Alder Hey Children's NHS
NHS Foundation Trust

Paediatric Laboratory Medicine (Pathology)

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Table of contents

1 PERSONNEL WHO SHOULD READ THIS DOCUMENT

All grades of staff should ensure that they have read the appropriate sections of this document before proceeding with any task.

2 GENERAL INFORMATION

This document describes the Quality Management System of the Pathology Laboratory at Alder Hey Children's NHS Foundation Trust. The document fulfils two functions. It describes the Quality Management System for the benefit of the laboratory's own management and staff, and it provides information for users and for inspection/accreditation bodies.

The sections of the Quality Manual are arranged so that they equate with the clauses of the ISO 15189:2012 standard. Other bodies may be listed including Human Tissue Authority (HTA), Health & Safety Executive (HSE) and The Medicines and Healthcare products Regulatory Agency (MHRA).

Under the title of each standard there is a brief description of the way in which the Laboratory seeks to comply with the particular standard and references are given to appropriate procedures. All processes and procedures specified herein are mandatory within the Laboratory.

Information regarding the distribution and review history of this document can be found from the electronic iPassport document control system.

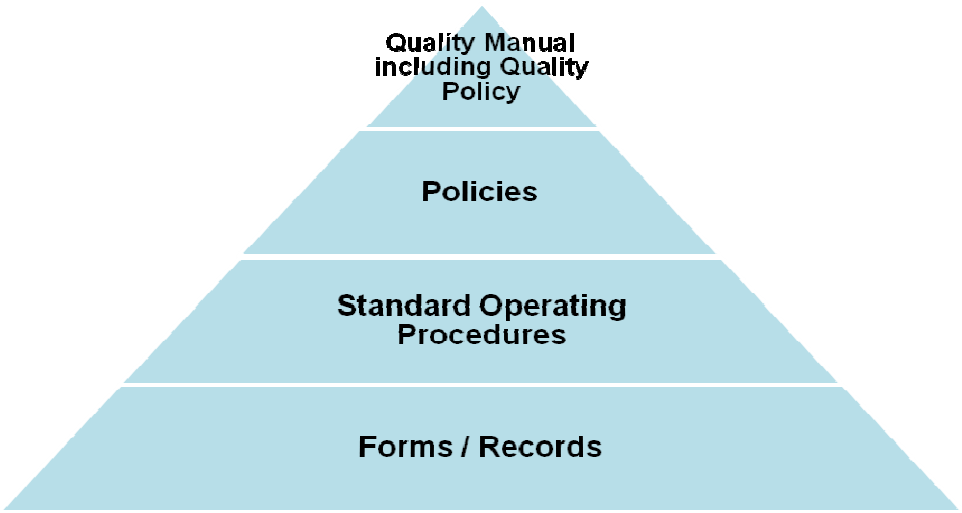
Reference to UKAS accreditation shall be displayed on all test reports (including medical laboratory reports) and certificates that contain results from tests that are within the accredited scope of the laboratory and that it has itself carried out. Reference should be made either by incorporation of the appropriate testing accreditation symbol or use of the wording 'a UKAS accredited medical laboratory No.9091

All non-accredited work shall be clearly identified as 'Not UKAS accredited.

All testing quotations and service agreements that make reference to UKAS accreditation shall clearly indicate those activities that are not UKAS accredited (GEN 6 Reference to accreditation and multilateral recognition signatory status by UKAS accredited bodies Edition 1 October 2021).

2.1 Structure of the documentation used in the quality management system

All documents used in the quality management system are controlled via iPassport web based electronic document control system. The hierarchical structure of the documentation is illustrated below:



Policies set out the commitment of the laboratory to follow a particular course of action.

Standard operating procedures (SOPs) are the practical way in which policies are translated into action. The quality management system includes SOPs for the management of resources, pre-examination, examination and post-examination processes and the quality management system evaluation. These SOPs are referred to within the relevant sections of this quality manual.

Forms and records are those documents on which records are made as evidence that a procedure has been carried out.

Identification of documents
All documents can be identified by a unique index number. The documents can be located via iPassport under “Laboratory Records”.

3 ORGANISATIONAL OVERVIEW

3.1 General overview

Paediatric Laboratory Medicine (Pathology) is part of the Division of Medicine at Alder Hey Children's NHS Foundation Trust. The Trust is one of Europe's biggest and busiest paediatric hospitals, and provides paediatric services to more than 200,000 children each year, serving an area that covers the North West, North Wales, Shropshire, the Isle of Man and Northern Ireland. As well as being a tertiary referral hospital for many conditions with paediatric specialists for most areas in children's medicine, the Trust also provides general paediatric service and clinics for the locality. It is also a teaching hospital, involved in the training of more than 600 medical students. Specialist services include bone marrow transplant, burns, cleft lip and palate, cancer, renal replacement and spinal injuries, with supra-regional services for cardiology and craniofacial surgery.

Paediatric Laboratory Medicine is composed of four disciplines; Biochemistry, Haematology including Blood Transfusion, Histopathology including Mortuary and Microbiology. The laboratories are situated on the first floor of the hospital and can be accessed via the door next to the Lecture Theatre at the end of the mezzanine seminar suite walkway (internal visitors). External visitors to the laboratory should exit the atrium via the rotating doors next to WHSmith. There is an intercom button that connects to specimen reception next to the double doors to the right.

The laboratory departments aim to provide a high quality, up to date, reliable and comprehensive paediatric laboratory medicine service, including a consultant advisory service for both patients in the hospital and those cared for by General Practitioners. The laboratory also provides advice and support regarding paediatric pathology to other hospital laboratories in the region. The main services provided by the laboratory are on site diagnostic and therapeutic investigations and mortuary services, as well as support of bedside and point of care diagnostic testing.

The Biochemistry and Haematology departments share responsibility for the provision of a regional Newborn Haemoglobinopathy Screening Service and the Biochemistry department provides a regional Newborn Screening Service for Phenylketonuria, Congenital Hypothyroidism, Cystic Fibrosis and Medium Chain Acyl CoA Dehydrogenase deficiency (MCADD), Maple Syrup Urine Disease (MSUD), Isovaleric Acidaemia (IVA), Glutaric Aciduria Type 1 (GA1), and Homocystinuria. The Histopathology department provides a regional network for foetal & perinatal Pathology. The mortuary serves the foetal and perinatal network and the Coroners and Home Office Pathologists within the North West, North Wales, Isle of Man and Northern Ireland regions.

