Pathology Quality Manual

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1 Introduction

1.1 Aim and purpose

This Quality Manual together with reference procedures describes the Maidstone and Tunbridge Wells NHS Trust (MTW) Pathology Quality Management System (QMS) for the benefit of the directorate's own management and staff, and to provide information for service users and for accreditation and regulation bodies.

This manual has been compiled to meet the requirements of ISO 15189:2012 and 2022 standards, Screening Quality Assurance Standards (SQAS), the Human Tissue Authority and Blood Safety and Quality Regulations, 2005 (BSQR).

2 Personnel

2.1 Who should read this document

All Pathology personnel must read this document via Q-Pulse as part of their induction and ensure aware of changes on each review.

2.2 Responsibility

The Quality Manager (QM) is responsible for the preparation and maintenance of this document and ensuring its availability to all Pathology personnel.

All Pathology personnel are responsible for ensuring they have read the most up to date revision of this document and acknowledged this on Q-Pulse.

2.3 Training requirements

All Pathology personnel undergo training and competency assessment in regards to the basic quality management system coordinated by the quality team. All Pathology personnel band 4 and above are also required to undergo training and competency assessment for audit and CA/PA processes coordinated by the quality team.

3 Definitions

- Quality Management System
- Q-Pulse – an electronic QMS utilised to support the delivery of the QMS; modules utilised include Audit, CA/PA, Documents, Assets, Supplier and Analysis module.
- Standard Operating procedure – a document established by consensus and approved by an authorised person that provides, for common and repeated use,

rules, guidelines or characteristics for activities or their results, aimed at optimum achievement in a given context.

4 General Information

We aim to provide clinically relevant service to our users though the provision of a timely, accurate, reliable, efficient, cost effective, high quality diagnostic and clinical service to our clinical colleagues and their patients within the resources available.

Pathology provides services for MTW, local GPs and other referring organisations (e.g. private hospitals, hospices and referring laboratories). The Pathology service is commissioned by NHS Kent and Medway Integrated Care Board (ICB) representing all NHS organisations and Kent and Medway local councils. Sussex Health and Care ICB also commissions the MTW Pathology service for some GPs where it is more logistically efficient to utilise MTW Pathology services than other local organisations.

Pathology is a directorate within the Core Clinical Services Division of MTW and comprises of the following departments: General Pathology, Blood Sciences, Cellular Pathology, Microbiology and Point of Care and with details of diagnostic assays including anticipated turnaround times are available via:
https://www.mtw.nhs.uk/gps/pathology/pathology-service-information/test-catalogue/

Immunology service is contracted to East Kent Hospitals University Foundation Trust (EKHUFT). Immunology samples are forwarded from the Clinical Biochemistry department at Maidstone to Immunology at William Harvey Hospital, Ashford.

4.1 General Pathology

General Pathology is comprised of Pathology IT, Pathology Quality and Phlebotomy which operate on both sites. The phlebotomy service provision covers all MTW patients, a base at Sevenoaks hospital and has a community service based at various GP practices where this service has been contracted by the ICB.

Where Pathology departments are situated on more than one site then the requirements of UKAS Gen1 General Principles for the Assessment for Conformity Assessment Bodies by the United Kingdom Accreditation Service are met (RWF-PATH-EXT419).

4.2 Blood Sciences

The Blood Sciences department comprises of Clinical Biochemistry, Haematology and Transfusion services available at the Maidstone General Hospital (MGH) and at Tunbridge Wells Hospital (TWH) at Pembury.

Blood Transfusion repertoire:

Blood transfusion provides pre-compatibility testing for blood products including blood grouping and antibody screening alongside managing blood products (red cells, platelets, cryoprecipitate and fresh frozen plasma) within MTW, hospices and KIMS.

The team consists of biomedical scientists within the laboratory and a team of transfusion practitioners who work as an interface between the laboratory and clinical area to ensure that the clinical service is safe, auditable, and timely meeting the needs of the users.

Clinical Biochemistry repertoire:

This section is primarily concerned with testing of routine and urgent samples for metabolic and endocrine investigations, paediatric biochemistry, protein & lipid biochemistry, tumour markers and toxicological investigations. Clinical advice is available 24/7 through a duty biochemist desk during core hours and through an on-call arrangement overnight and at weekends.

Haematology

Haematology services on both sites include full blood counts, routine coagulation, morphology, malarial screening, sickle cell screening and haematinics. Specialist screening services for haemoglobinopathies are located on the MGH site and specialist coagulation is located on the TWH site.

4.3 Cellular Pathology

Cellular Pathology comprises of Histology, diagnostic Cytology and Molecular Pathology based at the Maidstone site.

Histology

Biopsies and resections of human tissues are processed, sectioned and stained to allow examination under a microscope to provide a definitive diagnosis: often the presence or absence of cancer.

Diagnostic Cytology

Cytopathology is also commonly used to investigate diseases involving sterile body cavities (peritoneal, pleural, and cerebrospinal), and a wide range of other body sites. It is usually used to aid in the diagnosis of cancer, but also helps in the diagnosis of certain infectious diseases and other inflammatory conditions.

Molecular

A broadest definition of molecular pathology is the study of molecules in a disease state. In this context, the molecules studied are DNA, RNA and/or protein. Portions of DNA (known as genes) act as templates for the production of RNA which in turn acts as a template for the production of protein. Molecular pathology tests may look for the presence or absence of protein or RNA, or for an increase or decrease in the amount of these molecules. Molecular Histopathology uses molecular testing to predict the response of certain 'solid' cancers to specific drugs. This predictive testing forms the basis of 'personalised medicine' for such cancer patients, and includes: HER2 testing in breast and gastric cancer; EGFR and ALK testing in lung cancer; BRAF testing in melanoma; and RAS testing in colorectal cancer.

Additional information:

Medway NHS Foundation Trust and Dartford and Gravesham NHS Trust commission histopathology and non-gynae cytology services.

The cytology screening service is contracted by NHS England to Berkshire and Surrey Pathology service (BSPS) with specimens collected from histology by BSPS transport services.

4.4 Microbiology

The Microbiology service comprises of several speciality areas including Bacteriology, Mycology, Parasitology, Bacterial and Viral Serology, Infectious Disease Molecular Testing, and provision of antenatal serology in line with needs of the Infectious Diseases in Pregnancy screening programme.

4.5 Point of Care Testing (POCT)

POCT is the provision of ward-based diagnostics, predominantly blood and urine, across a range of pathology disciplines informing immediate patient management decisions. The

POCT team provide a governance structure that includes, but is not limited to, procurement advice, device evaluation, training and competency, quality assurance and audit of provision. POCT provision across the Trust is managed by pathology with staff based on each of the two acute sites who also cover services on both sites.

4.6 Antenatal and Newborn Screening

Pathology provides an antenatal and newborn screening service for MTW including the Infectious Diseases in Pregnancy Screening (IDPS) in Microbiology and Sickle Cell and Thalassaemia (SCT) (Haematology) programmes.
As required by the NHS service specification, Microbiology and Haematology are quality assured by UKAS accreditation on behalf of the UK Health Security Agency (UKHSA) screening SQAS against the International Standards Organisation (ISO) 15189 'Medical laboratories – Requirements for quality and competence'.

In the event of an incident relating to screening is identified, UKAS will inform UKHSA following the assessment visit. Incidents are addressed by SQAS according to the process for managing safety incidents in NHS screening programmes.

Pathology departmental leads for Microbiology (for IDPS) and Haematology (for SCT) laboratory attend the Trust Antenatal & Newborn Screening Group which occurs quarterly with minutes added onto Pathology Q-Pulse database.

Microbiology communicates positive results or rejected/ declined specimens with the antenatal screening coordinator team as detailed in RWF-MIC-LI343.
Haematology communicate results and follow up partner testing requests with the antenatal screening coordinator team as detailed in RWF-BS-HAEM-SOP7.

When required, non-conformities involving antenatal testing are reported to the UKHSA by maternity via a Serious Incident Assessment Form (SIAF). For further information, see https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes.

