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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
CS	Clinical Scientist
CPD	Continuing Professional Development
EFI	European Federation for Immunogenetics
EPT	External Proficiency Testing
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
HPCT	Haematopoietic progenitor cell transplantation
IBMS	Institute of Biomedical Science
ISO	International Organisation for Standardisation
LMG	H&I Lab Management Group
LIMS	Laboratory Information Management System
MDT	Multi-Disciplinary Team
MSC	Managed Service Contract
NHS GG&C	National Health Service Greater Glasgow and Clyde
PDP	Personal development plan
PhD	Doctor of Philosophy degree
QEUH	Queen Elizabeth University Hospital
QMR	Quarterly Management Review
QMS	Quality Management System
RHC	Royal Hospital for Children
RMS	Reagent Management System
UKAS	United Kingdom Accreditation Service

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1. Introduction

1.1. The Quality Manual

This Quality Manual describes the Quality Management System (QMS) of the 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 ISO15189:2012 Medical Laboratories – Requirements for quality and competence. The sections have been mapped to the correspondent ISO 15189 standards. 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 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 Q-Pulse of "acknowledgment" e-mails prompting staff to read the Quality Manual.

1.2. References

External quality documents are stored within Q-Pulse and distributed to all staff for acknowledgement. Reference is made to the undernoted documents to ensure compliance with required standards for accreditation. Additional UKAS publications are also available via Q-Pulse to describe methods of application for accreditation and for guidance within specific areas of the accreditation process.

EXTREFDOC18 UKAS Publication ISO15189 2012 STANDARDS

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

1.3. 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).

2. General Information

2.1. 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

2.2. 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.

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.org.uk/downloads/histocompatability-and-immunogenetics-user-manual/

4. Management requirements

4.1. Organisation and management responsibility

4.1.1. Organisation

4.1.1.1. General

The H&I laboratory shall meet the requirements of the ISO 15189 Standard and current EFI Standards when carrying out work at its permanent facilities or in associated facilities such as during attendance at clinical sites.

4.1.1.2. Legal entity

The H&I laboratory is located within NHS Greater Glasgow & Clyde 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

4.1.1.3. Ethical conduct

All NHS GG&C staff are required to adhere to the NHS GG&C '*Code of Conduct for staff*' (QDH&I122). The Code of Conduct for staff is based around the Standards of Business Conduct for NHS Staff contained in NHS Circular MEL (1994) 48 with updates to reflect the Bribery Act 2010. It also incorporates the NHS Greater Glasgow and Clyde Fraud and Whistle blowing Policies. The key elements of the Code of Conduct for Staff are that the employees of NHS Greater Glasgow and Clyde 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 adhering to public service values at all times 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.

NHS GG&C have produced the following documents for all staff:
Guidance on handling personal identifiable data (EXTREFDOC37)*:* this describes steps that must be followed when sending or receiving confidential and sensitive information.
*Internet Acceptable Use Policy (*EXTREFDOC30): this must be read by all members of staff with access to information systems and applications.

The handling and disposal of human material and records is governed by:

- *The Human Tissue Act (Scotland)* (EXTREFDOC35)
- *The Retention and Storage of Pathological Records and Specimens.* 5th Edition April 2015(QDH&I075)
- *Retention and Storage of Clinical Samples and reports* (QDH&I109)

4.1.1.4. Laboratory Director

Duties and responsibilities
The Laboratory Director (Dr Ann-Margaret Little) 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 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
- 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 Q-Pulse 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

Whilst the Laboratory Director is accountable for the overall operation and administration of activities within the laboratory, key activities are delegated to assigned individuals

1. Deputy to the Laboratory Director: Mrs Catherine Hastie
2. Laboratory Management: Mrs Ashleigh Lindsay
3. Quality Management: Dr Alayna McDade (Deputy: Ms Angela Richardson)
4. Health and Safety: Dr Claire Burt
5. Training: Mr David McKenzie

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

4.1.2. Management responsibility

4.1.2.1. Management commitment

The H&I laboratory is committed to the development and implementation of the QMS and to continual improvement of its effectiveness 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). See section 4.15.1
- establishing *quality objectives* - these objectives and plans are reviewed and updated at Quarterly Management Review (QMR) meetings
- defining responsibilities, authorities and interrelationships of all personnel as detailed within this document and within job descriptions available on Q-Pulse
- establishing communication processes as described in section 4.1.2.6
- employing a person as designated Quality Manager
- performing a QMR see *Management Quarterly Review Agenda (*QDH&I238) and *Management Quarterly Review Report* (QDH&I239)
- performing an AMR within one of the four QMR, which is reported on Q-Pulse (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 *Laboratory training policy* (LPTR001) and *Training programme for the IBMS Specialist Diploma* (LPTR002).

Management ensures adequate resources are available by:

- the careful selection, induction and training of appropriately qualified staff. NHS GG&C recruitment documents and policies can be accessed on https://www.nhsggc.org.uk/working-with-us/hr-connect/recruitment-service/
- providing equipment and consumables that are procured and maintained using Abbott's Reagent Management System, (RMS) and NHS "Pecos" request systems. Associated procedures include *Guidelines for selection and validation /verification of examination procedures* (QDH&I028) and *Laboratory Ordering and Stock management system* (LPRA048).
- 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.

4.1.2.2. Needs of users

The needs and requirements of users 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 (see section 4.1.2.6). 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 Q-Pulse (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 Quarterly Review Reports (QDH&I239)

The User Manual (QDH&I014) provides users and interested parties 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 2).

4.1.2.3. Quality policy

The H & I laboratory quality policy (QDH&I002) details the intent of its quality management system. The quality policy is reviewed within the QMR.

The quality policy is displayed on the laboratory notice board and is available on Q-Pulse.

4.1.2.4. Quality objectives and planning

The laboratory director, deputy director, laboratory manager, quality manager and team managers form the H&I laboratory management group (LMG) which defines the quality objectives of the laboratory and how they are to be measured. The LMG is responsible for ensuring that plans are made to meet these objectives (Quality Policy QDH&I002). Quality objectives are planned and reviewed at QMR meetings with an overarching AMR. Reports of the QMR and AMR are stored on Q-Pulse.

Each member of staff has a job description that sets out the roles, responsibilities, accountability and states terms and conditions of employment. All job descriptions are located within Q-Pulse.

4.1.2.5. Responsibility, authority and interrelationships

The Histocompatibility and Immunogenetics Service is within the Laboratory Medicine division of the Diagnostics Directorate of the Greater Glasgow and Clyde NHS Board (Figure 1).