More detailed information on the services offered by all of the individual departments is available from the staff intranet, the Meditech computer system and the Trust website:
Laboratory Medicine :: Alder Hey Children's Hospital Trust

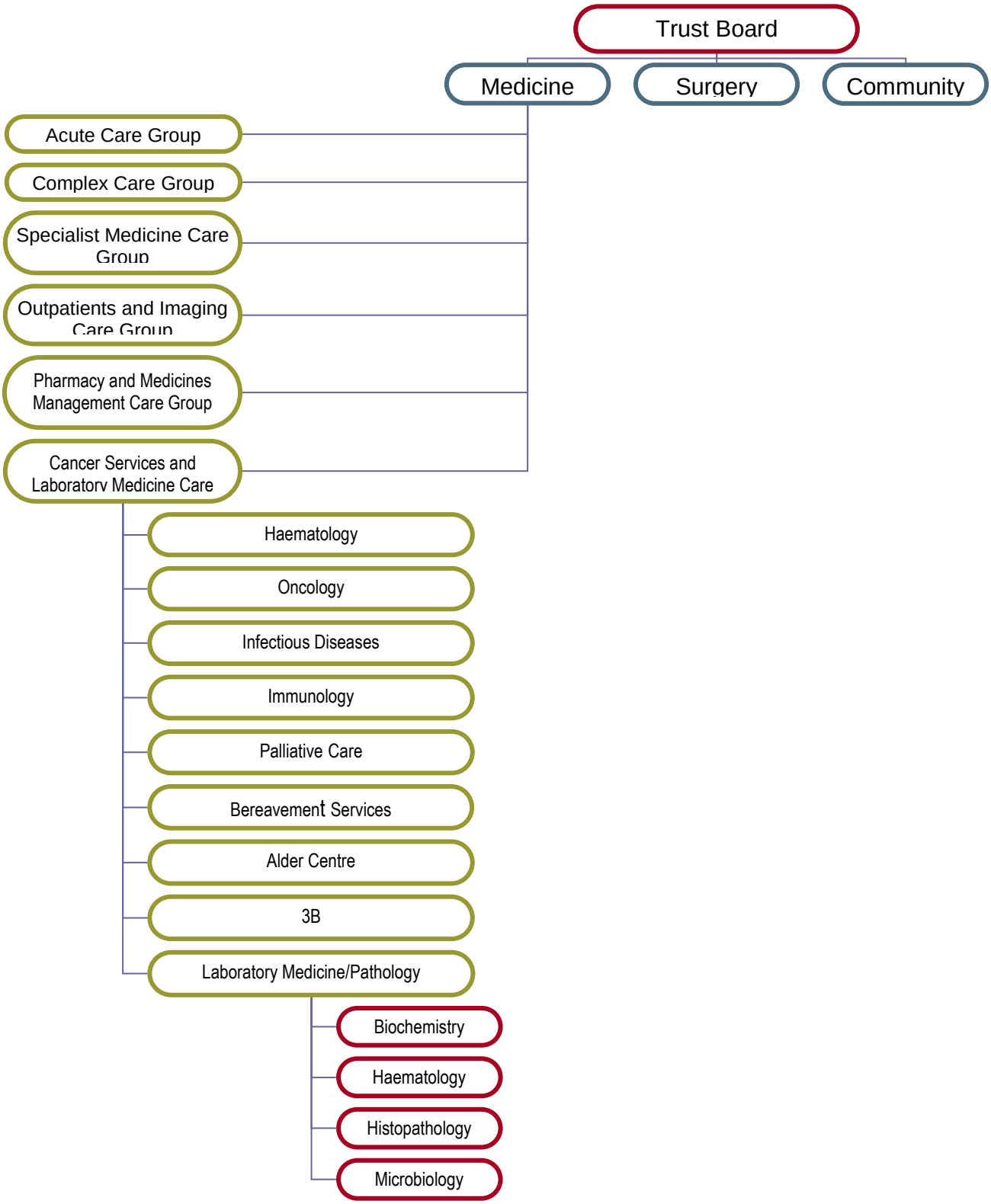
The postal address of the laboratory is:-

Pathology Department
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
L12 2AP

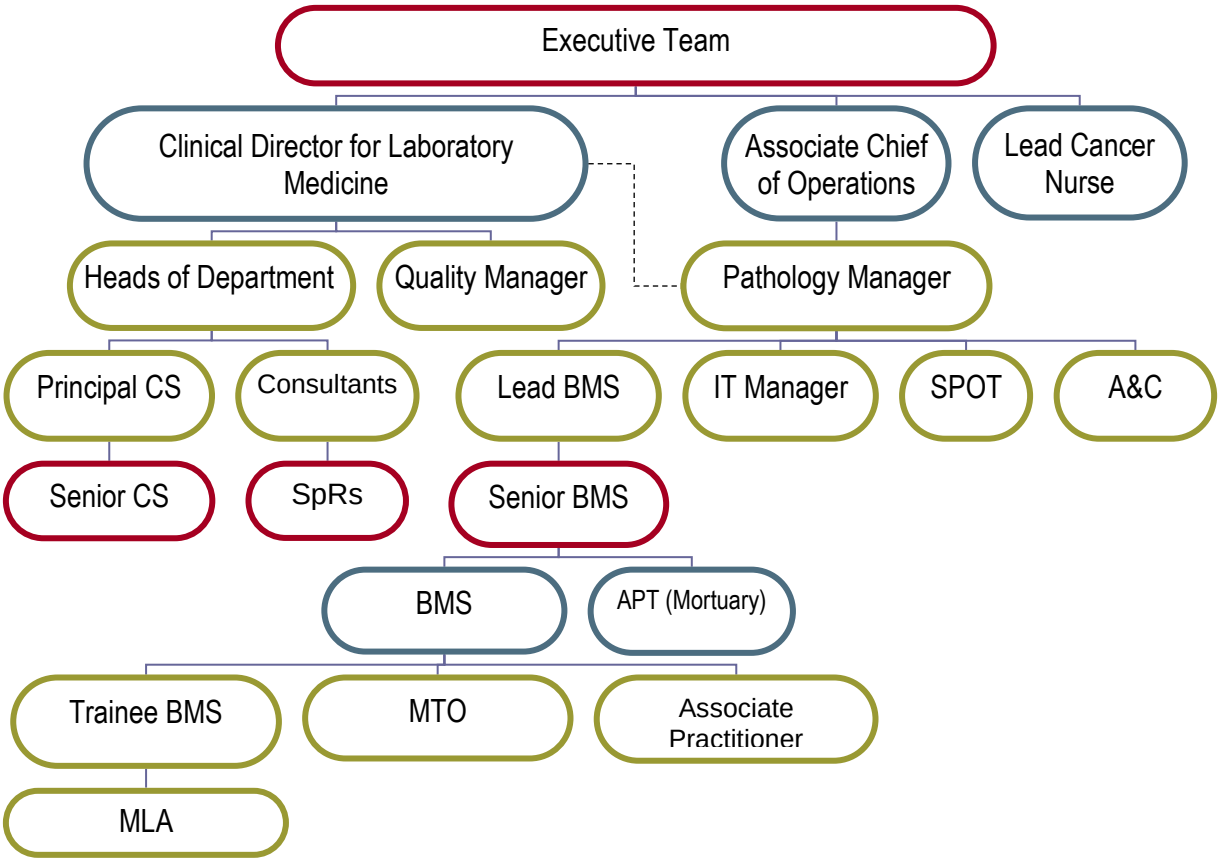
Telephone: 0151 293 3591

3.2 Management structure and accountability

There are three Divisions within the Trust (Medicine, Surgery and Community). Pathology/Laboratory Medicine is within the Medicine division and forms part of the Cancer Services and Laboratory Medicine Care Group. The organisational structure is illustrated below:



The Head of Department for each laboratory discipline is a Medical or Clinical Scientist Consultant Fellow of the Royal College of Pathologists. All members of staff within each discipline have direct line accountability to the Head of Department for both strategic direction and responsibility for the quality of work they produce. A Laboratory Manager oversees the technical, budgetary and administrative aspects of each discipline. The Laboratory Manager for each discipline is managerially accountable to the Head of Department for department specific issues and to the Pathology Manager for operational and professional issues. The organisational relationships within Pathology are illustrated below.