4.7 Contacts

Contact details for Pathology is available via the internet webpage:

https://www.mtw.nhs.uk/gps/pathology/pathology-service-information/how-to-contact-us/

Department	Telephone	Postal Address
Clinical Biochemistry	01892 635985	*Department name* Pathology Level -2 Tunbridge Wells Hospital at Pembury Tonbridge Road, Pembury, Tunbridge Wells, Kent TN2 4QJ
Haematology Laboratory Blood Transfusion Laboratory	01892 635403 01892 635550	
Point of Care	01892 635692	Pathology Level -2 Tunbridge Wells Hospital at Pembury Tonbridge Road, Pembury, Tunbridge Wells, Kent TN2 4QJ
Clinical Biochemistry	01622 224461	*Department name* Maidstone & Tunbridge Wells NHS Trust Maidstone Hospital Hermitage Lane Barming, Maidstone Kent, ME16 9QQ
Haematology Blood Transfusion	01622 224484 01622 224486	
Histology	01622 224051	
Diagnostic Cytology	01622 220132	
Molecular Pathology	01622 225643	
Microbiology	01622 224040	
Point of Care Testing	01892 635692	

5 The Quality Manual

This quality manual describes the QMS within MTW pathology for the benefit of the directorate's own management and staff and provides information for external pathology users and for regulatory/accreditation bodies.

The sections of the quality manual are arranged so that they provide statements to describe how the department complies with the ISO 15189:2012 and 2022 standards with a brief description of how pathology complies with this and reference is made to any corresponding procedure (where applicable).

Pathology policies and procedures are founded on MTW policies (available on Trust governance Q-Pulse module via intranet) e.g.

- Information Governance Policy

- People policies manual
- Waste policy and procedure for the management of healthcare
- Incident management policy and procedure
- Concerns and complaints, policy and procedure for management o
- Risk Management policy and procedure
- Social Media policy and procedure

6 Quality Policy

The quality policy is outlined in RWF-PATH-POL1.

The purpose of the quality policy is to define the QMS within pathology; it is formally reviewed annually at the pathology annual management review (AMR) and as required. Copies are displayed at each site and on the Pathology internet webpage Pathology Quality - Maidstone and Tunbridge Wells NHS Trust (mtw.nhs.uk).

7 Impartiality

MTW has two policies that all employees are required to comply with to ensure impartiality for service provision which are the Anti-fraud, bribery and corruption policy and the Conflicts of interests policy and procedure. All registered professionals are bound by their own registrations bodies code of conduct to ensure impartiality with the treatment of patients including not directly interacting with any relative or friend's care where possible.

Impartiality in tenders in assessed through the procurement setting where all individuals involved in the process are required to sign a non-disclosure waiver which will outline if there are any conflict of interests or not. If conflict of interests are identified; appropriate action will be taken including, where required removal; of said personnel from the tender process.

Impartiality in personnel management is paramount and established within Pathology by having access to different senior managers within the directorate's departments, across the Trust and within the Network for recruitment, HR investigations and management where required. Staff with direct relationships within the directorate are not permitted to line manage directly or indirectly one another to prevent potential bias or presumed bias.

8 Confidentiality

MTW Pathology ensures that confidentiality of patient information is maintained through a variety of mechanisms including a secure areas of work where patient information is not readily accessible to non-pathology personnel and the mandatory annual information governance training and assessment for all staff. This is also part of the standard induction for Pathology personnel outlined in the Pathology staff handbook (RWF-TRAIN-LI3).

9 Legal entity

MTW is the legal entity that is held responsible for the laboratory and its activities; this is led by the Trust board, comprising of the Chairman, non-executive Directors, Chief Executive Officer (CEO), and Executive Directors.

10 Ethical conduct

The ethical conduct expected of staff is outlined in the Pathology staff handbook (RWF-TRAIN-LI3) received by all personnel at induction documents and within the equality and diversity Trust training which is mandatory for all staff to undertake.

11 Laboratory Director (Clinical Director- CD)

The Pathology CD provides effective leadership of the medical laboratory service. They serve as a contributing member of the medical staff and their competence is assured by General Medical Council (GMC) licence to practice and Membership of the Royal College of Pathologists (RCPath). It is the responsibility of the CD to:

- Ensure that there are appropriate numbers of staff with the required education, training and competence to provide medical laboratory services that meet the needs & requirements of the users.
- Ensure the implementation of the quality policy
- Implement a safe laboratory environment in compliance with good practice and applicable requirements
- Ensures the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results and monitor clinical relevance of information generated
- Relate and function effectively with applicable accrediting & regulatory agencies (e.g. UKAS, HTA and MHRA as applicable), appropriate administrative officials,

the healthcare community and the patient population serviced, and providers of formal agreements, when required.

- Ensure the selection and monitoring of laboratory supplier.
- Ensure the selection of referral laboratories and monitoring of the quality of their service
- Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations.
- Oversee implementation of Quality Management System including performance and quality improvements, complaints & suggestions and contingency plans.
- Ensure that risk management is applied to all aspects of laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed
- Plan and direct research and development, where appropriate.

Duties and responsibilities are delegated to the departmental leads although ultimate accountability for the overall operation and direction of the service remains with the Clinical Lead.

The clinical lead for each department has executive accountability and the overall responsibility for the service provided. The responsibilities of the departmental clinical leads include, consultative, advisory, organisational, administrative and educational activities, relevant to the pathology service provided at MTW. Clinical leads are responsible for the implementation of the management system, including the application of risk management to all aspects of the laboratory operations so that risks to patient care and opportunities to improve are systematically identified and addressed.

Selected duties and/or responsibilities are delegated to individuals with appropriate competence, but the ultimate accountability for the overall operation, direction and regulatory compliance of the service lies with the clinical lead.

Clinical leads are predominantly based at one particular site, but will move across sites as and when necessary e.g. meetings, MDT's.

The consultants (and/ or clinical staff) in each department report to their respective clinical lead and are accountable through the pathology CD to Trust Medical Director (MD) with

exception of the Haematology Consultant staff who are part of the Oncology division and report through the Oncology CD to the Trust MD.

Where there are medical secretaries within departments, these predominantly report to their individual consultants unless otherwise stipulated in organograms within this document.
A Designated Individual (DI) is appointed from the Consultant Histopathology team and a practicing anatomical pathologist, supervises the licenced activity of the mortuary service and storage of tissue within the Cellular Pathology department and reports to the CEO. The DI has primary legal responsibility to ensure that activities are to ensure that all human tissue activities are conducted in line with the guidelines and standards published by the Human Tissue Act (HTA) by suitably trained staff.

The licence holder for the licensed mortuary activity at MTW who can apply to the HTA to vary the license as appropriate and the contact is the CEO.

12 Management commitment

The Head of Service (HoS) has responsibility for service delivery and financial balance as well as operations including scientific and professional management and modernisation of pathology services in line with local and national strategies (e.g. Kent and Medway Pathology Network). The HoS works closely with the CD, departmental leads and clinical leads to develop the service, manage its performance and plan for improvements.

The HoS provides management and operational leadership to the directorate, working with the departmental leads to ensure effective budget management, workforce management and planning and ensuring effective use of resources and equipment. The HoS has overall responsibility for ensuring that the Pathology directorate leads achieve and maintain compliance against ISO 15189 standards.

The HoS has direct management of the departmental leads, Pathology General Manager (GM), IT systems manager and Quality Manager (QM) (Pathology senior team). The Pathology senior team are supported by the GM who predominantly has responsibility for day to day service operations and any other function deputised by the HoS.

The departmental leads for each department work closely with the departmental clinical leads and Pathology CD and HoS to be responsible for the managerial direction and associated provision of the relevant pathology service including operational compliance with ISO 15189 standards, delegated scientific and professional responsibility respective to area of work, the pathology QMS and all other relevant standards and guidance.
The QM is responsible for overseeing the implementation and maintenance of the QMS across Pathology and words with the departmental leads and quality leads to ensure that the QMS process is implemented, maintained and continually improved to meet service users' needs and requirements in line with all relevant national and international standards and guidelines.

The QM also has delegated responsibility from the HoS to co-ordinate and oversee risk management for pathology, including management of pathology risks, incidents and service complaints and compliments.

The Pathology IT Manager oversees the directorate Laboratory Information Management System within a team which comprises of a deputy and support staff.

Deputies for key individuals; all key individuals within pathology have a designated deputy:

- The CD has no overall designated deputy, but will designate a clinical lead to deputise in their absence; the individual is chosen on availability.
- The HoS is deputised by the GM.
- All departmental leads are deputised by a chosen BMS/ Clinical Scientist within the department; the individual is chosen on availability and particular task.
- Clinical leads are deputised by clinical colleagues as appropriate at the time of their absence.
- The IT manager is deputised by the IT deputy.
- Other key individuals including the QM and training lead designate a deputy as necessary to another member of the associated committee e.g. a quality lead, or training lead.

