified and assessed by one or more of the following depending on the process:

- direct observation of routine work
- direct observation of equipment maintenance and function checks
- monitoring the recording and reporting of examination results
- review of work records

- assessment of problem solving skills
- participation in external proficiency testing (EPT) testing of samples
- Competency monitoring forms are located on eQMS.

b) The laboratory ensures that all personnel have the competence to perform laboratory activities for which they are responsible. Competency assessments are recorded as described within *LPTR001: Laboratory Training Policy*.
c) The laboratory has a process for managing competence of its personnel that includes requirements for frequency of competence assessment. This is described within *LPTR001: Laboratory Training Policy*.
d) The laboratory has documented information demonstrating competence of its personnel. The results of competency assessments are summarised in the '*LFTR2: Annual Staff Competency Records*' document.

6.2.3. Authorisation

Laboratory staff that are deemed competent (following appropriate training) in an activity will be authorised to undertake that activity until their next annual competency review *LPTR001 Laboratory Training Policy*.

6.2.4. Continuing education and professional development

All staff maintain personal records of their CPD. The Head of H&I Laboratory participates in the Royal College of Pathologists CPD scheme while other laboratory staff participate in the BSHI CPD scheme or maintain their own records. For Biomedical and Clinical Scientists, continued HCPC registration requires evidence of CPD. In conjunction with the LMT, the training manager evaluates and supports training programs to facilitate competency and training needs for all staff as and when required. Further education and training may be provided via formal academic courses, local seminars, tutorials and self-learning.

6.2.5. Personnel records

The laboratory has procedures and retains records for:

a) determining the competence requirements specified in 6.2.2 a);
b) position descriptions
c) training and re-training ;
d) authorisation of personnel;
e) monitoring competence of personnel.

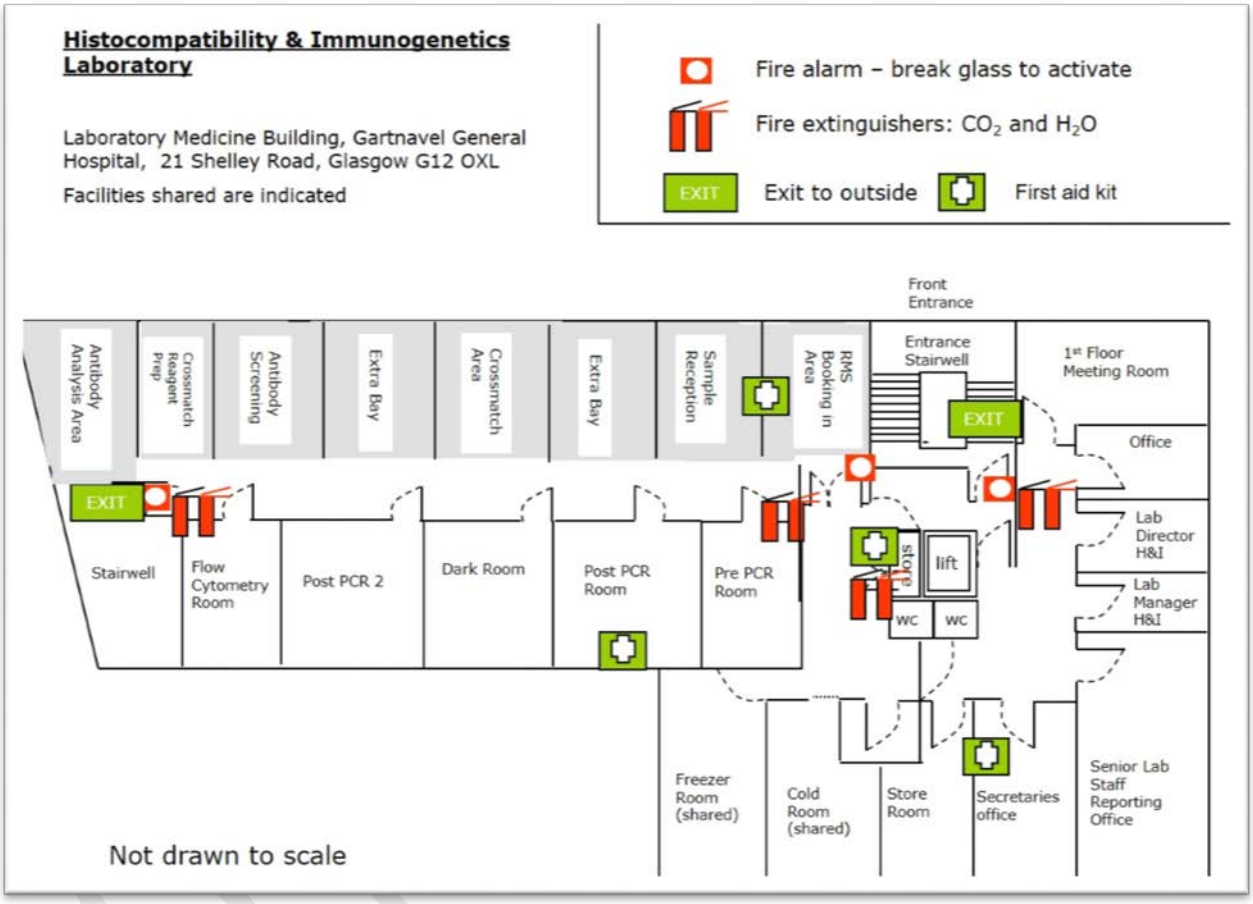
These procedures are described within LPRA014 *Laboratory Personnel Management*. Records are stored as described within QDH&I Retention and Storage of Clinical Samples and Documentation

6.3. Facilities and environmental conditions

6.3.1. General

The H&I laboratory is located on level 1 of the Laboratory Medicine Building within the grounds of Gartnavel General Hospital, see Figure 3 below:

Figure 3



Additional areas within the building used by H&I laboratory staff include:

- file storage room (level 2)
- a rest /tea room incorporating fridge, microwave and drinking water facilities (level 1 and 2)
- secured access male and female locker rooms with toilets and shower (level 2)
- wash room and autoclave (level 2)
- nitrogen vessel storage area and cryo-room (basement)

Disabled access to the building is available via a ramped fire exit and lift situated at the side of the building.

A review of the laboratory facilities and environmental conditions is undertaken at laboratory meetings and QMR meetings, to ensure conditions are appropriate for the performance of laboratory activities.

