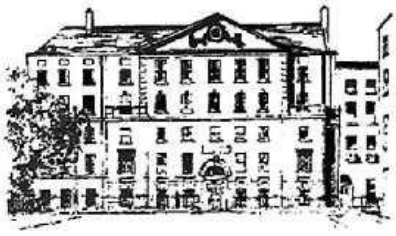


NATIONAL MATERNITY HOSPITAL
HOLLES STREET
DUBLIN 2

Department of Pathology and Laboratory Medicine

Quality Manual

0 Introduction

0.1 Purpose and Scope

The purpose of this document is to define the policies, practices and procedures that control the effective delivery of the services provided as it relates to the Department of Pathology and Laboratory Medicine, incorporating Haemovigilance, blood component traceability, infection control and surveillance.

0.1.1 Regulations and Standards

This document forms the organisation's response/approach to the requirements of the following regulations and standards:

1. The current version of the International Standard ISO 15189 titled "Medical Laboratories - Requirements for Quality and Competency".
2. EU Directive 2002/98/EC titled "Setting Standards of Quality and Safety for the Collection, Testing, Processing, Storage and Distribution of Human Blood and Blood Components" and amending directive 2001/83/EC.
3. EU Directive 2004/33/EC Annex IV titled "Storage, Transport and Distribution Conditions for Blood and Blood Components".
4. Statutory instrument 360 of 2005 which adapts the EU Directives as defined above into Irish law.
5. AML-BB current version titled "Minimum Requirements for Blood Transfusion Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC".
6. National Standards for the Prevention and Control of Healthcare Associated Infections in Acute Health Care Services 2018.
7. Infectious Disease (Amendment) (No. 2) Regulations 2024 (S.I. No. 528/2024).
8. In Vitro Diagnostic Medical Devices Regulations 2022 (S.I. No. 256/2022)
9. Health and Social Care Professionals Act 2005 (Amendment Act 2020).

Therefore, this manual incorporates within the ISO 15189 framework our top level response to meeting the minimum requirements as laid out in the AML-BB and the National Standards for the Prevention and Control of Healthcare Associated Infections documents as defined above.

0.2 Definitions

0.2.1 Quality Management System

Our quality management system (QMS) is based on the understanding that each individual is responsible for the quality of their contribution and that each supervisor and head of department has a responsibility to ensure that this policy is understood and followed at all times. In the event of conflict between this document and specific contracted requirements, then the latter shall take precedence.

0.2.2 Executive Management Team

The Master, Secretary-Manager, Director of Midwifery and Nursing, Clinical Director and Director of Finance.

0.2.3 Laboratory Management Team

Laboratory director, medical consultants and laboratory manager.

0.2.4 Quality Assurance Team

Laboratory director, medical consultants, laboratory manager, quality manager, haemovigilance officer, and medical scientists as required.

0.2.5 Quality Management Team

Quality manager, medical scientists with responsibility for the quality management system in each department, and Haemovigilance officer as required.

0.3 Organisation

The National Maternity Hospital (NMH), based in Holles Street, Dublin 2 has 182 beds and caters for >13,000 in-patient admissions, >4,500 day-case procedures, >13,000 emergency room attendances and >100,000 outpatient attendances per annum. The hospital encompasses the following main activities:

1. Obstetrics, including Fetal Medicine and Maternal Medicine
2. Gynaecology, including Cervical Check Colposcopy
3. Paediatrics, including neonatal intensive care
4. Anaesthesiology
5. Diagnostics including Laboratory medicine, Radiology and Genetics
6. Other support services including Perinatal mental health

0.3.1 Management Structure

The management structure of the NMH and its component departments (Organisational Chart) is outlined in appendix 6.2 of this document. The NMH comprises sub departments of Anatomical Pathology, Biochemistry, Microbiology, Haematology and Blood Transfusion. The NMH offers a 24-hour 7 days a week service in Biochemistry, Microbiology, Haematology and Blood Transfusion. Anatomical Pathology operates a 08.00-17.00 service Monday to Friday. Details of the service provided and contact details for key personnel are listed in the Primary Specimen Collection Manual (PP-CS-LM-4) and the Department of Pathology and Laboratory Medicine: Key Contacts (RF-CS-LM-23) document. Figure 1 gives a description of the services provided by the department. The services described here are designed to meet the needs and expectations of clinical personnel and patients.

Figure 1: Services of the Department of Pathology and Laboratory Medicine

Service Name	Service Description
Anatomic Pathology	The Anatomic Pathology laboratory deals with the gross and microscopic analysis of human tissue. Anatomic Pathology utilises various techniques to process tissue and demonstrate tissue components in normal and diseased states.
Blood Transfusion	The hospital Blood Bank provides routine and emergency group and compatibility testing for obstetric, gynaecological and paediatric patients. A blood grouping service is also offered to community GP practices to support the TOP programme. The blood bank laboratory provides a stock of manufactured blood products including solvent detergent plasma, albumin and Anti-D immunoglobulin. Service is provided for intrauterine transfusion. Cord bloods are assessed for Rhesus status and Anti-D immunoglobulin issued as appropriate.
Clinical Biochemistry	The Clinical Biochemistry laboratory provides routine and emergency biochemistry testing for obstetric, gynaecological and paediatric patients.
Haematology	The Haematology laboratory provides routine and emergency haematology testing for obstetric, gynaecological and paediatric patients.
Microbiology	The Microbiology laboratory provides routine and emergency microbial identification and susceptibility testing for obstetric, gynaecological and paediatric patients. They also provide this service for the Royal

Service Name	Service Description
	Victoria Eye and Ear Hospital (RVEEH). The service for the surveillance of infectious diseases is supported.
Consultant Service	Consultant services are available for Anatomic Pathology, Biochemistry, Blood Transfusion, Haematology and Microbiology. These services are available as required 24/7 via telephone.
Haemovigilance Service	All Haemovigilance incidents are documented and reported to the National Haemovigilance Office. The Blood Bank is committed in conjunction with the Haemovigilance officer to providing a reporting mechanism that assists the quality management review process. The Consultant Haematologist is responsible for the Haemovigilance/Traceability activity. A Hospital Transfusion Committee exists that includes the following: Hospital Master Consultant Haematologist Laboratory Manager Haemovigilance Officer Director of Paediatrics (or nominee) Director of Anaesthetics (or nominee) Director of Foetal Medicine (or nominee) Director of Nursing (or nominee) Chief/Senior Medical Scientist Blood Transfusion Clinical Risk Manager
Infection Prevention and Control Team	The Microbiology laboratory reports all significant isolates, and diagnoses from referral laboratories in accordance with the guidelines set down by Infectious Diseases (Amendment) Regulations 2020 S.I No. 53/2020. The surveillance scientist and infection prevention & control team also reports data to the Health Protection Surveillance Centre, European Antimicrobial Resistance Surveillance Network, Antenatal HIV Reporting, the British Paediatric Surveillance Unit, the HSE and other agencies, as required. The surveillance scientist in conjunction with the Consultant Microbiologist keeps a record of all infections reported in the laboratory. The hospital Infection Prevention & Control Team (ICT) includes the following: Consultant Microbiologist Surveillance Scientist Infection Control Midwife Specialist Antimicrobial Pharmacist The ICT reports to the multi-disciplinary infection prevention & control committee, chaired by the secretary/manager.

1 The Quality Policy of the Department of Pathology and Laboratory Medicine at the National Maternity Hospital

The Department of Pathology and Laboratory Medicine is committed to promoting and providing the highest quality diagnostic and consultative services for all its users. The department is committed to the implementation of the National Maternity Hospital mission statement.

The quality policy is implemented by the following means:

1. Implementation of a quality management system, the purpose of which is to review and continuously improve the quality of the services provided.
2. Setting quality objectives and plans to implement the quality policy and ensure it is appropriate to the purpose of the hospital.
3. Ensuring that all staff are familiar with the quality policy through publication of the quality manual to ensure user satisfaction.
4. Treating health and safety as a prime focus for both staff and visitors.
5. Upholding professional values and good professional practice.
6. Complying with all environmental legislation

The department will comply with the standards set by International standard ISO 15189, AML-BB, EU Directive 2002/98/EC, HIQA and INAB for the services and tests defined in the quality manual and is committed to:

1. Staff recruitment, training and development at all levels to provide an effective and efficient service to its users.
2. Providing and managing resources to ensure that laboratory examinations are processed to produce the highest quality results possible and fit for intended use.
3. Reporting results in ways, which are timely, confidential, accurate and are supported by clinical advice and interpretation when required.
4. Implementation of internal quality control, external quality assessment, audit and assessment of user satisfaction to continuously improve the quality of the service
5. The safe testing, distribution and transfusion of blood and blood components
6. Providing a service to its patients that is free from discrimination

Approved by:

_____ Date: _____/_____/_____
Dr Eoghan Mooney
Consultant Director

_____ Date: _____/_____/_____
Dr Susan Knowles
Consultant Director

_____ Date: _____/_____/_____
Dr Paul Downey
Consultant Director

_____ Date: _____/_____/_____
Mr Damian Lally
Laboratory Manager

2 Reference Documents

2.1 References Used

International Standard “ISO 15189” (current version) titled “Medical Laboratories – Requirements for Quality and Competence”.

2.1.1 Master Lists

Current master lists of controlled documentation are maintained electronically on Q-Pulse. These master lists constitute the department standard operating procedures, policies, guidelines, external books/guidelines/legislative documents and relevant and traceable standards, specifications and forms.

3 Q-Pulse

Q-Pulse® version 7.0.0.190 is a compliance management system and is in place at the NMH as an enterprise response tool for compliance with the QMS and ISO 15189 management requirements.

4 GENERAL REQUIREMENTS

4.1 Impartiality

Ethical Conduct

Laboratory Management ensure:

a) That there is no involvement in any activities that would diminish the confidence in the laboratory’s competence, impartiality, judgement or operational integrity.
b) That management and personnel are free for any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work.
c) That where potential conflicts in competing interests may exist, they shall be openly and appropriately declared.
d) That there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements. Staff are required to adhere to ethical guidelines pertinent to their regulated status.
e) That confidentiality of information is maintained. The hospital policies with regard to patient confidentiality are strictly adhered to. Each employee is contractually bound to desist from divulging any patient information. Any breaches of this policy will be fully investigated and appropriate censure will be taken.
f) That hospital procedures relating to The Data Protection Act 2018 are followed.
g) That all professionals adhere to the Code of Professional Conduct and Ethics set by their regulator.

The laboratory identifies risks to its impartiality on an on-going basis. A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new customers, etc.

If a risk to impartiality is identified, the laboratory mitigates such risks through defined procedures (PP-CS-LM-23 – Management of Risk in the Laboratory and MP-GEN-MQA – Management of Quality Assurance including Non-conformances and complaints) and ongoing evaluations (MP-GEN-AUDIT).

Impartiality is also managed by ensuring that the hospital's Confidentiality Policy, PP-HR-GEN-8, is signed as part of the contract of all new employees. The form RF-CS-LM-85, Ethical Conduct, is distributed to all staff annually.

4.2 Confidentiality

4.2.1 Management of Patient Information

This is achieved by ensuring that the hospital's Confidentiality Policy, PP-HR-GEN-8, is signed as part of the contract of all new employees. The form RF-CS-LM-85, Ethical Conduct, is distributed to all staff annually. The Laboratory Procedure Management of Data and Information, MP-GEN-DATAMAN, Section 2 also contains information on Patient Confidentiality and the Data Protection Act 2018. This document is read by all laboratory staff. See the department of pathology and laboratory medicine staff orientation and induction form, RF-CS-LM-45. Where research is being undertaken an application must be made to Pathology management who will consider if a full application for ethical approval is required. RF-CS-LM-45 also ensures that PP-CS-LM-2, Management of Research Studies: Specimens and Data, is read and acknowledged by all laboratory staff. The laboratory procedure on selection purchasing and management of equipment, MP-GEN-EQUIPMAN, outlines that it is the responsibility of all parties involved in procurement of the provision of services, to openly and appropriately declare where potential conflicts in competing interests may exist.

4.2.2 Release of Confidential Information

It is not routine for the laboratory to release confidential information on patients. There are occasions when the release of patient information into the public domain is required by law or authorised by contractual arrangements. Examples of this would be the National Cancer Control programme, the national Cancer Registry Ireland or surveillance information on infectious diseases.
Consent to release this information is achieved when the patient signs a GDPR form.
If information outside these scenarios is required to be released, the disclosure to patient's policy (PP-OG-GEN17) will be followed.

Notifiable Diseases:
List of Notifiable Diseases - Health Protection Surveillance Centre

NCRI
National Cancer Registry Ireland | Essential information on cancer in Ireland

NCC
National Cancer Control Programme - HSE.ie

4.2.3 Responsibility of Personnel with Confidential Information

Personnel, including any committee members, contractors, personnel of external bodies, or individuals with access to laboratory information acting on the laboratory's behalf, keep confidential all information obtained or created during the performance of laboratory activities. Confidentiality agreement (RF-CS-LM-85 Ethical Conduct) and non-staff confidentiality agreement (RF-CS-LM-194 – Non staff confidentiality agreement) are used to ensure this.

4.3 Considerations for Patients

Requirements regarding patients
Laboratory management ensures that patients' well-being, safety and rights are our primary considerations.
This is achieved though the following processes:

a) opportunities for patients and laboratory users to provide helpful information to aid the laboratory in the selection of the examination methods, and the interpretation of the examination results; - Bi annual user survey
b) provision of patients and users with publicly available information about the examination process, including costs when applicable, and when to expect results; PP-CS-LM-4
c) periodic review of the examinations offered by the laboratory to ensure they are clinically appropriate and necessary; PP-CS-LM-4
d) where appropriate, disclosure to patients, users and any other relevant persons, of incidents that resulted or could have resulted in patient harm, and records of actions taken to mitigate those harms; MP-GEN-MQA Open disclosure is included in hospital feedback management policy (PP-CS-QTY-6)
e) treatment of patients, samples, or remains, with due care and respect; PP-CS-LM-4
f) obtaining informed consent when required; PP-CS-GEN-3
g) ensuring the ongoing availability and integrity of retained patient samples and records in the event of the closure, acquisition or merger of the laboratory; MP-GEN-RECCON / MP-GEN-CLINCON
h) making relevant information available to a patient and any other health service provider at the request of the patient or the request of a healthcare provider acting on their behalf; LP-GEN-TELREP /PP-CS-LM-4
i) upholding the rights of patients to care that is free from discrimination. PP-CS-LM-1 – Quality policy

5 STRUCTURAL AND GOVERNANCE REQUIREMENTS

- Full name and address: Department of Pathology and Laboratory Medicine,
  - National Maternity Hospital, Holles Street, Dublin 2, D02 YH21.
- Telephone: 01 637 3531
- Fax: 01 676 5048
- Company Registration: 0052069G
- E-mail: dlally@nmh.ie
- **The laboratory is committed to performing its activities in accordance with the requirements of international standard ISO 15189 (current version). The scope of accreditation to ISO 15189 is controlled by INAB and displayed on their website** www.inab.ie**.**

5.1 Legality of the Laboratory

All activities are carried out in the permanent facility of the NMH. The legal entity is the National Maternity Hospital, Holles St, governed by the board of governors and is legally responsible for its activities. Company registration is 0052069G.

5.2 Laboratory Director

5.2.1 Laboratory Director Competence

For the purpose of International Standard ISO 15189, the term Laboratory Director refers to the current chairperson of the laboratory management team. This chair rotates between the consultant staff whose majority session commitment is to the National Maternity Hospital. The agreed term usually a minimum of 2-years and is reviewed annually and exceptions, if made, are minuted at the laboratory management meeting. See RF-CS-LM-23 for the current laboratory director.

The laboratory is thus directed by a person with the competence and delegated responsibility for the services provided. The responsibilities of the laboratory director are professional, scientific, consultative or advisory, organisational, administrative and educational matters relevant to the services offered by the laboratory.