Needs of users

The needs of the users are under continual review achieved by:

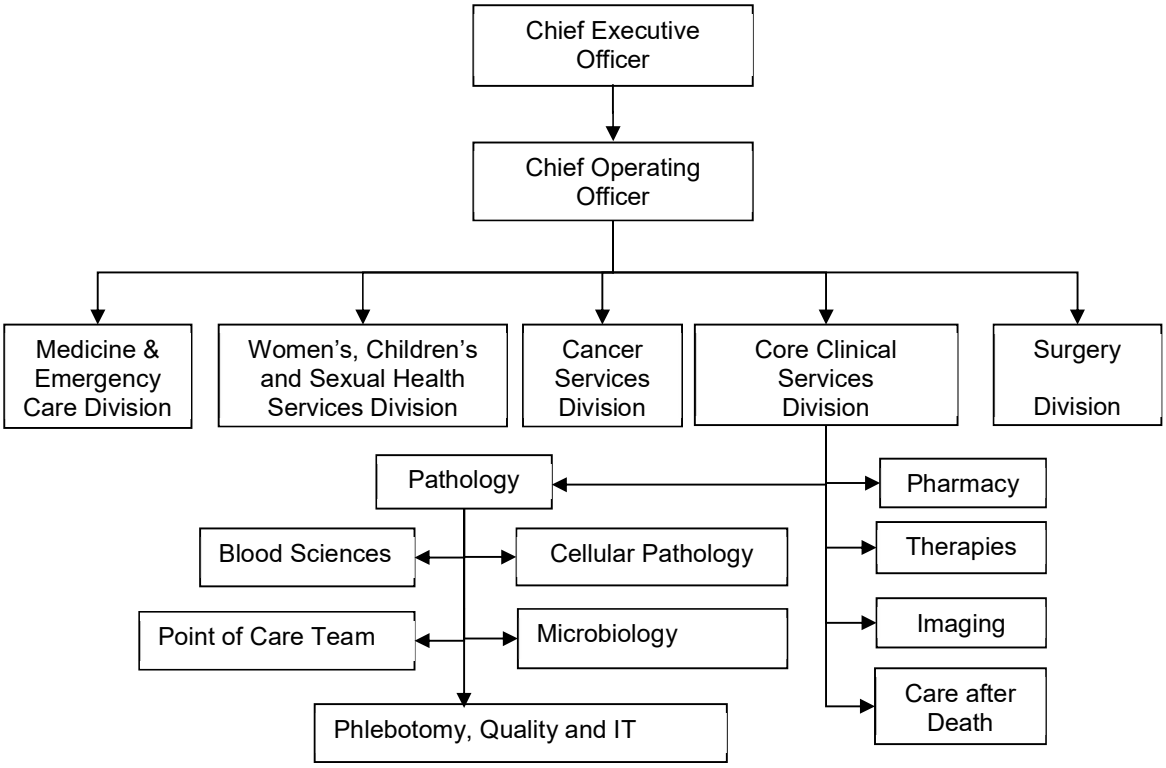
- Providing statistical information to MTW, ICB and other key stakeholders.
- Collaboration on clinical governance issues with users.
- Continual user engagement sessions which can occur via visits to the general practices (GPs), attendance at trust meetings (e.g. Hospital Transfusion Committee (HTC) or Multi-Disciplinary Meetings, review of verbal/ written communications such as queries and review of interactions with users during visits to the laboratory and open days held by the laboratory.
- Analysis of complaints/ compliments/ suggestion logs leading to change/improvements in the quality of the service delivered where necessary.
- Analysis of Trust incident reports raised by the users of the pathology service.
- Assessment of queries raised by users via e-mail or telephone
- Issue, review and management of both internal and external user surveys.

(See related procedure: RWF-PATH-SOP26: Complaints and Compliments Protocol and RWF-PATH-SOP31: User engagement).

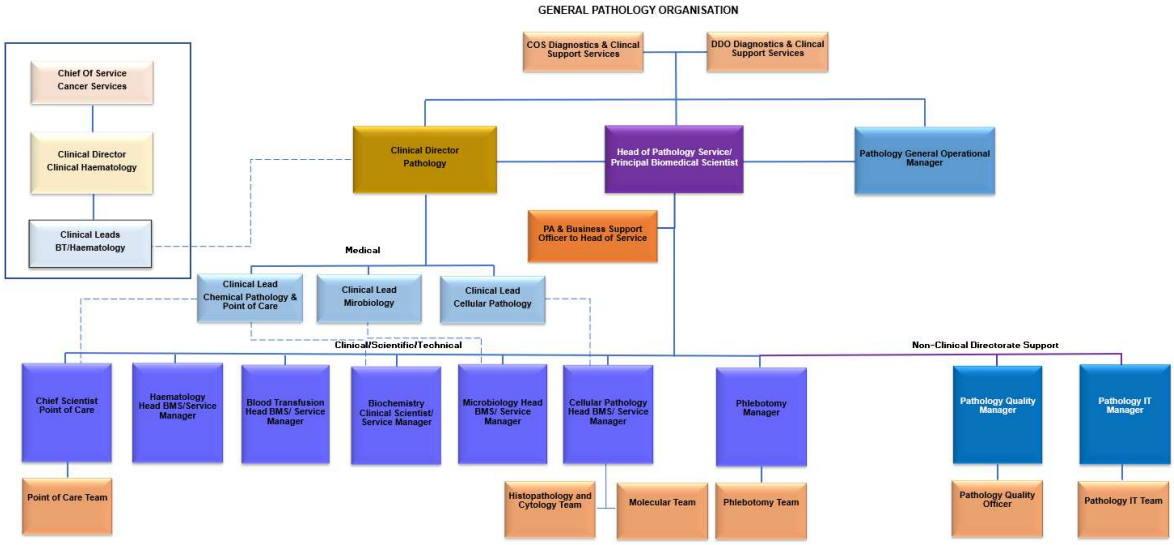
Assessment of users' needs by these mechanisms is translated into requirements, which form the focus of objective setting and planning. Assessment of user satisfaction is reviewed via user survey output and any actions from engagement activities; consideration of the findings forms part of a dedicated pathology departmental AMR when business plans and objectives are set.

13 Structure and authority

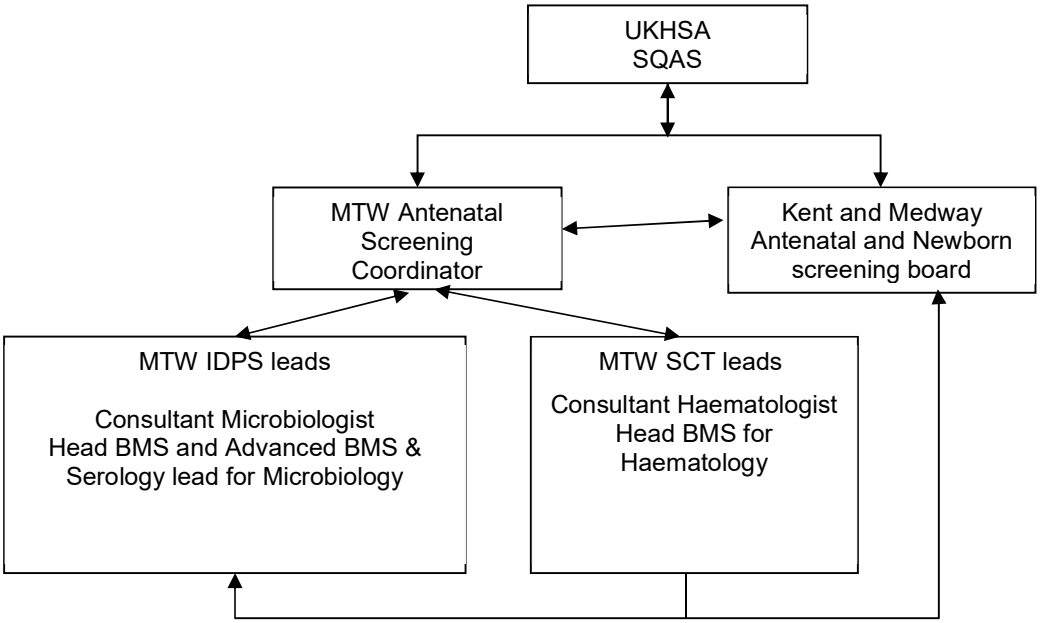
Pathology is part of the Core Clinical Services Division (CSS) which sits in the MTW structure as depicted below:



The relationships between the HoS, CD, departmental leads and departmental clinical leads is illustrated below:



Organogram to depict the working relationship for the Antenatal and Newborn Screening within MTW:



Please note: FASP requests are sent directly from Antenatal department to Oxford.