6.3.2. Facility controls

a) The main building, and each floor within the building, is accessible by authorised card access or with intercom access during working hours. The building access security system is overseen and managed by NHS GG&C Estates Department and each card is individually numbered and allocated. Cards are inactivated if lost or stolen.
b) All examination procedures include a review of limitations, interfering substances and potential sources of variation
c) The laboratory work areas are separated to prevent cross contamination e.g. pre and post-Polymerase Chain Reaction (PCR) rooms (Figure 3). There are quiet areas to facilitate an uninterrupted working environment.
d) There are safety facilities available within the laboratory including an emergency release facility for the walk in cold room. These are verified during the health and safety audits (*QDH&I003 Laboratory Health & Safety Handbook*).
e) The building and its infrastructure is maintained by NHS GG&C Estates and Facilities Department. They are responsible for building environment regulation with general domestic services provided by NHS GG&C ancillary support. Departmental cleaning and housekeeping practices are detailed in *LPXM073: Routine equipment/reagent maintenance* and checklist *LFXM073A* and in *LIMOL073: Instructions for completion of molecular GLP* and checklist *LFMOL073*

6.3.3. Storage facilities

a) The reception and storage of goods (e.g. equipment, reagents and consumables) is undertaken according to the manufacturer's instructions and described in SOPs referenced below:
    - *LPRA048: Laboratory ordering and stock management system*
    - *LPMOL046*: *Molecular stock control and evaluation of kits and reagents*
    - *LPAB065*: *Antibody stock control and evaluation*
    - *LPXM068*: *Titration testing of flow cytometry conjugates*
    - *LPXM077*: *Routine reagent preparation and QC*
    - *LPXM073*: *Routine equipment / reagent maintenance and checklist*
    - *LPXM089: FCXM reagent preparation, stock control and QC*
    - *QDH&I003: Laboratory Health & Safety Handbook*

    The storage of clinical material (samples) and documents and records is detailed in QDH&I109. Provision is made for the storage requirements described with samples, reagents and consumables stored within designated areas.

b) Patient samples and materials used in examination processes are stored separately to prevent cross contamination and deterioration.
c) All hazardous waste and biological waste is stored and disposed according to NHS GGC regulations.

6.3.4. Personnel facilities

Two toilets are available on level one (same level as laboratory and offices), with additional toilets and showers available on level 2. Drinking water is available as well as facilities for storage of personal protective equipment and clothing. There are areas assigned for personnel activities, such as meetings, quiet study and a rest area.

6.3.5. Sample collection facilities

There are no sample collection facilities at this site.

6.4. Equipment

6.4.1. General

The NHSGGC Procurement Policy is the divisional procedure for the procurement of equipment http://www.staffnet.ggc.scot.nhs.uk/Acute/Facilities/Procurement%20Department/Pages/default.aspx

Laboratory management ensures that the laboratory equipment is sufficient for the provision of services. This is reviewed during the QMR and AMR meetings.

The following documents govern the selection, purchasing and management of equipment:

Document	Title
QDH&I028	*Guidelines for selection and validation and verification of examination procedures*
QDH&I174	*Equipment/Software Error log*
LPXM073	*Routine equipment/reagent maintenance and checklist*
LPRA005	*Equipment preventative maintenance procedure*
RA02	*H&I RA02 Risk assessment - Use of Electrical equipment*
LFXM121	*Record of equipment temperature log*
AUD284	*Laboratory Equipment Audit*

6.4.2. Equipment requirements

a) The suitability of all equipment for the correct performance of laboratory activities is reviewed at QMR and AMR meetings, by reviewing nonconformities, repeat rates and any new developments within the field that may impact on the suitability of equipment in use. Any problems with equipment is raised at the monthly MSC meeting or HMT meeting if outwith the MSC.
b) All equipment used for the H&I service is located within the department at Gartnavel General Hospital. No POCT is undertaken by this service

c) All H&I laboratory equipment "assets" are listed within LPRA005 and/or eQMS module "Equipment & assets"
d) The procedure describing the maintenance and replacement of equipment is described in LPRA005

6.4.3. Equipment acceptance procedure

On receipt, all equipment is checked for faults. Upon installation, the equipment is assessed to ensure achievement of the necessary performance and requirements of the examinations concerned. Where applicable, an installation and operation qualification report will be provided by the installing company. Acceptance testing process is covered in *QDH&I028: Guidelines for selection and validation and verification of examination procedures* and the details of the validation are recorded in *QFH&I008: change control form.* Measurement Uncertainty is also calculated for appropriate tests (*QDH&215 I Measurement Uncertainty for HLA typing using molecular methods; QDH&I228 Measurement Uncertainty for the flow cytometry crossmatch; QDH&I299 Antibody Measurement Uncertainty)*

6.4.4. Equipment instructions for use

a) Safety warnings are clearly indicated where applicable and a risk assessment completed for each process.
b) Only trained, authorized and competent staff are permitted unsupervised access to equipment.
c) SOPs describing the correct use of equipment are available in eQMS
d) Equipment is used as specified by the manufacturer. Equipment is serviced and maintained to ensure optimal performance and longevity as recommended by the supplier (LPRA005).

6.4.5. Equipment maintenance and repair

a) Each piece of equipment is maintained and serviced with the frequency as outlined by the manufacturer. Procedure LPRA005 "Equipment preventive maintenance and repair procedure" describes the preventive maintenance programmes and how to record deviations from the manufacturer's schedules or instructions.
b) All equipment is subjected to a Risk Assessment including 'PAT' testing of electrical equipment to ensure that they are maintained in a safe working condition and working order. All hazardous materials are subjected to an annual COSHH assessment carried out which covers preventive measures, storage, spillage, disposal and first aid (*QDH&I 003 Lab H&S Handbook*).
c) Procedure *LPRA005 Equipment preventive maintenance and repair procedure* describes how to deal with equipment that is not suitable for use and how to investigate the impact this may have on work undertaken. Equipment found to be defective is labelled as such to prevent inadvertent use (*QDH&I191 Label for equipment not in use*). A non-conformance must be raised (*QDH&I116 Identification and management of nonconforming work*)

d) Equipment for repair, service or decommission is decontaminated and a label attached to inform service engineers/repair staff. A blank decontamination certificate is stored in eQMS as *Decontamination certificate* (QDH&I040). Equipment decontamination is described in *Disinfection / Decontamination Instruction* (LIMOL087). Visiting engineers and repair staff must formally sign the laboratory visitors book, and read H&S guidelines. They are provided with protective equipment (PPE) as required and given space to conduct repairs. After repair, equipment is verified prior to re-introduction to service (LPRA005).

6.4.6. Equipment adverse incident reporting

A record of all events with regards to maintenance and repair is recorded within eQMS. Adverse incidents attributable to specific equipment are recorded in incident error log books (*QDH&I174: Equipment/Software Error log*) which are located at the point of use. Each event is reviewed and reported to the MSC provider or the manufacturer as appropriate.

The laboratory has a procedure for responding to any manufacturer's recall or other notice, and how to take actions as recommended by the manufacturer. *LPRA005: Equipment preventive maintenance and repair procedure*

6.4.7. Equipment records

A record of all events with regards to purchase and equipment history is recorded and attainable from eQMS.

a) Manufacturer and supplier details and unique identity of equipment including software and firmware
b) dates of receipt, acceptance testing and entering into service
c) evidence that confirmed the equipment's acceptability for use when incorporated into laboratory
d) the current location
e) condition when received (e.g. new, used, reconditioned)
f) manufacturer's instructions (attached under properties within the asset record on eQMS)
g) programme for preventive maintenance
h) any maintenance activities performed by the laboratory or approved external service provider;
i) damage to, malfunction, modification, or repair of the equipment; records of faults (recorded as non-conformities on the equipment record) include the date of contact and reference number for the logged call to request repair.
j) equipment performance records such as reports or certificates of calibrations or verifications, or both, including dates, times and results;
k) status of the equipment such as active or in-service, out-of-service, quarantined, retired or obsolete.