Current H&I staff are listed in Table 1 and the current organogram is depicted (Figure 2).

Figure 1

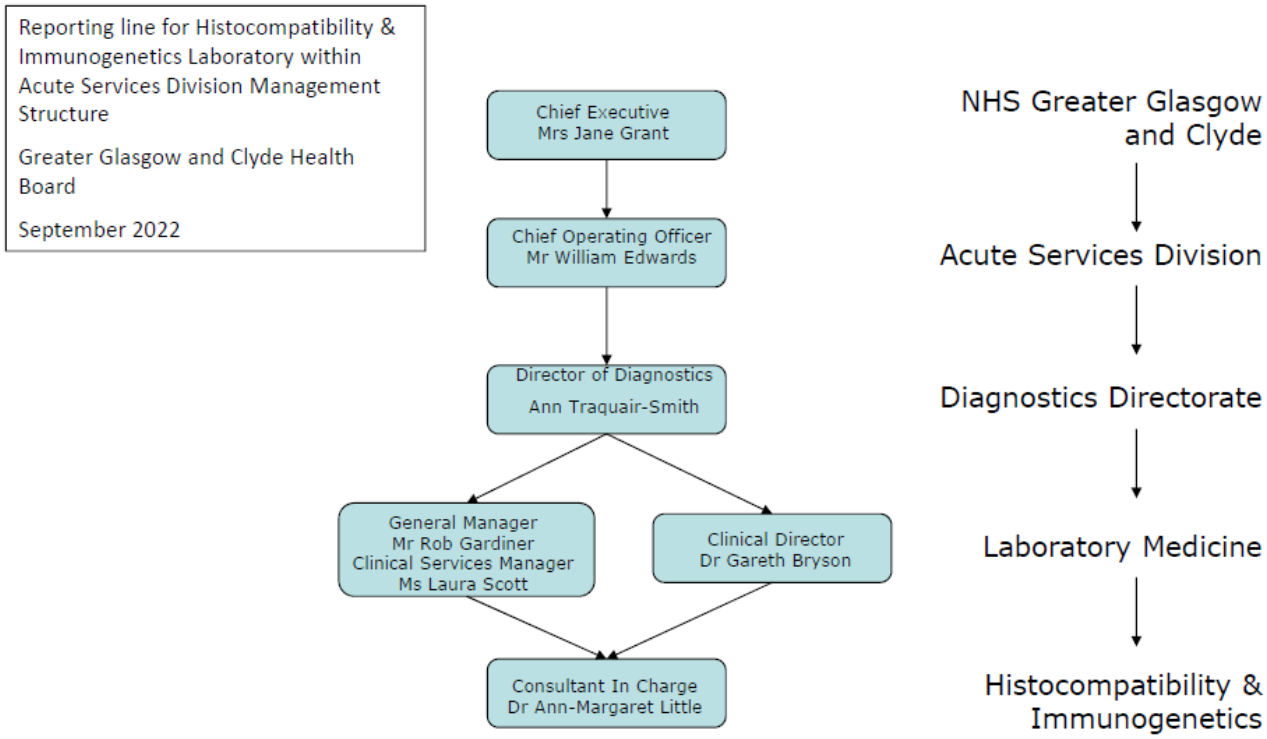


Figure 2

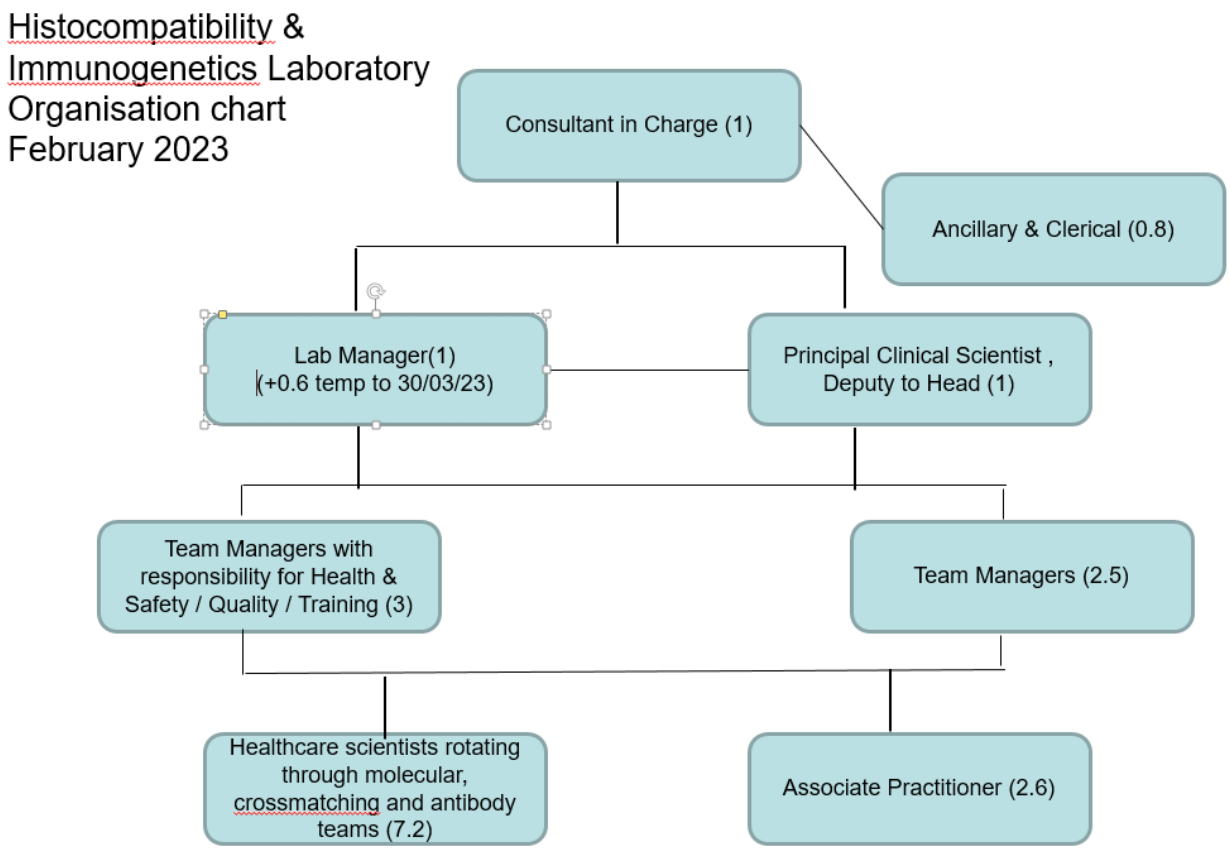

Histocompatibility & Immunogenetics Laboratory Organisation chart February 2023
Consultant in Charge (1)
Ancillary & Clerical (0.8)
Lab Manager(1) (+0.6 temp to 30/03/23)
Principal Clinical Scientist , Deputy to Head (1)
Team Managers with responsibility for Health & Safety / Quality / Training (3)
Team Managers (2.5)
Healthcare scientists rotating through molecular, crossmatching and antibody teams (7.2)
Associate Practitioner (2.6)