A+C	Administration and Clerical
APT	Anatomical Pathology Technologist (mortuary)
BMS	Biomedical Scientist
CS	Clinical Scientist
MTO	Medical Technical Officer
MLA	Medical Laboratory Assistant
SPOT	Transfusion Specialist

Members of staff currently in post are as follows:

Clinical Director for Laboratory Medicine	Dr Darren Powell
Deputy Clinical Director for Laboratory Medicine	Dr Catherine Collingwood
Associate Chief of Operations	Mr Mark Carmichael
Pathology Manager	Mrs Christine Hill
Quality Manager	Mrs Pamela Ashton
Deputy Quality Managers	Quality leads from each discipline act as deputy on a rotational basis: Debbie Riley (Senior BMS Biochemistry) Andrew Simpson (Senior BMS Haematology) Helen Clarry (Senior BMS Histopathology) Fiona Shaw (Senior BMS Microbiology) Tracey Shackleton (Transfusion Practitioner)
Training Manager	Christine Hill
Training Officers	Pamela Ashton, Christine Chesters, Catherine Hatch & Andrew Simpson
Health & Safety Lead	Paul Walsh
Deputy Health & Safety Leads	Irene Willmott, Deborah Riley & Jane McGrane
Head of Department (Biochemistry)	Dr Catherine Collingwood
Deputy Head of Department (Biochemistry)	Dr Darren Powell
Biochemistry Manager	Christine Chesters
Head of Department (Haematology)	Dr Russell Keenan

Deputy Head of Department (Haematology)	Dr Jessica Sandham
Haematology Manager	Andrew Simpson (Acting)
Head of Department (Histopathology)	Dr Daniel Hurrell
Deputy Head of Department (Histopathology)	Dr Rajeev Shukla
Histopathology Laboratory Manager	Pamela Ashton
Head of Department (Microbiology)	Dr Roisin Mulqueen
Deputy Head of Department (Microbiology)	Dr Christopher Parry
Consultant Virologist	Dr Anna Smielewska
Microbiology Manager	Catherine Hatch

The staffing structure for each discipline can be found as controlled documents, referenced below, on the Quality Management System (iPassport):

Histopathology/Mortuary – Histopathology 1602
Biochemistry – Biochemistry 1604
Haematology/Transfusion – Haematology 1605
Microbiology – Microbiology 1603

3.3 Meetings

The following meetings are held to ensure that a high quality laboratory service is maintained and that the laboratory departments comply with relevant standards and guidelines.

3.3.1 Leadership Team, Quality & Governance Meeting

These meetings are held monthly. Their function is to review laboratory-wide strategic and operational issues and to ensure that the Quality Management System is effective and meets the requirements of ISO15189:2012 standard and other quality standards. The meeting also reports to the Medicine Division Integrated Governance forum, Trust Health & Safety Meeting, Medicine Risk Register Review Meeting and the Clinical Director's forum.
The following members of staff attend the meetings:

- Clinical Director for Pathology (Chair)
- Quality Manager
- Heads of Department

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- Pathology Manager
- Laboratory Managers
- Principal Clinical Scientist
- IT Manager
- Specialist Practitioner of Transfusion

3.3.2 Pathology User Group meeting

These meetings are held every 3 months. The function of this committee is to ensure that the requirements of users of the laboratory services are met by obtaining feedback and recommendations on quality improvements. The committee also serves to inform and engage users in new laboratory developments. The following members of staff attend the meetings.

- Trust Consultant Representative(s)
- Clinical Director for Pathology
- Laboratory IT manager
- GP Representative
- Nurse Representatives
- Medical representatives
- Laboratory Consultants
- Laboratory Managers
- Specialist Practitioner of Transfusion
- Quality Manager for Pathology
- Outpatient Services Nurse Manager
- Head of Pharmacy

3.3.4 Hospital Transfusion Team

The function of the Hospital Transfusion Team is to ensure that MHRA BSQR ('The Blood Safety and Quality Regulations 2005') regulations are met. The transfusion team provides support to the rest of the hospital in the form of advice and training, to ensure that all transfusion practice guidelines are up to date, available and accessible, to provide a professional transfusion service that is efficient, timely and accurate and fulfils the requirements of all the hospital specialities, and to review and take appropriate action in relation to all blood transfusion related incidents and adverse events. The following members of staff attend the meetings:

- Specialist Practitioner of Transfusion
- Consultant Haematologist
- Haematology Laboratory Manager
- Senior Biomedical Scientist in Transfusion

3.3.5 Hospital Transfusion Committee

The following members of staff are members of the Hospital Transfusion Committee:

- Hospital Transfusion Committee Clinical Lead
- Haematology Laboratory Manager
- Specialist Practitioner of Transfusion (SPOT)
- Assistant to SPOT
- Haematology Head of Department
- Senior Biomedical Scientist for Transfusion
- Consultant representatives for Anaesthetics, Intensive Care, Neonatology, Nephrology
- Nursing representatives for Oncology, Intensive Care including ECMO, Neurosurgery, Burns, Emergency Department
- Theatre Leads
- Neurology and Orthopaedics Operational Manager
- Emergency Department representative
- Risk Management representative(s)
- Cardiac Advance Nurse Practitioner
- NHSBT representative
- Ward Manager

3.3.6 Departmental meetings

(Biochemistry, Haematology, Histopathology, and Microbiology) are held at least monthly and are chaired by the Head of Department or Laboratory Manager. The purpose of these meetings is to disseminate information relating to the above meetings and to discuss all aspects of the laboratory service with the staff. All members of staff are encouraged to attend these meetings.

Morning Huddles are held within each department on a daily basis.

A whole staff departmental meeting is held on a monthly basis where information from the Trust team brief is disseminated and also allows for staff feedback and suggestions.

3.3.7 Health and Safety Committee meetings

These meetings are held every 3 months. The function of this committee is to ensure that the Health and Safety System is effective and meets the requirements of current legislation. The Health and Safety Committee report to the Leadership Team Quality & Governance Meeting. Membership of the Health and Safety Committee is as follows:

- Health and Safety Officer (Chair)
- Clinical Director for Pathology
- Pathology Manager
- Quality Manager
- Biomedical Scientist representative from each laboratory department
- Mortuary APT

3.3.8 Training and Education Committee meetings

These meetings are held every 3 months. This committee seeks to support the training needs of all non-consultant staff working within the laboratory, and to promote the development of training across the laboratory in keeping with regulations laid down by regulatory and professional bodies e.g. Health and Care Professions Council (HCPC), UKAS, IBMS (Institute of Biomedical Science). The Training Committee reports to the Leadership Team, Quality and Governance Meeting. Membership of the training committee is as follows:

- Training Manager (Chair)
- Training Officers
- Training Lead from each laboratory department
- Clinical Director for Pathology
- Quality Manager
- Medical Laboratory Assistant representation
- Administrative & Clerical representation

3.3.9 Additional modes of communication

Minutes of the Leadership Team Quality and Governance Meetings will be added to the Quality Management System and circulated to all members of the group with tasks for completion evidencing acknowledgement of receipt and review.

Clinical input from Heads of Department or their representative will be provided, discussed during the meeting and feedback evidenced in the meeting minutes for circulation.

Comments, compliments, other feedback from users via MDT, email or telephone calls will be brought to the meeting for discussion, feedback provided and actions listed where applicable.

4 MANAGEMENT REQUIREMENTS

4.1 Organisation and management responsibility

4.1.1 Organisation

4.1.1.1 General

The laboratory aims to meet the requirements of international standard ISO15189:2012.

4.1.1.2 Legal entity

The laboratory is a part of Alder Hey Children's Hospital NHS Foundation Trust. The Trust is held legally responsible for the activities of the laboratory.

4.1.1.3 Ethical conduct

Trust policies are in place to ensure that:

a) there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality, judgement or operational integrity;
b) management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of the work;
c) where potential conflicts in competing interests may exist, they shall be openly and appropriately declared;
d) there are appropriate procedures to ensure that staff treat human samples, tissues or remains according to relevant legal requirements;
e) confidentiality of information is maintained.