These records shall be maintained and be readily available for the lifespan of the equipment or longer.

6.5. Equipment calibration and metrological traceability

6.5.1. General

All examination processes require consideration of Environmental conditions and Calibration Procedures (*LPXM071 Blank LP*).

6.5.2. Equipment calibration

All examination processes require consideration of Environmental conditions and Calibration Procedures (*LPXM071 Blank LP*). Each piece of equipment has an individual asset tag and is calibrated as recommended by the manufacturer as agreed within the specification of the validation and as indicated within LPRA005 and in relevant procedural SOPs.

A record of the service frequency, installation, maintenance and repair events is stored in eQMS. Laboratory calibration processes use certified reference material where these are available.

6.5.3. Metrological traceability of measurement results

Measurement uncertainty is described within *QDH&I165 Measurement Uncertainty*.

All data from genetic analysis (HLA genotyping) are aligned (using validated manufacturer's software) to the IPD-IMGT/HLA database. This is a specialist database for sequences of the human major histocompatibility complex (MHC) which includes the official sequences named by the WHO Nomenclature Committee For Factors of the HLA System (https://hla.alleles.org/nomenclature/committee.html).

6.6. Reagents and consumables

6.6.1. General

The laboratory has procedures that govern the selection, procurement, reception, storage, acceptance testing, and inventory management of reagents and consumables:

- *LPRA048*: *Laboratory ordering and stock management system*
- *LPMOL046*: *Molecular stock control and evaluation of kits and reagents*
- *LPAB065*: *Antibody stock control and evaluation*
- *LPXM068*: *Titration testing of flow cytometry conjugates*
- *LPXM077*: *Routine reagent preparation and QC*
- *LPXM073*: *Routine equipment / reagent maintenance and checklist*
- *LPXM089: FCXM reagent preparation, stock control and QC*
- *QDH&I003*: *Laboratory Health & Safety Handbook*

6.6.2. Reagents and consumables – Receipt and storage

The reception and storage of goods is undertaken according to the manufacturer's instructions and described in SOPs referenced above in 6.6.1.

6.6.3. Reagents and consumables – Acceptance testing

Quality acceptance testing is performed for new lots and shipments of reagents and consumables and is described in the procedures referenced above in 6.6.1. A new record is created within the quality control section of the reagent record in the eQMS equipment module according to *QIH&I002*.

6.6.4. Reagents and consumables – Inventory management

A monthly stock check of reagents is undertaken. The RMS is used to manage reagent and consumable inventory (*LPRA048*). An annual stock check is performed as close as possible to the end of the financial year and reported to NHS GG&C Finance Department.

6.6.5. Reagents and consumables – Instructions for use

Reagents and consumables are used according to the manufacturers' instruction and as detailed in the relevant SOP. Any deviation from manufacturer's instructions are described within the change control form *QFH&I008* for the assay.

6.6.6. Reagents and consumables – Adverse incident reporting

A non-conformance is completed and recorded on eQMS for any product which has resulted in an adverse incident or which has not been received in a satisfactory condition i.e. damaged, inadequate storage temperatures in transit. For products supplied via the MSC, the MSC provider must be contacted for resolution. For non-MSC products the manufacturer or supplier is contacted. All communications must be attached to the non-conformance in eQMS. The laboratory and quality managers must be copied into all correspondence and be immediately informed of identified incidents and supply issues. Should a manufacturer recall a product, this must be raised as an non conformance on eQMS and appropriately investigated.

6.6.7. Reagents and consumables – Records

For each reagent or consumable, a record exists that includes:

- identity of reagent consumable
- manufacturers information including instructions, name and batch or lot code
- date of receipt, expiration, entry into service and removal from service (if applicable)
- condition when received

records that confirmed the reagent or consumable's initial and ongoing acceptance for use

6.7. Service agreements

6.7.1. Agreements with laboratory users

The following documents describe current service agreements between the H&I laboratory and the clinical teams served.

- *QDH&I229: Service Agreement: adult renal transplant*
- *QDH&I230: Service Agreement: paediatric renal transplant*
- *QDH&I231: Service Agreement: HPC adult transplant*
- *QDH&I232: Service Agreement: adult cardiac transplant*
- *QDH&I234: Service Agreement: HPC paediatric transplant*
- *QDH&I295: Service Agreement: Monklands Hospital B27 testing*

6.7.2. Agreements with POCT operators

No POCT is undertaken for or by the H&I laboratory

6.8. Externally provided products and services

6.8.1. General

The laboratory is responsible for ensuring that externally provided products and services that affect laboratory activities are suitable when such products and services are:

a) intended for incorporation into the laboratory's own activities (e.g. unrelated donor searches);
b) provided, in part or in full, directly to the user by the laboratory, as received from the external provider (e.g. Cytomegalovirus (CMV) results)
c) used to support the operation of the laboratory (e.g. pipette calibration).

6.8.2. Referral laboratories and consultants

The laboratory acts as a mediator for the Queen Elizabeth University Hospital (QEUH) adult and Royal Hospital for Children (RHC) HPCT transplant unit and forwards clotted samples from HPC patients and Volunteer Unrelated Donors for Cytomegalovirus testing by the West of Scotland Specialist Virology Centre. The results for these tests are reported by the H&I laboratory to the transplant units (LIRA10 describes the processing of these samples and results obtained). Occasionally samples for testing in the NHS SNBTS East of Scotland H&I for pancreas transplant are forwarded with no results required in return. The procedure is documented in *LPXM053: Dispatch of specimens to other laboratories*.
LIRA35 List of referral laboratories provideds details of those laboratories that referrals may be made to.

A one in four on-call Consultant/Principal Clinical Scientist rota is available to support solid organ transplantation. Two of the consultants are based in Edinburgh Scottish Blood Transfusion Service. The on call rota is made available to laboratory and clinical teams via secure email. (*QDH&I236: Service Agreement Consultant Clinical Scientist)*

6.8.3. Review and approval of externally provided products and services

Selection, purchasing and ordering, assessment of suppliers, receipt and verification of identity and condition, issue and inventory management, risk assessment of their use and correct handling, and safe disposal is documented in *QDH&I028: Guidelines for selection and validation of examination procedures*, *LPRA048: Laboratory ordering and stock management system* and within SOPs specific for each examination process. Consideration is taken of quality of service provided, professionalism of supplier, costs (where knowledge of cost is known or permitted under the MSC, contractual obligation, recent performance, availability of stock, time to delivery and partnership.