Table 1

Laboratory Head	Ann-Margaret Little, BSc, PhD, FRCPath,
Principal Clinical Scientist (Deputy to Head)	Catherine Hastie, BSc, BSHI Dip, FRCPath
Laboratory Manager	Ashleigh Lindsay, BSc, MSc Helen McFarlane, FIBMS, BSHI Dip (until March 30th 2023)
Quality /Team Manager	Alayna McDade, BSc, PhD
Deputy Quality Manager/Team Manager	Angela Richardson, BSc, MSc
Training Manger/Team Manager	David McKenzie, BSc, MSc, BSHI Dip
Deputy Training Manager/Team Manager	Vacant
Health & Safety Manager/Team Manager	Claire Walker, BSc, PhD, BSHI Dip, DipRCPath
Team Managers	Andrew Blair, BSc, MSc Stacey Malone, FIBMS, BSc, MSc Michelle Thomson, BSc, MSc
Healthcare Scientists	Claire Baird, BSc, PhD Laura Barr, BSc Bill Christie, BSc CJ Dick, BSc Katy Harrison, BSc Caitlin McColl, BSc Elaine Paterson, BSc Diane Young, HNC
Associate Practitioners	Alistair Houston

	Nicola Immel Patricia Rigmond
Laboratory Administrator	Joan Hagen

The laboratory has 3 technical areas:

- Molecular typing
- Antibody detection and identification
- Crossmatching

4.1.2.6. Communication

To convey and allow the dissemination of information between all staff, regular formal and informal meetings are held as indicated below:

- NHS GG&C Management Meeting (monthly)
  Chair: Head of Haematology Service
  Representative: Head of H&I Laboratory (or lab manager /deputy)
  Remit: All aspects of laboratory management relating to the haematology and H&I services. The meeting is attended by the General Manager, Assistant General Manager, Clinical Director, Technical Services Managers (Haematology), Lab Managers (Haematology), Consultant Clinical Scientists (H&I, Haematology-oncology), Finance Manager, IT Manager, Human Resources Manager, Clinical Leads (Haematology), staff side representative.

- H&I laboratory staff meetings (minimum six times per year)
  Chair: Head of H&I Laboratory or deputy or Laboratory Manager
  Representatives: All laboratory and administrative staff
  Remit: On-going technical, staffing and equipment issues including H&S, Quality Management, Training, Activity. There is an opportunity for all staff to raise any issues regarding the workplace.

- QMR meetings (every three months and incorporating the AMR for the first meeting of the financial year)
  Chair: Head of H&I Laboratory
  Representatives: LMG: Head of H&I Lab, Deputy Head, Lab Manager, Team Managers (including Quality, Training and H&S Leads)
  Remit: To review quality objectives and activities.

- LMG meetings (as and when required)
  Chair: Head of H&I Laboratory or deputy or Laboratory Manager
  Representatives: Head of H&I Lab, Deputy Head, Lab Manager, Team Managers (including Quality, Training and H&S Leads)
  Remit: To discuss in detail any matter arising that impacts on the delivery of the service that has not been covered within the full lab meeting or the QMR.

- Educational and training meetings
  Organised by the Training Manager; usually scheduled every two months.

<u>Clinical meetings with H&I Representation</u>

- Adult Renal Transplant MDT Meetings (monthly- H&I attendance is scheduled as required)
  Attendees: Transplant surgeons, nephrologists, transplant coordinators
  Representative: Head of H&I Laboratory (or deputy)

Remit: Discussion of individual transplant patient cases

- Adult Renal Transplant List Review Meeting (as required, electronic or face to face)
  Attendees: Transplant coordinators
  Representative: Manager of H&I Laboratory
  Remit: Discussion of patients to be added to the transplant list

- Paediatric Renal Transplant MDT Meeting (monthly)
  Attendees: Transplant surgeons, nephrologists, transplant coordinators, other support staff
  Representative: Head of H&I Laboratory (or deputy) as required
  Remit: Discussion of individual transplant patient cases

- Adult HPCT Planning Meeting (weekly)
  Attendees: Haematology Transplant Consultants, Apheresis Unit Consultant, Stem Cell processing CCS, Transplant Coordinators, Data Managers, other transplant unit support staff
  Representative: Head of Laboratory, Deputy Head, Laboratory Manager, Team Manager on rotation
  Remit: Update on new patients referred, family searches, volunteer unrelated donor searches, potential matching and mismatching donors

- Paediatric HPCT Planning Meeting (weekly)
  Members: Paediatric transplant consultants, transplant coordinators, Data Managers, other transplant unit staff
  Representative: Head of H&I Laboratory (or deputy)
  Remit: Update on new patients referred, family searches, volunteer unrelated donor searches, potential matching and mismatching donors.

- Scottish National Advanced Heart Failure Service MDT meeting (weekly, attendance by invitation)
  Members: Cardiac transplant team surgeons, cardiologists, nursing and other support staff
  Representative: Head of H&I Laboratory (or deputy) as required
  Remit: Update on all cardiac patients being considered for transplantation and those being treated post-transplant

<u>Quality meetings</u>

- Quality Management and Compliance Meetings (QMC group) every two months or more often as required.

  Members: Quality Managers from Laboratory Medicine

  Representative: H&I Quality Manager or Deputy

4.1.2.7. Quality Manager

The Quality Manager reports to the LMG to ensure that the proper quality management procedures are followed.

The Quality Manager has responsibility for overseeing the implementation, maintenance and performance of the QMS and identifying need for improvement. The Quality Manager is responsible for reviewing complaints, incidents and audit outcomes. Continual quality improvement is driven by user requests, staff suggestions, service development, lean process analysis and in response to non-conformities.

4.2. Quality Management System

4.2.1. General requirements

This laboratory maintains a quality management system in accordance with the ISO 15189:2012 standards. The QMS is subject to on-going review, continuous quality improvement and modification.