For department specific organisation charts, please refer to the following documents:

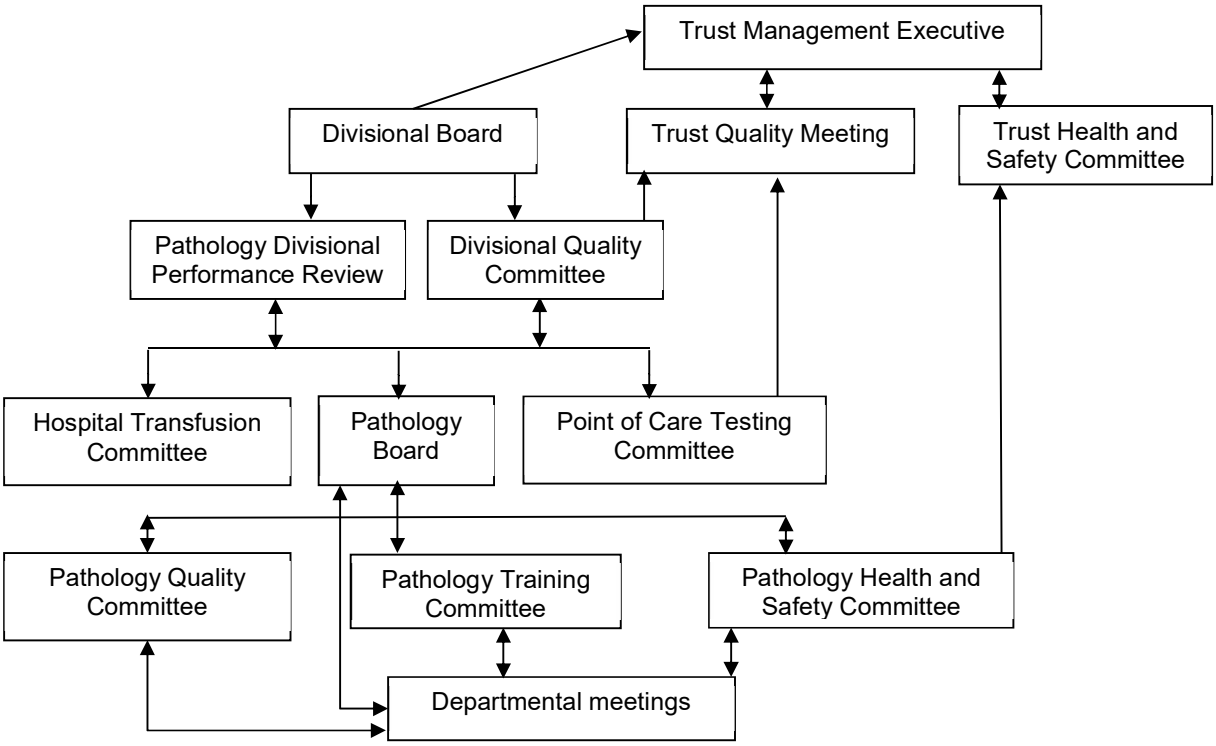
- Histology: RWF-CP-SPREAD7
- Molecular Pathology: RWF-CP-SPREAD9
- Microbiology: RWF-MIC-REC22
- Blood Sciences: RWF-BS1

Pathology also interacts with the following external organisations

- United Kingdom Accreditation Services (UKAS)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- UK Health Security Agency (UKHSA)
- Screening Quality Assurance Service (SQAS)
- Healthcare Safety Investigation Branch (HSIB)
- Human Tissue Authority (HTA)
- National Health Service Blood and Tissue (NHSBT)
- Kent County Council
- Kent Cancer Network

Communication

The Pathology meeting forums that define and maintain governance are outlined below:



Information flows freely between departmental site meetings and the pathology meetings via representative membership with Terms of Reference available for each type of meeting documenting the objectives, frequency and membership of each meeting.
Approved minutes are available on Q-Pulse to all staff.

Pathology Board meets monthly with agenda covering reports submitted from all departments, finance, HR, quality and IT to produce an overarching Pathology presentation report covering key areas to escalate, report on progress of action plans, celebrations and any other salient points which is also attended by the Pathology clinical leads and clinical director.

Pathology quality committee meets monthly and the meeting is attended by the QM and departmental quality leads; departmental leads and the Pathology triumvirate are welcome to attend but are not part of the key membership. Key agenda items to discuss are direction and strategy of the QMS, discussion of significant incidents, escalation of

key quality issues and discussion of resolution strategies, review of external assessment and guidance updates and cross department learning.

Pathology Health and Safety meets every two months and is attended by the Pathology Head of Service, departmental health and safety leads and the Trust Risk and Compliance Manager to review Pathology Health and Safety strategy, health and safety risk assessments, review of Health and Safety incidents (including RIDDOR) and compliance to Health and Safety guidance and standards.

Training and Education forum aims to meet alternate months and is are chaired by the overall training lead for Pathology. Each department is represented by their Training Officer with agenda including training strategy both local, in network and nationally in reference to the IBMS and NHSEI.

Terms of Reference (TOR) are agreed, reviewed annually and are available on Q-Pulse document module alongside all minutes, action logs and agendas for meetings described above.

The Pathology senior team ‘huddle’ meets via MS Teams daily to discuss key operational issues, information to be shared from Trust and any issues to be escalated and/ shared with one another.

Departmental communication forms include ‘huddles’, quality and governance meetings, general staff meetings and senior staff meetings to communicate information regarding the Trust, pathology service, Kent and Medway Pathology Network, Health and Safety, Training and QMS activities. Meeting minutes are recorded for each meeting and are available to staff to read (on Q-Pulse or via use of handwritten notes e.g. huddle).

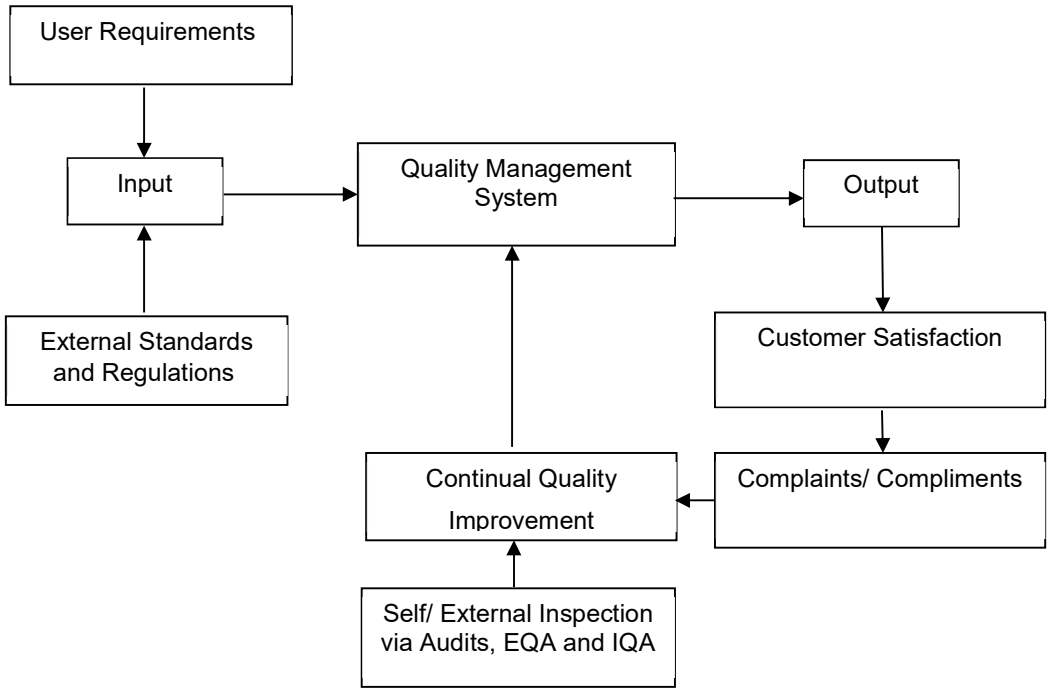
Communications between MTW and pathology occur via:

- Daily communications via Pulse to distribute trust news and information.
- Weekly briefings via Teams from the CEO.
- Communications stream via the divisional leadership (via meetings or clinical and/ or operations director to pathology HOS, Clinical Director and GM).

14 Quality management system

Pathology has established a QMS which is documented and maintained to continually improve the quality of the service and ensure it meets the needs and requirements of its users.