The laboratory management ensures the availability of reagents, calibrators, and quality control material required to provide a service that meets the needs and requirements of users. Suppliers are approved as part of the tender process to provide goods or services. Stock levels are determined by senior members of staff based on predicted usage. The purchasing of most reagents, calibrators and quality control material is determined by senior laboratory staff and ordered via a MSC using the RMS software system (LPRA048 & EXTREFDOC10).
Non-MSC reagents and consumables are managed using the *NHS GG&C Pecos system* (EXTREFDOC17) and are approved by the Laboratory Manager, Head of H&I Department (or Clinical Services Manager) as described in *LPRA048*: *Laboratory Ordering and Stock Management System*.
Any actions arising from the evaluation of the performance of external providers is recorded as a non conformance on eQMS.

7. Process requirements

7.1. General

Risk and Incident Management is described within QDH&I247

7.2. Pre-examination processes

7.2.1. General

The department aims to ensure that all H&I service users are fully aware of the services provided and sample requirements. This information is provided within *QDH&I014: H&I User Manual*.

7.2.2. Laboratory information for patients and users (a-g)

The department aims to ensure that all H&I service users are fully aware of the services provided and sample requirements. This information is provided within the *QDH&I014: H&I User Manual* which is available on the laboratory website: https://www.nhsggc.scot/staff-recruitment/staff-resources/laboratory-medicine/histocompatibility-and-immunogenetics/.
Patient consent is described within 7.2.4.3

7.2.3. Requests for providing laboratory examinations

7.2.3.1. General

a) Requests accepted (*LPMOL091: Sample reception, acceptance and rejection*) by the Department for examination(s) shall be considered as an "agreement", between the test requestor, and the Department. Submission of a request to the laboratory indicates that consent for testing has been given.
b) The examination request must provide sufficient information to ensure:
   - unequivocal traceability of the patient to the request and sample;
   - identity and contact information of requester (where reporting of results is required e.g. disease association);
   - identification of the examination(s) requested;
   - informed clinical and technical advice, and clinical interpretation can be provided.
c) The examination request can currently only be received in paper format using the H&I laboratory "yellow request form" (*QDH&I184*) or forms produced via TrakCare
d) Where necessary for patient care, the laboratory shall communicate with users or their representatives, to clarify the user's request.

7.2.3.2. Oral requests

The procedure for managing oral requests for examinations, including the requirement for written confirmation within 24 hours is described in *LPMOL091*

7.2.4. Primary sample collection and handling

7.2.4.1. General

Guidance for specimen collection, handling and transport is provided in the user manual (*QDH&I014*). Requirements for sample volume, preservatives are reviewed at QMR/AMR meetings to ensure sufficient amounts of sample are properly collected.

7.2.4.2. Information for pre-collection activities

These are provided in the user manual (*QDH&I014*) see section 3.

7.2.4.3. Patient consent

The laboratory receives samples collected by venepuncture and buccal / saliva swabs and therefore consent for testing is inferred. For deceased donor sampling, consent is managed by the Organ Donation and Transplantation (ODT) Directorate of NHS BT.

The laboratory shares patient data with NHS BT Organ Donation and Transplantation for the purposes of listing patients for renal transplantation. Patient consent is documented by the transplant coordinator and indicated on the referral to activate form (LFXM087). The laboratory shares patient data with the Anthony Nolan Register for the purposes of

undertaking an unrelated donor search. Patient consent is documented on the 'VUD' form (LFRA042).

7.2.4.4. Instructions for collection activities

Details of specimen types and volumes are available in the user manual (*QDH&I014*) see section 3; Trakcare and the yellow request form (*QDH&I184*). Additional information is available for buccal samples. The responsibility for procedures relating to how samples are taken and the management of materials used in the collection process are managed by the requesting institution.

7.2.5. Sample transportation

a) To ensure the timely and safe transportation of samples, the laboratory user manual (QDH&I014 section f) provides instructions for:
   1) packaging of samples for transportation;
   2) ensuring the time between collection and receipt in the laboratory is appropriate for the requested examinations;
   3) maintaining the temperature interval specified for sample collection and handling;
   4) any specific requirements to ensure integrity of samples, e.g. pre-arranging tests to be undertaken with the laboratory prior to transportation

   In addition deceased donor material delivered to the laboratory by taxi will be accompanied with written instructions for the driver in the event of specimen leakage (see QDH&I 139)
   When the laboratory is responsible for the transport of specimens to other laboratories, the procedure *LPXM053: Dispatch of specimens to other laboratories* is followed.

b) If the integrity of a sample has been compromised and there is a health risk, the individual / organisation responsible for the transport of the sample shall be notified immediately and action taken to reduce the risk and to prevent recurrence (see *QDH&I 139: URGENT form for sending deceased donor samples* and *LPMOL091:Sample reception, acceptance and rejection*).

c) The *QDH&I097: NHS GGC Transport and Disposal of Specimen Containers and Specimens Policy* describes the minimum standard to which operators should aim when transporting specimens within and between hospital premises and to outside (non NHS GG&C) agencies. Any inadequacy of sample transportation systems are reported as a non-conformity which are reviewed at QMR meetings.

7.2.6. Sample receipt

7.2.6.1. Sample receipt procedure

On arrival in reception area, specimens are sorted and processed by trained staff according to the following SOPs:

- *LPMOL091: Sample reception acceptance and rejection*

- *LPMNZ02: Booking in patient samples using Manzen Software*
- *LIAB002A: Sample processing guidelines for antibody testing*

An audit of the pre-analytical process forms part of the recurring annual audit schedule.

These procedures ensure that all samples are unequivocally traceable by request and labelling to an identified patient. There are documented criteria for sample acceptance and rejection. Problems with samples are described in the final report if not dealt with at an earlier stage according to the examination procedure requested for the sample. Samples received are recorded in the LIMS (Manzen) with date sample taken and date received. Samples requiring urgent attention e.g. deceased organ donor are prioritised.

7.2.6.2. Sample acceptance exceptions

a) Handling exceptions to the sample acceptance procedure are described within LPMOL091. These exceptions require review by a Team Manager or above and details of the exception must be documented within the patient/donor's electronic file.
b) Comments on the quality of the sample received, if poor (including viability, haemolysis, volume, and packaging) are placed on accompanying paperwork / worksheets for samples which will have a report prepared. Comments on the sample quality are made on the final report issued.

7.2.7. Pre-examination handling, preparation, and storage

7.2.7.1. Sample protection

Procedures are in place for securing patient samples ensuring sample integrity and preventing loss or damage during, handling, preparation and storage.

- *LPMOL091: Sample reception, acceptance and rejection*
- *LPMNZ02: Booking in patient samples using Manzen software*
- *LFXM093: Record of specimens sent by post, redirected or discarded*
- *LIAB002A: Sample Processing Guidelines for Antibody Testing*
- *LIMOL066: Molecular HLA typing guidelines*
- *LIMOL087: Disinfection Instruction*

7.2.7.2. Criteria for additional examination requests

There is no time limit for additional or further examination procedures for DNA and serum extracted from primary samples and stored according to laboratory procedures. It is routine procedure to perform additional examination requests on samples received for transplant patients as results from the first line of testing (e.g. antibody screen) defines the next test to be undertaken.

7.2.7.3. Sample stability

Where relevant, the time between sample collection and preparation of the sample for examination is specified within *LPMOL091: Sample reception, acceptance and rejection*.