4.2.2. Documentation requirements

4.2.2.1. General requirements

The processes for operation of a QMS are outlined in this Quality Manual. Evidence to support establishment of a QMS include the Quality Manual, the Quality Policy, the appointment of a Quality Manager, and the implementation of a QMS driven and managed by Q-Pulse software. Q-Pulse software acts as the central hub for all QMS documentation.
The scope of the QMS encompasses all controllable events occurring before, during and after the examination process. External documents including standards relating to the H&I service provided are also managed within Q-Pulse.

Records of internal audits are held electronically in Q-Pulse and include audits performed, non-conformities identified, recommendations and timescale for corrective and preventative actions and monitoring of the effectiveness of intervention.

4.2.2.2. Quality Manual

The Quality Manual (QDH&I001) describes the quality policy, QMS, 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 Q-Pulse for acknowledgement.

4.3. Document control

All documents are controlled within an electronic document management system, Q-Pulse (Ideagen). The Quality Manager is responsible for coordinating and enforcing the document control activities in accordance with procedure [(QDH&I015]].
Documents conform to ISO 15189 and EFI standards with title, unique identifier, date, revision number, page number and authorisation recorded. Only current revisions are available via Q-Pulse

with obsolete documents archived. Documents are colour coded as indicated in Figure 3 to allow easy identification and help prevent unauthorised photocopying. Documents are reviewed at a minimum of every two years. All procedures and policies are approved by the laboratory director or deputy. All managerial and health and safety documents are approved by the laboratory manager. Documents such as laboratory instructions, notices and guides are approved by team managers.

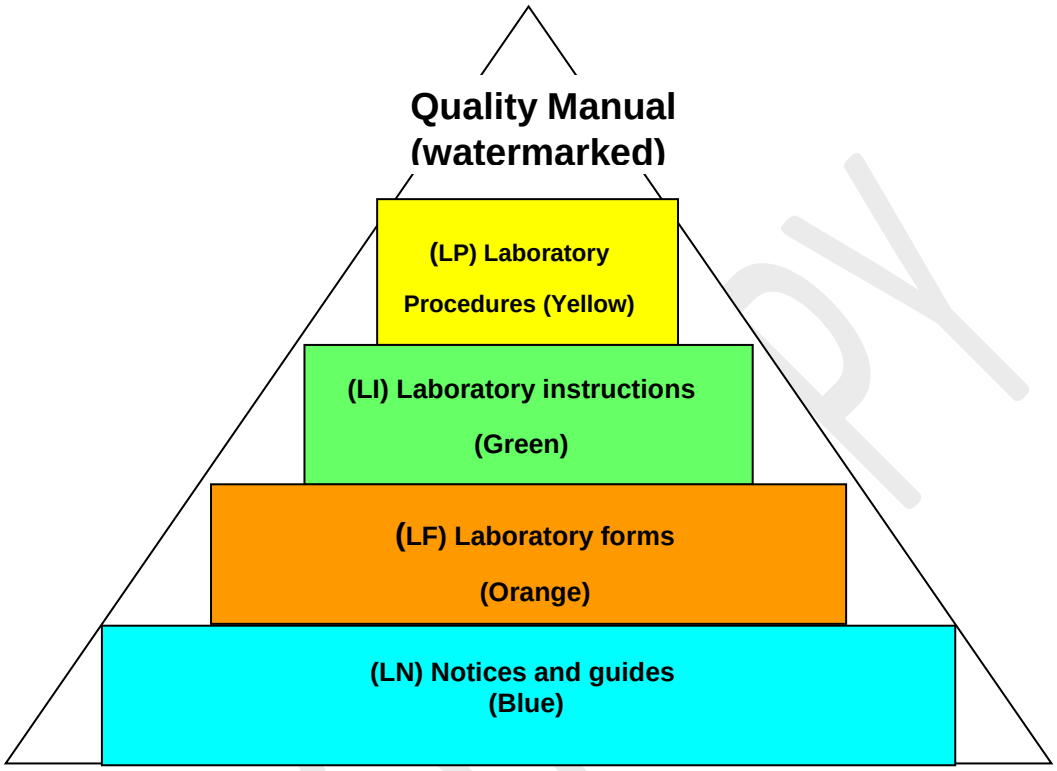


Figure 3: Document hierarchy and A4 paper colour. Non-colour coded documents are watermarked

4.4. Service Agreements

4.4.1. Establishment of service agreements

Service level agreements are maintained by NHS GGC Diagnostics management. The provision of appropriate testing, skills and expertise for these services is ensured via accreditation with the United Kingdom Accreditation Service (UKAS) and EFI and by participation in relevant national external quality assessment schemes (e.g. NEQAS).

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

4.4.2. Review of service agreements

When an agreement needs to be amended after laboratory services have commenced, the same agreement review process shall be repeated and any amendments shall be communicated to all affected parties and stakeholders (QDH&I259).

4.5. Examination by referral laboratories

The laboratory does not select and evaluate referral laboratories but will forward samples as requested by the end users. 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. Occasionally samples for testing in the NHS SNBTS East of Scotland H&I for pancreas transplant are forwarded. The procedure is documented in *Dispatch of specimens to other laboratories* (LPXM053).

4.5.1. Selecting and evaluating referral laboratories and consultants

A one in four on-call Consultant 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.

4.5.2. Provision of examination results

The laboratory reports examination results to the referring professional. There are SOPs to ensure all essential elements are reported in an unambiguous fashion with authorship of comments documented for example: *Preparing reports for solid organ patients and donors (LPRA001), Reporting disease association results* (LPRA012) and *Reporting HLA typing results for HPC patients and potential donors* (LPRA038).

4.6. External services and supplies

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 *Guidelines for selection and validation of examination procedures* (QDH&I028), *Laboratory ordering and stock management system* (LPRA048) 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 Managed Service Contract, 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 Managed Service Contract (MSC) using the Reagent Management System (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 Assistant General Manager) as described in *Laboratory Ordering and Stock Management System* (LPRA048).

4.7. Advisory services

The laboratory communicates with users via regular meetings (see section 4.1.2.6). This includes providing advice on:

- individual clinical cases (provided by the Consultant/Principal Clinical Scientist)
- provision of professional judgments on the interpretation of results generated,
- promotion of the effective use of laboratory services
- consultation on scientific or logistical matters e.g. failure of samples to meet minimum criteria

The effectiveness of the laboratory's communication with users is measured by user feedback, the outcome of which is reviewed at the QMR.