Information Governance (Management Framework Policy and Strategy) M45
Commercial Sponsorship Policy (M64)
Company Representatives Policy (M61)
Freedom of Information Policy (M25)
Conflicts of Interest policy (M20)

4.1.1.4 Laboratory Director

The Laboratory is directed by a consultant Fellow of The Royal College of Pathologists. There is a designated deputy for the Clinical Director.

Through appropriate designees, the Clinical Director is responsible for the following:

- Responsible for the quality of laboratory service and ensures that there are appropriate numbers of staff with the required education, training and competence to provide a service that meets the needs and requirements of the users.

- Ensures that all members of staff participate in appropriate educational programmes and that systems are in place to maintain the safety of all members of staff, visitors and patients

- Ensures that appropriate responses are provided in order to address complaints, requests or suggestions from staff and/or users of the service.

- Provides effective and efficient administration including budget planning and financial management.

- Plans and directs research and development.

- Ensures that contingency plans are designed and implemented to ensure that essential services are available at all times.

- Relates and functions effectively with accreditation and regulatory agencies, appropriate administrative officials, the healthcare community and the patient population served.

4.1.1.5 Pathology Manager

- Following the strategic direction set by the Clinical Director, ensures the implementation of the strategic direction for the laboratory.

- Responsible for the operational management and continuous improvement of services, including technological developments and modernisation of laboratory services.

- Responsible for ensuring the maintenance of the Quality Management System for the laboratory and assisting the Clinical Director in the maintaining UKAS accreditation.

- Overall managerial and budgetary responsibility for the staff and scientific & technical activities of the laboratory departments.

- Managerial and budgetary responsibility for General Pathology Administrative & Clerical staff.

4.1.1.6 Quality Manager

- Responsible for the implementation and maintenance of the Quality Management System in order to maintain accreditation of the laboratories to ISO 15189:2012 and other relevant standards and reports to the Clinical Director on issues of quality.

- Ensures that laboratory policies and procedures are produced, implemented and regularly reviewed in accordance with the relevant standards.

- Manages the document control system for the laboratory.

- Responsible for supervision of the internal audit schedule for the laboratory and ensuring that effective follow-up actions are taken.

- Responsible for ensuring that a suitable system for recording of adverse incidents, assessment of underlying causes, and appropriate remedial, corrective and preventive actions are in place to prevent re-occurrence of incidents.

- Formulates and undertakes regular surveys of user satisfaction with the laboratory service, and ensures that the requirements of users are reflected within defined quality performance measures and objectives.

- Informs other laboratory managers of the outcomes of audits and the progress of quality management projects, and provides guidance and recommendations on such issues.

There are designated quality leads who may deputise for the Quality Manager on a rotational basis where the need arises.

4.1.1.7 Heads of Department

- Responsible for internal and external quality assurance assessment procedures and follow up of issues of analytical quality; ensuring those adverse incidents within their own department are appropriately investigated and followed up.

- Contribute to structures within the Trust that deal with clinical governance and effectiveness including participation in the relevant governance and quality meeting.

- There are designated deputy heads of department.

- The Head of each Department is responsible to the Clinical Director for Pathology

4.1.1.8 Laboratory Managers

- Managerially accountable to the Head of Department for department specific issues and to the Pathology Manager for operational and professional issues.

- Responsible for ensuring the day to day operation of the Quality Management system within their own department under the direction of the Quality Manager.

- Responsible for overseeing the technical, budgetary and administrative aspects of their own discipline.

- Responsible for ensuring that policies and procedures are appropriately implemented within their own department.

- Responsible for ensuring that internal audits are carried out within their own department as documented in the laboratory audit schedule.

- Responsible for ensuring that appropriate remedial, corrective and preventive actions are taken following adverse incidents reported within their own department.

The Senior Biomedical Scientists deputise for the Laboratory Managers within each department

4.1.1.9 Designated Individual (DI)

A Designated Individual, appointed from the Consultant Histopathology team, supervises the licensed activity of the mortuary service. The Designated Individual has primary (legal) responsibility to ensure that activities are conducted properly, by people who are suitable to carry out those activities, and that all the necessary requirements are complied with. The designated individual must complete the HTA accredited training. The Designated Individual currently in post is Dr Rajeev Shukla. There are Persons Designated and a Nominated Individual for the licensed activities.

4.1.2 Management Responsibility

4.1.2.1 Management Commitment

Laboratory management is committed to the development and implementation of the quality management system and to continually improving its effectiveness using the following mechanisms:

a) The importance of meeting the needs and requirements of users as well as regulatory and accreditation requirements is communicated to staff via departmental staff meetings and regular all staff meetings.

b) A Quality Policy (PA Policy-0005) has been established and is displayed within the department.

c) Quality indicators (Laboratory Medicine 1647) and objectives & plans (Laboratory Medicine 1642) are established at Annual Management Review. Quality Indicators are reviewed monthly and Quality Objectives and Plans are reviewed quarterly at Laboratory Medicine Governance Committee meetings.

d) Responsibilities, authorities and interrelationships of all personnel are defined and documented within their job descriptions.

e) Effective communication with all staff

f) A Quality Manager is appointed

g) The conduction of management reviews

h) Ensuring that all members of staff are competent to perform their assigned duties.

i) Ensuring that adequate resources are available to enable the proper conduct of pre-examination, examination and post-examination activities.

4.1.2.2 Needs of Users

Laboratory management ensures that the laboratory services, including appropriate advisory and interpretive service, meet the needs of patients and those using laboratory services.

4.1.2.3 Quality Policy

The laboratory Quality Policy (PA Policy-0005) is displayed within the department and is reviewed annually, the content of which is detailed below:

The Laboratory is committed to providing a comprehensive paediatric clinical laboratory and interpretive service of the highest quality to both internal and external users. Laboratory management will:

- Ensure that they are aware of, and take into consideration the needs and requirements of the service users
- Ensure the laboratory contributes effectively to a positive patient experience and clinical outcome
- Work closely with the clinical teams to ensure that the patient pathway is optimised
- Work with, and support the initiatives of the Trust Divisions

The services provided by the laboratory include:

- Paediatric Histopathology including paediatric surgical and autopsy, fetal & perinatal services
- Paediatric Microbiology including bacteriology, mycology, virology, serology and infection control.
- Routine and specialist metabolic Biochemistry and allergy testing
- Routine and specialist Haematology including haemophilia, leukaemia, and oncology
- Blood Transfusion service including provision of all blood products as required by its users.
- Newborn screening for phenylketonuria, congenital hypothyroidism, cystic fibrosis, MCADD, haemoglobinopathies and inherited metabolic diseases

(Glutaric Aciduria Type 1, Isovaleric Acidaemia, Homocystinuria and Maple Syrup Urine Disease).

- Point of Care Testing

In order to ensure that the needs and requirements of users are met, the laboratory will:

- Operate a Quality Management System
- Set quality objectives and plans to achieve continual improvement of the service
- Set and monitor Key Performance Indicators (KPIs) that reflect patient outcome
- Carry out an annual review of requests and suitability of procedures and sample requirements to ensure that the laboratory repertoire is fit for intended use
- Ensure that all personnel are familiar with the Quality Manual and all procedures relevant to their work
- Commit to the health, safety and welfare of all its' staff in accordance with relevant health and safety and environmental legislation
- Ensure that visitors to the department are treated with respect and that due consideration is given to their safety while on site
- Uphold professional values and remain committed to good professional practice and conduct.