7.3. Examination processes

7.3.1. General

The laboratory selects examination procedures which aim to meet the needs and requirements of users. All examination procedures are validated to ensure suitability for their intended use. Written evidence is retained to demonstrate procedures and equipment function in accordance with the manufacturer's specifications. Assessment of ongoing suitability of examination procedures is included within the QMR and AMR.

7.3.2. Verification of examination results

a) Validated examination procedures used without modification are subject to independent verification by the H&I laboratory before being introduced to routine use. This involves confirming the performance characteristics of the procedure and documenting the verification. The SOP describing validation/verification is: *QDH&I028: Guidelines for selection and validation of examination procedures*. This describes the processes for assessing examination methods to ensure the required performance is achieved.
b) The performance specifications for each examination methods are verified by undertaking tests and following the active SOPs for each method to ensure that the results achieved are valid and as expected for clinical decision making. (*LPAB065: Antibody stock control and evaluation of kits and reagents; LPXM089: FCXM reagent preparation, stock control, and QC; LPMOL046: Molecular stock control and verification of kits and reagents*)
c) Verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making.
d) All verification (evaluation) results are reviewed and recorded as described within the procedures listed above in b) and c), by personnel with the appropriate authorisation and competence
e) If a method is revised by the manufacturer, verification will be performed to specifically evaluate the change.
f) The records of verification are retained on eQMS as described in *QDH&I002 Using eQMS for recording reagent QC*. The records include the:
    1) performance specifications to be achieved,
    2) results obtained, and
    3) a statement of whether the performance specifications were achieved and if not, action taken (non-conformance raised).

7.3.3. Validation of examination methods

a) The laboratory validates examination methods derived from the following sources:

1) laboratory designed or developed methods (e.g. flow cytometry crossmatch);
2) validated methods subsequently modified. (e.g. luminex bead assays)

b) The procedure: *Guidelines for selection and validation of examination procedures* (QDH&I028) describes the processes for assessing examination methods to ensure the required performance is achieved and that the results are valid to allow clinical decision making.
c) The personnel responsible and competent to review and authorise the validation results is specified on the validation documentation (*QFH&I008 Change Control Form*) with the appropriate authorisation and competence shall review the validation results.
d) When changes are proposed to a validated examination method, the clinical impact shall be reviewed, and a decision made as to whether to implement the modified method.
e) The following records of validation are retained (*QFH&I008 Change Control Form*):
   1) the validation procedure used;
   2) specific requirements for the intended use;
   3) determination of the performance specifications of the method;
   4) results obtained;
   5) a statement on the validity of the method, detailing its fitness for the intended use.

7.3.4. Evaluation of measurement uncertainty (MU) (a-h)

The laboratory's quality document: QDH&I165: *Measurement Uncertainty* provides information on variables (not limited to biological variation) within a process that can affect the measurement values. Any process-specific uncertainties are described within the individual examination SOP.

All examination procedures are reviewed minimally every two years and included within the review is an evaluation of MU. Where MU is not relevant, an explanation is given in the examination SOP.

MU information is made available to laboratory users (*QDH&I014 Laboratory User Manual*) on request.

7.3.5. Biological reference intervals and clinical decision limits (a-d)

Biological reference intervals and clinical decision limits, when needed for interpretation of examination results are described within each examination procedure, which are reviewed minimally every two years.

When changes are made to an examination or pre-examination method, the laboratory reviews the impact on associated biological reference intervals and clinical decision limits. This will be done when the SOPs are updated. Any changes will be communicated to the users when applicable.

7.3.6. Documentation of examination procedures (a-c)

SOPs for the conduct of all examinations are prepared according to *QDH&I015: Guidelines for the preparation and control of Laboratory Documents.* All SOPs are subject to document control and aim to comply with the standards set out in ISO 15189:2022.

SOPs are available at the location of use and/or electronically in eQMS.

7.3.7. Ensuring the validity of examination results

7.3.7.1. General

Each examination procedure details how the results obtained are monitored, recorded and reviewed:

Flow cytometry crossmatch:	*LPXM094 FCXM Acquisition and Reporting*
One Lambda antibody testing:	*LPAB056 Analysis of LABScreen Assays*
Lifecodes antibody testing:	*LPAB064 Analysis of Lifecodes Luminex antibody assays*
PCR-SSO:	*LPMOL075A PCR-SSO Luminex Computer Work and Analysis*
NGS:	*LPNGS05 Analysis of NGS results using NGSengine*

7.3.7.2. Internal quality control (IQC)

The procedures described above (7.3.7.1) contain details on how internal quality control is utilised to monitor the ongoing validity of examination results and ensures validity pertinent to clinical decision making.

Quality control material supplied with commercial products are described within the SOPs for all HLA typing methods and all HLA antibody screening and identification methods. In-house flow crossmatches are performed with control material obtained from the National Institute of Biological Standards and Controls (NIBSC), third party commercial sources and/or from previously tested patient material.

The acceptance or rejection of laboratory results is dependent on the laboratory test passing quality control criteria. The use of data obtained from quality control samples is described within the SOPs for each laboratory test and this is subject to on-going review for each of the examination processes. The laboratory shall prevent the release of patient results if IQC fails the defined acceptability criteria.

IQC material is selected so it is fit for purpose, factors considered are: stability regarding the properties of interest, reacting in a manner as close as possible to patient samples and allowing analysis of results near clinical decision limits.

7.3.7.3. External quality assessment (EQA)

The H&I laboratory participates in the EQA (also referred to as EPT) relevant to the tests performed. Each year an evaluation of available EPT schemes is undertaken and a plan made for the testing and reporting of EPT activities according to *QDH&I193: Procedure for EPT evaluation, registration, testing and reporting*.

All EPT testing results are communicated to staff via laboratory staff meetings. Performance results are recorded in an audit (eQMS) and unacceptable results are raised as an non conformance from this audit. When anomalies or penalties are noted, they are investigated by the Quality Manager/ Team Manager. Corrective and preventative action is always taken and is reported to the senior management group. Review and action points of all returns received from EPT schemes are stored on eQMS. Overall performance is reviewed as part of the QMR.

All examinations (except C1q testing) have UKAS accredited EPT schemes. C1q EPT is provided by the Eurotransplant Reference Laboratory, which is approved by EFI.

If an examination was to be introduced to the laboratory and an EQA programme was not available, ISO 15189:2022 is followed to identify an acceptable alternatives to EQA schemes.

7.3.7.4. Comparability of examination results (a-e)

HLA typing and HLA antibody tests are performed on multiple samples from the same individual and may be performed using different methods and / or different equipment. The results of all tests are compared to all previous sample results before reporting. All unexpected discrepancies (e.g. change in HLA type) are investigated as a non-conformance. Other discrepancies (e.g. change in HLA antibody profile) are confirmed by investigating the clinical background and re-testing as described within relevant examination procedures.

SOPs LPAB059 and LPAB061 describe action to be taken when different HLA antibody specificity tests give non-concordant results.
SOP LPMOL090 describes action to be taken when different HLA typing tests give non-concordant results. The laboratory notifies users of any differences in results when these may impact on clinical decisions.