4.8. Resolution of complaints

Complaints are thoroughly investigated and corrective action taken as necessary. The Quality Manager is responsible for reviewing complaints, reporting to the Director and Laboratory Manager and recording the complaint process in Q-Pulse; this is detailed in *Identification and Control of Non-conformities* (QDH&I116) and *NHS GG&C Complaints procedure* (QDH&I170).
These procedures ensure that:

- all complaints are taken seriously
- the client is dealt with in a courteous manner
- every effort is made to resolve the issue immediately at a local level
- the client is kept informed about the progress of the complaint
- corrective action is taken as soon as possible
- root cause analysis is performed to prevent recurrence

4.9. Identification and control of non-conformities

Procedure *Use of Q-Pulse software* (QDH&I022) and *Identification and control of non-conformities* (QDH&I116) describe the action to be taken when a non-conformity is identified in any aspect of the pre-examination, examination or post-examination processes. This procedure ensures that:

- the responsibilities and authorities for the handling of the non-conformities are designated
- the immediate actions to be taken are defined
- the extent of the non-conformity is determined
- examinations are halted and reports withheld (as necessary)
- the medical significance of any non-conforming examinations is considered and where appropriate the user (e.g. requesting clinician) is informed
- the results of any non-conforming examinations already released are recalled or appropriately identified
- the responsibility for authorisation for the resumption of examinations is defined

- each episode of non-conformity is documented and recorded, with these records being reviewed at regular specified intervals by the laboratory management
- all incidents that affect the care of a patient or Health and Safety of staff are reported on DATIX. These include, but are not limited to, incidents related to building faults, contact with or exposure to hazardous substances, environmental hazards, fire alarm activations, injury by animals, moving & handling, needle stick/sharps, radiation exposure, slips, trips and falls, security and violence or aggression. DATIX is the software used by NHS Greater Glasgow and Clyde for clinical and non-clinical incident reporting, managing complaints and legal claims. Datix*Web* is the web-based application that allows any staff member to report an incident. DATIX is accessed from the staff intranet under 'applications'. All members of staff can report via DATIX with guidance provided in Data Incident Form 1 Manual Risk Management Information System (EXTREFDOC57)

4.10. Corrective action

The laboratory and staff investigate and, where possible, remove the root cause of non-conformities following Identification *and control of non-conformities* (QDH&I116). Removing the root cause of a problem is true corrective action (i.e. preventing recurrence). Corrective action for the identification and elimination of the causes of non-conformities are recorded and escalated via Q-Pulse. This ensures investigation of non-conformities, evaluation of the need for corrective action, implementation of corrective action within an agreed timescale, recording corrective action taken and monitoring its effectiveness.

4.11. Preventive action

The laboratory aims to identify potential non-conformities and to take preventive action to reduce non-conformities. This includes determining the root cause of potential non-conformities, assessing the need for preventive action, implementing preventive action within an agreed timescale, recording the results and reviewing the effectiveness of the preventive action taken.
QDH&I243 *Preventive Action* outlines the laboratory's compliance with UKAS publication (EXTREFDOC18) *Medical Laboratories – Requirements for quality and competence (ISO 15189:2012) 4.11 Preventive Action*

4.12. Continual improvement

The laboratory management ensures participation in continual quality improvement and assesses the laboratory's performance at quarterly and annual management reviews. Quality improvement includes the implementation of corrective action and preventive action as well as addressing issues highlighted in the analysis of performance indicators. The effectiveness of all action taken is reviewed. Participation in the quality improvement programme forms part of the development, training and education of all staff. Internal audit of the QMS and examination processes (QDH&I034), participation in external quality assessment and identification and control of non-conformities and potential non-conformities (QDH&I116) form part of the continual quality improvement process.

4.13. Control of records

The procedure for records generated during, before, and after examinations is controlled and defined in QDH&I015. Controlled records and storage arrangements are listed in QDH&I109. The retention time for these records is based on the Report of the Working Party of the Royal College of Pathologists and the Institute of Biomedical Science *The Retention and Storage of Pathological Records and Specimens.*5th Edition April 2015(QDH&I075).

4.14. Evaluation and audits

4.14.1. 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 audits of the QMS itself. Documentation to aid this process includes: *Yearly audit planner* (QDH&I103), *Internal Audit* (QDH&I034), *Examination Audit of Competency* (LFTR10), *Performance Review by Year* (QDH&I152) and Quarterly Management Review records (QDH&I239).

4.14.2. Periodic review of requests, suitability of procedures and sample requirements

The examinations provided by the laboratory and the suitability of samples are reviewed during the QMR and in response to user requests.

4.14.3. Assessment of user feedback

User feedback is assessed as described in section 4.1.2.2 Needs of users

4.14.4. Staff suggestions

Staff are encouraged to make suggestions at monthly staff meetings, during training, audit or reviewing of SOPs and procedures. Staff are also invited to make suggestions via Q-Pulse. 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

4.14.5. Internal audit

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 (as described in section 4.9) 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 Q-Pulse.

4.14.6. Risk management

All processes undergo a health and safety risk assessment, and these are managed within Q-Pulse. *QDH&I247 Risk and Incident Management* describes the processes undertaken for the identification and management of risks (and incidents) within the H&I laboratory. NHS GG&C's policy on the use of a risk register is described within -*EXTREFDOC74 Risk Register Policy and Guidance.*

4.14.7. Quality indicators

Key Performance Indicators (KPI) are established and reviewed at the AMR meetings and reviewed at the QMR. The outcomes are reported in the QMR report (QDH&I239) and the AMR report (QDH&I256).

4.14.8. Reviews by external organisations

The H&I laboratory participates in External Proficiency Testing (EPT) Schemes via the National External Quality Assurance Scheme (NEQAS). All results are communicated to staff via monthly staff meetings. When non-conformities are identified, they are investigated; corrective action is taken and reported via the laboratory staff meeting (QDH&I137).

4.15. Management review

4.15.1. General

The LMG conducts a quarterly review of the QMS "Management Quarterly Review" (Agenda QDH&I238 and Report QDH&I 239). This encompasses a review of the quality objectives set for the current year, the internal audits of the QMS and examination processes, EPT reports and the status of non-conformities.

4.15.2. Review input

This encompasses all included in sections 4.6, 4.8, 4.9, 4.11, 4.12, 4.14.2, 4.14.3, 4.14.4, 4.14.5, 4.14.6, 4.14.7, 4.14.8, 5.6.3.

4.15.3. Review activities

The review of non-conformities, trends and patterns that indicate process problems is described in 4.15.1.

4.15.4. Review output

The reports of the QMR and AMR are recorded and stored electronically; this includes key objectives for the subsequent year and plans for their implementation. These reports are disseminated to laboratory staff via Q-Pulse and key findings reported at full lab meetings.

5. Technical requirements

5.1. Personnel

5.1.1. General

The organisation adheres to NHSGG&C personnel policies. Departmental personnel management is detailed in covered under *Laboratory Personnel Management* (LPRA014).