5.2.2 Laboratory Director Responsibilities

The Laboratory Director (or designate/s):

a) Provides effective leadership of the laboratory service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities.
b) Relates and functions effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, and the patient population served, and providers of formal agreements, when required.
c) Ensures that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs and requirements of the users.
d) Ensures the implementation of the quality policy.
e) Implements a safe laboratory environment in compliance with good practice and applicable requirements.
f) Serves as a contributing member of the medical staff for those facilities served.
g) Ensures the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results.
h) Selects and monitors laboratory suppliers.
i) Selects referral laboratories and monitors the quality of their service.

j) Provides professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organizations.
k) Defines, implements and monitors standards of performance and quality improvement of the medical laboratory service.
l) Monitors all work performed in the laboratory to determine that clinically relevant information is being generated.
m) Addresses any complaint, request or suggestion from staff and/or users of laboratory services.
n) Designs and implements a contingency plan to ensure that essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable.
o) Plans and directs research and development, where appropriate.
p) Applies risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed

5.2.3 Delegation of Duties or Responsibilities

The Laboratory Director may delegate selected duties and/or responsibilities to qualified and competent personnel; and this will be documented. The Laboratory Director has the ultimate responsibility for the overall operation and administration of the laboratory. The Laboratory Director (or their designates for delegated duties) have the necessary competence, authority and resources in order to fulfil the requirements of ISO 15189.

There is a full team of clinical staff with consultants specialised in each disciple who are responsible for their own department. For any technical duties the laboratory manager is in place, for all QA duties the QM is responsible.

5.3 Laboratory Activities

5.3.1 Scope of Activities

The laboratory is committed to performing its activities in accordance with the requirements of international standard ISO 15189 (current version). The scope of accreditation to ISO 15189 is controlled by INAB and displayed on their website **www.inab.ie**.

Ref: PP-CS-LM-4 for laboratory activities which claim conformity with ISO 15189 2022

5.3.2 Conformance with Requirement

Laboratory activities are carried out in such a way as to meet the requirements of this ISO15189, the users, regulatory authorities and organizations providing recognition. This applies to the complete range of specified and documented laboratory activities, regardless of where the service is provided.

5.3.3 Advisory Activities

The NMH provides an extensive advisory service. The contact details for all Consultants and departments are listed in the Primary Specimen Collection Manual, PP-CS-LM-4. A list of key contacts, RF-CS-LM-23, is available on Q-Pulse which lists the consultants and their deputies. The results of all examinations are advice to clinical colleagues. Therefore, the written report is advice. In addition to this advice is offered at multidisciplinary meetings and Consultant rounds/clinics where cases are discussed. The department collaborates actively with clinical colleagues, contributing to sections of the Annual Clinical Report. The following is a list of the some of the advisory services offered by the department:

1. Advise on choice of examinations and use of the service.
2. Clinical indications and limitations of examination procedures.
3. Specimen type and examination turnaround times.
4. Appropriate biological reference ranges.
5. Frequency of requesting the examination.
6. Professional judgements on the interpretation of results of examinations.
7. Advising on individual clinical cases.

8. Promotion of the effective utilisation of laboratory services.
9. Consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria.
10. Education of clinical and ancillary staff in laboratory medicine and Haemovigilance matters.
11. Choice of blood and blood products.
12. Management of severe haemorrhage.

All advice offered by laboratory staff follows protocols agreed by the Consultant. The National Haemovigilance Office provides advisory services for Blood Transfusion and Haemovigilance. Meetings between representatives of laboratory staff and internal hospital clinical staff are held as outlined below. The purpose of such meetings is to ensure the best possible delivery of service. Minutes are held by the attendees as appropriate. Information from these meetings enables continual feedback to the laboratory and QMS.

Figure 2: Schedule of Meetings with Laboratory Involvement

Meeting	Attendance	Frequency
Maternal-Foetal medicine	Consultant and SpR Pathologists, Laboratory Manager, Medical Scientists.	Weekly
Neonatal	Consultant and SpR Microbiologist, Consultant Haematologist, Laboratory Manager	Weekly, as required
Gynaecology	Consultant and SpR Histopathologists, Laboratory Manager	Monthly
Clinico-Pathology Conference	Consultant and SpR Pathologists, Laboratory Manager, Medical Scientists.	Fortnightly
Perinatal Morbidity and Mortality	Consultant and SpR Pathologists, Laboratory Manager, Medical Scientists	Monthly
Medical Staff Meeting	Consultant Pathologists.	Monthly
Heads of Department	Laboratory Manager.	Monthly
Drugs & Therapeutics	Consultant and SpR Microbiologist	Quarterly
Clinical Incident Review Group	Director of Pathology, Laboratory Manager, Haemovigilance Officer.	As required if an NC requiring laboratory input is discussed.
Clinical Governance Executive	Consultant Histopathologist, Consultant Microbiologist	Monthly
Infection Prevention & Control	Consultant and SpR Microbiologist, Surveillance Scientist.	Quarterly
Transfusion Committee	Master, Consultant Haematologists, Consultant anaesthetist, Laboratory Manager, Chief / Senior Medical Scientists Blood Transfusion, Haemovigilance Officer.	Tri-annually
User Groups	Consultant Pathologists, Laboratory Manager, Users.	Scheduled
Quality Assurance	Consultant Pathologists, Laboratory Manager, Quality Officer, Haemovigilance Officer and Medical Scientists as required.	12 times per year/ As required
Head of Department, Lab	Laboratory Manager, Chief / Senior Medical Scientists	6 times per year
Laboratory Staff Meetings	All Laboratory Staff in each Department	As required

Meeting	Attendance	Frequency
QRH&S committee meeting	Laboratory Manager, Health and safety rep	Every 3 months
Sepsis	Consultant Microbiologist, Microbiology SpR	Quarterly

5.4 Organisational Structure

5.4.1 General

The management structure of the NMH and its component departments (Organisational Chart) is outlined in Appendix 2 of this document. The laboratory specifies the responsibility, authority, lines of communication and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities. It specifies its procedures to the extent necessary to ensure the consistent application of its laboratories activities and the validity of the results. The NMH comprises sub departments of Anatomical Pathology, Biochemistry, Microbiology, Haematology and Blood Transfusion. The NMH offers a 24 hour 7 days a week service in Biochemistry, Microbiology, Haematology and Blood Transfusion. Anatomical Pathology operates a 08.00-17.00 service Monday to Friday. Details of the service provided and contact details for key personnel are listed in the Primary Specimen Collection Manual (PP-CS-LM-4) and the Department of Pathology and Laboratory Medicine: Key Contacts (RF-CS-LM-23) document. Figure 1 gives a description of the services provided by the department. The services described here are designed to meet the needs and expectations of clinical personnel and patients.

Figure 3: Services of the Department of Pathology and Laboratory Medicine

Service Name	Service Description
Anatomic Pathology	The Anatomic Pathology laboratory deals with the gross and microscopic analysis of human tissue. Anatomic Pathology utilises various techniques to process tissue and demonstrate tissue components in normal and diseased states.
Blood Transfusion	The hospital Blood Bank provides routine and emergency group and compatibility testing for obstetric, gynaecological and paediatric patients. A blood grouping service is also offered to community GP practices to support the TOP programme. The blood bank laboratory provides a stock of manufactured blood products including solvent detergent plasma, albumin and Anti-D immunoglobulin. Service is provided for intrauterine transfusion. Cord bloods are assessed for Rhesus status and Anti-D immunoglobulin issued as appropriate.
Clinical Biochemistry	The Clinical Biochemistry laboratory provides routine and emergency biochemistry testing for obstetric, gynaecological and paediatric patients.
Haematology	The Haematology laboratory provides routine and emergency haematology testing for obstetric, gynaecological and paediatric patients.
Microbiology	The Microbiology laboratory provides routine and emergency microbial identification and susceptibility testing for obstetric, gynaecological and paediatric patients. They also provide this service for the Royal Victoria Eye and Ear Hospital (RVEEH). The service for the surveillance of infectious diseases is supported.
Consultant Service	Consultant services are available for Anatomic Pathology, Biochemistry, Blood Transfusion, Haematology and Microbiology. These services are available as required 24/7 via telephone.

Service Name	Service Description
Haemovigilance Service	All Haemovigilance incidents are documented and reported to the National Haemovigilance Office. The Blood Bank is committed in conjunction with the Haemovigilance officer to providing a reporting mechanism that assists the quality management review process. The Consultant Haematologist is responsible for the Haemovigilance/Traceability activity. A Hospital Transfusion Committee exists that includes the following: Hospital Master Consultant Haematologist Laboratory Manager Haemovigilance Officer Director of Pathology Director of Paediatrics (or nominee) Director of Anaesthetics (or nominee) Director of Foetal Medicine (or nominee) Director of Nursing (or nominee) Chief/Senior Medical Scientist Blood Transfusion Clinical Risk Manager
Infection Control Team	The Microbiology laboratory reports all significant isolates, and diagnoses from referral laboratories in accordance with the guidelines set down by Infectious Diseases (Amendment) Regulations 2020 S.I. No. 53/2020.The surveillance scientist and infection control team also reports data to the Health Protection Surveillance Centre, European Antimicrobial Resistance Surveillance Network, Antenatal HIV Reporting, the British Paediatric Surveillance Unit, the HSE and other agencies, as required. The surveillance scientist in conjunction with the Consultant Microbiologist keeps a record of all infections reported in the laboratory. The hospital Infection Control Team (ICT) includes the following: Consultant Microbiologist Surveillance Scientist Infection Control Midwife Specialist Antimicrobial Pharmacist The ICT reports to the multi-disciplinary infection control committee, chaired by the secretary/manager.

5.4.2 Quality Management

The laboratory has a quality management team, led by a quality manager, who, irrespective of other responsibilities, and whom in conjunction with departmental Chief Medical Scientists and appointed Departmental Quality Representatives, has the authority and resources needed to carry out their duties, including:

a) implementation, maintenance and improvement of the management system;
b) identification of deviations from the management system or from the procedures for performing laboratory activities;
c) initiation of actions to prevent or minimize such deviations;
d) reporting to laboratory management on the performance of the management system and any need for improvement;
e) ensuring the effectiveness of laboratory activities.

5.5 Objectives and Policies

For the purpose of ISO 15189 laboratory management have defined the intent of its QMS in a quality policy. Laboratory management shall ensure that the quality policy:

a) Is appropriate to the purpose of the organisation.
b) A statement on the laboratory's standard of service and ensuring tests are fit for intended use, to the purpose of the National Maternity Hospital. That they are in compliance with ISO 15189 and that a continual improvement of the quality of laboratory services is provided.
c) The objectives of the quality system.
d) A commitment to ensuring all personnel are familiar with and understand the organisations quality policies and objectives and implementing/ adhering to authorised procedures at all times.
e) Is reviewed for continued quality of its examinations and compliance with the quality management system.
f) The management's commitment to compliance with the International Standard ISO 15189, EU Directive 2002/98/EC, AML-BB, EU Directive 2002/98/EC, HIQA and INAB for the services and tests defined in this quality manual.

The quality policy provides a framework for establishing and reviewing quality objectives and is reviewed for continuing suitability.

Laboratory management have established quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the establishment. These quality objectives are measurable and consistent with the quality policy. Laboratory management ensures that planning of the QMS is carried out to meet the requirements and the quality objectives. Laboratory management ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. See procedure Management of Quality Assurance, MP-GEN-MQA), and Management of Quality Objectives, RF-CS-LM-150.

5.6 Risk Management

PP-CS-LM-23

a) Laboratory management establish, implement, and maintain processes for identifying risks of harm to patients and opportunities for improved patient care associated with its examinations and activities, and develop actions to address both risks and opportunities for improvement (see 8.5).
b) The laboratory director ensures that these processes are evaluated for effectiveness and modified, when identified as being ineffective.

6 RESOURCE REQUIREMENTS

6.1 General

The laboratory has available the personnel, facilities, equipment, reagents, consumables and support services necessary to manage and perform its activities.

6.1.1 Job Descriptions

Job descriptions that describe the responsibilities, authorities and tasks for all personnel are out lined using the template MF-GEN-JOBDES. Job descriptions for each post are held by the Human Resource Department and the post holder. The Laboratory Manager holds electronic copies of job descriptions on their computer.

6.1.2 Personnel Introduction to the Organisational Environment

It is the policy of the NMH that all new employees, temporary or permanent, should receive induction training. We recognise that new employees need help in settling into their new environment. There are two elements to our induction process: a general hospital corporate induction programme held on a regular basis, which all new staff must attend, and an individual departmental induction process given by the Chief/Senior Scientist or designated person. Details of this induction are recorded on the Department of Pathology and Laboratory Medicine Staff Orientation and Induction form, RF-CS-LM-45.

6.1.3 Training

The Laboratory provides training for all personnel. Training is provided to staff by the Senior Medical Scientists or their designated nominees. All scientists within the department are under the supervision of a trainer until deemed competent in accordance with the Management of Training procedure, MP-GEN-TRAIN. Training will include the following areas:

- The quality management system.
- Assigned work processes and procedures.
- The Winpath LIS.
- Health and Safety to include the prevention or containment of the effects of adverse incidents.
- Ethics.
- Confidentiality of patient information.

The effectiveness of this training programme is reviewed by competency and proficiency testing, annual review and trending of incidents.

6.2 Personnel

The organisational plan for the Department of Pathology and Laboratory Medicine is included in Appendix 6.3 titled “Organisational Chart”. The policy Personnel Management, MP-GEN-PERMAN, outlines all policies relating to personnel. Job descriptions define the qualifications for the post and the duties to be undertaken.

6.2.1 General

The laboratory has access to a sufficient number of competent persons to perform its activities.
All personnel of the laboratory either internal or external that could influence the laboratory’s activities act impartially, ethically, are competent and work in accordance with the laboratories management system.
The laboratory communicates to laboratory personnel the importance of meeting the needs and requirements of users as well as the requirements of ISO 15189.

The laboratory has a programme to introduce personnel to the organisation, the department or area in which the person will work, the terms and conditions of the employment, staff facilities, health and safety requirements and occupational health facilities.

MP-GEN-PERMAN provides a documented procedure for personnel management. Records are maintained for all personnel to indicate compliance with requirements.

6.2.2 Competence

The laboratory specifies the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, retraining, technical knowledge, skills and experience.

The laboratory ensures that all personnel have the competence to perform laboratory activities for which they are responsible. The laboratory has a process for managing competence of its personnel, which includes requirements for the frequency of competence assessment. The laboratory has documented information demonstrating competence of its personnel.

Following appropriate training, the laboratory assesses the competency of each person to perform assigned managerial or technical tasks. Competence of laboratory staff can be assessed by using any combination or all of the following approaches under the same conditions as the general working environment:

- Direct observation of routine work processes and procedures.
- 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.
- Examination of specially provided samples such as previously examined samples, or External Quality Assurance (EQA).
- Competency of staff in Haemovigilance activities is in the format of a questionnaire.

Retraining including proficiency assessment occurs as a corrective action following investigation of customer complaints or other non-conforming events. Retraining including proficiency assessment occurs every 18 months for staff performing emergency on-call duty.

Ref: MP-GEN-Train

6.2.3 Authorisations for Personnel

This is defined in PP-CS-LM-13 Roles and Responsibilities and MP-GEN-DATAMAN

6.2.4 Continuing Education

It is the policy of the Department of Pathology and Laboratory Medicine that staff take part in regular Continuing Professional Development (CPD). Specifically, the medical Consultants take part in regular professional development and participate in the Medical Council Programme for Continual Medical Development. The Medical Scientists register commenced on 31st March 2019. Medical Scientists comply with the CPD requirements as set down in the Code of Professional Conduct and Ethics. A continuing education programme is available to staff who participate in managerial and technical processes. This mandatory CPD programme has been developed by laboratory management and awards CPD points for various professional development activities. Each staff member is responsible for recording their CPD points on the CPD Tracker template, RF-CS-LM-95. Laboratory personnel are also encouraged to enrol in the CPD programme of the Academy of Clinical and Medical Laboratory Science. Haemovigilance Officers attend development programmes organised by the National Haemovigilance Office. Records of continuous education are documented and available for review by external regulatory or accreditation bodies. Records of CPD are reviewed during performance review. Staff are encouraged to be active participants in their professional and

academic bodies through participation in National and International Committees and lecturing to students.

6.2.5 Personnel Procedure

Records of relevant educational and professional qualifications, training and experience, and assessments of competence of all staff are maintained. These records are readily available to relevant personnel and include but are not limited to:

a) Educational and professional qualifications.
b) Copy of certification or license, when applicable.
c) Previous work experience.
d) Job descriptions.
e) Introduction of new staff to the laboratory environment.
f) Training in current job tasks.
g) Competency assessments.
h) Records of continuing education and achievements.
i) Reviews of staff performance.
j) Reports of accidents and exposure to occupational hazards.
k) Immunisation status, when relevant to assigned duties.

Some of the records listed above are not stored in the laboratory, but are in other specified locations e.g. Human Resources, Clinical Risk and Occupational Health Departments. These documents are accessible as required.