All results are recorded within the patient file on the LIMS and are easily retrieved for comparisons.

7.4. Post-examination processes

7.4.1. Reporting of results

7.4.1.1. General

a) The H&I laboratory aims to provide accurate, clear and unambiguous reports for its users using the LIMS (Manzen). The preparation and production of examination reports is described within:

- *LPRA001: Preparing reports for solid organ patients and donors;*
- *LPRA038: Reporting HLA typing results for HPC patients and potential donors;*
- *LPRA006: Reporting HLA types to ODT for solid organ transplantation;*
- *LPRA012*: *Reporting disease association results;*
- *LPRA39: Reporting a B27 result*

b) The procedures listed above in a) describe to notify users when examination results are delayed, based on the impact of the delay on the patient.
c) All information associated with issued reports is retained in accordance with *QDH&I109 Retention and Storage of Clinical Samples and Documentation*

7.4.1.2. Result review and release

All examination results are reviewed for acceptability by the tester who reviews control values, trends and equipment performance. The results are then checked and approved (authorised) by a second member of staff prior to reporting. This process, including who can issue reports and to whom the reports are sent, is described in the SOPs specific to the methodology (described in 7.4.1.1).

7.4.1.3. Critical result reports (a-c)

Critical result reports are described within *LPRA001: Preparing reports for solid organ patients and donors.*

7.4.1.4. Special considerations for results

a) Instruction *LIRA7: Reporting information on SERPR database* describes how results for renal patients may be reported in a simplified way for the benefit of the clinician treating the patient i.e. the results are located together with other clinical information. *SOP LPRA004: Preparing updates for the weekly adult and paediatric HPC transplant planning meeting* describes how summarised results for bone marrow transplant patients and donors are reported for the weekly meetings held with the transplant units. All these results are formally reported.
b) Preliminary (or interim) reports are described within SOPs listed in 7.4.1.1
c) SOP LPRA013 Delivering laboratory results by fax, email or telephone describes acceptable methods for the delivery of results including recording the information.
d) The laboratory does not provide results directly to patients.
e) Anonymised laboratory examinations may be utilised in accordance with any legal or regulatory requirements.

7.4.1.5. Automated selection, review, release and reporting of results

Not applicable to the H&I laboratory

7.4.1.6. Requirements for reports

All reports of laboratory tests include the following information,

a) unique patient identifier, the date of primary sample collection and the date of the issue of the report.
b) identification of the laboratory;
c) name or other unique identifier of the user;
d) type of primary sample
e) identification of the examinations performed;
f) identification of the examination method used,
g) examination results
h) clinical decision limits (BSHI/BTS Guidelines on detection of alloantibodies),
i) identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available;
j) identification of the person(s) reviewing the results and authorizing the release of the report
k) identification of any results that need to be considered as preliminary;
l) indications of any critical results;
m) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end (e.g. page number to total number of pages).

7.4.1.7. Additional information for reports

a) When necessary for patient care, the time of primary sample collection will be included. This will apply when a patient has had multiple samples taken on the same day e.g. pre and post plasma exchange.
b) Time of report release, is given for all deceased donor crossmatch reports. For all other reports, it can be given (the data is held on the LIMS) when needed.
c) Identification of all examinations or parts of examinations performed by a referral laboratory, including information provided by consultants, without alteration, as well as the name of the laboratory performing the examinations.
d) When applicable, a report shall include interpretation of results and comments on:
    1) sample quality and suitability that can compromise the clinical value of examination results;
    2) discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;
    3) possible risk of misinterpretation when different units of measurement are in use regionally or Nationally (e.g. MFI from different manufacturers);
    4) result trends or significant changes over time (i.e. changes in antibody profiles over time can be commented on).

7.4.1.8. Amendments to reported results

The process for the issue of an amended or revised results / report is detailed in the reporting SOPs. The user is informed of the reason for the amendment in an “amended report”. This report gives details of the patient or donor’s identity and the date of the original report. The amended report is dated and authorised by the person making the

change. The original report and the amended report remain within the patient's unique record in the laboratory LIMS system and can be recalled for audit purposes.

7.4.2. Post-examination handling of samples

The laboratory has a documented procedure that specifies the length of time samples are to be retained and the conditions underwhich samples are stored. (*QDH&I109 Retention and Storage of Clinical Samples and Documentation*).

Following the examination of a sample, the

a) patient and source identification of the sample is maintained, with the information being stored on the LIMS.
b) suitability of the sample for additional examination is known, comments are added to the LIMS if the sample is not suitable for testing.
c) sample is stored in a manner that optimally preserves suitability for additional examination
d) sample can be located and retrieved, and
e) sample is discarded appropriately

7.5. Non conforming work

Procedure *QDH&I022: Use of Q pulse software* and *QDH&I116 Identification and management of nonconforming work* describe the process to be taken when a non-conformity is identified in any aspect of the pre-examination, examination or post-examination processes. This process ensures that:

a) the responsibilities and authorities for the management of nonconforming work are specified;
b) immediate and long-term actions are specified and based upon the risk analysis process established by the laboratory;
c) examinations are halted, and reports withheld when there is a risk of harm to patients;
d) an evaluation is made of the clinical significance of the nonconforming work, including an impact analysis on examination results which were or could have been released prior to identification of the nonconformance;
e) a decision is made on the acceptability of the nonconforming work;
f) when necessary, examination results are revised, and the user is notified;
g) the responsibility for authorising the resumption of work is specified. The laboratory shall implement corrective action commensurate with the risk of recurrence of the nonconforming work. The laboratory shall retain records of nonconforming work and actions as specified in 7.5 a) to g).

7.6. Control of data and information management

7.6.1. General

The laboratory utilises an H&I specific LIMS called 'Manzen' developed by Tissue

Typing Systems UK Ltd.

QDH&I 110: Management of Data and information describes how the laboratory ensures the confidentiality of patient information.

7.6.2. Authorities and responsibilities for information management

Manzen is accessed by user name and password. All users are assigned a "role" which is dependent on the level of access required. This includes, read only, administrator and authoriser and senior authoriser. This controls who can access patient information, enter data,change data and authorise the release of reports.

7.6.3. Information systems management

QDH&I110: Management of Data and information describes the management of systems (electronic and paper) used for the collection, processing, recording, reporting, storage and retrieval of examination data and other information held within the laboratory.

Software and updates specific to examination processes are validated and verified prior to use. The results are recorded within ERH&I or CCH&I documents located on eQMS and forms specific to the software procedure. This is explained within the following examination procedures

- *LPAB057: Luminex software and data maintenance (antibodies)*
- *LPMOL096: Management of HLA typing software and IMGT/HLA Database updates*
- *LPMOL098: Updating allele and typing databases in SCORE software*

Records of software and databases utilised in examination processes are maintained with the results of the examination.