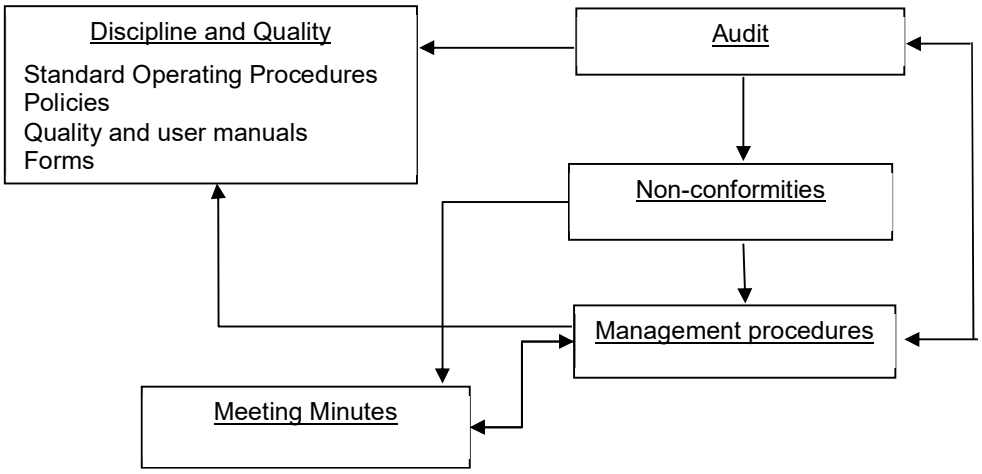
The following diagram depicts the sequence and interaction of maintaining the QMS including continual evaluation from both internal and external sources to ensure that the needs and requirements of users are continually met.



The components and relationship within the QMS system are described throughout this quality manual.

Pathology has consulted users and risk assessed (RWF-PATH-RAP2) compliance to GEN6 and does not issue reports or utilise the UKAS symbol for any purpose.

An outline of the structure and relationships of the documentation used in the QMS is depicted in the diagram below:



15 Quality objectives & planning

Pathology determines objectives for each of the departments; these must adhere to the principles of SMART (Specific, Measurable, Agreed, Realistic and Timescale). For each objective determined a related quality indicator (QI) can be used to aid in the monitoring of the success of these objectives. The determination of the departmental objectives is based on review of user interaction, consideration of MTW strategy, consideration of the QMS, and business planning for the next year e.g. change in analytical platforms.

The determination of quality objectives occurs at the AMR and can include any rolled over QO's from previous year not yet completed; these are included in the AMR meeting minutes and are distributed to all staff via use of Q-Pulse document module.

Review of the QOs occurs at a department level with a minimum quarterly review undertaken by the department senior team.

16 Risk management

All processes within pathology (pre-examination, examination and postexamination stages) are risk assessed to identify potential pitfalls and put in place effective mitigation steps. Risks that cannot be successfully mitigated as acceptable (i.e. risk rating calculated as 8 or over) are placed on the directorate risk register and reviewed monthly to assess progress and evaluate effectiveness of action plans until agreed residual risk rating (usually classed as between 1-5) has been achieved which is monitored monthly at Pathology Board.

17 Document control

Pathology utilises Q-Pulse document module to manage documentation within the department; the use and management of this module is overseen by the QM and department quality leads. Documentation held on Q-Pulse includes information pertinent to the QMS or specific examination processes within a department (e.g. kit inserts, standard operating procedures, policies, forms and notices).

The document module ensures a robust management of the documentation by allocating each document file a:

- Unique identification number.
- Audit trail (of revisions and reviews).
- Review periods automatically set based on type of document and date of last review.
- Documentation lead.

Q-Pulse document module also provides an electronic record of staff that have read documents that are retained on system using the copyholder and acknowledgement function. Use of document module in Q-Pulse document module is described in RWF-PATH-SOP27 Use of Q-Pulse: document module.

18 Service agreements

Pathology services are supplied to MTW, GPs, other NHS organisations (use of MTW pathology as a referral centre) and on individual bases to requestors/ patients on submission of test requests and forms. Services to GP's are agreed via contracts with the local Integrated Care Board (ICB) (with details of the agreement ensuring pathology will have the capability, capacity, repertoire and resources to meet the requirements of any contract.

Receipt of any pathological specimens is considered a request; and therefore, a contract with both the requestor and patient to ensure that the requested tests will be processed and any and all results issued will be of high quality, safe and from an accredited service.

19 Examination by referral laboratories

When required, pathology refers specimen requests to referral centres for additional/ specialised testing. The choice of the referral centre utilised is assessed by formal

evaluation including review of accreditation to ISO 15189:2012/ 2022, service record, cost, transport provision, consideration of sustainability and transformation plans, expertise and sample requirements. The procedure for selection and review of referral laboratories is detailed in RWF-PATH-SOP18: Process for Selection and Review of Suppliers (including referral centres).

The referral laboratories utilised are listed within pathology test catalogue available on the public pathology webpages and are managed as suppliers using the supplier module on Q-Pulse with annual review to ascertain continuing suitability.

20 External services and supplies

Pathology selects and approves suppliers based on their ability to supply what is required, continual supporting mechanisms and that it is fit for purpose using the procedures detailed in RWF-PATH-SOP18: Process for Selection and Review of Suppliers (including referral centres) and RWF-PATH-SOP34: Management of Reagents and Consumables.
Where required, MTW procurement are consulted when entering into any contracts for the purchasing of external services, equipment, reagents and consumables when the financial cost requires a tendering process to be followed. The suppliers are managed using the supplier module on Q-Pulse with annual review to ascertain continuing suitability.

21 Advisory services

Pathology provides relevant advisory service via the issue and maintenance of pan pathology and departmental specific information (including contacts) which are available to all users on the MTW webpages including information pertinent to the test repertoire offered by the departments:
https://www.mtw.nhs.uk/gps/pathology/.

Advisory services are also available from interpretative comments and ranges issued on reports and availability of clinical advice from all department's clinical leads and consultant teams attending multidisciplinary team meetings and ward rounds or on request of advice from service user.

22 Resolution of complaints

All complaints are investigated, documented and responded to within pathology as part of good governance; these are discussed within pathology team meetings, where

relevant and shared learning can occur at the pathology quality committee and are documented in the AMR. Review of complaints is part of assessing user's needs and requirements and directly feeds an input into the development of the QMS. See RWF-PATH-SOP26: Complaints and Compliments Protocol and RWF-PATH-SOP31: User Engagement.

23 Non-conformities

There is a process in place for the identification, recording, management and monitoring of all nonconformities, including those identified in pre-examination, examination and postexamination processes to minimise the risks to users (including halting examinations as necessary, recall of results and revision of results where necessary), and that corrective and preventive actions are taken to eliminate the root cause(s) and potential causes which may lead to reoccurrence. This is achieved using the CAPA module on Q-Pulse and the procedure is documented in RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI).

The status of non-conformities, corrective and preventive actions are monitored and reported as a quality indicator for all departments and collated for review at the AMR.

23.1 Corrective action

This occurs to eliminate the root cause of the non-conformity. Corrective action includes a precursor activity known as a root cause analysis which is an investigation into identifying how or why the non-conformity occurred (use the "why, why, why, why template" until you reach the true cause). Once the root cause has been identified; appropriate corrective action may be determined and actioned.

23.2 Preventive action

This action is taken or could be taken to prevent a possible non-conformity from occurring and can be identified indirectly in an audit, a risk assessment, spot checks or sporadically.

23.3 Review of effectiveness of CA/PA

Review of effectiveness of corrective and preventive actions is undertaken via the review of trends by the Quality Manager and of the non-conformities by the departmental Quality

Lead to determine if the same root cause occurs again in same or similar process with these trends discussed in monthly reports.

24 Continual improvement

Pathology employs a continuous quality improvement system, which involves the continual assessment, evaluation and evolution of the service; this is documented within RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI).

Quality improvement may arise from

- Feedback from user engagement i.e. surveys/ meeting forums/ interactions
- Adverse incident reporting
- Identification of nonconformities (immediate action, RCA and CAPA)
- Investigation of complaints
- Audit (internal and external)
- Internal and external quality assurance programs
- Assessments Inspections (internal and external)
- Exit interviews
- Recommendation from an external source e.g. NICE Guidance

The results of the quality improvement programme forms part of the development, training and education of all staff. This is achieved and evidenced through staff appraisal, meetings and inclusion of quality improvement into staff training. The evaluation of the process ensures that the patient is at the heart of the service and processes are streamlined by eliminating non-value adding steps, staff skills are utilized appropriately and the service maximizes the use of technology.

25 Control of records

Pathology complies with the Royal College of Pathologists (RCPath) “Guidelines for Retention and Storage of Pathological Samples and Archives in Pathology Laboratories, 5th edition via procedures RWF-PATH-SOP32- Management, control, retention and storage of process and quality records. These procedures include: identification and indexing. security, retention, storage and retrieval, disposal, compliance with BSQR (2005) and the HTA conditions of license.