The laboratory will comply with ISO 15189:2012 standard for medical laboratories and is committed to:

- Staff recruitment, training, development and retention at all levels to provide a full and effective service to its users
- Ensuring that laboratory staff maintain professional registration where appropriate with the relevant bodies
- Appropriate procurement and maintenance of equipment and other resources that are needed for the provision of the service
- The collection, transport and handling of all specimens in such a way as to ensure the correct performance of laboratory examinations
- The use of examination procedures that will ensure the highest achievable quality of all tests performed
- Reporting results of examinations in ways which are timely, confidential, accurate and clinically useful
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.

- The setting and monitoring of Quality Indicators to evaluate performance and ensure effective patient care.

4.1.2.4 Quality Objectives and planning

The laboratory management team defines the quality objectives (Laboratory Medicine 1642) of the laboratory and is responsible for ensuring that plans are made to meet these objectives. The Annual Management Review determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the quality management system. Quality Objectives are reviewed on a quarterly basis at the Leadership Team Governance & Quality Meeting.

4.1.2.5 Responsibility, authority and relationships

Responsibilities, authorities and interrelationships are defined, documented and communicated within the laboratory organisation (see section 3.2).

4.1.2.6 Communication

Information is communicated to staff via regular staff meetings and records of the items discussed in staff meetings are maintained.

Stakeholders of the laboratory service are able to communicate with laboratory staff via telephone, email, letter, or by visiting the department in person. Multidisciplinary team meetings are held where necessary.

Users of the laboratory service are also invited to Pathology user Group meetings.

Refer also to section 3.3.9

4.1.2.7 Quality Manager

A Quality manager has been appointed and has delegated responsibility and authority for:

a) ensuring that the processes needed for the Quality Management System are established, implemented, and maintained;

b) reporting to laboratory management, at the level at which decisions are made on laboratory policy objectives and resources, on the performance of the quality management system and any need for improvement;

c) ensuring the promotion of awareness of users' needs and requirements through laboratory organisation.

4.2 Quality Management System

The Laboratory has established, implemented and maintained a Quality Management System that is described in this Quality Manual. The Quality Management System provides for the integration of all processes required to fulfil the Laboratory Quality Policy and objectives and meet the needs and requirements of its users.

The Laboratory continues to improve its effectiveness by the conduct of an Annual Management Review and by evaluation and quality improvement activities described in sections 4.8 – 4.14 of this manual.

The Quality Manual is reviewed on an annual basis by the Quality Manager and Clinical Director on behalf of Laboratory Management and issued under the authority of the Clinical Director for Pathology.

4.3 Document Control

Laboratory Management has established, and aims to maintain a document management Procedure for Document Control (PA SOP-0016) to define the controls needed to:

a) ensure that documents are legible and clearly identified
b) review and approve documents for adequacy prior to issue
c) review and update documents as necessary
d) ensure that current versions of documents are in use at all times
e) prevent the unintentional use of obsolete documents
f) ensure that at least one copy of any obsolete document is retained in accordance with Royal College of Pathologists guidance.

This is achieved with the use of iPassport document control software.

4.4 Service agreements

There is a Standard Operating Procedure for the Review of Service level Agreements (Pathology 50) to ensure that the following conditions are met:

a) The requirements of users of the service and of the provider of the laboratory services, including the method to be used, are defined, documented and understood.
b) The laboratory has the capacity and resources to meet the requirements.
Laboratory personnel have the skills and expertise necessary for the performance of the relevant tests.
c) Methods selected are appropriate and able to meet the needs of the service users.
d) Users of the service are informed of any deviations from the agreement that may impact upon test results.
e) Reference is made to any work referred by the laboratory to a referral laboratory or consultant.

4.5 Referral laboratories

Standard Operating Procedures for the referral of specimens to other laboratories are available in each department:

Title of Document	Index	Department
Samples for External Analysis (SAS) and Toxicology	BC SOP-0017	Biochemistry
Sample requirements, transport and the review/monitoring procedure for send away samples	HP SOP-0117	Histopathology
Referral of Specimens to Other Laboratories – Haematology	HT SOP-1172	Haematology
Procedure for processing Send Away Samples	MBSAS	Microbiology
Processing samples to send to a referral laboratory for Mycobacterial investigations including TB Culture, TBPCR and IGRA	MBTBSAS	Microbiology

Records of all referral laboratories and their relevant repertoires are maintained. Records of all specimens referred with dispatch dates are maintained. The arrangements with referral laboratories are periodically reviewed to ensure that requirements including terms of External Quality Assessment (EQA) performance, accreditation status and turnaround times continue to be met.

4.6 External service and supplies

Equipment is selected and managed in accordance with the Procedure for the Procurement and Management of Equipment (PA SOP-0007) and the Trust Medical Device and Equipment Management Policy (RM15).

Maintenance of all major instruments and items of equipment is carried out according to the manufacturers' recommendations. Preventative maintenance, operational problems, breakdowns, repair by in-house or supplier's/manufacturer's representatives, etc. are recorded in the maintenance log for each piece of equipment.

4.7 Advisory Services

Laboratory management ensures that the needs and requirements of the users drive the services they receive from the Laboratory. We are committed to ensuring that users have the opportunity to express their views and concerns, share their ideas with us and influence service decisions. The needs of the users are kept under constant review through regular Pathology User Group Meetings at which both internal and external users are invited to discuss any matters or concerns. This meeting is also taken as an opportunity to update the users on service developments within the Laboratory.

The relationship of the Laboratory with users of the service is also maintained via regular clinical multidisciplinary team meetings.

Where appropriate, user requirements are used to form the focus of objective setting and planning within the quality management system. User satisfaction surveys of

both internal users of the laboratory services and Primary Care users are carried out every two years and an action plan is formulated from the results of each questionnaire. Consideration of the findings from user satisfaction surveys form part of the annual management review.

The Laboratory web pages contain information on samples types and volumes, turnaround times and contact details for communication with the laboratory. The Trust Meditech computer system also provides information on sample types and quantities required when users of the service are requesting examinations.

Consultant clinical advice is available at all times and regular multidisciplinary team meetings are held in order for users of the service to discuss cases or to raise any issues regarding the laboratory service.

4.8 Resolution of Complaints

Complaints are addressed via the Procedure for Assessment of User Satisfaction and Complaints (PA SOP-0017).

The Quality Manger, Pathology Manager and Clinical Director are responsible for reviewing complaints and ensuring that appropriate action has been taken. Complaints are disseminated by the Trust as part of a weekly report, reviewed at the monthly Leadership Team Quality & Governance meeting and as part of the Annual Management Review. The Heads of Department disseminate details of complaints to all members of staff at the monthly departmental staff meetings where appropriate.

4.9 Identification and Control of Non-conformities

Non-conformities are addressed using the Procedure for the Identification and Control of Non-Conformities (Pathology 27090).

4.10 Corrective action and 4.11 Preventive action

Remedial, corrective and preventive actions are determined and carried out in accordance with the Procedures for the Management of Evaluation and Continual improvement (PA SOP-0009) and Procedure for the Identification and Control of Non-Conformities (Pathology 27090). The laboratory makes use of quality improvement outcomes in the education, training and development of the staff.

4.12 Continual improvement

The laboratory is committed to continually evaluate and improve activities and practices in order to deliver the highest achievable level of service to its users. This policy of continual improvement is underpinned by procedures for identifying and controlling non-conformities wherever they exist within the laboratory (Procedure for the Management of Evaluation and Continual Improvement, PA SOP-0009).