Medical staff must be on a specialist division or visiting EEA practitioner's division of the Register of Medical Practitioners. A certification or license is not required by the Laboratory Manager, Medical Scientists, Laboratory Aides or Administrative Staff in order to practice.

6.3 Facilities and Environmental Conditions

The laboratory operates so that its workload can be performed without compromising the quality of work, quality control procedures, and safety of personnel, patients and visitors. The Director of Pathology and Laboratory Manager ensure that the accommodation and environmental conditions in the laboratory, in areas of the hospital where primary specimen collection and Point of Care Testing (POCT) under the management of the laboratory is carried out are fit for their intended use and are maintained so as to continue to be functional and reliable.

6.3.1 Facility Maintenance and Environmental Conditions

The laboratory work areas are clean and well maintained at all times. This activity is performed in accordance with the hygiene standard requirements.

Environmental control is in place for fridges/freezers/incubators via continuous temperature monitoring so that they operate within defined specifications. The temperature is monitored by an automated system, Kelsius CoolCheck. This is a high security environmental monitoring system, which records temperature readings at the defined intervals under normal conditions and more frequently under alarm conditions. The system has a transaction log, which records details of when a problem occurred, who was notified and action taken. Critical areas/locations storing blood components have been temperature mapped and are re-qualified on an annual basis. Where the laboratory facilities and its environment do not meet stated or understood requirements, then such events are documented as internal service non-conformities.

The Kelsius system is serviced annually and there is a service contract with Kelsius CoolCheck. A service and maintenance log is kept. There is air conditioning in the Blood Sciences and

Microbiology laboratories. Down draft extraction is in place in Anatomical Pathology. Air monitoring is performed in Anatomical Pathology, records of which are kept in the Engineering and Health and Safety departments.

It is the policy of the laboratory to monitor, control and record environmental conditions as required. Where the data from such recording is out of specification then a non-conformity is completed and appropriate corrective and preventative actions taken.

Laboratory management provide a quiet and uninterrupted work environment where it is needed. In the Anatomical Pathology laboratory, there is a designated area for each Consultant Pathologist to carry out microscopy work

6.3.2 Facility Controls

6.3.2.1 Laboratory and Office Facilities

The design and workflow of the laboratory and office facilities provides an environment suitable to the tasks undertaken. The following conditions are in place:

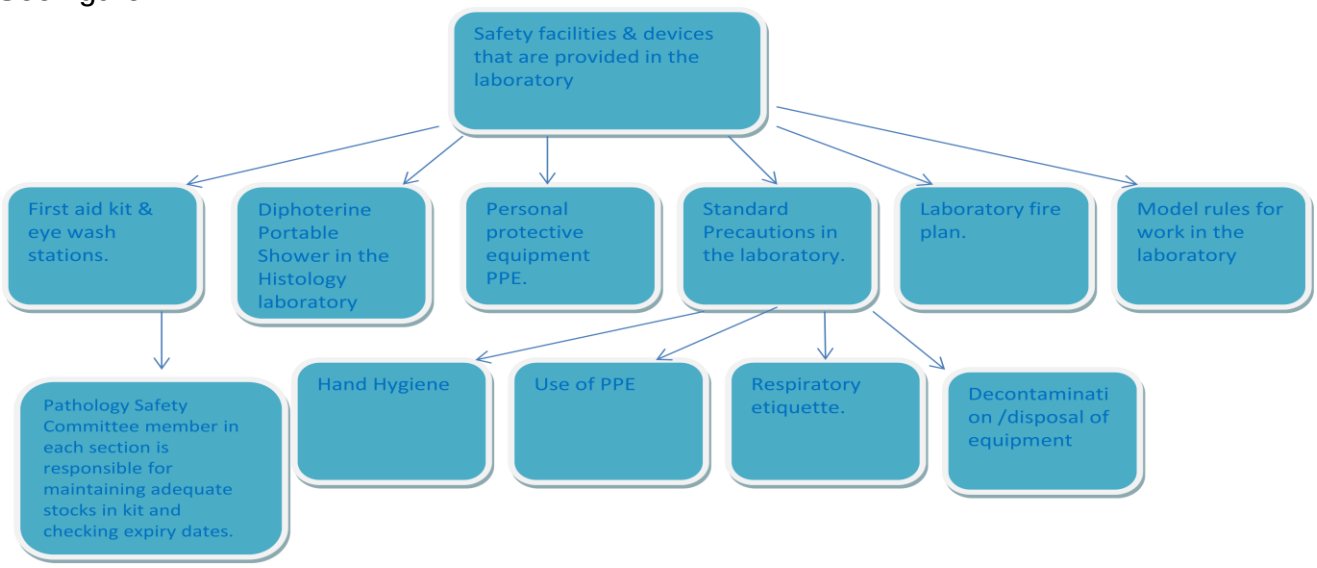
a) Access to areas affecting the quality of examinations is controlled. The Blood Sciences and Microbiology laboratories are controlled by security badge access. Access to the Anatomical Pathology laboratory is controlled via a keypad locked door with limited access. Areas not controlled by swipe card are locked when not in use.

b) Medical information, patient samples, and laboratory resources are protected from unauthorised access. All patient samples and laboratory resources are stored in the laboratory and units of the hospital that are controlled by security badge access. The exception is storage of wax blocks in the Anatomical Pathology laboratory which are stored in a locked store. Electronic medical information is stored on the LIS which is password protected, and an audit trail is available of all users who accessed all results with dates and times provided. For access to the Winpath LIS, all users are given a unique used ID/password. The Laboratory Manager approves the use of the LIS. Access to laboratory records in clinical areas is controlled by the Hospital Information Governance Policy. Electronic access in clinical areas is via password control managed by the hospital IT department.

c) Facilities for correct performance of examinations. The pathology and laboratory medicine safety statement, MP-GEN-SAFETY, outlines legislative requirements for an adequate working environment. These include: adequate power supply (including contingency), adequate lighting, adequate ventilation and temperature control, that noise and vibration do not interfere with analysis, adequate water supply, appropriate access to biological and fume cabinets, and provision for adequate disposal of biological and non-biological waste. These requirements are provided in the laboratory. It is the policy of the laboratory to monitor and control these conditions as required. Where facilities required are out of specification, then a non-conformity is completed and appropriate corrective and preventative actions taken.

d) Communication systems within the laboratory are appropriate to ensure the efficient transfer of information. Laboratory management recognises the value of good communication systems within the laboratory. This includes:
   - Standard E-mail system.
   - Laboratory meeting minutes, available on the Q-Drive once accepted.
   - Notice boards.
   - Memos.
   - Scientific updates.
   - The department has a dedicated seminar room/recreation area which provides opportunity for information sharing.

e) Safety facilities are provided and functioning regularly verified. The laboratory follows the hospitals Safety Statement which is under the remit of the Health and Safety Department. The hospital safety statement highlights the hospital managements' commitment to the safety, health and welfare. The hospital Health and Safety Department carry out annual risk assessment reviews on all areas within the hospital. These compliment Health and Safety reports submitted to the NMH Health and Safety Department by the unit managers and department heads to form the basis of the Hospital Risk Register. The pathology and laboratory medicine safety statement, MP-GEN-SAFETY, outlines the safety facilities and devices that are provided for the laboratory. See figure 7.



6.3.2.2 Storage Facilities

Adequate storage space is provided to ensure the continuing integrity for specimens, slides, Anatomical Pathology blocks, retained micro-organisms, documents, equipment, reagents, consumables, records and results. Storage for clinical specimens is available at room temperature, vented cabinets and refrigeration at 4°C-20°C and -80°C as appropriate. Computer systems are backed up each night.

There is effective separation between discrete laboratory sections, activity, and clinical samples and materials used in testing, to prevent incompatible activities operating in the one location, and cross contamination.

Storage and disposal of dangerous materials is performed in compliance with current statutory regulations and provisions.

6.3.2.3 Facilities for Personnel

Laboratory management provide access to washrooms, a supply of drinking water and to facilities for storage of Personal Protective Equipment (PPE).

The Blood Sciences laboratory contains three bathrooms. Access to fresh drinking water is provided in the Senior Room. A swipe controlled locker room for storage of PPE is located at the entrance to the lab. Two bathrooms are located in the basement where the Microbiology laboratory is located. Access to fresh drinking water is provided and there is a storage area for PPE located at the entrance to the lab. The Anatomical Pathology laboratory is located in the main hospital, with a bathroom located within the department. Access to fresh drinking water is provided, and there are lockers and a storage area for PPE located at the office area of the laboratory.

There is a seminar room for meetings. Staff also have access to the hospital library for quiet study. There are 2 restrooms available for on-call staff.

6.3.2.4 Facilities to Collect Samples

There are no patient sample collection facilities located in the laboratory. Patient sample collection facilities are located in the out-patients, semi-private, gynaecology and private clinics. These clinics encompass an area for sample collection that have:

- Separate waiting and collection areas.
- Collection areas that offer patient privacy and comfort.
- Room for an accompanying person.
- Access to disabled toilet facilities.
- Appropriate first aid materials for both patients and staff.
- The specifically designated Phlebotomy facilities, within the campus, are designed specially and take into consideration patients with disabilities, providing adequate privacy. The design of the primary specimen collection facility is such to ensure the optimisation of collection as well as affording the patient every comfort and enables the collection to be undertaken in a manner that does not invalidate results or adversely affect the quality of the examinations.

6.4 Equipment

6.4.1 General

The laboratory adheres to MP-GEN-EQUIPMAN for the selection, procurement purchasing, installation acceptance testing, handling, transport, storage, use, maintenance and decommissioning of equipment, in order to ensure proper functioning and to prevent contamination or deterioration. Laboratory management ensures that the necessary equipment for the provision of services is available through capital and material budgetary submissions. Only equipment fit for its intended purpose is used by the laboratory. The laboratory replaces equipment as needed to ensure the quality of examination results.

6.4.2 Requirements

Before new equipment is put into routine use, it must have demonstrated its performance capability with respect to stated user requirements or implied or understood requirements. It is the policy of the laboratory that critical materials undergo a document check before being put to routine use. The procedure for Verification of Equipment and Methods in the Laboratory, PP-CS-LM-21, is followed to ensure that equipment is shown to function as required during routine use. This functioning is demonstrated by the use of quality control specimens and demonstrating proficiency by passing the relevant third party assessment schemes as appropriate.

Each item of equipment is uniquely labelled with an asset number and is documented on the asset register which is maintained on Q-Pulse.

Where the equipment is used outside of the laboratory's permanent control, or equipment manufacturers functional specification, laboratory management ensures the ISO18189 requirements are met.

The laboratory maintains and replaces equipment as needed to ensure the quality of examination results.

6.4.3 Equipment Acceptance Procedure

MP-GEN-EQUIPMAN defines how equipment is accepted for use within the laboratory.

6.4.4 Equipment Instructions for Use

The laboratory has appropriate safeguards to prevent unintended adjustments of equipment that can invalidate examination results.

Only trained personnel operate the equipment. Personnel have available (at the point of use) the relevant standard operation procedures and user manuals to operate the equipment. Refer to the document register on Q-Pulse for the master listing of relevant procedures. Standard operating procedures and or user manuals define the safety precautions to be adhered to when using equipment. The equipment is used as specified by the manufacturer, unless validated by the laboratory. Electrical safety is assured by service engineers. Storage and disposal of waste materials is performed in compliance with current statutory regulations and provisions.

6.4.5 Equipment Maintenance and Repair

Equipment is maintained in a safe working condition and working order. This shall include electrical safety, any emergency stop devices and the safe handling and disposal of hazardous material by authorised personnel.

Preventative maintenance programmes are in place for equipment used for test and inspection purposes. The preventative maintenance programme will at a minimum follow the manufactures recommendations as set out in the relevant equipment manual(s). To ensure equipment is maintained in a safe working condition and in working order, service contracts are in place and maintained for critical equipment. In accordance with MP-GEN-EQUIPMAN, the procedure for Selection, Purchasing and Management of Equipment. Service contracts control calibration and preventative maintenance requirements, as outlined in the manufacturer's instructions.

The following details must be recorded for all major items of equipment:

- Dates of planned maintenance.
- Record of downtime.
- Dates when instrument decontaminated.

The above details should be recorded in the asset details of in the assets module of Q-Pulse.

When equipment is found to be defective, it is taken out of service, clearly labelled **"DO NOT USE"**, and appropriately stored until it has been shown by calibration, quality control material or otherwise to be functional. Records of such events are maintained in the assets module of Q-Pulse. Such events are documented as occurrences. In such instances corrective action requires a review to verify the validity of results traceable to the equipment in question. A non-conformance can be raised for the downtime from the asset module.

6.4.6 Equipment Adverse Incident Reporting

Instrument failures which result in incorrect results being reported (or near misses) are recorded and processed as per incident reporting procedures outlined in MP-GEN-MQA. Serious adverse incidents associated with instrument failure are reported to the competent authority, the HPRA. Such incidents are also reported to the hospital Clinical Governance Committee.

The procedure for responding to any manufactures' recall or other notice and actions to be taken are outlined in MP-GEN-MQA.

6.4.7 Equipment Records

The following records in Figure 4 are maintained for each item or similar piece of equipment used for testing purposes:

Figure 4: Equipment Records

Record ID	Record Description	Record Location
a)	Manufacturer and supplier details, unique identity of equipment, including software and firmware.	Asset ID label is located on each piece of equipment and in asset module. All other details are also maintained on the asset module.
b)	Dates of receipt, acceptance testing and entering into service.	This record is maintained on the asset module.
c)	Evidence that equipment conforms with specified acceptability criteria	Validation of equipment–Equipment file/Q-Pulse CA/PA Calibration of equipment–Equipment file/Q-Pulse Asset module QC–On equipment/ floppy/hardcopy/equipment file/validation data EQA–EQA file (hardcopy) or through the scheme website
d)	Current location	Asset module.
e)	Conditions when received e.g. new, used or reconditioned	Asset module
f)	Manufacturer's instructions/ manual	All manufacturers' instructions are recorded as an external document on Q-Pulse, where available this leads to a link to an electronic copy.file, if not will be in equipment file
g)	Programme for PM	PM records, asset module of Q-Pulse
h)	Maintenance activities performed by laboratory or approved external service provider	PM records, asset module of Q-Pulse
i)	Damage, malfunction, modification and repair	These records are maintained in the equipment file, asset module and as non-conformities.
j)	Equipment performance records to confirm ongoing acceptance for use.	QC – On equipment/ floppy/ hardcopy EQA – EQA file (hardcopy), UOM
k)	Status of equipment such as active or in service, out of service, quarantined, retired or obsolete	These records are maintained in the equipment file, asset module and as non-conformities.

The procedure MP-GEN-RECCON details the retention times of the above records.

6.5 Equipment Calibration and Metrological Traceability

MP-GEN-EQUIPMAN describes the procedures for the calibration of equipment that directly or indirectly affects examination results.

Laboratory management establish and maintain documented procedures to control, calibrate and maintain all inspection measuring and test equipment so as to demonstrate the proper functioning of the equipment relevant to specified requirements.

a) All equipment is used taking into account the manufacturer's instructions.
b) External suppliers of calibration should be selected on the basis of accreditation status.
c) For calibration standards the metrological traceability is recorded.
d) The required measurement accuracy and functioning is confirmed via maintenance schedules, internal quality control and external quality assurance.
e) Calibration status and dates (complete and due) are recorded in the asset module of Q-Pulse or on the analyser.
f) Where calibration gives rise to a correction factor there are processes for ensuring that these are entered and confirmed as correct.
g) Safeguards are in place to ensure that only authorised staff carry out calibrations and adjust equipment.

All equipment requiring calibration is listed on the asset module of Q-Pulse. Calibration certificates are scanned and stored with the asset record. Calibration schedules are at least annual for defined equipment types. Refer to MP-GEN-EQUIPMAN, the procedure for the Selection, Purchasing and Management of Equipment. The asset module also alerts the user to the date of recalibration. The status of calibration is clearly identified on the equipment by suitable labels which identify the date of calibration, whom the calibration was performed by, and the due date of the next calibration. This process is not applicable for daily routine calibration of some analysers. Details and results of such calibrations are recorded in the equipment logs.

The Senior Medical Scientist in charge is responsible for the management of the calibration activity. They must verify that all documentation of calibration for an item of equipment, received from an external supplier is checked to ensure the equipment has passed calibration and that the calibration is traceable. Non-conforming equipment is identified and labelled.

Decontamination procedures as appropriate are performed prior to any service or maintenance.

For examinations where metrological traceability of standard cannot be assured, certified reference materials or consensus standards/methods are used.