26 Evaluations

Pathology ensures the service meets the requirements of its users, by means of on-going evaluation and improvement processes. These processes include internal and external quality assurance schemes, internal quality control, assessment of user feedback including complaints and compliments, staff suggestions, internal audit, risk management, department specific and directorate quality indicators and reviews of external organisations alongside continual quality improvement mechanisms. These are reviewed monthly at the pathology quality committee and departmental quality meetings and when significant escalated to the Pathology Board. Outcomes of the evaluation and improvement process are reviewed as part of the AMR and can form the basis of the departmental objectives for the coming year.

At the AMR a formal review of the department's requests, examinations provided and the sample requirements needed to perform these for continuing suitability occurs; intermittent reviews can arise from user feedback, staff suggestions, or quality improvements.

Staff suggestions contribute to the development of the QMS and can occur via documental change requests, at a staff communication forum (huddle/ meeting) or use of the staff suggestion CAPA wizard on Q-Pulse.

All pathology departments design and manage an internal audit schedule of their examination processes and adherence to the QMS as a self-evaluation tool. In addition, there is a pan-pathology audit calendar which assesses processes which affect all departments e.g. transport, phlebotomy and organisational requirements. Non-conformities identified as part of internal audit programme are managed as per RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI). The process for planning, conducting, evaluating, monitoring and reviewing the audit are described in RWF-PATH-SOP3: Internal audit.

Quality indicators are reviewed for appropriateness at the AMR for monitoring achievement of QOs, examination processes (pre-examination, examination and postexamination), compliance to the QMS and human resources requirements to give a picture of overall performance and therefore the relationship to effective patient care.

These are monitored on a monthly basis within departments and any identified issues are managed as risks and where appropriate are discussed with users.

Pathology is subject to assessment through a variety of external organisations i.e. assessment bodies (both regulatory and accreditation). Annual assessment occurs from the HTA as part of the mortuary license and MHRA via submission of a self-assessment tool which may prompt a desktop or on-site assessment. UKAS conducts annual assessments using a four-year cycle of three surveillance visits and one full assessment for each department. For all of the above organisations additional assessments can occur through significant change in practice or organisation or in response to a serious incident. Any non-conformity identified through these visits are managed as per RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI) with assessment report, findings and response to findings retained electronically.

It is important to note that pathology is also subject to review by the Health and Safety Executive (HSE), British Safety Council (BSC), Care Quality Commission (CQC), Environment Agency (EA), National Institute of Clinical Excellence (NICE) and the Institute of Biomedical Science (IBMS).

27 Management reviews

Pathology conducts an annual review of the QMS in each department including review of trends of incidents, quality improvements, the quality policy and QO set the previous year. Department specific examination activities are also reviewed to ensure continuing suitability, adequacy, effectiveness and support of patient care. The review considers the following information:

a) The periodic review of requests, and suitability of procedures and sample requirements
b) Assessment of user feedback
c) Staff suggestions
d) Internal audits
e) Risk management (including evaluation of effectiveness of implemented improvements and actions taken to address risk)
f) Use of quality indicators

g) Reviews by external organisations
h) Results of participation in inter-laboratory comparison programs
i) Monitoring and resolution of complaints
j) Performance of suppliers
k) Identification and control of nonconformities
l) Results of continual improvements including current state of corrective actions and preventive actions (i.e. assessment of effectiveness of actions)
m) Follow up actions from previous management reviews
n) Changes in the volume and scope of work, personnel, and premises that could affect the quality management system
o) Recommendations for improvement, including technical requirements

Departmental reports are prepared and discussed at formal meetings with records kept of reports and minutes of these meetings on Q-Pulse. From the reports, QOs are reviewed for achievement, to carry forward or to discontinue. New QOs may arise from discussion at the AMR and can be fed into the forthcoming business plan. Dissemination of the AMR report and minutes are made to staff via use of the distribution list in Q-Pulse document module. All AMR objectives and expected outputs are discussed at departmental level with formal review meetings occurring quarterly.

28 Personnel

Pathology seeks to ensure there are appropriate numbers of staff with the required education and training to meet the needs and requirements of the users and appropriate national legislation and regulations.

Posts within Pathology include those registered with the Health Care Professions Council (HCPC)/ Nursing and Midwifery Council/ General Medical Council or working towards this i.e. as trainee Biomedical Scientists (BMS) and clinical scientists. Staff who hold registration with the HCPC are required as part of continuing registration to participate in continuing professional development (CPD).

Job descriptions and contracts

All staff are issued with job descriptions and contracts of employment, upon commencement of employment with the Trust. Any applications for amendment in contract

or job description is undertaken between staff member and line manager (and as required, departmental lead/ member of Pathology triumvirate) in line with Trust policy.

Personnel introduction to the organisational environment

All pathology personnel on joining MTW undertake Trust induction via online learning before a start date is agreed and are given a Pathology induction commencing on their start date with the organization that is tracked through the monthly reviews as part of their six-month probation.

Training

MTW Pathology recognises that the quality of its work is directly related to the quality of the staff it employs and the training delivered by the directorate and therefore had documented its commitment to training in the Pathology Training Policy Statement RWF-TRAIN-POL1.

Pathology provides training to all new starters on the following:

- Quality Management System (staff tasked to read this manual and related documents, quality policy and undergo training regarding QMS with the quality manager)
- Departmental assigned work processes and procedures appropriate for role
- Applicable laboratory information system (undertaken within department)
- Health and Safety specific to the department being worked in
- Ethical conduct (included within the Staff Handbook)
- Confidentiality of patient information (encompassed within mandatory annual information governance training and assessment)

All staff have access to the Trust's education and learning services including the online e-learning portals, libraries, NHS materials and Q-Pulse.

Training for all pathology personnel is outlined in Pathology Staff Training RWF-TRAIN-SOP1 and is coordinated by designated departmental training officers who are responsible for the documentation of all training programmes for their staff, training plans and records.

Overarching governance of the training officers is through the Pathology Training Committee.

Specific training needs

- Blood Transfusion personnel undertake Good Manufacturing Practice (GMP) training in compliance with BSAR, 2005 standards.

Competence Assessment

Competency is assessed using a variety of approaches including; direct observation, assessment of problem solving, observation of equipment use, monitoring of records and re-examination of samples. Competency to perform assigned tasks is assessed following training and periodically thereafter (but not in excess of 2 years) with additional retraining and reassessment occurring when necessary. Records of competency assessments are kept in staff training records.

Reviews of staff performance

Reviews of staff performance for non-medical staff (also known as annual joint reviews/ appraisal/ PDRs) are conducted in accordance with MTW policies and occur at a minimum annually; with new starters having monthly reviews within their 6-month probation period to discuss the needs of the service and individual in order to maintain and improve quality of service and encourage productive working relationships. The appraisal format includes consideration of the following:

- Review of Trust and pathology objectives and plans
- Review of the job description
- Review and setting of personal objectives (in line with trust and pathology ones)
- Review of training and development needs of the staff member (can create objectives from these too).
- Review of CPD activities (where applicable to job through continued registration with relevant organisation).

Records of these reviews and details are registered on the online HR system and made available to the individual.

Medical staff reviews are conducted in accordance to Trust policies.

Continuing Professional Development

Pathology is committed to promoting CPD at both a personal and professional level, with support provided to those staff completing registration and specialist training and encouragement and time will be given to those wishing to study for an MSc or other qualifications relevant to role. CPD sessions are made available to staff to attend via the department, Trust of Kent and Pathology Network.

Financial support will be allocated, wherever possible and when required, at the discretion of the departmental leads and through governance of the directorate Training Committee.

Personnel records

MTW holds relevant personnel records for each member of staff in line with GDPR and RCPath requirements; these can be held in a variety of places (e. Trust HR, online HR systems, occupational health, within pathology areas- both hard copy and electronic format):

a) Educational and professional qualifications
b) Copy of certificate of registration where applicable
c) Previous work experience
d) Job descriptions
e) Induction documents
f) Training records
g) Competency assessments
h) Record of continuing education and achievements
i) Record of staff performance
j) Reports of accidents and exposure to occupational hazards
k) Immunisation (when relevant)

Note: where hard copies are retained with confidential information within them, these are kept securely in a departmental office area.

29 Accommodation and environmental conditions

29.1 Laboratory & Office facilities

Access to pathology areas is restricted to authorised personnel only via personnel Trust ID cards on electronic door access leading to each specific departmental area. The

access given to personnel is limited to only those requiring entry to areas that they need to gain access for; porters have access as appropriate. Audit trail on use of ID card access is available from MTW security who maintain records of use for 30 days. All visitors at any site are required to report to relevant reception area to gain entry to respective section, with all external visitors required to document visit into the visitor record book.