The following processes have been established to identify non-conformities and to maximise improvement opportunities:

- Internal audits

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- Management reviews
- External quality assessment
- Internal Quality Control
- Incident reporting
- Individual performance review
- Audit of user complaints
- User satisfaction surveys
- Research and development
- Clinical Audit
- Turnaround time monitoring
- Document control
- Equipment maintenance records

Processes for continual quality improvement include:

- Remedial action (action taken at the time of a non-conformity to mitigate its immediate effects)
- Corrective actions (actions required to eliminate the root causes of non-conformities in order to prevent recurrence)
- Preventive actions (processes for identifying opportunities for improvement)
- Monitoring of quality indicators
- Improvement processes

4.13 Control of Records

This standard is met by the Procedure for Control of Records (PA SOP-0005)

4.14 Evaluation and Audits

4.14.1 General

Laboratory management has planned and implemented the evaluation and internal audit processes needed to:

a) Demonstrate that all processes are being conducted in a manner that meets the needs and requirements of users.

b) Ensure conformity to the Quality Management System

c) Continually improve the effectiveness of the Quality Management System.

Audits of the Quality Management System and of the examination processes are carried out in accordance with the Procedure for Internal Audit (PA SOP-0003).

The Quality Manager, in discussion with the Laboratory Managers, is responsible for the implementation of the annual audit calendar. Should particular needs be identified, additional audits will be undertaken.

Where possible, auditors are independent of the activities to be audited.

The member of staff responsible for the area of activity to be audited ensures that timely actions are taken to eliminate any non-conformities identified and their underlying causes.

Audits, non-conformity details and CAPA are placed on iPassport. Audits are reviewed during Annual Management Review to allow for continual review of the effectiveness of corrective actions.

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

The examinations provided by the laboratory and sample requirements are reviewed annually as part of the laboratory audit calendar.

4.14.3 Assessment of User Feedback

Laboratory management ensures that user satisfaction surveys are conducted as described in the Procedure for Assessment of User Satisfaction and Complaints (PA SOP-0017) in order:

● to obtain information necessary to evaluate performance and user needs
● to identify aspects of the service that may need to be improved in order to keep users satisfied
● to gather suggestions for improvements

Records are kept of the information collected and an action plan is monitored via the Laboratory Medicine Governance Committee meetings.

4.14.4 Staff suggestions

Staff suggestions for the improvement of any aspect of the laboratory service are raised in a variety of ways as described in PA SOP-0009 Procedure for the Management and Evaluation of Continual Improvement including:

- Whole staff departmental meetings
- Discipline specific departmental meetings
- Senior staff meetings
- Huddles
- Staff suggestion box in the staff rest room to capture anonymous suggestions
- Email
- Staff appraisal

Staff suggestions is an agenda item on the Leadership Team Quality & Governance meeting where suggestions are assessed, implemented as appropriate and fedback to staff via email, staff meetings, dated notices on the rest room board or with the staff who made the suggestion.

Records of suggestions are maintained on a spreadsheet on the shared k-drive with actions and outcomes for review and in meeting minutes.

4.14.5 Internal Audit

Internal audits are carried out to determine whether all activities in the quality management system, including pre-examination, examination and post-examination:

a. conform to the requirements of ISO 15189:2012 standard and
b. are implemented, effective and maintained.
c. conform to HTA & MHRA requirements

Audits are carried out in accordance with its Procedure for Internal Audit (PA SOP-0003).

4.14.6 Risk Management

The laboratory carries out risk assessments to evaluate the impact of work processes and potential failures on examination results as they affect patient safety, and modifies processes where necessary to reduce or eliminate identified risks. The decisions and actions taken are documented. Risk assessments are documented on iPassport as part of each standard operating procedure.

4.14.7 Quality Indicators

Quality Indicators (Laboratory Medicine 1647) are established in order to monitor and evaluate laboratory performance. Quality Indicators are established at the Annual Management Review meeting and are reviewed monthly at Leadership Team Quality & Governance meeting (PA SOP-0009 Procedure for the Management and Evaluation of Continual Improvement).

4.14.8 Reviews by external organisations

Following reviews by external organisations, an action plan with appropriate remedial, corrective and preventive actions, is implemented to address non-conformities arising from the inspection. Records of action plans are maintained.

4.15 Management Review

Laboratory Management carries out an annual review of the Quality Management System (including the quality policy and objectives) in order to assess its overall effectiveness over the past year and to set objectives for the coming year. A report of the meeting is sent to United Kingdom Accreditation Service for the purpose of re-registration.

5 TECHNICAL REQUIREMENTS

5.1 Personnel

5.1.1 General

This standard is fulfilled by the Procedure for Personnel Management (PA SOP-0006). Recruitment and selection of staff are carried out in accordance with the Trust Recruitment and Selection Policy (E2). Each member of staff has a job description

and a contract of employment which are in compliance with current legislation and provide clear terms and conditions of service.

5.1.2 Personnel qualifications

Qualifications, reflecting the appropriate education, training, experience and skills, are documented for each position.

5.1.3 Job descriptions

All personnel have a job description which describes their responsibilities, authorities and tasks which are reviewed and signed off by the individual staff member and manager during the PDR process.

5.1.4 Personnel induction

Laboratory Management ensures that all new members of staff follow a formal programme of corporate and local induction as described in the Trust Induction Policy (E6). The policy contains a checklist which provides documented evidence of participation in the programme.

5.1.5 Training

Laboratory management ensures that appropriate training is provided for all staff as described in the Laboratory Medicine Training and Education Plan (Laboratory Medicine 734) and Laboratory Medicine Training Strategy (Laboratory Medicine 735).

A Training Manager has been appointed to ensure that staff training and development are managed effectively. The Training Officers and Training Leads work to ensure that all members of staff have a training and education programme in accordance with the laboratory Training Policy. Training and education is in accordance with Trust policies and guidelines from the relevant professional and registration bodies and includes the Quality Management System, assigned work processes and procedures, Meditech 6 and other relevant laboratory information systems, health and safety including the prevention or containment of adverse incidents, ethics and confidentiality of information.

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All members of staff are given the opportunity for further education and training in relation to the needs of the service and their own professional development.

All trainee members of staff have a designated supervisor.

5.1.6 Competence assessment

Competency to perform assigned tasks is assessed following training and periodically thereafter. Retraining and reassessment occur when necessary and following long periods of staff absence. Records of all training and education are maintained.

5.1.7 Reviews of staff performance

Laboratory management aims to ensure that all members of staff participate in an annual joint review linked to the Trust Values that includes consideration of:

a) stated objectives and plans of the laboratory
b) the job description of the staff member
c) personal objectives of the staff member
d) training and development needs of the staff member.

All members of staff performing annual joint reviews receive training, and the members of staff being reviewed are provided with a full explanation of the process. Records of all staff joint reviews are maintained.

5.1.8 Continuing education and professional development

All personnel are encouraged to take part in continuing education activities. Each member of staff maintains their own continuing professional development (CPD) portfolio and this is reviewed during their annual joint review.

Laboratory management endeavours to ensure that the following resources are made available for training and education:

- access to reference material and information services
- access to a conveniently situated quiet room for private study
- staff attendance at meetings and conferences
- financial support.

5.1.9 Personnel records

Comprehensive and accurate staff records are maintained for each member of staff. These records are held either by the Laboratory Manager in each discipline (Biomedical Scientists, Anatomical Pathology Technologists, Medical Technical Officers, Associate Practitioners, Medical Laboratory Assistants and Medical secretaries), the Pathology Manager (General Pathology Administrative and Clerical staff) or the Head of Department (Medical staff and Clinical Scientists). Staff information is also maintained centrally by the Trust. Individuals have the right of access to their own records but the records of other members of staff are confidential.