5.1.2. Personnel qualifications

Each position within the department has a job description and a job profile that indicates the minimum qualifications required for the post. All Biomedical Scientists and Clinical Scientists are registered every two years with the HCPC. Qualifications and competencies obtained are recorded within training records.

5.1.3. Job descriptions

Job descriptions describe the responsibilities, authorities and tasks for personnel and are located for each grade in Q-Pulse.

5.1.4. Personnel introduction to the organisational environment

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 *H&I Departmental Induction Checklist* **(**LFTR14).

All new staff undertake an orientation and induction programme described within SOP *Laboratory Personnel Management* (LPRA014). Records of laboratory induction are retained by the Laboratory Manager/Training Manager. This programme covers conditions of employment, staff facilities, health and safety and occupational health services.

5.1.5. Training

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 Q-Pulse. The effectiveness of the training programme is audited annually and recorded in Q-Pulse. Training covers:

- QMS
- Laboratory work processes
- Manzen (laboratory information management system)
- 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)

5.1.6. Competence assessment

Competence is assessed at least annually as described within the laboratory training policy (LPTR001).

Competence is 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 EQA testing of samples

Competency monitoring forms are located on Q-Pulse.

5.1.7. Reviews of staff performance

All staff must participate in an annual personal development plan (PDP). This review is part of a continual process of planning, monitoring, assessing and supporting individuals to develop their capabilities and potential to fulfil their job role and job purpose. Service objectives and personal development objectives are discussed and reviewed in the context of the current NHS GG&C PDP programme. The PDP involves consideration of:

- the service objectives and plans of the laboratory
- current job description and duties
- duties and development of individual role
- training needs and personal objectives (documented electronically in GG&C PDP software)
- evidence of individual action if agreed personal objectives are not met
- evidence that management has recognised the agreed development needs of individuals

The PDP is carried out in accordance with *NHS GG&C policy* (LPRA014). All staff performing NHS GG&C PDP reviews have completed the formal training course provided by the NHS.

5.1.8. Continuing education and professional development

All staff maintain personal records of their continued professional development (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.

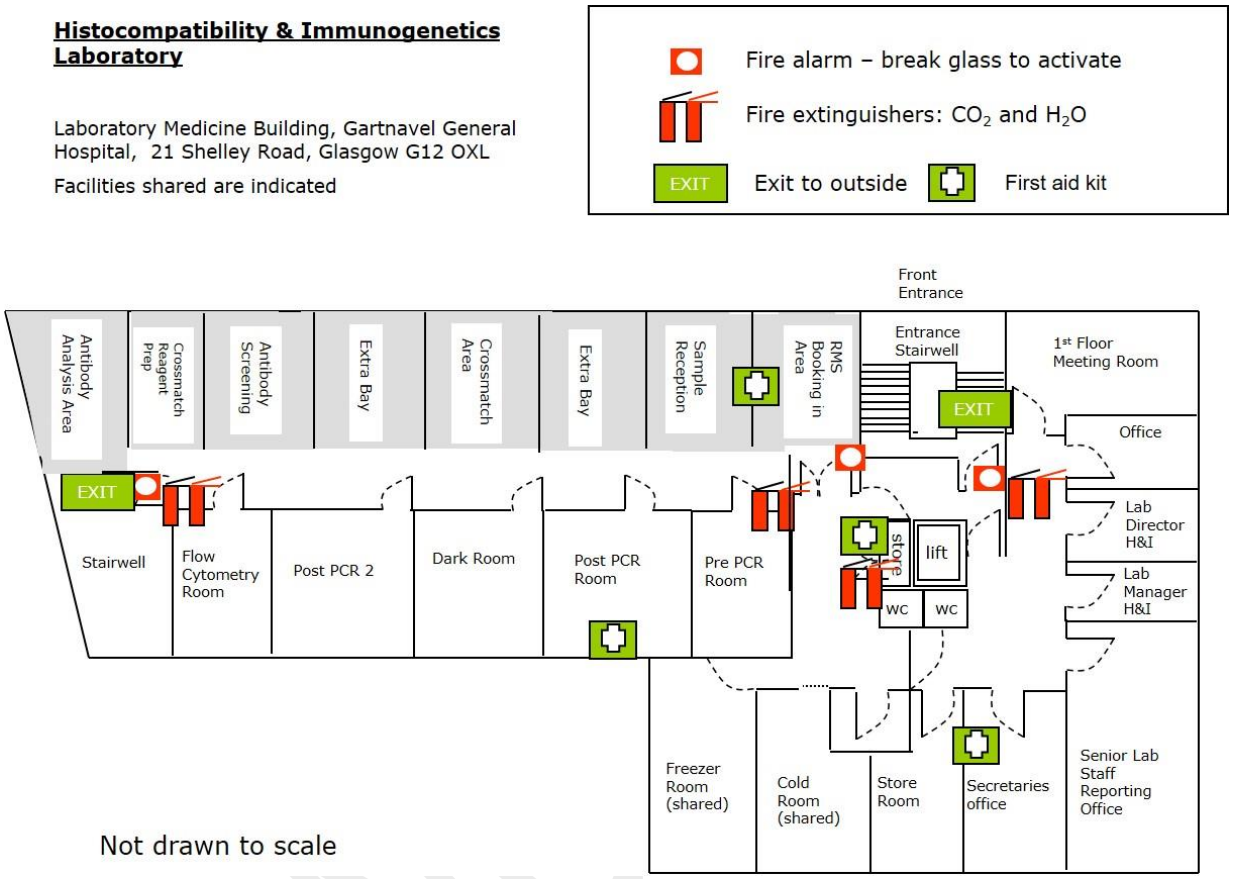
5.1.9. Personnel records

Staff records are held in a locked file within the Laboratory Manager's and Head of laboratory's office. The content of the staff records is described in LPRA014 *Laboratory Personnel Management*.

5.2. Accommodation & environmental conditions

The H&I laboratory is located on level 1 of the Laboratory Medicine Building within the grounds of Gartnavel General Hospital, see Figure 4 below:

Figure 4



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 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)

The main 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 key fob is individually numbered and allocated. Cards are inactivated if lost or stolen.

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

5.2.1. General

The current facilities allow appropriate use of equipment, safe and efficient processing of specimens, physical separation of office and laboratory activities and appropriate storage.

5.2.2. Laboratory and office facilities

See figure 4 above

5.2.3. Storage facilities

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

5.2.4. Staff facilities

All staff have access to washrooms, basic catering facilities, drinking water, changing areas with secure storage for personal effects, shower facilities, reclining chairs (for use by "out of hours" staff) and personal protective equipment including gloves, goggles, laboratory coats and low temperature handling equipment (insular gloves, face shield).