The premises are designed to ensure there is sufficient space to guarantee the quality, safety and efficiency of the services provided to the users and for the health and safety of pathology personnel. Pathology areas are separated so as to reduce and eliminate cross contamination where appropriate. Environmental conditions such as temperature are routinely monitored. In areas of lone working man down alarms are provided for use. The environment also ensures that access to areas affecting quality of work are controlled, environmental monitoring of conditions is carried out to safeguard correct performance of examinations, and safety equipment is readily available and regularly maintained.

29.2 Storage facilities

The provision of sufficient storage space, under the correct conditions, is important in maintaining the integrity of samples, reagents and records. There is temperature-controlled storage space for reagents, samples and other material as required which are stored in a manner that prevents cross contamination and separates validated, non-validated and quarantined material. Storage facilities for blood and blood products meet the requirements as described by MHRA and BSQR, 2005.

29.3 Staff facilities

All Pathology staff have access to facilities for changing, secure locked storage for personal possessions, toilets and showers, and a rest area (staff room) with basic catering facilities. There are also areas available within pathology on each site for private/ quiet study and meetings.

29.4 Patient sample collection facilities

Phlebotomy at MTW is under the management of pathology and suitable space has been provided for each phlebotomy clinic within their designated areas at each site for the

Trust for outpatients. Within these areas and also for inpatients, there is provision to maintain privacy for patients with sufficient clinical support if required.

29.5 Facility maintenance & environmental conditions

Pathology ensures that there is a safe working environment in accordance with current safety guidelines and legislation with continuous review of working environment through workplace risk assessment and health and safety audit.

The Pathology Head of Service holds overall responsibility for directorate health and safety for personnel, patients and visitors and with relevant health and safety practices documented in RWF-BS-SOP5, RWF-CP-SOP6, and RWF-MIC-SOP61 for Blood Sciences, Cellular Pathology and Microbiology respectively. Day to day management of health and safety issues is delegated to the departmental health and safety leads with central governance through the directorate Health and Safety Committee.

There are Containment level three facilities in the Microbiology department that comply with HSE guidelines and only designated staff are allowed to enter the facility as stated in Microbiology Safety Rules: RWF-MIC-SOP61.

All chemicals used within pathology have a COSHH assessment undertaken which is available on Q-Pulse document module and used for performing examination risk assessments. Wherever possible; pathology utilises reagents that have minimal or low harm to any users/ people who may come into contact with these. Risk assessments are performed on all activities and procedures performed in the department assessing biological, chemical and mechanical risks in addition to risks of uncertainty in the process.

Incidents that require reporting to the Trust (e.g. patient harm, security, health and safety or non-pathology error) are made using InPhase to facilitate non-pathology staff i.e. MTW governance and anyone who is allocated as part of the report or investigation team access to the incident form to review and update.

All Pathology Field Safety Notices and CAS alerts are reviewed by departmental quality leads and registered with outcomes on the Trust InPhase system.

30 Equipment

Pathology has a procedure for the management of equipment and associated records (see RWF-PATH-SOP29 Procurement and Management of Equipment) which adhere to MTW procurement and national policies. Change control is utilised when changing equipment to ensure that validation is performed and procedures are written that include COSHH and risk assessments (see RWF-PATH-SOP24 Validation/ Verification SOP). Q-Pulse is utilised to hold equipment and supplier records:

a) Identity of equipment (Asset module)
b) Manufacturer, model and serial number (Asset module)
c) Contact information for supplier or manufacturer (Supplier module)
d) Date of receipt and date entered into service (Asset module)
e) Location (Asset module)
f) Condition when received (Asset module)
g) Manufacturer's instructions (Document/ asset module via use of manual attached)
h) Validation documentation (Document/ Asset and/ or CA/PA module)
i) Equipment maintenance records (Asset module)
j) Acceptance for use records (Asset module)
k) Details of damage or repair (Asset and/ or CAPA module)

All instrumentation is serviced and maintained as directed by the manufacturer with records retained in line with RCPath guidance of this. Equipment is decontaminated as required (i.e. pre-maintenance where possible and prior to decontamination). MTW EME conducts electrical safety testing of all electrical equipment within the department prior to instalment and periodically thereafter, (the repeat testing interval is risk assessment based, where annual re-testing is not practicable).

31 Equipment calibration and metrological traceability

Use of precision pipettes, automated and semi-automated analysers, centrifuges, balances, fridges, freezers, incubators and timers are an essential part of pathology procedures used to produce accurate test results. These pieces of equipment therefore must be regularly calibrated to ensure traceability of the results which they provide. The

RWF-PATH-POL6 Uncertainty of Measurement and RWF-PATH-POL4 Metrological Traceability procedure provides details on traceable calibration for these.

32 Reagents and consumables

It is essential to have an effective management of all the materials used within pathology to give assurance that any and all results issued are correct. Pathology ensures that an adequate supply of consumables, reagents, calibration and quality control materials are available to cover scope of practice; these are received, stored, used and disposed of as stated in RWF-PATH-SOP3 Management of Reagents and Consumables.

Specific instructions for acceptance testing and storage, use and disposal can be found in the department SOP's.

Any non-conformity that is directly due to any reagent, consumable or equipment will be reported as a CAPA; see RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI).

33 Pre-examination processes

33.1 Information for patients and users

Pathology provides information regarding the services it provides to users (both internal and external to MTW) via the internet webpages at https://www.mtw.nhs.uk/gps/pathology/.

The pathology pages include information on the pathology directorate including webpages for each department service including the South East England General Histopathology EQA Scheme, the quality policy, ordering supplies, links to referring organisations (i.e. EKHUFT for Immunology service and guidelines) contact information to the Pathology senior team, contact information for each department for clinical advice, certificates and scope of accreditation to ISO 15189:2012/ 2022 by UKAS.

Pathology provides information to all users regarding tests available (see test catalogue section), sample collections techniques, sample and request form acceptance criteria (and any other specialist requirements including specimen volumes, containers needed, clinical protocols, timing of collection etc) and referral laboratories via the pathology internet webpages:

Tests available, sample collection techniques and Referral laboratories - Maidstone and Tunbridge Wells NHS Trust (mtw.nhs.uk)

33.2 Request form information

Pathology provides three mechanisms for ordering pathology tests which include a manual request form and two forms of electronic order comms. Internally to MTW; the electronic order comms system used is via the PAS (AllScripts Sunrise) to order tests and review results; externally all GPs have access to use Sunquest ICE to make requests. In addition, blood transfusion has specific request forms for sample and blood product requests.

33.3 Request forms / order comms provide space for:

- Sufficient information to allow unequivocal identification of the patient
- Identification of the location and of the requesting individual
- Type of specimen and anatomical site of origin if relevant
- Investigation required
- Relevant clinical information
- Date and time of specimen collection
- Date and time of receipt of sample by the laboratory

Pathology provides information regarding acceptance criteria for requests and request forms to users available on the pathology webpage: Ordering Tests - Maidstone and Tunbridge Wells NHS Trust (mtw.nhs.uk). (Note; where this criterion is not met; the request will be rejected).

Pathology accepts verbal requests for Blood Sciences where samples have already been sent to the laboratory. Verbal requests are not accepted in other departments; an appropriate request form must be sent from the clinical team to Pathology service.

Note: refer to MTW Blood Transfusion Policy and Procedure (RWF-OPPPCSS-C-PATH1) for specific information relating to blood product requests

33.4 Primary sample collection & handling

Information regarding pre-collection and collection activities, specimen packaging and storage and transportation to pathology is available to users on the public internet webpages:

Transport, Laboratory opening hours and locations, results and customer services - Maidstone and Tunbridge Wells NHS Trust (mtw.nhs.uk)

In addition; MTW Pathology Phlebotomy service has a SOP (Blood Sample Collection SOP: RWF-BS-PHLEB-SOP2) on the procedures for sample collection activities and the MTW Blood Transfusion Policy and Procedure (RWF-OPPPCSS-C-PATH1) outlines specific requirements for blood product requests and cross matching.

When a patient presents to a GP surgery, theatre or clinic (e.g. phlebotomy, outpatient, antenatal etc) and participates in a sample collecting procedure, consent can be assumed.