5.2 Accommodation and Environmental Conditions

5.2.1 General

The Laboratory provides a working environment in which staff may perform required functions in accordance with national legislation and guidelines. The environment includes space for the following:

a) the functioning and use of all equipment
b) specimen reception
c) separation of incompatible activities

d) facilities for staff
e) facilities for storage

Access to the facilities is restricted to authorised personnel or those accompanied by them.

5.2.2 Laboratory and office facilities

Laboratory and office facilities provide:
a) controlled access to areas affecting the quality of examinations
b) safeguarding of medical information, patient samples and laboratory resources from unauthorised access.
c) environmental conditions which allow for the correct performance of examinations
d) communication systems to allow the efficient transfer of information
e) safety facilities and devices whose function is regularly verified.

5.2.3 Storage facilities

In order to maintain the integrity of samples, reagents and records the laboratory has provided sufficient, separate storage facilities that are in accordance with national legislation, regulations and guidelines for:

a) process and quality records
b) clinical material
c) blood and blood products
d) hazardous substances
e) drugs, vaccines and other therapeutics
f) reagents
g) waste material for disposal

5.2.4 Staff facilities

To ensure personal safety, comfort and hygiene, the following staff facilities are readily available:

a) toilet accommodation
b) shower facilities
c) a rest area
d) basic catering facilities and access to a supply of drinking water
e) a changing area and secure storage for personal effects
f) storage for protective clothing
g) safe and secure working arrangements

5.2.5 Patient sample collection facilities

Facilities for specimen collection and examination of patients are provided by the Outpatients Department and include:

a) a waiting/reception area with suitable facilities and access for disabled persons.
b) a phlebotomy area which offers privacy and recovery facilities.
c) toilet facilities for patients separate from those provided for staff.

d) notices advising patients and visitors of health and safety precautions.

5.2.6 Facility maintenance and environmental conditions

The laboratory Health and Safety committee has defined and implemented a Health and Safety Policy (Pathology 145) and Procedure (PA SOP-0004) to ensure a safe working environment in accordance with current safety guidelines and legislation, and is responsible for the following issues:

a) provision of personal protective equipment
b) delegation of day to day health and safety management to the appointed Health and Safety Officer
c) providing model rules for staff and visitors to the laboratory
d) consultation with infection control
e) ensuring staff awareness of their health and safety responsibilities.

The Health & Safety Procedures include the following:

a) action in the event of a fire
b) action in the event of a major spillage of dangerous chemicals or clinical material
c) action in the event of an inoculation incident
d) reporting and monitoring of accidents and incidents
e) COSHH/risk assessments
f) disinfection processes
g) decontamination of equipment
h) chemical handling
i) storage and disposal of waste
j) specimen collection and handling, transportation, reception and referral to other laboratories

5.3 Laboratory Equipment, Reagents and Consumables

5.3.1 Equipment

5.3.1.1 General

Equipment is managed in accordance with the Procedure for the Procurement and Management of Equipment (PA SOP-0007) and the Trust Medical Device and Equipment Management Policy (RM15). Departmental specific requirements are detailed in:

Title of Document	Index	Department
Management of equipment in Histopathology	Histopathology 37532	Histopathology
Microbiology Equipment & maintenance procedures	MBEQUIPMENT	Microbiology
Management of Equipment in Biochemistry	Biochemistry 2277	Biochemistry
Mortuary Equipment Maintenance & Servicing	Histopathology 37523	Mortuary

5.3.1.2 Equipment acceptance testing

The laboratory verifies upon installation and before use that equipment is capable of achieving the necessary performance and that it complies with the requirements relevant to any examinations concerned.

5.3.1.3 Equipment instructions for use

Equipment is operated at all times by trained personnel. Instructions for use, safety and maintenance of the equipment are readily available.

5.3.1.4 Equipment calibration and metrological traceability

Procedures for calibration are available for each piece of equipment to ensure metrological traceability of results.

5.3.1.5 Equipment maintenance and repair

Each piece of equipment has a documented programme of preventive maintenance to ensure that equipment is maintained in a safe working condition and in working order. Wherever equipment is found to be defective, it is taken out of service and clearly labelled. The defective equipment is not available for use until it has been repaired and shown by verification to meet the relevant acceptance criteria.

The effect of any defects on previously reported patient results is investigated and remedial, corrective and preventive actions taken where necessary.

Where possible, equipment is decontaminated before service, repair or decommissioning. Suitable space for repairs and appropriate personal protective equipment is provided.

Where equipment is removed from the direct control of the laboratory, its performance is verified before it is returned to laboratory use.

5.3.1.6 Equipment adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific equipment are investigated and reported to the manufacturer, to MHRA and via the Trust incident reporting system.

5.3.1.7 Equipment records

Records for each item of equipment that contributes to the performance of examinations are maintained by the Biomedical Engineering Department and Interserve Facilities maintenance.

5.3.2 Reagents and consumables

5.3.2.1 General

The management of reagents, calibration and quality control material is described in the individual departmental standard operating procedures. All reagents and other

materials used are not used beyond their respective expiry dates and all reagents. Calibration and quality control materials are stored as recommended by the manufacturer. Disposal of reagents and materials is detailed in the appropriate standard operating procedures.

Departmental specific requirements are detailed in:

Title of Document	Index	Department
Management of reagents and consumables in Histopathology	HP SOP 0181	Histopathology
Acceptance testing for reagents and consumables	Biochemistry 1359	Biochemistry
Validation of critical reagents	HBT 036	Haematology
Stock control of Reagents, Test kits, Media, antibiotic discs and consumables	MBSTOCK	Microbiology

5.3.2.2 Reagents and consumables – Reception and storage

Reagents and consumables are stored according to the manufacturer's specifications.

5.3.2.3 Reagents and consumables – Acceptance testing

The laboratory is in the process of developing procedures for acceptance testing of reagents and for consumables whose performance can affect the quality of examinations.

5.3.2.4 Reagents and consumables – Inventory management

The laboratory has established an inventory control system for reagents and consumables. Uninspected and unacceptable reagents are segregated from those that have been accepted for use.

5.3.2.5 Reagents and consumables – Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers are readily available.

5.3.2.6 Reagents and consumables – Adverse incident reporting

Adverse incidents and accidents that can be attributed directly to specific reagents or consumables are investigated and reported to the manufacturer, to other appropriate authorities and via the Trust incident reporting system.

5.3.2.7 Reagents and consumables – Records

Records are maintained for each reagent and consumable that contributes to the performance of examinations.

5.4 Pre-examination process

5.4.1 General

The laboratory has documented procedures and information for pre-examination activities to ensure the validity of the results of examinations.

5.4.2 Information for patients and users

Information for users is available on the Trust intranet and internet web sites. This includes information regarding opening hours, contact details for key members of staff and availability of advice and interpretation on laboratory tests. Information on specimen requirements for individual tests is available on the Trust Meditech computer system. The information provided for users of the service by the laboratory is regularly reviewed as part of the assessment of user satisfaction.