6.5.1 General

The laboratory specifies calibration and traceability requirements that are sufficient to maintain consistent reporting of examination results. For quantitative methods of a measured analyte, specifications include calibration and metrological traceability requirements. Qualitative methods and quantitative methods that measure characteristics rather than discrete analytes, specify the characteristic being assessed and the requirements necessary for reproducibility over time.

6.5.2 Equipment Calibration Procedure

MP-GEN-EQUIPMAN describes the calibration of equipment that directly or indirectly affects examination results. The procedures specifies:

a) conditions of use and manufacturer's instructions for calibration;
b) recording of the metrological traceability;
c) verification of the required measurement accuracy and the functioning of the measuring system at specified intervals;
d) recording the calibration status and date of re-calibration;
e) ensuring that, where correction factors are used, these are updated and recorded when re-calibration occurs;
f) handling of situations when calibration was out of control, to minimize risk to service operation and to patients.

6.5.3 Metrological Traceability to the International System of Units

a) The laboratory has established and maintains metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference.
b) The laboratory ensures that measurement results are traceable to the highest possible level of traceability and to the International System of Units (SI) through:
   - calibration provided by a competent laboratory; or
   - certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI
c) Where it is not possible to provide traceability other means for providing confidence in the results are applied, including but not limited to:

d) Results of reference measurement procedures, specified methods or consensus standards, that are clearly described and accepted as providing measurement results fit for their intended use and ensured by suitable comparison
e) Measurement of calibrator by another procedure
f) For genetic examinations, traceability to genetic reference sequences are established.
g) For qualitative methods, traceability can be demonstrated be testing of known material or previous samples sufficient to show consistent identification and if applicable intensity of reaction.

MP-GEN-EQUIPMAN

6.6 Reagents and Consumables

6.6.1 General

Each laboratory department has a documented procedure for the selection, procurement, reception, storage, acceptance testing, and inventory management of reagents and consumables.
Reagents and consumables are used according to the manufacturer's specifications

6.6.2 Receipt and Storage

The laboratory stores received reagents and consumables according to manufacturer's instructions. Reagent and consumables are stored in designated temperature controlled environments where required. Reagents that require refrigeration or freezing are stored in reagent fridges/freezers that are temperature controlled. This is monitored by the Kelsius temperature monitoring system. Each department has a documented procedure relating to equipment failure that provides a designated back-up fridge/freezer in the event of failure.
When the laboratory is not the receiving facility, it ensures that the facility has adequate storage and handling capabilities to maintain supplies in a manner that prevents damage and deterioration.

6.6.3 Acceptance Testing

Each new batch of examination kits with changes in reagent, procedure, lot number or consignment, has its performance verified before use. This is performed according to the documented procedure on batch acceptance in each department. Any consumables that affect the quality of examinations shall also be verified before use.

6.6.4 Inventory

Each department has an inventory control system for reagents and consumables. This system segregates uninspected and unacceptable reagents.

6.6.5 Instructions for Use

Current manufacturer's instructions and instructions for use, of reagents and consumables are available on Q-Pulse. External documents are recorded and given a document number. Where they are available as an electronic file they are attached in Q-Pulse, or else stored as a hard copy in the relevant department. Reagents and consumables are used according to the manufacturers specifications. If they are intended to be used for other purposes refer to PP-CS-LM-21.

6.6.6 Adverse Incidents

Adverse incidents and accidents associated directly with specific reagents and consumables should be recorded and processed as per non-conformance reporting procedures outlined in MP-GEN-MQA and reported to the supplier. Serious adverse incidents associated with specific reagents and consumables are reported to the HPRA. Refer to MP-GEN-MQA for manufacturer's recall or any other notice and actions to take recommended by the manufacturer.

6.6.7 Records

The following records listed in Figure 5 are maintained for each reagent and consumable that contributes to the performance of examinations.

Figure 5: Reagents and Consumables - Records

Record ID	Record Description	Record Location
a)	Identity of the reagent or consumable	Batch acceptance log in individual department.
b)	Manufacturer's name, batch or lot number	Batch acceptance log in individual department.
c)	Contact information for the supplier or manufacturer.	Supplier module of Q-pulse
d)	Date of receipt, expiry date, date of entering into service, and date material was taken out of service where applicable.	Batch acceptance log in individual department
e)	Conditions when received (acceptable or damaged).	Batch acceptance log in individual department
f)	Manufacturer's instructions.	This record is maintained in the equipment file or at the point of use whichever is appropriate. All manufacturers' instructions are recorded as an external document on Q-Pulse, where available this leads to a link to an electronic copy.
g)	Records to confirm reagent or consumable initial acceptability for use.	Acceptance log in individual department
h)	Performance records to confirm ongoing acceptance for use.	QC – On equipment/ floppy/ hardcopy/in equipment file EQA – EQA file (hardcopy) or on the scheme website
i)	Reagents prepared, resuspended or combined in-house, persons undertaking the preparation, date and expiry	Recorded on the reagent.

6.7 Service Agreements

The procedure Management of Service Agreements, Referral Laboratories and External Service and Supplies, PP-CS-LM-18, controls the establishment and review of agreements for providing medical laboratory services. Each request form accepted by the laboratory is considered an agreement. This agreement takes into account the request, the examination and the report. The laboratory services available and the information needed on the request to ensure appropriate examination and result interpretation are defined in the Primary Specimen Collection Manual, PP-CS-LM-4, and is available electronically on Q-Pulse for hospital wide information. The following conditions are met when the NMH enters into an agreement to provide medical laboratory services:

a) The requirements of the customers, users and of the provider of the laboratory services, including the examination processes used are defined and documented in the Primary Specimen Collection Manual, PP-CS-LM-4.
b) The laboratory has the capability and resources to meet the requirements. This is reviewed at the Annual Management Review (AMR).
c) Laboratory personnel have the skills and expertise necessary for the performance of the intended examinations. This is documented in the Management of Training procedure, MP-GEN-TRAIN.
d) Examination procedures selected are appropriate and able to meet the customers' needs. All examinations procedures are validated for their intended use and the identity of the persons performing the examination is recorded. Where there are changes in existing arrangements (for

new examination procedures or changes to existing examination procedures) and prior to making any change laboratory management ensures:

i. That the test method has been documented verified and approved and is comparable with the existing method and meets the manufacturer's specification.
ii. That an internal quality control programme and external quality assessment scheme is defined, documented and in place.
iii. That the laboratory has the capability in terms of method, materials, personnel, equipment and environment to meet the new or amended requirements.
iv. That from a clinical perspective the changes meet the clinical needs of the patient.

e) Customers and users are informed of deviations from the agreement that impact upon the examination results.
f) Reference is made to any work referred by the laboratory to a referral laboratory or Consultant.

Review of Service Agreements

The acceptance of any contract is based on the incoming inspection process, which verifies defined requirements are met as per the Specimen Reception procedure, LP-GEN-SPECREC. On rejection of a contract (failed incoming inspection), the customer is informed, by phone where possible, or in writing and a repeat specimen may be requested as per the requirements. All rejected contracts are documented on the Laboratory Information System (LIS). A report is issued with a reason for not testing. Repeat specimens may not be possible in Anatomic Pathology, and in some instances for Microbiology or with foetal sampling. Therefore, when these specimens do not meet the incoming inspection process the clinician is contacted and all efforts are made to correctly identify the specimen received. It is the responsibility of the clinician to identify the specimen and this identification confirmation process is documented in LIS.

Reviews of agreements to provide medical laboratory services include all aspects of the agreement. Records of these reviews are stored in Q-Pulse and include any changes to the agreement and any pertinent discussions. Where an agreement needs to be amended after laboratory services have commenced, the same agreement review process is repeated and any amendments communicated to all relevant parties.

6.7.1 Agreements with Laboratory Users

This is defined in PP-CS-LM-18

6.7.2 Agreements with POCT Operators

This will be defined in PP-CS-LM-18 once POCT is included in the laboratories scope of accreditation

6.8 External Products and Services

PP-CS-LM-18 defines the practice for the selection, purchasing and approval of external services, equipment, reagents and consumables considered to be critical to the delivery of its service. An electronic master list of critical equipment, reagents, consumables and external services is maintained in Q-Pulse. Continuous review is achieved by recording any untoward performance in the CA/PA module of Q-Pulse. In this way a continuous picture will be built up to enable an accurate evaluation of service.

6.8.1 General

The laboratory ensures that externally provided products and services that affect laboratory activities are suitable when such products are:

a) Intended for incorporation into the laboratory's own activities;
b) Provided, in part or in full, directly to the user by the laboratory, as received from the external provided;

c) Used to support the operation of the laboratory.
d) It may be necessary to collaborate with other organisational departments to fulfil this requirement.

6.8.2 Referral Laboratories and Consultants

The laboratory, with the advice of users of laboratory services is responsible for selecting the referral laboratory, referral consultants and suppliers. The NMH monitors the quality of performance and ensures that the referral laboratories, referral consultants and suppliers are competent to perform the requested examinations. The laboratory procedure on Management of Service Agreements, Referral Laboratories and External Service and Supplies, PP-CS-LM-18, outlines how the choice of referral laboratories, consultants and suppliers used by the NMH is based on one or more of the following criteria:

- Accreditation status.
- Range of tests provided.
- Reputation of Institution or individual experts.
- The laboratory communicates its requirements to referral laboratories and consultants who provide interpretations and advice for;
    a) The procedures, examinations, reports and consulting activities to be provided;
    b) Management of critical results;
    c) Any required personnel qualifications and demonstration of competence.
    d) Unless otherwise specified in the agreement, the referring laboratory are responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.
    e) A list of all referral laboratories and consultants' is maintained on Q-Pulse.

6.8.3 Define, Review and Approval

The laboratory has procedures for and retains records for:

a) Defining, reviewing and approving the laboratory's requirements for all externally provided products and services;
b) Defining the criteria for qualification, selection, evaluation of performance and re-evaluation of external providers;
c) Referral of samples;
d) Ensuing that externally provided products and services conform to the laboratory's established requirements, or where applicable to the relevant requirements of ISO15189, before they are used or directly provided to the user;
e) Taking any actions arising from the evaluations of the performance of external providers.

The NMH evaluate and select referral laboratories, consultants and suppliers based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratories requirements. These referral laboratories, consultants and suppliers must meet the clearly defined requirements of the product/service being purchased. The basis on which the supplier is selected is recorded and may satisfy one or more of the following:

- The supplier is registered in an appropriate quality assurance system.
- The supplier is the sole supplier of a particular product.
- The supplier has a proven record of reliability without being in a quality assurance system.
- Historical evaluation based on price, quality and delivery.
- They are registered with the Health Products Regulatory Authority (HPRA).
- The supplier has achieved appropriate certification or validation.

A master list of all relevant evaluated referral laboratories, consultants and suppliers is stored in Q-Pulse. Continuous review is achieved by recording any untoward performance in the CA/PA module

of Q-Pulse. In this way a continuous picture will be built up to enable an accurate evaluation of service. If a contract is amended, the contract is treated as a new contract and reviewed in the same manner. All amendments will be communicated to the relevant personnel.

Provision of Results

The NMH (and not the referral laboratory) is responsible for ensuring that examination results of the referral laboratory are provided to the person making the request. The NMH prepares the report and includes all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report indicates which examinations were performed by a referral laboratory or Consultant. The author of any additional remarks is clearly identified.

Each laboratory has adopted the most appropriate means of reporting referral laboratory results which takes into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. Where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories, this process is not hindered by commercial or financial considerations. Requests and results of all samples referred are stored as per MP-GEN-RECCON.

7 PROCESS REQUIREMENTS

7.1 General

The laboratory identifies potential risks to patient care in the pre-examination, examination and post examination processes. These risks are assessed and mitigated to the extent possible. The residual risk is communicated to users as appropriate.

The identified risks and effectiveness of the mitigation process is monitored and evaluated according to the potential harm to the patient. The laboratory identifies opportunities to improve patient care and has a framework to manage these opportunities. Ref PP-CS-LM-23.

7.2 Pre-Examination Process

7.2.1 General

The laboratory has documented procedures and information for pre-examination activities, contained in the laboratory Primary Specimen Collection Manual, PP-CS-LM-4.

7.2.2 Information to Patients and Users

The laboratory has information for patients and users this is contained in the laboratory Primary Specimen Collection Manual, PP-CS-LM-4, and is available to all on the hospital intranet, at www.nmh.ie. This includes:

a) The location of the laboratory, operating hours and contact information,
b) The procedure for requesting and collection of samples,
c) The scope of laboratory activities and time for expected availability of results,
d) The availability of advisory services,
e) Factors known to significantly impact the performance of the examination or the interpretation of the results
f) The laboratory complaints process.
g) The department maintains a suite of information leaflets for tests it carries out to assist patients and their families to give informed consent

7.2.3 Requests

7.2.3.1 General

The laboratory has a suite of paper and electronic request forms. The paper request forms are available in the laboratory and are controlled in Q-Pulse. The electronic request forms are nationally agreed and are held on the MN-CMS portal.

PP-CS-LM-4 outlines the procedures to be followed for verbal requests. Laboratory staff assist users, or their representatives, to ensure clarity of requests.

The Laboratory Manager/Director of Pathology ensures where new forms or amendments to existing forms are required that prior to implementation any such changes are discussed and agreed with the relevant clinical users.

Each request received by the laboratory for examinations is considered an agreement. The examination request provides sufficient form to ensure:

- Unequivocal traceability of the patient to the request and sample,
- Identity and contact information of the requester,
- Identification of the test requested,
- Informed clinical and technical advice and clinical interpretation may be provided

The examination request information may be provided in a format or medium as deemed appropriate by the laboratory and acceptable to the user. The laboratory has a suite of paper and electronic request forms. The paper request forms are available in the laboratory and are controlled in Q-Pulse. The electronic request forms are nationally agreed and are held on the MN-CMS portal. The Laboratory Manager/Director of Pathology ensures where new forms or amendments to existing forms are required that prior to implementation any such changes are discussed and agreed with the relevant clinical users.

PP-CS-LM-4 outlines the procedures to be followed for verbal requests. Laboratory staff assist users, or their representatives, to ensure clarity of requests.

7.2.3.2 Oral Requests

This is defined in PP-CS-LM-4

7.2.4 Collection and Handling of Primary Samples

7.2.4.1 General

An approved Primary Specimen Collection Manual, PP-CS-LM-4, which records specific instructions for the proper collection and handling of primary specimens, is circulated to the primary users of the laboratory services, those responsible for sample collection whether based in the hospital or not. The manual is available on Q-Pulse and the hospital intranet.

In a situation where the user requires deviations and exclusions from, or additions to the documented collection procedure, these are recorded and included in all documents containing examination results. The potential risk and impact on the patient outcome of acceptance or rejection of the sample is assessed, recorded and communicated to the appropriate personnel

The laboratory periodically reviews requirements for sample volume, collection device and preservatives for all sample types, as applicable, to ensure that neither insufficient or excessive amounts of samples are collected and samples are properly collected to preserve the analyte.

7.2.4.2 Pre-Collection Activities

The Primary Specimen Collection Manual, PP-CS-LM-4, includes the following instructions in Figure 6 for pre-collection activities:

Figure 6: Instructions for Pre-Collection Activities

Record ID	Instructions for Pre-Collection Activities:	Primary Specimen Collection Manual PP-CS-LM-4
a	Preparation of the patient (e.g. instructions to care givers, sample collectors and patients).	Section 2 Patient identification and consent, Section 3.2 Venepuncture and collection Departmental data for additional information
b	Type and amount of sample to be collected with descriptions of the containers and any necessary additives and order of draw when relevant.	Departmental data and SI-NOT-GEN1, SI-NOT-GEN2
c	Special timing of collection where relevant,	Departmental data
d	Provision of clinical information relevant to, or affecting sample collection, examination performance, or result interpretation (e.g. History of administration of drugs)	Section 4 Requesting test MN-CMS Section 5 Requesting test paper request Departmental data
e	Sample labelling for unequivocal identification of the patient , as well as source and site of sample, and labelling, when several samples from the same patient are to be collected, including multiple pieces of tissues or slides.	Section 4 Requesting test MN-CMS Section 5 Requesting test paper request Departmental data
f	The laboratory's criteria for acceptance and rejection of samples specific to the examinations requested.	Section 7 Specimen acceptance requirements

7.2.4.3 Patient Consent

The lab follows the hospital policy on consent - PP-CS-GEN-3 – Obtaining Patient Consent
All procedures carried out on a patient require informed consent**.** Consent may be given orally, in writing, and in certain limited circumstances by implication e.g. holding out an arm for a blood pressure reading. Courtesy and respect is required at all times. Consent may be verbal in emergency situations and documented in the healthcare record. In an emergency life-threatening situation where the patient is unable to consent or to appreciate what is required a healthcare professional, acting in the best interests of the patient, may administer the necessary medical treatment to save the life or preserve the health of the patient without formal consent. This exemption is limited to situations where the treatment is immediately necessary to save the life or preserve the health of the patient.