5.2.5. Patient sample collection facilities

Not applicable

5.2.6. Facility maintenance and environmental conditions

The building and its infrastructure is maintained by NHS GG&C Estates 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

Environmental conditions e.g. temperature are recorded on worksheets specific to examination processes and monitored using a temperature monitoring system. See QDH&I201 *Management of Temperature Control*

The laboratory sections are separated to prevent cross contamination e.g. pre and post-PCR rooms (Figure 4). There are quiet areas to facilitate an uninterrupted working environment.

5.3. Laboratory equipment, reagents, and consumables

5.3.1. Equipment

5.3.1.1. 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.

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*
LIMOL073	*Instructions for Completion of Molecular GLP List*
AUD284	*Laboratory Equipment Audit*

5.3.1.2. Equipment acceptance testing

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 G*uidelines for selection and validation and verification of examination procedures* and the details of the validation are recorded in QFH&I008 *change control form.*

5.3.1.3. Equipment instructions for use

Only trained members of staff are permitted unsupervised access to equipment. SOPs for each piece of equipment are available in Q-Pulse. Equipment is serviced and maintained to ensure optimal performance and longevity as recommended by the supplier (LPRA005). Safety warnings are clearly indicated where applicable and a risk assessment completed for each process.

5.3.1.4. Equipment calibration and metrological traceability

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 Q-Pulse. Laboratory calibration processes use certified reference material where these are available.

5.3.1.5. Equipment maintenance and repair

Each piece of equipment is maintained and serviced with the frequency as outlined by the manufacturer. LPRA005 describes the program of preventive maintenance. Equipment found to be defective is labelled as such to prevent inadvertent use (QDH&I191).

Equipment for repair, service or decommission is decontaminated and a label attached to give assurances to service engineers. A blank decontamination certificate is stored in Q-Pulse as *Decontamination certificate* (QDH&I040). Equipment decontamination is described in *Disinfection / Decontamination Instruction* (LIMOL087).

Visiting engineers and repair staff must formally sign entry and read H&S guidelines. They are provided with protective equipment (PPE) as required.

After repair, equipment is verified prior to re-introduction to service (LPRA005).

5.3.1.6. Equipment adverse incident reporting

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

5.3.1.7. Equipment records

A record of all events with regards to purchase and equipment history is recorded and attainable from Q-Pulse. This data includes:

a) identity of equipment
b) manufacturers name model serial number
c) contact information for supplier of manufacturer
d) date of receiving and date of entering into service
e) location
f) condition when received (e.g. new reconditioned)
g) manufacturer's instructions
h) records that confirmed the equipment's initial acceptability for use when incorporated into laboratory
i) maintenance carried out and the schedule for PM
j) equipment performance records
k) record of faults (recorded as non-conformities on the equipment record) including a the date of contact and reference number for the logged call to request repair.

5.3.2. Reagents and consumables

5.3.2.1. General

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

Laboratory ordering and stock management system (LPRA048)

Molecular stock control and evaluation of kits and reagents (LPMOL046)

Antibody stock control and evaluation (LPAB065)

Titration testing of FACS conjugates (LPXM068)

Standardisation of rabbit complement (LPXM050)

Routine reagent preparation and QC (LPXM077)

Routine equipment / reagent maintenance and checklist (LPXM073)

FCXM reagent preparation, stock control and QC (LPXM089)

Laboratory Health & Safety Handbook (QDH&I003)

5.3.2.2. Reagents and consumables- reception and storage

The reception and storage of goods is undertaken according to the manufacturer's instructions and described in SOPs referenced above in 5.3.2.1

5.3.2.3. Reagents and consumables- Acceptance testing

Quality acceptance testing is performed for new lots and shipments of reagents and is described in the procedures referenced above in 5.3.2.1. A new record is created within the quality control section of the reagent record in the Q-Pulse equipment module according to QIH&I002.

5.3.2.4. 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 is possible to the end of the financial year and reported to NHS GG&C Finance Department.

5.3.2.5. 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.

5.3.2.6. Reagents and consumables- adverse incident reporting

If an adverse incident is attributable to a reagent or consumable, a report will be generated - see 5.3.2.7 below

5.3.2.7. Reagents and consumables- records

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

- identity of reagent consumable
- manufacturers name and batch or lot code
- contact information of supplier

- date of receipt, expiration, entry into service and removal from service (if applicable)
- condition when received
- manufacturer's instructions
- records that confirmed the reagent or consumable's initial acceptance for use
- date of preparation for use

A non-conformance is completed and recorded on Q-Pulse 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 is contacted. All communications must be attached to the non-conformance in Q-Pulse. The laboratory and quality managers must be copied into all correspondence and be immediately informed of identified incidents and supply issues.

5.4. Pre-examination processes

5.4.1. 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 the *H&I User Manual* (QDH&I014) see section 3.

5.4.2. Information for patients and users

This information is provided by the H&I User Manual (QDH&I014) – see section 3

5.4.3. Request form information

The *H&I Request Form* (QDH&I184) allows space for the inclusion of:

- patient identification (including a unique identifier)
- contact details of the requesting clinician including the destination for the report
- type of sample
- examinations requested
- relevant clinical information
- date and time of sample collection and receipt
- priority status

If request forms are incomplete or the incorrect form is used, the sender is contacted, and this is recorded within the patient / donor record on Manzen.

5.4.4. Primary sample collection and handling

5.4.4.1. General

Guidance for specimen collection, handling and transport is provided in the user manual (QDH&I014).

5.4.4.2. Instructions for pre-collection activities

These are provided in the user manual (QDH&I014).

5.4.4.3. Instructions for collection activities

These are provided in the user manual (QDH&I014).

5.4.5. Sample transportation

The *NHS GGC Transport and Disposal of Specimen Containers and Specimens Policy* (QDH&I097) 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.

This policy is subject to periodic audit to ensure:

- timely transportation of samples
- transportation at an acceptable temperature
- integrity of the sample and the safety of the carrier, public and laboratory staff

The following documents help ensure safe and efficient transport of samples to the laboratory out of normal working hours:

Form/Map to be attached to incoming deceased donor specimens (QDH&I139).

When the laboratory is responsible for the transport of specimens to other laboratories, the procedure *Dispatch of specimens to other laboratories* is followed (LPXM053).