5.4.3 Request form information

A large proportion of requests are made electronically, using the Meditech computer system. Both electronic and paper requests require the following information:

a) sufficient information to allow unequivocal identification of the patient
b) identification(s) and the location of the requestor
c) date and time of specimen collection
d) type of specimen and where appropriate, anatomical site of origin
e) investigations requested
f) date and time of receipt of samples by the laboratory
g) relevant clinical information
h) location(s) to which the results are to be sent
i) laboratory accession number

5.4.4 Primary sample collection and handling

5.4.4.1 General and 5.4.4.2 Instructions for pre-collection activities

Information regarding specimen collection and handling is available within the laboratory information pages on the intranet and internet.

https://alderhey.nhs.uk/services/laboratory-medicine

Clinical Support - Pathology

http://intranet/ClinicalSupport/Clinical%20Support%20Document%20Upload/PA%20Policy-0007__v12.3.pdf

5.4.4.3 Instructions for collection activities

There are Trust Guidelines for Capillary Blood Sampling and a Trust packaging, handling and delivery of laboratory specimens' policy (RM50).

Information regarding specimen requirements is available on the Meditech computer system and on the laboratory information pages on the intranet and internet.

5.4.5 Sample transportation

The Procedure for Specimen Transportation (PA SOP-0002) and the Trust Packaging, Handling And Delivery Of Laboratory Specimens Policy (RM50) have been implemented to ensure the timely arrival of specimens at the correct destination at minimum risk to both laboratory and non-laboratory personnel. Procedures for specimen transportation meet all regulatory requirements. Model rules are supplied to couriers of laboratory specimens.

Department specific requirements are listed in:

Title of Document	**Index**	**Department**
Selecting & evaluating referral centres & consultants, sample requirements and transportation	HP SOP 0117	Histopathology
Selection and Monitoring of Referral Laboratories	Biochemistry 1660	Biochemistry
Selection and Monitoring of Referral Laboratories	HT-SOP 1200	Haematology
Procedure for processing Send Away Samples	MBSAS	Microbiology

5.4.6 Sample reception

All specimen reception activities are conducted in accordance with the Procedure for Specimen Reception for each department. These procedures include:

a) linking of the request and specimen
b) recording of request form and specimen information
c) recording the date and time of receipt of specimens
d) handling urgent specimens
e) ensuring staff safety
f) criteria for rejection of specimens
g) recording of rejected specimens
h) notification of the user concerning rejected specimens

Title of Document	**Index**	**Department**
Sample reception for Histopathology samples	HP SOP0001	Histopathology
Microbiology specimen reception and acceptance/rejection criteria	MBRECEPTION	Microbiology
Specimen reception Transfusion	HBT-001	Transfusion
Specimen reception, storage and disposal	HT SOP 0001	Haematology
Specimen reception, Handling & Disposal	BC SOP 0007	Biochemistry

Authorised personnel systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them.

5.4.7 Pre-examination handling, preparation and storage

The procedure(s) for Control of Clinical Material describe the processed for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage:

Index for Control of Clinical Material procedure	**Department**
Biochemistry 33710	Biochemistry
HT SOP-0232	Haematology
HP SOP-0136	Histopathology
MBCCM	Microbiology

5.5 Examination Process

5.5.1 Selection, verification and validation of examination procedures

5.5.1.1 General

All examination procedures are validated for their intended use prior to introduction.

Procedures are validated and authorised for use by qualified and competent person(s). The methods used for validation and the results obtained, are recorded.

Laboratory management consults with users of the service before changing established examination procedures. When examination procedures are changed so that results or their interpretation may be significantly different, then the implications are explained to users prior to the introduction of the change and this is recorded.

5.5.1.2 Verification of examination procedures

Validated examination procedures used without modification are subject to independent verification by the laboratory before being introduced into routine use.

5.5.1.3 Validation of examination procedures

Examination procedures derived from non-standard methods, in house laboratory methods, standard methods used outside of their intended scope or validated methods subsequently modified are validated as described in the procedure(s) for verification and validation of methods.

5.5.1.4 Measurement uncertainty of measured quantity values

The laboratory is in the process of the determination of Uncertainty of Measurement for each measurement procedure. Laboratory Medicine 921 SOP for determination of uncertainty of measurement and traceability describes this procedure. Uncertainty of

measurement for technical procedures is described in individual Histopathology SOP's. Measurement Uncertainty is also described in:

Title of Document	Index	Department
Assessment of Uncertainty of Measurement in Histopathology	Histopathology 1649	Histopathology
Assessing Measurement of Uncertainty for Microbiology testing	MBMoU	Microbiology
Procedure for the determination of uncertainty of measurement and traceability	Laboratory Medicine 921	Laboratory Medicine

5.5.2 Examination procedures

All examination procedures are performed in accordance with the Standard Operating Procedures (SOPs) of each department. SOPs are written with sufficient detail for a new staff member with appropriate basic training to perform the procedure and are authorised by a senior member of staff. They are stored as controlled documents on the iPassport laboratory document control system and are readily available at the relevant points of use where necessary. All members of staff are trained in the proper use of SOPs and adherence to them is mandatory.

Where external documents (e.g. manuals, commercial kit inserts) are used as the primary method procedure, each document is checked prior to use to ascertain whether procedures have changed.

SOPs are reviewed at pre-determined intervals as described in the Procedure for Document Control (PA SOP-0016) in order to maintain their fitness for purpose.

5.6 Post-Examination Process

The quality of examinations is ensured by performing all procedures under controlled conditions that include appropriate pre-examination processes, the provision of trained staff, appropriate premises and environmental conditions, equipment, materials, information systems.

Internal Quality Control is used wherever possible and requirements for Internal Quality Control are included as part of the standard operating procedure for each examination. The laboratory participates in appropriate External Quality Assessment (EQA) schemes where possible. And the performance of the laboratory departments in these schemes is reviewed at laboratory meetings. The following procedures describe the use of IQC and EQA in each department:

IQC and EQA procedures	
Department	**SOP Index**
Biochemistry	Biochemistry 33702

Haematology	Haematology 46322
Histopathology	HP SOP-0067
Microbiology	MBIQA & MBNEQAS

The laboratory uses EQA results as a valuable resource in the education, training and development of the staff.

5.7 Post-examination processes

The laboratory has procedures to ensure that authorised members of staff review the results of examinations before release, evaluate the results against internal quality control and, as appropriate, available clinical information and previous examination results.

All clinical material received by the laboratory is handled according to the relevant procedures for the control of clinical material. Each laboratory department has a procedure for the control of clinical material which forms part of the departmental standard operating procedures (see section 5.4.7).

5.8 Reporting of results

Laboratory management has established procedures for controlling all aspects of results reporting including telephoned reports (PA SOP-0010) and amended reports (PA SOP-0028). These procedures ensure that laboratory results are communicated to users in a manner that is effective, timely and confidential.

Clinical advice and interpretation of laboratory results by qualified members of staff is available at all times. Details of this service are provided on the Trust intranet and internet websites. Interpretive comments are appended to reports where appropriate. The availability and quality of interpretive advice and comments is assessed in regular User Satisfaction Surveys and members of staff providing interpretive advice participate in interpretive comment quality assurance schemes where available.

Expected turnaround times for examinations are documented and monitored as quality indicators. In cases where expected turnaround targets are not met, the causes are investigated and remedial and/or corrective action(s) are taken.

Laboratory reports are clear, unambiguous and contain sufficient information to enable the user to interpret the results. Reports or letters following receipt of results from referral laboratories include a means of identifying the referral laboratory and appropriate interpretive comments of the referral laboratory.

5.9 Release of Results

All results are reviewed by authorised personnel according to Standard Operating Procedures. Results are evaluated against internal quality control and, as appropriate, available clinical information and previous examination results.

5.10 Laboratory Information Management

Procedures for Laboratory information management is described in the Procedure for the Management of Data and Information (PA SOP-0008).