7.2.4.4 Sample Collection Activities

The Primary Specimen Collection Manual, PP-CS-LM-4, includes the following instructions in Figure 7 for collection activities:

Figure 7: Instructions for Collection Activities

Record ID	Instructions for collection activities:	Primary Specimen Collection Manual PP-CS-LM-4
a	Verification of the identity of the patient from whom a primary sample is collected.	Section 2.2 Clinical Procedure for Patient Identification
b	Verification and when relevant, recording that the patient meets pre-examination requirements (e.g. fasting stats, medication status, time of last dose, cessation, sample collection at predetermined time or time intervals	Section 2.2 Clinical Procedure for Patient Identification
c	Collection of primary samples, with descriptions of the primary sample containers and any necessary additives, as well as order of draw, where relevant.	Departmental data and SI-NOT-GEN1, SI-NOT-GEN2
d	Labelling of primary samples in a manner that provides an unequivocal link with the patients from whim they are collected.	Section 3.2 Venepuncture Procedure /Collection of Specimens Section 4 Requesting test MN-CMS Section 5 Requesting test paper request
e	Recording of the identity of the person collecting the primary sample and the collection date and where relevant time.	Section 4 Requesting test MN-CMS Section 5 Requesting test paper request
f	Requirements for separating or dividing the primary sample where necessary	Departmental data
g	Stabilisation and proper storage conditions before collected samples are delivered to the laboratory	Section 6.1 Pre-Analytical Specimen Storage
h	Safe disposal of materials used in the collection process	Section 3.2 Venepuncture Procedure /Collection of Specimens

7.2.5 **Transportation of Samples**

The laboratory monitors and ensures by appropriate means that specimens are transported to the laboratory in such a way that the validity of the test results is not compromised. This is accomplished by the following:

a) The Primary Specimen Collection Manual, PP-CS-LM-4, clearly identifies any special time related requirements associated with specific tests to the user. Before testing the laboratory verifies these requirements are complied with.
b) The Primary Specimen Collection Manual, PP-CS-LM-4, under the special requirements section, clearly identifies any specific temperature requirements associated with preserving the integrity of

specific test parameters. Before testing the laboratory verifies these requirements are complied with.

c) Adherence to regulations controlling transport of specimens. Refer to "The European Agreement Concerning the International Carriage of Dangerous Goods by Road (UNADR)", EXT-CS-LM-10.

If the integrity of a sample is compromised and there is a health risk, the organisation responsible for the transport of the sample is notified immediately and action take to reduce the risk and to prevent recurrence.

The Primary Specimen Collection Manual, PP-CS-LM-4, defines for the users of laboratory services, requirements for specimen delivery from within and outside the hospital. The laboratory has established and periodically evaluates adequacy of sample transportation systems.

7.2.6 Reception of Samples in the Laboratory

7.2.6.1 Process for Reception

The laboratory has a procedure for Sample Reception, LP-GEN-SPECREC, which ensures that the following documented conditions are met:

a) Samples must be traceable by request and labelling to an identified patient or site.
b) The laboratory policy on acceptance or rejection of samples is applied. Where the specific requirements of the incoming inspection process for specimens and forms are not met for key indicators, the specimen is rejected and a second specimen is requested.
c) In general, a practice of "Zero Tolerance Policy" is in place for essential details and where a discrepancy is identified, in labelling, sample instability the specimen is rejected. In situations where the sample is clinically critical or irreplaceable and the laboratory chooses to process the sample the final report shall indicate the nature of the problem and indicate that caution is required when interpreting the result, and the form RF-CS-LM-20, Pathology Specimen Non-conformance form, completed. When these specimens do not meet the incoming inspection process the clinician is contacted and all efforts are made to correctly identify the specimen received. It is the responsibility of the clinician to identify the specimen and this identification confirmation process is documented in Winpath. All non-conforming primary specimens (even when tests are not performed) must be registered on the LIS. The electronic registration will identify the reason for rejecting the specimens and the action taken e.g. second specimen requested. The details required on specimens is located in the Primary Specimen Collection Manual, PP-CS-LM-4.
d) All specimens received into the laboratory, either during routine or out of hours, are recorded electronically on the Winpath LIS. The electronic receipt of specimens controls the following:
e) Date/time of receipt of specimens.
f) The tests requested and any non-conforming events.
g) Audit trail (including who received the specimen).
h) Primary specimens and associated forms are checked on receipt by authorised personnel including Medical Scientists, Senior Anatomical Pathology Technician and Laboratory Aides to ensure they meet the criteria in place for the acceptance and rejection of primary specimens. The acceptance or rejection is based on an inspection process, where each specimen is reviewed for compliance with defined criteria as it applies to:
i) Suitability of the request form.
j) Labelling of the primary specimens.
k) Quality of the specimens (age, haemolysis, lipaemia, volume etc.)
l) A Histopathologist (Consultant or Registrar), Senior Anatomical Technician or authorised Medical Scientists will review all requests before testing is commenced.
m) The laboratory has documented procedures in place for the receipt, labelling, processing and reporting of primary specimens received by the laboratory and are marked as urgent. Where blood components/products are required urgently, where the patient has a clinically significant

antibody or in emergency situations, the requesting doctor must communicate directly with the Blood Transfusion laboratory.

n) All sample portions or aliquots are labelled so that they are traceable to the original primary specimen.

7.2.6.2 Exceptions in Acceptance of Samples

The Primary Sample Collection Manual, PP-CS-LM-4, has documented the exceptions in acceptance of samples

This considers the best interests of the patient in receiving care, when a sample has been compromised due to:

a) Incorrect patient or sample identification,
b) Sample instability due to, for example, delay in transport,
c) Incorrect storage or handling temperature,
d) Inappropriate container, and
e) Insufficient sample volume.

When a compromised clinically critical or irreplaceable sample is accepted after consideration of the risk to patient safety, the final report indicates the nature of the problem and advises caution when interpreting results can be affected.

7.2.7 **Handling, Preparation, and Storage of Samples**

The laboratory has procedures and facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities. Specimens from outpatient clinics received after 17:30 (Monday to Friday) may be held to the next working day for analysis following authorisation from a senior member of staff. Specimens received out of hours which do not require urgent analysis are stored in the appropriate fridge in the Blood Sciences laboratory.

The Primary Sample Collection Manual, PP-CS-LM-4, also has documented time limits for requesting additional or further tests on the primary sample. These are outlined in the section for each department.

7.2.7.1 Protection of Samples

The Primary Sample Collection Manual, PP-CS-LM-4, has documented the Protection of samples

7.2.7.2 Additional Examination Requests

The Primary Sample Collection Manual, PP-CS-LM-4, has documented the requirements for additional examination requests, including time limits for additional examination requests on the same sample.

7.2.7.3 Stability of the Samples

The Primary Sample Collection Manual, PP-CS-LM-4, has documented the stability of samples for each department. This considers the stability of the analyte in a primary sample, the time between sample collection and performing the examination, is specified and monitored at sample receipt.

7.3 Examination Process

7.3.1 General

The laboratory uses validated examination procedures (testing) which meet the needs of its users. The laboratory uses examination procedures (testing) that are in widespread use and have been published or referenced in authoritative textbooks and journals. However, certain reagent manipulations may be required appropriate for the method used. The effectiveness of these manipulations is verified using internal and external quality control procedures. The audit trail in the LIS records those who perform activities.

The performance specifications for each examination method relates to the intended use of that examination and its impact on patient care. All procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities are kept up to date and available to personnel. Personnel follow established procedures and the identity of persons performing significant activities in examination processes are recorded. Authorised personnel periodically evaluate the examination methods provided by the laboratory to ensure that they are clinically appropriate for the requests received.

7.3.2 Verification of Examination Methods

Testing procedures or amended procedures are validated or verified as fit for purpose by the laboratory prior to being introduced into routine use. The laboratory obtains information from the manufacturer for confirming the performance characteristics of the procedure. The performance characteristics should comply with the User Requirement Specification (URS). The URS ensures that when a system or piece of equipment is selected, it will deliver the functions required, comply with applicable standards and regulations and have all the documents and records to enable successful validation to be completed.

Independent verification by the laboratory is as extensive as necessary to meet needs. It confirms that the performance claims for the test/examination procedure have been met. The laboratory documents the procedure used for verification in a validation plan, using the template RF-CS-LM-47. The validation plan is prepared and approved by the senior in charge before beginning the validation process. A validation protocol will be created to provide evidence that the system performs as intended. The protocol will include the following:

- Scope of validation.
- Selection of a validation team and a statement on the competence of the staff involved.
- Timeline for completion.
- Procedures for installation, operational and performance qualifications.
- Acceptance criteria.
- Justification.
- Performance characteristics.
- Reference documentation.
- Change control.
- Executive summary.

The performance specifications for the examination method confirmed during the verification process is relevant to the intended use of the examination results. The laboratory ensures the extent of the verification of examination methods is sufficient to ensure the validity of results pertinent to clinical decision making. Personnel with the appropriate authorization and competence reviews the verification results and records whether the results meet the specified requirements. If a method is revised by the issuing body, the laboratory will repeat verification to the extent necessary.
The following records of verification shall be retained:

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

7.3.3 Validation of Examination Method

The laboratory validates examination procedures derived from the following sources:

- Non-standard methods.
- Laboratory designed or developed methods.
- Standard methods used outside their intended scope.

- Validated methods subsequently modified.

Each method in use in the laboratory must be fully validated by the laboratory. The validation is as extensive as required and it should confirm through the provision of evidence that the method:

- Is suitable for the intended purpose.
- Performs to an acceptable level in the laboratory, when compared to the performance claims made by the manufacturer.
- As a minimum meets the same standard as the test being replaced.

The laboratory records the results of validations and the procedures used for such validation in a validation report, using the template RF-CS-LM-48. New methods and procedures selected for use must be evaluated and found to give satisfactory results before being used for medical examinations. These evaluations are reviewed and approved by laboratory management in the report. It is also documented through raising a new Change Management (CM) event with its own identification number using the CA/PA module of Q-Pulse. This will track the outcomes in the same way as all the non-conformance events can be tracked in Q-Pulse.

When changes are made to a validated procedure the influence of the change is documented and where appropriate revalidation may be performed:

- Following repeated failed QC results.
- Following any major change, performed under change control and deemed to require revalidation/re-qualification.
- Following a major non-conformance.
- Following a complaint from users.

Such validation is not expected to be as detailed as for a full validation and may vary depending on the extent of the repair carried out or the non-conformance raised. This procedure ensures that the method is functioning satisfactorily before return to use.

7.3.4 Evaluation of Measurement Uncertainty

Uncertainty of measurement may be influenced by a number of factors. These should be considered during method validation. The laboratory must define the performance requirements for the measurement uncertainty of each measurement procedure. This is a key step in deciding whether a test is fit for purpose. The measurement uncertainty for each measurement procedure in the examination phase should be determined to report measured quantity values on patients' samples.

The measurement uncertainty components are those associated with the actual measurement process, starting with presentation of the sample to the measurement procedure and ending with the output of the measured value or test results. Sources that contribute to uncertainty may include sampling, specimen preparation, portion selection, calibrators, reference materials, input quantities, equipment, environment, specimen condition and operator skill. It is assessed as applicable, and recorded in the validation plan, RF-CS-LM-47, and the validation report, RF-CS-LM-48.

Measurement uncertainty values can be calculated using values obtained by measuring IQC materials under intermediate precision conditions. This allows for the varying of factors such as changing reagent or calibrator batches, or using different operators.

Reasonable efforts across each discipline are made to identify sources of uncertainty and to quantify them to establish an overall estimate of uncertainty. Estimates of measurement uncertainty are available to users on request from each department.

PP-CS-LM-21, the procedure for Validation of Equipment and Methods in the Laboratory, outlines the laboratory approach to measurement uncertainty. The laboratory reviews estimates of measurement uncertainty on an annual basis. This is done through a scheduled annual audit of measurement uncertainty in each department. The review is recorded on the form RF-CS-LM-84 and recorded in the annual audit.
For examination procedures where evaluation of MU is not possible or relevant, the rationale for exclusion from MU shall be documented.
MU information is available to laboratory users on request. When users have inquiries on MU, the laboratory's response takes into account other sources of uncertainty, such as, but not limited to biological variation.
MU should be taken into consideration when performing verification of a method, where relevant.
Where tests include a measurement step but do not report a measured value, the laboratory should calculate the uncertainty of the measurement step where it has use in accessing the reliability of the procedure or has an influence on the test result.

7.3.5 Biological Reference Intervals and Clinical Decision Limits

Biological reference intervals are defined and documented by the laboratory in the Primary Specimen Collection Manual, PP-CS-LM-4. This information is also communicated to users on laboratory reports.

Biological reference intervals are reviewed periodically. Where the laboratory has reason to believe that a particular interval is no longer appropriate for the reference population then an investigation is undertaken, followed if necessary, by corrective action and updated on the laboratory information system using PP-CS-LM-32 Advanced use of Winpath.

A review of biological references intervals shall also take place if examination or pre- examination procedures are changed. Biological reference intervals are not relevant to Blood Transfusion, Anatomical Pathology and certain areas of Microbiology.
For examinations that identify presence or absence of a characteristic, the biological reference interval is the characteristic to be identified, e.g. genetic examinations

Clinical Decision Values/Reports of Critically Abnormal Results are results which are generally unexpected and which are so abnormal that they may have implications for the immediate treatment of the patient. They may indicate a life-threatening situation. Details for clinical staff on what reports will be telephoned are outlined in the Primary Specimen Collection Manual, PP-CS-LM-4. For scientific staff, each department has identified the circumstances under which results should be telephoned. This information is available in LP-GEN-TELREP, the procedure for Telephoning / Faxing of Results.

7.3.6 Examination Procedure

Examination procedures are documented by the laboratory and are available on Q-Pulse the laboratory quality management system so that all staff in the laboratory has access to them. The appropriate documents are also distributed to each member of staff as required by those responsible for training.

Work instructions, which are condensed documents that summarise key information, are acceptable for use in the laboratory at work stations where test and examination procedures are performed. All printed copies must be on buff paper only, and the number of printed copies is referred to in the original document. All work instructions must have a full documented procedure available for reference.

All documents that are associated with the performance of a test including procedures, summary documents, product inserts are subject to document control. In addition to this documentation must include where applicable details of:

1) Purpose of the examination.
2) Principle of the procedure used for examinations.
3) Performance characteristics as appropriate e.g. accuracy and precision, detection limit, sensitivity, specificity etc.
4) Type of primary specimen (e.g. plasma, serum, urine).
5) Patient preparation.
6) Type of container and additives.
7) Required equipment and reagents.
8) Environmental safety controls /Risk assessment.
9) Calibration procedures (metrological traceability).
10) Procedural steps.
11) Quality control procedures.
12) Interferences (e.g. lipaemia, haemolysis, bilirubinaemia) and cross reactions.
13) Principle of procedure for calculating results, including uncertainty of measurement.
14) Biological reference intervals.
15) Reportable interval of patient examination results.
16) Instruction for determining result when it is not within the measurement interval.
17) Alert/ critical values, where appropriate.
18) Laboratory interpretation.
19) Potential sources of variability.
20) References

The Laboratory Manager ensures all examination procedures are complete, current and reviewed. The laboratory Consultants/nominee provides details of current examination procedures including performance specifications etc. to clinical users on receipt of request for same.

It is the policy of the laboratory that the relevant Consultant, Laboratory Manager or nominee inform clinical users in advance of change to an examination procedure, where the change has an impact on result interpretation. Records of changes to existing test procedures are managed through the change management module of Q-Pulse. All changes to test methodologies are discussed in advance by the laboratory management committee. Such changes are referred to the appropriate hospital committee if necessary. This notification of change can be accomplished by various methods including: direct mailing, laboratory newsletters, memos, or as part of the examination report.

7.3.7 Ensuring the Validity of Examination Results

7.3.7.1 General

The laboratory has a procedure for monitoring the ongoing validity of results. The resulting data is recorded in a way that trends and shifts are detectable and, where practicable, statistical techniques are applied to review the results. This monitoring is planned and reviewed.