7.6.4. Downtime plans

The following documents (and documents referred to within) describe the processes to be followed to maintain operations in the event of failure or during downtime in information systems that affect *the laboratory's activities:*

- *EXTREFDOC112: Business Continuity Plan H&I*
- *EXREFDOC172: Contingency Plan for Manzen Client Support*
- *LIXM084: Manzen contingency: Obtaining patient and sample information without Manzen*
- *QDH&I197 Contingency agreement with SNBTS Edinburgh*

7.6.5. Off site management

Off site management of software provided by external companies is coordinated by the MSC provider.

7.7. Compaints

7.7.1. Process

NHS GG&C has a complaints policy *QDH&I170 Complaints Engagement Policy* and procedure (https://www.nhsggc.scot/contact-us/complaints/). In addition, the laboratory has a process for handling complaints (QDH&I 116) that includes the following:

a) a description of the process for receiving, substantiating and investigating the complaint, and deciding what actions shall be taken in response;
b) tracking and recording the complaint, including the actions undertaken to resolve it;
c) ensuring appropriate action is taken.

The complaints procedure is available within the user manual which is publicly available.

7.7.2. Receipt of complaint

a) Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint.
b) The laboratory shall be responsible for gathering all necessary information to determine whether the complaint is substantiated.
c) Whenever possible the laboratory shall acknowledge receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.

7.7.3. Resolution of complaint

Investigation and resolution of complaints shall not result in any discriminatory actions.

The resolution of complaints shall be made by, or reviewed and approved by, persons not involved in the subject of the complaint in question. Where resources do not permit this, any alternative approach shall not compromise impartiality.

7.8. Continuity and emergency preparedness planning

The laboratory has a business continuity plan *EXTREFDOC112: Business Continuity Plan H&I* which describes the action plan should there be an emergency situation or other conditions when laboratory activities are limited, or unavailable to enable continued provision of service. Specific contingency plans exist for individual pieces of equipment and tests and these are described within *QDH&I257: Laboratory Contingency Plan.*

8. Management system requirements

8.1. General requirements

8.1.1. General

The H&I laboratory maintains a management system in accordance with the ISO 15189:2022 standards.

8.1.2. Fulfilment of management system requirements

The management system is subject to on-going review, continuous quality improvement and modification. Quarterly management review meetings take place, the agenda (QDH&I238) and the record of the meetings (QDH&I239) are available on eQMS.

8.1.3. Management system awareness

All laboratory staff are provided with training to enable them to be aware of the management system (*LPTR004: Quality Management System Training Programme*). This includes having knowledge of:

a) relevant objectives and policies;
b) their contribution to the effectiveness of the management system, including the benefits of improved performance;
c) the consequences of not conforming with the management system requirements.

'Quality Management' is a fixed agenda item for laboratory meetings which are attended by all staff in the department.

8.2. Management system documentation

8.2.1. General

Management system documentation is described within this document, the *QDH&I001: Quality Manual*. This includes the quality policy (*QDH&I002: Quality Policy*), the management system, the organisation and management structure of the laboratory, roles and responsibilities of laboratory management, documentation and the activities supporting the QMS. The Quality Manual is introduced to staff at time of induction and annually at staff annual review. All new versions are distributed to all staff via eQMS for acknowledgement.

8.2.2. Competence and quality

The objectives and policies referred to within the Quality Policy and Quality Manual address the competence, quality and consistent operation of the laboratory.

8.2.3. Evidence of commitment

The laboratory's commitment to the management system is illustrated by the documented quarterly management reviews that are undertaken to review effectiveness of adherence to the objectives and policies.

QDH&I239: Quarterly management review record

8.2.4. Documentation

All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document are controlled within an electronic document management system, eQMS (Ideagen). The Quality Manager is responsible for coordinating and enforcing

the document control activities in accordance with procedure *QDH&I015: Guidelines for the preparation and control of laboratory documents*.

8.2.5. Personnel access

All personnel have access to the management system documentation and related information that is applicable to their responsibilities via eQMS.

8.3. Control of management system documents

8.3.1. General

As described for 8.2.4

8.3.2. Control of documents

Documents conform to ISO 15189:2022 and EFI standards. All documents are managed on eQMS (password required) as described in *QDH&I015: Guidelines for the preparation and control of laboratory documents.*
Documents:

a) possess a unique identifier,
b) require approval before being issued by authorised personnel,
c) are reviewed at a minimum of every two years and updated when required,
d) are available at the place of use, with paper versions having their location documented on eQMS,
e) changes and the current revision status of documents are identified
f) documents are accessed by eQMS which requires password access with various levels of usage
g) as above
h) the use of obsolete documents is prevented by replacing them with active documents and documenting the removal of obsolete paper documents on eQMS,
i) obsolete documents remain controlled and accessible via eQMS.
j) Documents are retained as described in *QDH&I109: Retention and Storage of Clinical Samples and Documentation*.

8.4. Control of records

8.4.1. Creation of records

The laboratory maintains records to demonstrate fulfilment of this document using the eQMS quality management database. The use of eQMS is described in *QDH&I022: Use of* eQMS *software.*

8.4.2. Amendment of records

A record of all amendments made to records is held within the eQMS software, where previous versions of records can be located together with the history of changes made and by whom. Separately, records of samples received and tests undertaken are stored within

the LIMS (Manzen), which has a tracking feature which shows a history of changes made and when and by whom.

8.4.3. Retention of records

The laboratory's procedure for the retention of records is described within *QDH&I109: Retention and storage of clinical material and documentation.*

8.5. Actions to address risks and opportunities for improvement

8.5.1. Identification of risks and opportunities for improvement

The laboratory's procedure for the management of risks and opportunities for improvement is described in *QDH&I247: Management of risks and opportunities for improvement.*

8.5.2. Acting on risks and opportunities for improvement

All identified risks and opportunities for improvement are acted upon with the outcomes recorded on eQMS and within minutes of QMR (*QDH&I239: Quarterly management review record*) and/or laboratory meetings (*QDH&I168: Agenda & Minutes of full staff meetings*).

8.6. Improvement

8.6.1. Continual improvement

Continual improvement is undertaken by establishing quality objectives (*QDH&I146d: Quality Objectives for period xxxx/xxxx*) and reviewing these at the QMR meeting, the minutes of which (*QDH&I239: Quarterly management review record*) are shared with all laboratory staff. Continual quality improvement is described within (*QDH&I244: Quality Objectives and Indicators*).

8.6.2. Laboratory patients, user, and personnel feedback

The needs and requirements of patients and users are reviewed annually at the AMR (*QDH&I256: Annual Management Review*). The H&I laboratory has representation at various clinical meetings and therefore receives regular feedback regarding the quality of the H&I service. The laboratory director and other senior biomedical and clinical scientists are in daily contact with users to provide advice.
In practice the needs of the users are identified by:

- feedback from clinical users at regular MDT meetings
- any complaints received from users are registered within eQMS (*QDH&I022: Use of* eQMS *Software*) and corrective action taken is documented (*QDH&I116: Identification and control of nonconformities*). User feedback is shared with all staff at full staff laboratory meetings. Actions taken because of the feedback are presented at the QMR meetings and reported within the Management Quarterly Review Reports (*QDH&I239*)

The User Manual (*QDH&I014*) provides patients and users with contact telephone numbers, test sample and storage requirements, the minimum criteria for acceptance and processing

of a sample, modes of sample handling, the repertoire of tests, and target turnaround times. The user manual also details the protocol for activation of patients on the renal deceased donor transplant list and the processes required for work-up in related and unrelated HPCT. The User Manual is accessible on Staffnet (NHS GG&C Staff) and the internet (see section 3).