33.5 Sample transportation

Transportation of samples to and within MTW is undertaken by a variety of staff including porters, drivers, clinical staff members and pathology staff or can be transported by the Pneumatic Tube System. Samples referred to MTW pathology from EKHUFT, DGT and MFT are transported using the network inter-trust transport system provided by together solutions (subsidiary company of EKHUFT), which is timetabled, whereby samples are sent between network pathology laboratories or alternatively by a courier organised by them. Samples from external areas i.e. GP surgeries and community clinics are collected and brought to the laboratory in appropriately insulated boxes via use of the MTW transport service (where this has been contracted from the user) or by courier service (organised by the referring user).

Ad-hoc and contingency transport is provided by couriers contracted by the referring organisation (at MTW, this is undertaken by the Transport department).

Specimen Transport SOP RWF-PATH-SOP21 documents these mechanisms further and also includes how this audited by the pathology service.

33.6 Sample reception

There are designated specimen reception areas for Microbiology and Cellular Pathology specimens and at each site for Blood Sciences which perform initial sorting of all pathology samples to ensure they are sent to the appropriate department to undergo pre-analytic

examination including review of specimen integrity, prioritisation dependent on urgency and/ or time constraints of request and data entry into the LIMS.

33.7 Pre-examination handling, preparation & storage

Pathology ensures that all samples are stored securely and are subject to temperature monitored areas or pre-examination methods (e.g. centrifugation and freezing) if not processed immediately.

34 Examination processes

The selection of examination procedures is based on discussion between senior medical and technical staff, national recommendations and with due consideration to the requirements of the users of pathology services. RWF-PATH-SOP29 Procedure for the Procurement and Management of equipment and RWF-PATH-SOP24 Validation/ Verification SOP describe how pathology procures and verifies/ validates new and existing (re-verification/ validation) equipment/ methodologies into the department. This includes development of User Requirement Specification (URS), Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ)

Pathology incorporates all instructions for methods and processes used in the QMS and for examinations (including pre and post stages) in Standard Operating Procedures (SOPs) which are available to pathology staff electronically on Q-Pulse and with hard copies where required. Technical SOPs conform to the template set out in RWF-PATH-SOP32 Management, control, retention and storage of process and quality. A management (non-technical) SOP template is also available for use when documenting non-technical tasks/ methods.

Measurement of uncertainty is undertaken for all processes; whether it is quantitative or qualitative to identify potential significance on result produced and therefore on patient diagnosis/ prognosis or treatment; for further information refer to RWF-PATH-POL6 Uncertainty of Measurement or individual assay's calculated uncertainties held by specific department.

35 Ensuring quality of examination results

There are department specific procedures in place for internal quality control (IQC)/ internal quality assurance (IQA) to be processed to ensure the quality, validity and reproducibility of results before release.

To provide assurance over the accuracy of the results issued by pathology (including between sites and equipment); wherever possible all assays are registered with a relevant external quality assessment scheme (EQA) provider (e.g. National External Quality Assessment Service (UK NEQAS)). Where an EQA scheme is not available, alternative approaches for determining the acceptability of examination results has been adopted including exchanging samples with other laboratories (inter laboratory comparisons). Performance is reviewed within department quality meetings and at the pathology quality forum; any poor performance arising from either method are logged and managed as described in RWF-PATH-SOP17 Identification, reporting and management of Non-Conformities and Continual Quality Improvement (CQI) including notifying users where there are clinical implications or change in agreed contract of service provision.

These procedures are within department specific SOPs:

Department	Related SOPs
Clinical Biochemistry	Internal Quality Control Policy: RWF-BS-BIO-SOP25 External Quality Assurance Manuals: RWF-BS-BIO-SOP89 & RWF-BS-BIO-SOP57
Cellular Pathology Histology: Cytology:	Procedure for Evaluation, Quality Improvement and Quality Assurance: RWF-CP-SOP2 Selection, Validation & recording of Control Material: RWF-CP-HIS-SOP35 Quality Control Procedures: RWF-CP-CYT-SOP11
Haematology and Blood Transfusion	External Quality Assessment: RWF-BS-BT/HAEM-SOP10
Microbiology	Internal Quality Assurance SOP: RWF-MIC-SOP46 External Quality Assessment SOP: RWF-MIC-SOP45

36 Post-examination processes

Results for all examinations are reviewed by appropriately authorised personnel as per department specific procedures throughout pathology before release and accepted as valid by the use of IQC and maintenance programmes. Where applicable; review of patient history, clinical details and other results are used to interpret a result's significance and prompt further action. Where results are auto validated and authorised; validation of the review criteria is undertaken.

Pathology has procedures for the identification, collection, retention, storage, maintenance and safe disposal of clinical samples within each of the departments:

- Blood Sciences, Control of Clinical Material RWF-BS-SOP9
- Cellular Pathology- Procedure for Control of Clinical Material RWF-CP-SOP9
- Microbiology: Specimen Procedure RWF-MIC-SOP43

37 Reporting of results

Results are authorised in accordance with procedural documents and are electronically generated; electronic reports are available using ICE for GP users; MTW staff can access results using Sunrise AllScripts. Hard copy results are sent out where no electronic link is available or else as agreed with users (both internal and external) via the MTW mail service. If there are any delays or errors encountered in reporting, pathology ensures that this is communicated to the service users and appropriate action is taken to address this. The report contains the following information where applicable:

- Examination procedure identification
- The name of the laboratory issuing the report
- Identification of the laboratory that issued the report
- Unequivocal identification of the patient and location on each page
- Name and contact details of requestor
- Date of sample collection
- Type of sample
- Measurement procedure
- SI units
- Biological reference intervals and clinical decision values (especially critical results) Result interpretation

- Additional cautionary or explanatory notes
- Identification of examinations undertaken by research where no measurement performance is available
- When possible, the identity of the authorizer (s) of the report
- Date of report
- Page number to total number of pages

Where samples are rejected or appropriate clinical interpretive comments are required; these are captured within the report.

38 Release of results

Results may be released automatically or manually; autovalidation is determined by the configuration of rules written into the respective software and are defined in individual SOPs.

When results are released through autovalidation, the laboratory ensures that the criteria for auto-validation are set using biological reference intervals, have been understood by staff and can be suspended when there are IQC failures or queries over the quality of the results.

Where manual validation is used, only trained authorised personnel may do this (predominantly requires registration to formal body e.g. HCPC) using specific SOPs for the assay to highlight clinical decision values that require urgent communication to requesting team e.g. when to phone the clinician (RWF-PATH-POL12: Communicating of critical results).

Where interim reports are issued these are highlighted as interim and it is advisable where possible to wait final report before making clinical decisions.

Departmental procedures (Cellular Pathology see RWF-CP-SOP20, Clinical Biochemistry see RWF-BS-BIO-SOP2, Blood Transfusion see RWF-BS-BT-SOP29 and for Microbiology see RWF-MIC-SOP2) also ensure the following occurs when reports are amended:

- The revised report is clearly identified as a revision and includes reference to the date and patient's identity in the original report.

- The user is made aware of the revision.
- The revised reports show the date and time of the change and the person's responsible for the change.
- The original report entries remain in the record when revisions are made (available via I.T. team).

39 Laboratory information management

The department is committed to meeting its information security obligations to meet the needs of users, clients, patients and staff with respect to confidentiality, integrity and availability, which are defined as within RWF-PATH-SOP25: The Management of Data and Information.

Pathology department has an IT team who are responsible for the management of patient data used to provide a service for pathology users. Pathology utilises a laboratory information system (LIMS) to record and store patient information. Access to electronic data is controlled and restricted by individual password security and assigned privilege rights, thus maintaining confidentiality and data protection. The system is backed up daily with this information held safely and securely by IT and an annual LIMS recovery exercise is conducted with the Trust managed by the Pathology IT team.

Pathology complies with the Caldicott principles, the Freedom of Information Act, General Data Protection Regulation (GDPR) and Data Protection Act.

40 Continuity and emergency preparedness planning

All departments within the Pathology directorate hold a Business Continuity Plan (BCP) which is held on Q-Pulse document module that covers a variety of scenarios that may occur to interrupt service and actions to be followed if these occur to continue to provide the maximum service feasible and escalation paths. The scenarios include, but are not limited to loss of water, power, premises, staffing, loss of controlled storage areas and disruption to supply of reagents and consumables and mitigation plans including sharing resources within Pathology, triaging requests, movement to utilisation of referring laboratories (including for screening services) etc.

These plans are annually reviewed and at a minimum tested for one particular scenario each year (this can be on a real-life exercise e.g. loss of power overseen by Trust). All tested

activations of BCP are documented on CA/PA using a BCP template which will require evaluation of the actions taken, if there are improvements to be made and actions agreed.

The departmental lead is responsible for ensuring that these BCPs are maintained and updated as required and staff are aware of these with understanding of what to do in BCP scenarios included as part of initial training in the directorate.