7.3.7.2 Internal Quality Control (IQC)

The laboratory designs quality control (QC) procedures that monitor the ongoing validity of examination results, according to specified criteria, that verifies the attainment of the intended quality and ensures validity pertinent to clinical decision making. The approach to quality control is based on principles of in-process QC checks as well as controlling the tests. The key inputs to each process

will be reviewed and signed off on a daily basis. It is the policy of the laboratory to focus on elimination or reduction of errors in the following critical areas of activity:

1) Specimen collection, inspection and registration.
2) Laboratory Information System including interfaces and data entry contingency.
3) Primary processing including centrifugation and aliquoting.
4) Testing processes (using QC specimens). All known errors in the internal QC systems are documented.

The intended clinical application of the examination is considered, as the performance specifications for the same measurement can differ in different clinical settings. The procedure allows for the detection of either lot-to-lot reagent or calibrator variation, or both, of the examination method. To enable this, the laboratory procedure should avoid lot change in IQC material on the same day/run as either lot-to-lot reagent or calibrator change, or both. The use of third-party IQC material should be considered, either as an alternative to, or in addition to, control material supplied by the reagent or instrument manufacturer.

Quality Control Materials

The laboratory selects IQC material that is fit for its intended purpose. When selecting IQC material, facets that are considered include:

1) stability with regard to the properties of interest;
2) the matrix is as close as possible to that of patient samples;
3) the IQC material reacts to the examination method in a manner as close as possible to patient samples;
4) the IQC material provides a clinically relevant challenge to the examination method, has concentration levels at or near clinical decision limits and when possible, covers the measurement range of the examination method.
   IQC is performed at a frequency that is based on the stability and robustness of the examination method and the risk of harm to the patient from an erroneous result.

If appropriate IQC material is not available, the laboratory may consider the use of other methods for IQC. Examples of such other methods may include:

1) trend analysis of patient results, e.g. with moving average of patient results, or percentage of samples with results below or above certain values or associated with a diagnosis;
2) comparison of results for patient samples on a specified schedule to results for patient samples examined by an alternative procedure validated to have its calibration metrologically traceable to the same or higher order references as specified in ISO 17511;
3) retesting of retained patient samples.

Quality Control Data

Each department in the laboratory documents that patient results must not be released in the event of an IQC failure. When IQC results indicate that examination results are likely to contain significant errors, the results are rejected and relevant patient samples retested after the error has been resolved. Results from patient samples analysed after the last successful quality control event are reviewed and consideration is given to the requirement to repeat where possible and the requirement to alert the clinical team if it is anticipated that the result would be significantly different.

IQC data is recorded in such a way that trends and shifts are detectable and where applicable, statistical techniques are applied to review the results. IQC data is reviewed at regular intervals to detect trends in performance that may indicate problems in the system. If performance trends in IQC results that indicated problems are noted or if IQC failures are recorded, a non-conformance is raised in Q-Pulse and appropriate investigation into the failure is carried out. Corrective and preventative action is then implemented and reviewed by the clinical team in charge of the department concerned.

7.3.7.3 External Quality Assessment (EQA)

The laboratory monitors its performance of examination methods, by comparison with results of other laboratories. This includes participation in EQA programmes appropriate to the examinations and interpretation of examination results, including POCT examination methods.

Our testing laboratory participates in a range of third party external quality assessment (EQA) schemes and proficiency programmes.

The laboratory manager and/or medical consultants formally review the results of EQA schemes. The output of this review is presented at the quality assurance meeting. An overview of performance is presented at the AMR meeting (refer to Section 4.15). Failures in EQA schemes and IQC methods are documented and investigated according to MP-GEN-MQA, the procedure for Managing Quality Assurance.

The laboratory documents the procedure for participation in interlaboratory comparisons or EQA in the Managing Quality Assurance, MP-GEN-MQA, document. Each department also has a local documented procedure for dealing with specific EQA schemes in their own departments.

It is the policy of the laboratory to ensure that EQA specimens, in so far as possible, are treated as routine specimens. EQA chosen by the laboratory should as far as possible provide material to be analysed that provides clinically relevant challenges that mimic patient samples. EQA specimens go through the normal registration, pre-examination and post- examination process. EQA specimens are used to check the competency of staff.

When selecting EQA programme(s), the laboratories consider the type of target value offered.

Target values are:

1) independently set by a reference method, or
2) set by overall consensus data, and/or
3) set by method peer group consensus data, or
4) set by a panel of experts.

Alternative Approaches

Where formal EQA schemes are not available, are inadequate or do not challenge the full range of the analyte, the laboratory may develop other approaches to determine the acceptability of examination results. The laboratory may use external derived primary specimens or portions of same to verify the test method. The laboratory will justify the rationale for the chosen alternative and provide evidence of its effectiveness. Examples of materials that could be used include:

- Certified reference materials.
- Samples previously examined.
- Material from cell or tissue repositories.
- Exchange of samples with other laboratories.
- Control materials that are tested daily in interlaboratory comparison programmes.

Analysis of Interlaboratory Comparison Samples

It is laboratory policy to integrate EQA samples into the routine workflow in a manner that represents as much as possible the routine testing of patient specimens. EQA specimens are examined by staff who routinely perform pre-examination, examination and post examination procedures using the same procedures used in the routine testing of patient specimens. The exception to this is, that the laboratory does not refer EQA samples for confirmatory testing where required, although this would be done with routine patient samples.

The laboratory does not collaborate with other programme users regarding samples submitted for examination.

Evaluation of Laboratory Performance

The review of the results and any associated corrective actions of inter-laboratory comparison are discussed with relevant staff. Discussion of EQA results is done at departmental meetings. EQA results are also discussed and presented at the annual management review.

If EQA results do not meet predetermined criteria it is recorded as non-conformance in Q-Pulse and appropriate investigation into the failure is carried out, including an assessment of whether the non-conformance is clinically significant as it relates to patient samples. Corrective and preventative action is then implemented by departmental staff and reviewed by the clinical team in charge of the department concerned. If it is determined that the impact is clinically significant, a review of patient results that could have been affected and the need for an amendment is considered and users advise as appropriate.

Results are reviewed to detect trends in performance that may indicate problems in the system. If performance trends in results that indicate problems are noted, a non-conformance is raised in Q-Pulse and appropriate investigation is carried out. Corrective and preventative action is then implemented and reviewed by the clinical team in charge of the department concerned.

A formal National Quality Assurance programme has been developed the by the Faculty of Pathology, RCPI for Anatomical Pathology. See EXT-CS-AP-12, National QA Programme in Histopathology SOP Monthly upload and local review of QA programme data.

7.3.7.4 Comparability of Examination Results

Where the same procedures, equipment and methods are in use, a comparison of results is performed. This is assessed through review of EQA /IQC or patient samples using the different procedures equipment and methods in place. This is performed on initial verification and on an ongoing basis if there are 2 of the same analysers on site. The laboratory records the results of comparability performed and its acceptability, where differences are identified, the impact of those differences on biological reference interval and clinical decision limits are evaluated and acted upon. The laboratory will inform users of any clinically significant differences in comparability of results.

7.4 Post-Examination Process

7.4.1 Reporting of Results

7.4.1.1 General

a) Examination results are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedure. The report includes all available information necessary for the interpretation of the results.
b) The laboratory has a procedure 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 management system requirements.

7.4.1.2 Review and Release of Results

Only authorised personnel (trained personnel) shall review, evaluate and authorise the release of results. The review and release process is defined by Review and Release of Results, MP-GEN-RESREL.

7.4.1.3 Reports of Critical Results

When examination results fall within established critical decision limits:

a) the user or other authorised person is notified as soon as relevant, based on clinical information available;
b) actions taken are documented, including date, time, responsible person, person notified, results conveyed, verification of accuracy of communication, and any difficulties encountered in notification;
c) the laboratory has an escalation procedure for laboratory personnel when a responsible person cannot be contacted.

This is described in procedure Review and Release of Results, MP-GEN-RESREL.

7.4.1.4 Special Considerations

This is described in procedure Review and Release of Results, MP-GEN-RESREL.

For the test results which may have serious implications for the patient, consent to report the result(s) to the requesting clinician(s) is implied within the agreement to take the sample and order the test. This includes an expectation that the requesting clinician/team will provide adequate counselling when conveying the result to the patient.

7.4.1.5 Automated Reporting of Results

MP-GEN-RESREL has a procedure for automated selection, review, release and reporting of results, established that ensures:

a) the criteria for automated selection, review and release is specified, approved, readily available and understood by personnel responsible for authorizing the release of results;
b) the criteria are validated and approved before use, regularly reviewed and verified after changes to the reporting system that can affect their proper functioning and place patient care at risk;
c) results selected by an automated reporting system for manual review are identifiable; and as appropriate, date and time of selection and review, as well as identity of the reviewer are retrievable;
d) when necessary, rapid suspension of automated selection, review, release and reporting is applied.

Some reports for particular sample types auto-authorise in Microbiology and Haematology following completion of the results. This is defined by department in PP-CS-MIC-66 and PP-CS-HAE-29. If printed reports are available, they are reviewed prior to dispatch to ensure demographic correctness and completeness of examination and are then delivered directly by the Pathology Department to ward receptions and clinics.

7.4.1.6 Requirements for Result Reports

The laboratory includes the following reports attributes to ensure results are communicated effectively:

a) unique patient identification, the date of primary sample collection and the date of the issue of the report, on each page of the report
b) identification of the laboratory issuing the report
c) name or other unique identifier of the user
d) type of primary sample and any specific information necessary to describe the sample (e.g. source, site of specimen, macroscopic description)
e) clear, unambiguous identification of the examinations performed;
f) identification of the examination method used, where relevant, including, where possible and necessary, harmonised (electronic) identification of the measurement and measurement principle
g) examination results with, where appropriate, the units of measurement, reported in SI units, units traceable to SI units, or other applicable units

h) biological reference intervals, clinical decision limits, likelihood ratios or diagrams/nomograms supporting clinical decision limits as necessary
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. However, all authorisation transactions including name are recorded electronically and are available for review on the LIS transaction log. Medical Council Registration number is included for all reports authorised by medical staff. Pre-authorised results (electronic signature COMP) are deemed authorised under the authority of Consultant in charge of the department. Results from referral laboratories, where printed on NMH paper are authorised by COMP. The name of the referral laboratory is indicated in the body of the report. The referral/back up laboratory report number is recorded internally on Winpath for reference.
k) identification of any results that need to be considered as preliminary
l) indications of any critical results
a) 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).

- The following text will be appended in the footer of all hardcopy printed reports for Haematology, Biochemistry and Microbiology, where accredited activities are being reported: *'An INAB accredited testing laboratory Reg No 240MT. Excludes tests performed in referral laboratories'.*
- The following text will be appended in the footer of all hardcopy printed reports for Blood Transfusion, where accredited activities are being reported: *'An INAB accredited testing laboratory Reg. No 240MT. Excludes tests performed in referral laboratories. ®Denotes tests performed in a non INAB accredited referral laboratory'.*
- The following note will be added to the body of each Histology hard copy printed report and electronic report: *'The NMH is an INAB accredited testing laboratory. Registration number 240MT. This covers testing carried out in this facility. For histology this excludes C9; Adipophilin; GATA 3; Alcian Blue; Grocotts; Alcian Blue/PAS; ZN; Reticulin; Elastin VG; MSB; Van Gieson; PAX8 and SARS CoV-2'.*
- The following text will be visible on Blood Transfusion, Haematology, Biochemistry and Microbiology electronic reports for where accredited activities are being reported: *'The NMH is an INAB accredited testing laboratory (Reg.No. 240MT). Tests performed in referral laboratories are excluded from this scope'.*

7.4.1.7 Additional Information for Result Reports Report Content

a) When necessary for patient care, the time of primary sample collection shall be included.
b) Time of report release, if not contained in the report, is readily available when needed. All time release transactions are recorded electronically and are available for review on the LIS transaction log. 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.
c) When applicable, a report includes interpretation of results and comments on:
    i. sample quality and suitability that can compromise the clinical value of examination results;
    ii. discrepancies when examinations are performed by different procedures (e.g. POCT) or in different locations;
    iii. possible risk of misinterpretation when different units of measurement are in use regionally or nationally;
    iv. result trends or significant changes over time.

7.4.1.8 Amendments to Reported Results

In assuring quality of service to users it may be necessary to recall a result or to amend a report. The procedure in place in the laboratory outlines the criteria for issuing amended reports and the procedure to be followed when recalling results and or issuing amended reports. Departmental procedures are operable throughout the Department of Pathology and Laboratory Medicine, and ensures that:

a) The reason for change is recorded and included in the amended report
b) The new amended report clearly outlines that it is a deviation from the original, and the original copy is left in the patient's chart and is marked as corrected or incorrect
c) Where a report has been amended the clinical area will be notified directly and made aware of the amendment.
d) The revised report shows the time and date of the change and the name of the person responsible for amendment.
e) The original report and the correct report are retained on Winpath, the original copy is also left in the patient's chart and is marked as incorrect.

7.4.2 **Post-Examination Handling of Sample**

The laboratory follows a procedure for the control of clinical material. It encompasses the procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples. After testing, primary specimens and portions of specimens are stored in accordance with legal and clinical requirements as per the procedure for Control of Clinical Material, MP-GEN-CLINCON.

The laboratory ensures that after the examination the patient and source identification of the sample are maintained, suitability of the sample for additional examination is known, sampled is stored in a manner that optimally preserves suitability for additional examination and the sample can be located and retrieved.

Primary specimens, portions of specimens and material used in the testing process but no longer required, are disposed of safely in accordance with hospital procedures.

7.5 **Non-Conforming Work**

The laboratory has documented procedures to identify and manage non conformities in any aspect of the QMS. The procedure MP-GEN-MQA ensures that:

a) The responsibilities and authorities for handling nonconformities are designated.
b) The immediate actions and long-term actions to be taken are defined and based upon the risk analysis process established by the laboratory.
c) The extent of the nonconformity is determined.
d) Examinations are halted and reports withheld where there is a risk of harm to patients.
e) An evaluation is made of the clinical significance of the non-conforming work, including an impact analysis on examination results which were or could have been released prior to identification of the non-conformance;
f) The medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed.
g) The results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified as necessary.
h) The responsibility for authorisation of the resumption of examinations is defined.
i) Each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

When it is determined that nonconformities in pre-examination, examination and post-examination processes could recur or that there is doubt about the laboratory's compliance with its own

procedures, the laboratory shall take action to identify, document and eliminate the cause(s). Corrective action to be taken shall be determined and documented.

7.6 Information Systems Management

7.6.1 General

The laboratory has access to the data and information required to provide a service which meets user needs through a number of systems. These include:

- The laboratory information system (LIS), Winpath.
- A patient manager system, iPIMS.
- An electronic health record, MN-CMS.
- A laboratory quality management system, Q-Pulse.

Laboratory information systems have a major impact on all phases of operating activity process, and procedures. The Winpath LIS captures, processes, reports and stores data concerning the identification of patients and specimen analysis. The system is online in all the wards via Winpath Ward Enquiry 5. This facilitates result enquiry for users of the Pathology service. Authorised results transfer to MN-CMS and can be reviewed in the patient electronic health record available in every clinical area.

Laboratory management ensures confidentiality of the patient is maintained at all times by adhering to the confidentiality policy. This applies to all employees and is detailed in all contracts of employment. Acceptance of the terms and conditions of the contract indicate compliance and acceptance of this policy.

7.6.2 Authorities and Responsibilities

The Laboratory Manager and Information Systems Scientist are responsible for the local management of the LIS, and ensure that all LIS related procedures in place are strictly adhered to. The infrastructure, servers and hardware are the responsibility of the ICT department.

The laboratory defines the authorities and responsibilities of all personnel who use the system through a password control system. Access to Winpath is password controlled. Passwords are designated by the laboratory manager and different levels of access are assigned to staff depending on the requirements of their position. Access levels define who has authority to:

a) Access patient data and information.
b) Enter patient data and examination results.
c) Change patient data or examination results.
d) Authorise the release of examination results and reports.

An audit trail displays any actions that were made on a particular laboratory number including the identification of the person who performed it.