Staff are encouraged to make suggestions at laboratory staff meetings, during training, audit or reviewing of SOPs and procedures. Staff are also invited to make suggestions via eQMS. NHS Scotland has instigated iMatter to record responses to a staff survey. The H&I laboratory has two iMatter teams which meet annually to review survey feedback and identify areas for improvement. NHS GG&C may distribute additional staff surveys for feedback on specific areas e.g. Equality and Diversity

8.7. Nonconformities and corrective actions

8.7.1. Actions when nonconformity occurs

The procedure *QDH&I116: Identification and control of nonconformities* describes the action to take when a nonconformity occurs. This includes:

a) how to respond to the nonconformity and, where applicable:
    1) identify and implement immediate action to control and correct the nonconformity;
    2) address the consequences of the non conformity (e.g. inform users) , with a particular focus on patient safety including escalation to the appropriate person.
b) to determine the cause(s) of the nonconformity via root cause analysis.
c) to identify and implement corrective action to eliminate the cause(s) of the nonconformity, to reduce the likelihood of recurrence or occurrence elsewhere, by:
    1) reviewing and analysing the nonconformity;
    2) determining whether similar nonconformities exist, or could potentially occur;
    3) assessing the potential risk(s) and effect(s) if the nonconformity recurs.
d) to implement any action needed.
e) to review and evaluate the effectiveness of any corrective action taken.
f) to update risks and opportunities for improvement, as needed.
g) to make changes to the management system, if necessary.

8.7.2. Corrective action effectiveness

The effectiveness of corrective action is reviewed by the Quality Manager or above.

8.7.3. Records of nonconformities and corrective actions

All nonconformities and corrective actions are recorded on eQMS with those with major or extreme being reported on DATIX.

8.8. Evaluations

8.8.1. General

The laboratory has an established practice of planning and implementing audits of pre-examination, examination and post-examination processes to ensure conformity to the QMS, and to ensure the requirements of patients and users are met. Documentation to aid this process includes: *QDH&I103: Yearly audit planner*, *QDH&I034: Internal Audit*, *LFTR10: Examination Audit of Competency*, *QDH&I152: Performance Review by Year* and *QDH&I239: Quarterly Management Review records*.

8.8.2. Quality indicators

The process of monitoring quality indicators (and Key Performance Indicators, KPI) is described in *QDH&I244: Quality Indicators*. Key Performance and Quality Indicators are established and reviewed at the AMR meetings and reviewed at the QMR. The outcomes are reported in the *QDH&I239: QMR report* and the *QDH&I256: AMR report*.

8.8.3. Internal audits

There is planned internal audit of the pre-examination, examination and post-examination processes (QDH&I034) with the audit cycle being completed each year (QDH&I103).

Audits are performed by trained, designated auditors who are independent of the team/work area under evaluation. Any non-conformity identified is investigated and corrective action is undertaken. All audits are reviewed at QMR, with findings discussed at laboratory meetings. An annual review of audit activity is reported at the AMR. Audit reports are recorded within eQMS.

8.9. Management Reviews

8.9.1. General

The senior management team conducts a quarterly review of the management system (*QDH&I238: Agenda* and *QDH&I239: Report*). This is to ensure the laboratory's management system continues to be suitable, adequate and effective. Also the review checks that the policies and objectives related to the fulfilment of accreditation standards are suitable. Annually one of the reviews (annual management review) has an extended agenda to review annual activity.

8.9.2. Review input

The QMR (and AMR) have agenda (QDH&I 238 and QDH&I 311) that include the following:

a) status of actions from previous management reviews, internal and external changes to the
b) management system, changes in the volume and type of laboratory activities and adequacy of
c) resources;
d) fulfilment of objectives and suitability of policies and procedures;

e) outcomes of recent evaluations, process monitoring using quality indicators, internal audits,
f) analysis of non-conformities, corrective actions, assessments by external bodies;
g) patient, user and personnel feedback and complaints;
h) quality assurance of result validity;
i) effectiveness of any implemented improvements and actions taken to address risks and
j) opportunities for improvement;
k) performance of external providers;
l) results of participation in interlaboratory comparison programmes;
m) evaluation of POCT activities (not included as not undertaken)
n) other relevant factors, such as monitoring activities and training.

8.9.3. Review output

The output from the management review (QDH&I 239 and QDH&I256) records the decisions and actions related to:

a) the effectiveness of the management system and its processes;
b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;
c) provision of required resources;
d) improvement of services to patients and users;
e) any need for change.

All actions are recorded on action tracker document with specified timeframes for completion.

Appendix 1 *QDH&I002: Quality Policy*, published separately

The Quality Policy of the NHS Greater Glasgow & Clyde Histocompatibility and Immunogenetics Service

The Histocompatibility and Immunogenetics (H&I) Laboratory is committed to the needs and requirements of patients and users by providing an impartial high quality H&I service within the framework of the NHS Greater Glasgow and Clyde Policies and Procedures. In order to accomplish this, the laboratory will:

- provide a supra-regional, highly specialised, scientific and clinical service in support of solid organ and haematopoietic stem cell transplantation, and tests for specific genes to aid disease diagnosis and drug therapies
- operate a quality management system to integrate and control the organisation, procedures and resources
- set quality objectives and establish quality indicators to continuously evaluate performance
- ensure that all laboratory personnel are familiar with the Quality Manual and all relevant procedures to ensure patient and user satisfaction
- commit to the health, safety and welfare of all staff and visitors to the laboratory
- commit to good professional practice and conduct
- work to ensure that NHS Scotland values are adhered to i.e. care and compassion, dignity and respect, openness, honesty and responsibility, quality and teamwork
- manage patient information with respect to their privacy and confidentiality

The Laboratory will implement and comply with standards set by ISO 15189: 2022 and the European Federation of Immunogenetics. The laboratory is committed to:

- staff recruitment, training, development and retention at all levels in order to provide a full and effective service to its users
- the proper procurement and maintenance of equipment and other resources as needed for service provision
- the collection, transport and handling of all specimens to ensure the correct performance of laboratory examinations and the safety of handlers
- the use of examination procedures that will ensure the highest achievable quality of all tests performed
- reporting results of examinations in a manner that is timely, confidential, accurate and clinically useful
- continual quality improvement by assessing the requirements of patients and users, in addition to internal laboratory audits and external quality assessment
- complying with relevant environmental legislation
- performing duties as would befit a centre of excellence in the specialised field of Histocompatibility and Immunogenetics

Signed on behalf of the
NHS GGC Histocompatibility and Immunogenetics Service

Signed version available on QPulse and laboratory website	Mrs Catherine Hastie (Head of Laboratory) Date: 11/12/2025