5.4.6. Sample reception

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

- *Sample reception acceptance and rejection* (LPMOL091)
- *Booking in patient samples using Manzen Software* (LPMNZ02)
- *Sample processing guidelines for antibody testing* (LIAB002A)

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 laboratory information management system (Manzen). Samples requiring urgent attention e.g. deceased organ donor are prioritised.

5.4.7. Pre-examination handling, preparation and storage

Samples are managed as described in procedures listed in 5.4.6.

There is no time limit for additional or further examination procedures for DNA and serum extracted from primary samples and stored according to acceptable procedures.

5.5. Examination processes

5.5.1. Selection verification and validation of examination procedures

5.5.1.1. 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. The SOP describing validation/verification is: *Guidelines for selection and validation of examination procedures* (QDH&I028).

5.5.1.2. Verification of examination procedures

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.

5.5.1.3. Validation of examination procedures

Validations are required for non-standard methods**,** laboratory designed or developed methods**,** standard methods which are used outside their intended scope and validated methods which have been subsequently modified.

5.5.1.4. Measurement uncertainty of measured quantity values

QDH&I165: *Measurement uncertainty* provides information on variables within a process that can affect the measurement values. Any process-specific uncertainties are described within the individual process SOP.

5.5.2. Biological reference intervals or clinical decision values

Definitions for biological reference intervals or clinical decision values are included as part of each individual SOP e.g. those relevant to CDC crossmatching are addressed in LPXM086.

5.5.3. Documentation of examination procedures

Standard operating procedures (SOPs) for the conduct of all examinations are prepared according to *Guidelines for the preparation and control of Laboratory Documents* (QDH&I015). All SOPs are subject to document control and aim to comply with the standards set out in ISO 15189:2012.

Standard Operating Procedures are available at the location of use and/or electronically in Q-Pulse.

5.6. Ensuring quality of examination results

5.6.1. General

The laboratory ensures the quality of examinations by performing them under the conditions defined in the SOPs specific to the examination process.

5.6.2. Quality control

5.6.2.1. General

Commercial and in-house examinations include internal quality controls to verify the quality of the results.

5.6.2.2. Quality control materials

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 methods; CDC and 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.

5.6.2.3. Quality control data

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.

5.6.3. Inter-laboratory comparisons

5.6.3.1. Participation

This laboratory participates in the 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 *Procedure for EPT evaluation, registration, testing and reporting* (QDH&I193).
All EPT testing results are communicated to staff via laboratory staff meetings. Performance results are recorded in an audit (Q-Pulse) and unacceptable results are raised as an NC 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 Q-Pulse.

5.6.3.2. Alternative approaches

All examinations have UKAS accredited EPT schemes available for inter-laboratory comparison.

5.6.3.3. Analysis of inter laboratory comparison samples

QDH&I193 describes the registration, testing and data processing for EPT.

5.6.3.4. Evaluation of laboratory performance

Performance in EPT is presented at staff meetings. Where performance criteria are not fulfilled, corrective action is taken. This process is recorded in Q-Pulse. Overall performance is reviewed as part of the QMR.

5.6.4. Comparability of examination results

Comparability of examination results is established by comparing results for patient samples using different equipment and methods when appropriate. 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 practice.

5.7. Post-examination processes

5.7.1. Review of results

All post examination results are reviewed for acceptability by the tester who reviews control values, trends and equipment performance. The results are then checked and approved by a second member of staff prior to reporting. This process is described in the SOPs specific to the methodology.

5.7.2. Storage, retention& disposal of clinical samples

The laboratory has a documented procedure for the storage, retention and disposal of clinical samples and reports (QDH&I109).

5.8. Reporting of results

5.8.1. General

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

Preparing reports for solid organ patients and donors (LPRA001)

Reporting HLA typing results for HPC patients and potential donors (LPRA038)

Reporting HLA types to ODT for solid organ transplantation (LPRA006)

Reporting disease association results (LPRA012)

Reporting a B27 result (LPRA39)

5.8.2. Report Attributes

The report format includes scope for inclusion of comments regarding sample quality, sample suitability and interpretive comments. These are described within SOPs listed within 5.8.1.

5.8.3. Report content

The SOPs listed in 5.8.1 describe the content that is included within reports issued.

5.9. Release of results

5.9.1. General

Results are reviewed by authorised personnel prior to release as described in section 5.7 and 5.8. Any issues with the sample that have not been dealt with at the time of sample receipt are detailed in the report.

Procedure *Sending results by fax, email or telephone* (LPRA 013) describes processes for sending reports that are not issued in paper format.

All reported results adhere to current World Health Organisation (WHO) nomenclature.

5.9.2. Automated selection of reporting of results

The laboratory does not operate an automated selection and reporting facility.

5.9.3. Revised reports

The process for revision of a report is detailed in the reporting SOPs. The user is informed of the amendment made in an "amended report". This gives details of the patient or donor's identity and the date of the original result. 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.

5.10. Laboratory information management

5.10.1. General

The laboratory utilises an H&I specific LIMS called 'Manzen' developed by Tissue Typing Systems UK Ltd.

Management of Data and information (QDH&I110) describes how the laboratory ensures the confidentiality of patient information.

5.10.2. Authorities and responsibilities

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.

5.10.3. Information system management

Management of Data and information (QDH&I110) 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 Q-Pulse and forms specific to the software procedure. This is explained within the following examination procedures

Luminex software and data maintenance (antibodies) (LPAB057)

Management of HLA typing software and IMGT/HLA Database updates (LPMOL096)

Updating allele and typing databases in SCORE software (LPMOL098)

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

Appendix 1 **Quality Policy published separately**

The Quality Policy of the NHS Greater Glasgow & Clyde Histocompatibility and Immunogenetics Service, Glasgow (QDH&I002) revision 6

The H&I Laboratory is committed to providing its users with the highest quality and standard of 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, technical, scientific & clinical service in support of solid organ and haematopoietic stem cell transplantation and tests for a number of susceptibility genes as an aid to disease diagnosis
- operate a quality management system that will integrate and control the organisation, policies, procedures, processes and resources
- set quality objectives and plans in order to implement and maintain this Policy, whilst ensuring continual quality improvement
- ensure that all laboratory personnel are familiar with this policy, the Quality Manual and all relevant procedures
- commit to the health, safety and welfare of all staff and visitors
- uphold professional codes and values and commit to good professional practice and conduct

The Laboratory will implement and comply with standards set out by local, national and international regulatory bodies such as United Kingdom Accreditation Services 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
- auditing the needs of users; internal laboratory audits and external quality assessment as part of continual quality improvement
- disposal of waste material and reagents as outlined by local Hospital guidelines and in conformity with 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 on printed copy	Dr Ann Margaret Little (Head of Laboratory)
	Date