7.6.3 Information Systems

Laboratory management and the IT department are responsible for ensuring that the information systems in use in the laboratory for the collection, processing, recording, reporting, storage, retrieval of examination data and that information is:

a) Suitably validated as adequate for use in the facility by the supplier before introduction. Any changes to the system must be authorised and documented before implementation. This is achieved through the change management procedure in Q-Pulse. The validation and verification should include functioning of interfaces between the LIS and laboratory instrumentation or the patient information system.

b) The system, including day to day running is documented. This is documented in LP-GEN-WINPATH, and is available to all users.
c) Computer programmes and routines are adequately protected via passwords and permissions to prevent access, alteration or destruction by casual or unauthorised persons.
d) Safe guarded against tampering or loss, taking cybersecurity into account. The IT Department is responsible for maintaining the system backups. This is done nightly Monday to Saturday i.e. 6 times a week, so data is safeguarded.
e) Computers and automated equipment are operated in an environment which complies with supplier specification. In the event of non-computerised systems being used conditions should safeguard the accuracy of manual recording and transcription.
f) CliniSys has an annual preventative maintenance contract in place which covers the maintenance of the integrity of the operating system and laboratory application software. All system failures are recorded in Q-Pulse and appropriate corrective and preventative actions put in place as per policy.
g) The systems are managed in compliance with national and international requirements regarding data protection this is documented in the hospital management of data and information document.

Procedures are established and implemented for protecting the integrity of data at all times. This ensures that test results, associated information and comments are accurately reproduced. Winpath has a report preview function that allows the user to view the finished report electronically before printing.

The laboratory verifies that the results of examinations, associated information and comments are accurately reproduced, electronically and in hardcopy, where relevant through the procedures, PP-CS-LM-31, Management of Winpath, and PP-CS-LM-32, Advanced Use of Winpath; and through the annual audit, IT Dept Verification of Electronically Stored Data.

7.6.4 Downtime

In the event of system failure during normal working hours, the Laboratory Manager is first contacted, and if necessary either Information Systems Scientist, the IT Department or a service engineer from CliniSys is called. Instructions for system failure are available on Q-Pulse.

7.6.5 Off-Site Management

This is defined in MP-GEN-DATAMAN

7.7 Complaints

7.7.1 Process

The laboratory has a process for handling complaints which is defined in MP-GEN-MQA. It 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.

A description of the process for handling complaints is publicly available (PP-CS-LM-4)

7.7.2 Reception of Complaints

a) Upon receipt of a complaint, the laboratory confirms whether the complaint relates to laboratory activities that the laboratory is responsible for and, if so, shall resolve the complaint.

b) The laboratory receiving the complaint is responsible for gathering all necessary information to determine whether the complaint is substantiated.
c) Whenever possible the laboratory acknowledges receipt of the complaint, and provide the complainant with the outcome and, if applicable, progress reports.
d) The Primary Specimen Collection Manual, PP-CS-LM-4, outlines how the Department of Pathology and Laboratory Medicine handles user complaints. The laboratory will document all perceived or real grievances from clinicians, patients or other related parties and investigate as formal complaints. Complaints are dealt with in the first instance by the head of department. Records of all complaints including appropriate investigations and corrective actions taken are reviewed and maintained in Q-Pulse.

7.7.3 Resolution of Complaints

Investigation and resolution of complaints will not result in any discriminatory actions.
The resolution of the complaints is 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.
The customer complaints process and outputs are reviewed at the monthly quality assurance meeting. Clinical Governance is made aware of written complaints to ensure compliance with hospital policy. Monitoring and resolution of complaints are reviewed as part of the AMR. The laboratory is committed by use of surveys to establishing a method of measuring customer satisfaction.

7.8 Plan for Emergency Situations

The laboratory ensures that risks associated with emergency situations or other conditions when laboratory activities are limited, or unavailable, have been identified, and a coordinated strategy exists that involves plans, procedures, and technical measures to enable continued operations after a disruption.
Plans are periodically tested and the planned response capability exercised, where practicable.
The laboratory:

a) establishes a planned response to emergency situations, taking into account the needs and capabilities
a) of all relevant laboratory personnel;
b) provides information and training as appropriate to relevant laboratory personnel;
c) respond to actual emergency situations;
d) takes action to prevent or mitigate the consequences of emergency situations, appropriate to the magnitude of the emergency and the potential impact.

The plan for emergency situations is described in PP-CS-LM-29

8 MANAGEMENT SYSTEM REQUIREMENTS

8.1 General Requirements

8.1.1 General

Laboratory management have established a QMS that is defined in its totality by the procedures it operates to control processes which meet the defined policies and are compatible with the ethos at the National Maternity Hospital. Laboratory management ensures that all relevant personnel understand the documented policies, processes and procedures and are committed to continually monitoring and evaluating the effectiveness of the QMS in accordance with ISO 15189. The QMS provides for the integration of all processes required to fulfil the quality policy and objectives. In addition, the QMS meet the needs and requirements of the users.

The management system includes:

- responsibilities (8.1)
- objectives and policies (8.2)
- documented information (8.2, 8.3 and 8.4)
- actions to address risks and opportunities for improvement (8.5)
- continual improvement (8.6)
- corrective actions (8.7)
- evaluations and internal audits (8.8)
- management reviews (8.9)

8.1.2 Fulfilment of Requirements

This is achieved by ensuring the management system includes all listed in 8.1.1

8.1.3 Awareness

The laboratory ensures that all laboratory staff are aware 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.
d) This is achieved through training and performance management

8.2 Documentation of the Management System

8.2.1 Policies and Objectives

Laboratory management have established quality objectives, including those needed to meet the needs and requirements of the users, at relevant functions and levels within the establishment. These quality objectives are measurable and consistent with the quality policy. Laboratory management ensures that planning of the QMS is carried out to meet the requirements and the quality objectives. Laboratory management ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. See procedure Management of Quality Assurance, MP-GEN-MQA), and Management of Quality Objectives, RF-CS-LM-150.

8.2.2 Competency and Quality

The objectives and policies address the competence, quality and consistent operation of the laboratory.

8.2.3 Evidence of Commitment

Laboratory management shows evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.

Fundamental to our QMS is laboratory management's commitment to ensuring procedures and programmes are in place which are regularly monitored and demonstrate function of the QMS. Laboratory management is responsible for providing the necessary resources and information (human, material, equipment) to meet the requirements to support the operation and monitoring of the QMS. Laboratory management implements actions necessary to achieve planned results and continual improvement of these processes.

8.2.4 Documentation

All documentation, processes, systems, and records, related to the fulfilment of the requirements of this document are included in, referenced from, or linked to the management system.
The sequence and interaction of the QMS is defined by the master list of documents including the traceability and Haemovigilance activities. Key QMS processes and their interaction are defined in Appendix 6.1 titled "Pathology Department Quality Assurance Process Flow". These key elements are controlled by the management procedures in Q-Pulse. Routine maintenance of the QMS by the Quality Officer ensures that the operation and control of these processes are effective.

8.2.5 Personnel Access

All laboratory personnel have access to the parts of the management system documentation and related information that are applicable to their responsibilities.

8.3 Document Control

8.3.1 General

All documents are controlled in accordance with ISO 15189.

8.3.2 Control of Documents

Q-Pulse is used to manage the document control cycle and provides immediate access to the documents that comprise the quality management system. To ensure that only approved and the most recent revision of documents is in place, only controlled versions of documents are in use. Approved documents are located in the active register of Q-Pulse. The procedure PP-CS-LM-16 controls all documents and information (from internal and external sources) that form part of the laboratory's quality documentation including Haemovigilance/ traceability. All approved documents, which are embedded in Q-Pulse, are controlled and cannot be changed unless a new revision is requested.

Procedures PP-CS-LM-16 and MP-GEN-RECCON ensure:

a) All documents issued to laboratory personnel as part of the QMS are reviewed and approved by approved personnel prior to issue.
b) All documents include:
   i. A title
   ii. A unique identifier
   iii. Date of current edition
   iv. Page number and total number of pages
   v. Authority for issue

   These are included in the document headers in Q-Pulse.
c) Current authorised editions are identified on a document register or master index. The online use of Q-Pulse provides a master index of all documents for viewing and for full control of documentation.
d) Only current authorised editions are available at points of use. All documents used in the Department of Pathology and Laboratory Medicine are stored and accessed electronically as per MP-GEN-RECCON.

e) Hand amendments are not permitted. Any minor changes to the document are tracked through change requests as per PP-CS-LM-16. Where major modifications are required before the review date a new revision should be drafted, approved and issued. The issue, revision and approval of document control procedures are the responsibility of the Quality Officer.
f) Changes to documents are identified.
g) Documents are legible.
h) They are reviewed and updated at a frequency that ensures they remain fit for purpose. Documents are reviewed for adequacy every three years or as required to ensure that they comply with current policies and procedures. The Quality Manual, The Primary Sampling Manual and the Ethical Conduct form are exceptions with annual review. All revisions are approved prior to implementation.
i) Retained or archived superseded master documents are transferred to the obsolete register of Q-Pulse. Obsolete versions of documents are removed automatically from the point of use when the revised version is being implemented. Printed obsolete copies of document types are destroyed
j) There are different levels of user access to Q-pulse based on staff grade and training. All access is password protected to prevent unauthorised access, unauthorised changes or any deletions or removals.

Document Types

Documents are structured in Q-Pulse to facilitate online viewing. The Department of Pathology and Laboratory Medicine is classified under care services within the hospital document management system. The QMS documents are divided as follows:

Figure 8: Document Types

Document Type	Prefix
External Documents	EXT-CS
Patient Information	PI-CS
Policies and Procedures	PP-CS
Quality Manual	QM-CS
Records and Forms	RF-CS
Staff Information	SI-CS
Staff Memo	SI-MEM
Work Instructions	WI-CS
Safety Data Sheets	SDS-LAB

Within these document types there may be subdivisions by department as follows:

Document Sub Type	Prefix
Anatomical Pathology	- AP -
Biochemistry	- BIO -
Blood Transfusion	- BT-
General Pathology	- LM -
Haemovigilance	- HV -
Haematology	- HAE -
Management	- LM -
Microbiology	- MIC -
Phlebotomy	- PHE -
Specimen Reception	- SR -

Note: Many documents forming part of the QMS were generated using a different numbering nomenclature. They have been reclassified based on the current types.

8.4 Control of Records

8.4.1 Creation of Records

The laboratory has established and retains legible records to demonstrate fulfilment of ISO15189. This is described in MP-GEN-RECCON

8.4.2 Amendments of Records

The laboratory ensures that amendments to records can be traced to previous versions or to original observations. Both the original and amended data and files are kept, including the date and where relevant the time, of the alteration, an indication of the altered aspects and the personnel making the alteration. This is described in MP-GEN-RECCON

8.4.3 Retention of Records

a) The laboratory has implemented the procedures needed for the identification, storage, protection from unauthorised access and changes, back-up, archive, retrieval, retention time, and disposal of its records.
b) The retention times for records are specified.
c) Reported examination results are retrievable for as long described.
d) All records are accessible throughout the entire retention period, legible in whichever medium the records are kept, and available for laboratory management review.

This is described in MP-GEN-RECCON

8.5 Actions to Address Risks and Opportunities for Improvement

8.5.1 Identification of Risks and Opportunities for Improvement

The laboratory identifies risks and opportunities for improvement associated with the laboratory activities to:

a) prevent or reduce undesired impacts and potential failures in the laboratory activities;
b) achieve improvement, by acting on opportunities;
c) assure that the management system achieves its intended results;
d) mitigate risks to patient care;
e) help achieve the purpose and objectives of the laboratory.

Ref: MP-GEN-MQA

8.5.2 Acting on Risks and Opportunities for Improvement

The laboratory prioritises and acts on identified risks. Actions taken to address risks are proportional to the potential impact on laboratory examination results, as well as patient and personnel safety.
The laboratory records decisions made and actions taken on risks and opportunities.
The laboratory integrates and implements actions on identified risks and improvement opportunities into its management system and evaluate their effectiveness.
Ref: MP-GEN-MQA

8.6 Improvement

8.6.1 Continual Improvement

The laboratory is committed to continually improving the effectiveness of the QMS, including the pre-examination, examination and post-examination processes. It does this through the use of management reviews to compare the laboratory's actual performance in its evaluation activities, corrective actions and preventive actions with its intentions, as stated in the quality policy.

Improvement activities are directed at areas of highest priority based on risk assessments. Action plans for improvement are developed, documented and implemented, as appropriate. The

effectiveness of the actions taken are determined through a focused review or audit of the area concerned.
Opportunities for improvement are identified through risk assessment, use of the policies, review of the procedures, overall objectives, external evaluation reports, internal audit findings, complaints, corrective actions, management reviews, suggestions from personnel, suggestions or feedback from patients and users, analysis of data and EQA results.

Laboratory management ensures that the laboratory participates in continual improvement activities that encompass relevant areas and outcomes of patient care. Where continual improvement strategies identify opportunities for improvement, laboratory management shall address them regardless of where they occur. Laboratory management communicate to staff improvement plans and related goals.

Laboratory management is dedicated to the use of surveys in order to establish a method of measuring the laboratory's contribution to patient care. Where such surveys identify opportunities for improvement, laboratory management will take all necessary steps to ensure such opportunities for improvement are taken. Furthermore, laboratory management will avail of all relevant opportunities to ensure participation in hospital quality improvement activities whose objective is to improve patient care. Laboratory management is committed to continual improvement by means of providing all necessary and suitable education and training opportunities to laboratory and Haemovigilance personnel.
Ref – MP-GEN-MQA

8.6.2 Laboratory Patients, User, and Personnel Feedback

The laboratory seeks feedback from its patients, users, and personnel. The feedback is analysed and used to improve the management system, laboratory activities and services to users.
Records of feedback are maintained including the actions taken. Communication is provided to personnel on actions taken arising from their feedback.
Ref – MP-GEN-MQA

8.7 Non-Conformities and Corrective Actions

8.7.1 Actions when Non-Conformity Occurs

The procedure MP-GEN-MQA identifies and manages non conformities in any aspect of the QMS and ensures that the laboratory:

1. Responds to the nonconformity and, as applicable:
   a. Takes immediate action to control and correct the nonconformity;
   b. Addresses the consequences, with a particular focus on patient safety including escalation to the appropriate person.
2. Determines the cause(s) of the nonconformity.
3. Evaluates the need for corrective action to eliminate the cause(s) of the nonconformity, in order to reduce the likelihood of recurrence or occurrence elsewhere, by:
   c. reviewing and analysing the nonconformity;
   d. determining whether similar nonconformities exist, or could potentially occur;
   e. assessing the potential risk(s) and effect(s) if the nonconformity recurs.
4. Implement any actions needed.
5. Reviews and evaluates the effectiveness of any corrective action taken.
6. Update risks and opportunities for improvement
7. Makes changes to the management system, if necessary.

8.7.2 Corrective Action Effectiveness

The procedure MP-GEN-MQA ensures that:
Corrective actions are appropriate to the effects of the nonconformities encountered and identified causes are mitigated.

8.7.3 Records of Non-Conformities and Corrective Actions

The laboratory retains records in Q-Pulse as evidence of the
a) nature of the nonconformities, cause(s) and any subsequent actions taken, and
b) evaluation of the effectiveness of any corrective action**.**

8.8 Evaluations

8.8.1 General

The laboratory management team has established and maintains documented procedures for planning and implementing evaluations so as to verify whether quality activities and related results conform to planned arrangements and to determine the effectiveness of the QMS. The evaluation process is used to continually improve the effectiveness of the QMS. Elements of ISO 15189 and AML-BB are audited based on risk. The schedule and scope of evaluations demonstrate that pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of our users. The Quality Manager defines the evaluation schedule which includes audits of Haemovigilance activities and traceability by tracking blood components from receipt to transfusion.

8.8.2 Quality Indicators

Quality indicators are in place to monitor and evaluate performance throughout the critical aspects of pre-examination, examination and post-examination processes. The process for implementation and monitoring of quality indicators is documented in the procedure Management of Quality Assurance, MP-GEN-MQA, and Management of Quality Objectives, RF-CS-LM-150. Quality indicators are periodically reviewed to ensure their continued appropriateness. The laboratory, in conjunction with its users, have established turnaround times appropriate to clinical needs. These are periodically reviewed.

8.8.3 Internal Audits

Internal audits are:

1) Planned and organised by the Quality Manager
2) Conform to the requirements of ISO 15189 and AML-BB.
3) Performed by trained laboratory staff under the direction of the Quality Manager
4) Are implemented according to the audit schedule and that audits are effective and maintained.
5) Scheduled such that staff do not audit of their own activities for horizontal audits ensuring objectivity and impartiality of the audit process;
6) The audit schedule takes into account the status and importance of processes, technical and management areas to be audited as well as the results of previous audits. The audit criteria, scope, frequency and methods are defined in the relevant audit checklists.

The procedure Internal Audit of Quality Management System, MP-GEN-AUDIT, controlling this activity defines the following:

a) The responsibility and requirements for planning, conducting, reporting results and maintaining records.
b) The frequency and type of audit (vertical and horizontal).
c) Priority is given to risk to patients from laboratory activities;
d) Ensures objectivity and impartiality of the audit process
e) Classification of nonconforming events.

f) The reporting activity.
g) Corrective actions shall be taken without delay to eliminate the causes of the detected non conformities. That follow up is performed to ensure that the stated corrective actions have been taken and that such actions are effective.
h) The mechanism for close out of nonconforming issues.
i) The documentation is traceable to the audit process. That records of this activity (audit schedule, audit checklist, audit report and audit non conformities) are maintained.
j) That the Quality Manager authorises audit reports.
k) That audit reports are discussed at:
   I. Department meetings
   II. Laboratory management meetings
l) That audits are reviewed and closed by laboratory management at the quality assurance meeting.

8.9 Management Reviews

8.9.1 General

Laboratory management reviews the QMS annually to ensure its continuing suitability, adequacy and effectiveness and support of patient care. This review will include Haemovigilance/Traceability activities.

8.9.2 Review Input

The laboratory management review addresses the following aspects of the laboratory:

1. status of actions from previous management reviews, internal and external changes to the management system, changes in the volume and type of laboratory activities and adequacy of resources;
2. fulfilment of objectives and suitability of policies and procedures;
3. outcomes of recent evaluations, process monitoring using quality indicators, internal audits, analysis of non-conformities, corrective actions, assessments by external bodies;
4. patient, user and personnel feedback and complaints;
5. quality assurance of result validity;
6. effectiveness of any implemented improvements and actions taken to address risks and opportunities for improvement;
7. performance of external providers;
8. results of participation in interlaboratory comparison programmes;
9. evaluation of POCT activities;
10. other relevant factors, such as monitoring activities and training.

The review analyses information for causes of nonconformities, trends and patterns that indicate process problems. The review also includes assessing opportunities for improvement and the need for changes to the QMS, including the quality policy and quality objectives. The quality and appropriateness of the laboratory's contribution to patient care is, to the extent possible, also objectively evaluated.

8.9.3 Review Output

Laboratory Management review report

The report from the management review documents any findings, decisions made and actions taken related to:

1. the effectiveness of the management system and its processes;
2. improvement of the laboratory activities related to the fulfilment of the requirements of this document;
3. provision of required resources;

4. improvement of services to patients and users;
5. any need for change.

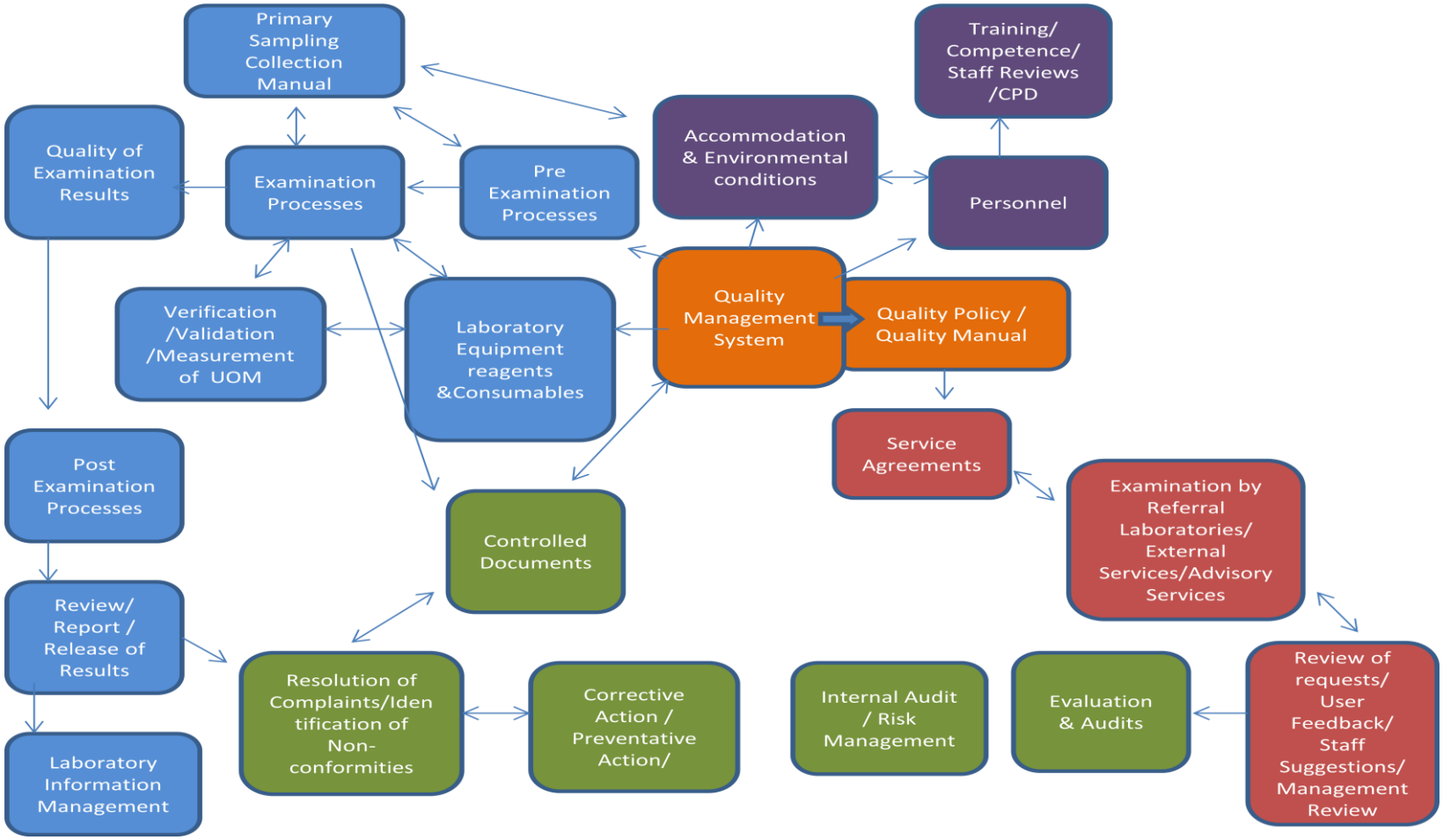
The management review agenda and report are stored as a commissioned audit in Q-Pulse and available to view by all laboratory staff. Observations and actions to be taken are entered into the findings section of the audit by laboratory management. This links directly to the CA/PA module of Q-Pulse. The CAPA module is used to track and ensure that actions arising from the AMR are completed within a defined timeframe. The goals and objectives set at the previous management review should be revisited at the next review so that progress versus plan can be measured. The minutes are distributed to all Consultant staff as referenced in RF-CS-LM-23, the key personnel document.

The review is chaired by the Director of Pathology and is attended by the:

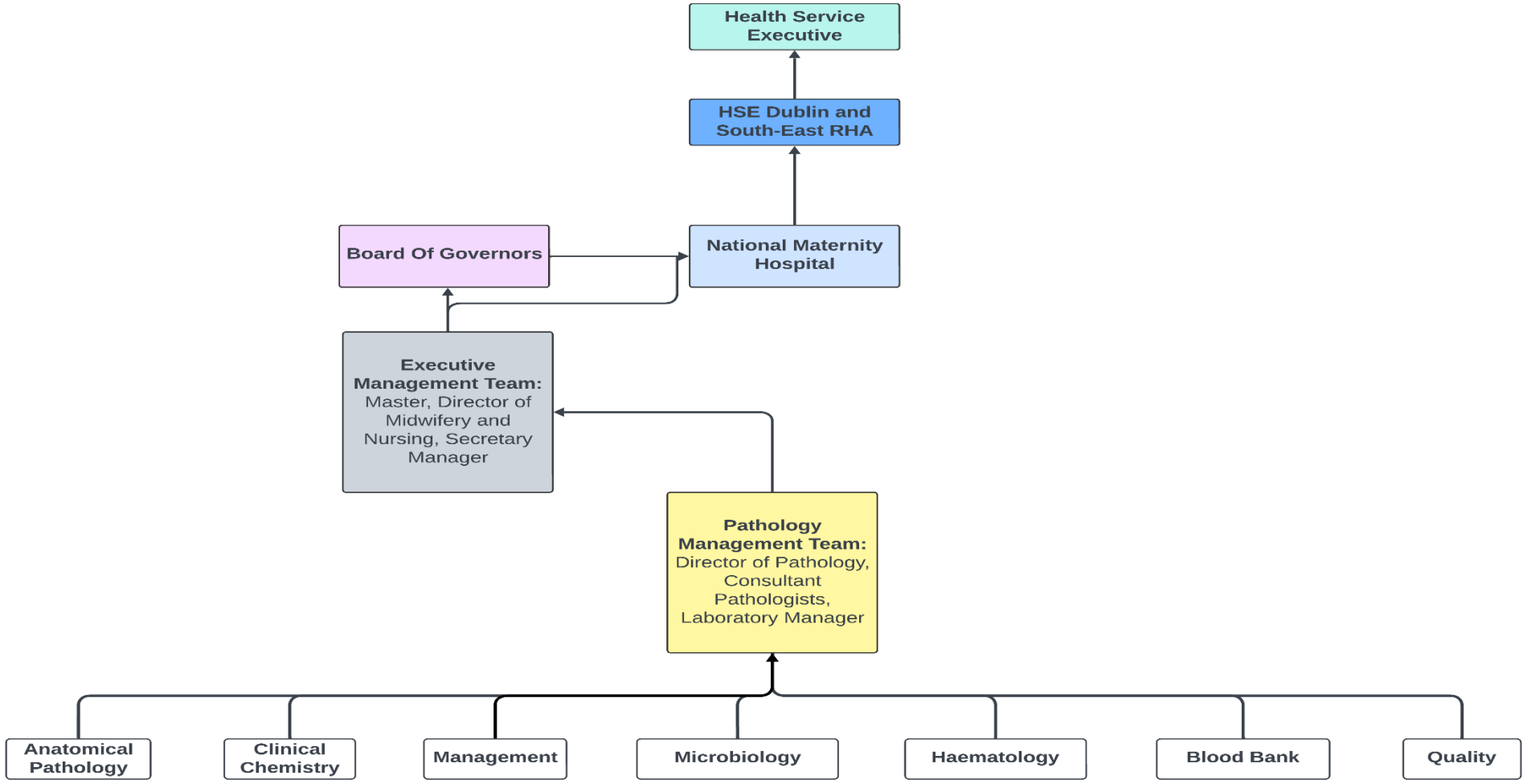
1. Director of Pathology
2. Consultant Haematologist
3. Consultant Histopathologist(s)
4. Consultant Microbiologist
5. Consultant Chemical Pathologist
6. Laboratory Manager
7. Quality Manager
8. Chief/Senior Scientists
9. Haemovigilance Officer
10. Senior Administrative Staff

9 Appendices

9.1 Appendix 1: Pathology Department Quality Assurance Process Flow



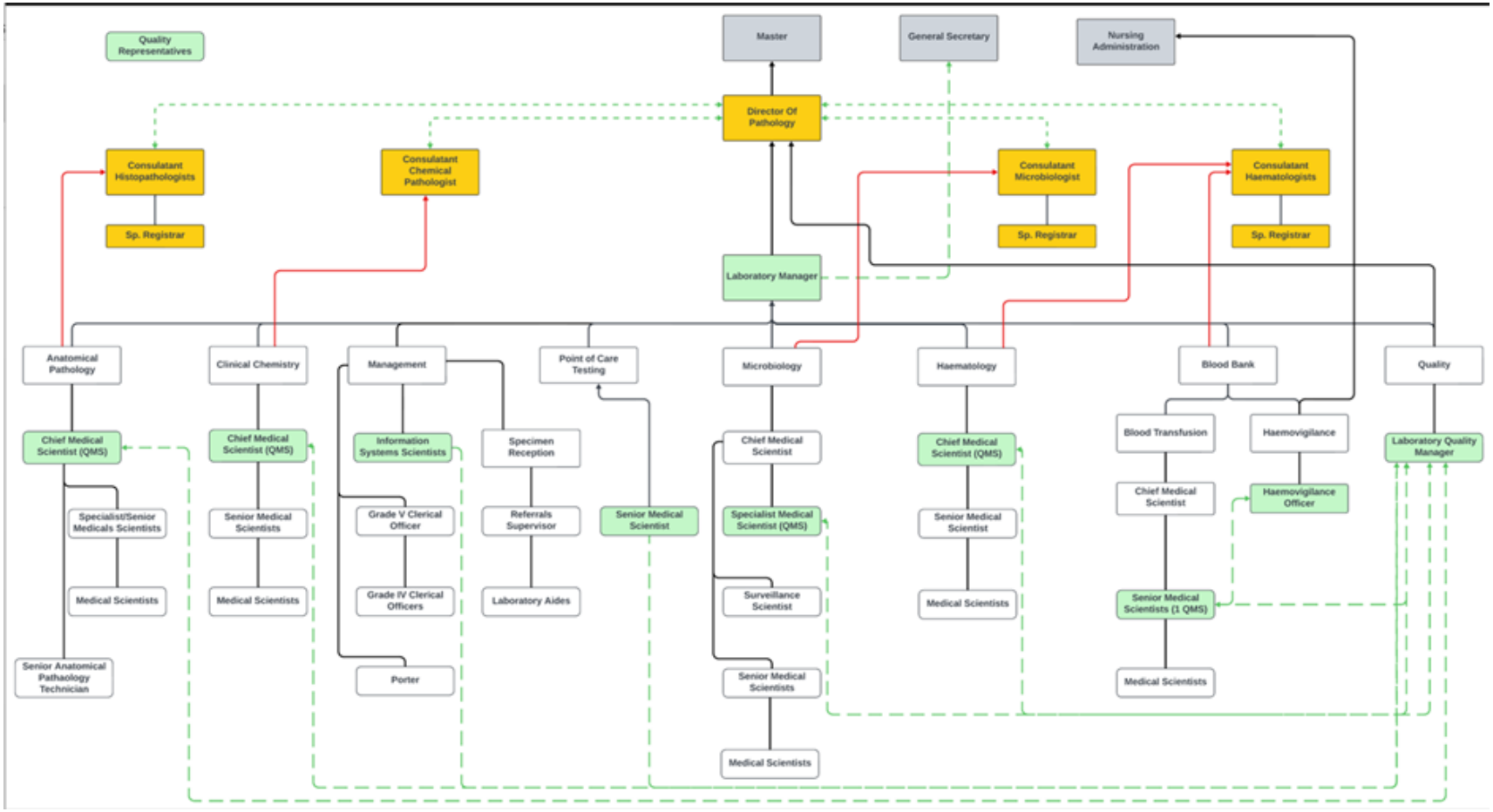
Appendix 2: Department of Pathology and Laboratory Medicine Organisational Charts, National Maternity Hospital



National Maternity Hospital Department of Pathology and Laboratory Medicine

Convention for organisational chart:

1. Black lines indicate Direct reporting relationships and flow up the chart
2. Red Lines indicate Direct and Clinical reporting relationships and flow in the direction of the arrow
3. Green Lines indicate liaison relationships and flow in the direction of the arrow


Quality Representatives
Master
General Secretary
Nursing Administration
Director Of Pathology
Consulatant Histopathologists
Consulatant Chemical Pathologist
Consulatant Microbiologist
Consulatant Haematologists
Sp. Registrar
Sp. Registrar
Sp. Registrar
Laboratory Manager
Anatomical Pathology
Clinical Chemistry
Management
Point of Care Testing
Microbiology
Haematology
Blood Bank
Quality
Chief Medical Scientist (QMS)
Chief Medical Scientist (QMS)
Information Systems Scientists
Specimen Reception
Chief Medical Scientist
Chief Medical Scientist (QMS)
Blood Transfusion
Haemovigilance
Laboratory Quality Manager
Specialist/Senior Medicals Scientists
Senior Medical Scientists
Grade V Clerical Officer
Referrals Supervisor
Senior Medical Scientist
Specialist Medical Scientist (QMS)
Senior Medical Scientist
Chief Medical Scientist
Haemovigilance Officer
Medical Scientists
Medical Scientists
Grade IV Clerical Officers
Laboratory Aides
Surveillance Scientist
Medical Scientists
Senior Medical Scientists (1 QMS)
Senior Anatomical Pathaology Technician
Porter
Senior Medical Scientists
Medical Scientists
Medical Scientists