QUALITY MANUAL

This document together with referenced procedures represents the Quality Management System (QMS) of the Pathology Department, East Kent Hospital University NHS Foundation Trust (EKHUFT. It has been compiled to meet the requirements of ISO 15189:2012 Standards, Screening Quality Assurance Service (SQAS), the Human Tissue Authority (HTA) and the Blood Safety and Quality Regulations 2005 (BSQR). All services within pathology adhere to the same QMS and this quality manual is common to all specialities.

CONTENTS PAGE

1. GENERAL INFORMATION

1.1 Pathology

The Pathology Department is within the Clinical Support Services Care Group (CSS CG) division of EKHUFT. Pathology comprises of the following disciplines:

- Cellular pathology including Mortuary
- Clinical biochemistry including immunology
- Haematology and Blood Transfusion including Phlebotomy
- Haemostasis and Thrombosis
- Microbiology
- Point of Care

EKHUFT provides services to a population of over 720,000 and has services in the hospitals below:

- Buckland Hospital, Coombe Valley Road, Dover, Kent CT1 3LP Tel: 01304 201624
- Kent and Canterbury Hospital (K&CH), Ethelbert Road, Canterbury, Kent CT1 3NG Tel: 01227 766877
- Queen Elizabeth the Queen Mother Hospital (QEQMH), St Peters Road, Margate, Kent CT9 4AN Tel: 01843 225544
- Royal Victoria Hospital, Radnor Park Avenue, Folkestone, Kent CT19 5BN Tel: 01303 850202
- William Harvey Hospital (WHH), Kennington Road, Willesborough, Ashford Kent TN24 0LZ Tel:01233 633331

Each hospital site provides a variety of services, the provision of which depends upon local service needs. Phlebotomy is available across all of the hospitals, Blood science laboratories are located at K&CH, QEQMH and WHH (the main laboratory being at WHH) with cellular pathology and microbiology based at the main laboratory at WHH and haemophilia at K&CH. Where pathology disciplines 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 (DIR-EX-132).

1.2 Clinical Biochemistry including immunology

The services provided by clinical biochemistry are described below. The discipline is spilt into two main sections: general clinical biochemistry and immunology. The discipline also supports a multi-disciplinary point of care testing (PoC) team.

General Biochemistry

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.

Immunology

Clinical biochemistry is responsible for the provision of the autoimmune serology and allergy testing service within the Trust and also provides a laboratory immunology service for other hospitals within the county. Interpretive advice is available from senior staff within the laboratory and also through a service level agreement with the Protein Reference Unit at St George's Hospital, Tooting.

Research

Clinical Biochemistry supports an active research programme focusing on renal disease markers and clinical aspects of protein and lipid biochemistry, often collaborating with external research and academic partners. Research is published in peer reviewed journals and is disseminated at national and international meetings.

The postal address is: -

Clinical Biochemistry
William Harvey Hospital
Kennington Road,
Willesborough
Ashford, Kent
TN24 0LZ

Tel: 01233 633331
723-8054

1.3 Point of Care (PoC)

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

PoC provision across the Trust is managed by pathology with staff based on each of the three acute sites who also cover services on all trust sites.

The postal address is: PoC Coordinator
Pathology
Kent and Canterbury Hospital
Canterbury
Kent CT1 3NG

Direct dial: 01227 864368

Additional information on the services provided by the PoCT team can be obtained from:

Joan Butler, PoC Coordinator, joan.butler@nhs.net.

1.4 Haematology & Blood Transfusion

Haematology

Haematology services on all sites include full blood counts, routine coagulation, morphology, malarial screening, sickle cell screening and haematinics. Specialist screening services for haemoglobinopathies are located on the QEQMH site and leucocyte immunophenotyping is located on the K&CH site.

Phlebotomy

Phlebotomy services are managed by the blood transfusion coordinator and provide both an appointment based and ad hoc service for EKHUFT and direct access patients.

Blood Transfusion

The blood transfusion laboratory 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 EKHUFT, hospices, other local independent hospitals and the Kent Surrey and Sussex Air Ambulance.

The blood transfusion 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.

The postal address is: -

Haematology & Blood Transfusion
William Harvey Hospital
Kennington Road,
Willesborough
Ashford, Kent
TN24 0LZ

Tel: 01233 633331
Haem Ext 723-8065
BT Ext 723-6017

1.5 Haemostasis and Thrombosis

The Haemophilia and Thrombosis Centre based at Kent and Canterbury Hospital (K&CH) is one of twenty six comprehensive care centres nationally for the diagnosis and treatment of haemostasis disorders.

The laboratory provides the specialist coagulation services for EKHUFT and other hospitals across Kent and Sussex. It offers a full range of specialist investigations for patients with inherited and acquired disorders of haemostasis and thrombosis using state of the art analysers, molecular genetics and manual techniques where required. The laboratory also provides training and scientific support for PoC INR testing across the Trust.

A 24/7 routine coagulation screening service is provided by the blood science laboratories on all three acute sites across the trust under the scientific direction of the haemostasis and thrombosis laboratory.

The postal address is:

Haemostasis and Thrombosis laboratory
Haemophilia and Thrombosis Centre
Kent & Canterbury Hospital
Ethelbert Road,
Canterbury
Kent
CT1 3NG

Tel: 01227 766877
Ext: 722-5135 or
DD: 01227 806329

1.6 Cellular Pathology

The services provided by cellular pathology include histology, non-gynaecological cytology, andrology (service provision at WHH only) and mortuary. Cellular pathology is located at WHH, with the addition of a Mohs clinic located at K&CH.

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.

Non-gynaecological 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.

Andrology

Investigation of male infertility and vasectomy service.

Mortuary Service

Cellular pathology provides a hospital and public mortuary service to HM Coroners in East Kent at three of our hospital sites. The K&CH is only a body storage facility, whilst at QEQMH and WHH there are body storage and autopsy facilities.

The postal address is: -

Cellular Pathology
William Harvey Hospital
Kennington Road,
Willesborough
Ashford, Kent
TN24 0LZ

Tel: 01233 633331
Ext: 723-6016
DD 01233 616016

1.7 Microbiology

Microbiology encompasses three sections; general microbiology, mycology and virology. The laboratory is part of the Clinical Virology Network. It is also designated as a specialist virology centre and is also a member of the UK Clinical Mycology Network. The microbiology service is consultant led and has forged links with the Biomedical Sciences Department at the University of Kent.

General Microbiology

This section is primarily concerned with the isolation, identification and susceptibility testing of bacterial, fungal and parasitic infections. Methods used include microscopy, culture, molecular and mass spectrometry.

Virology

Virology is primarily concerned with the serological detection of antibody or antigen to determine infection or protective immunity. Virology uses molecular methods to detect viruses in respiratory, genital and CSF specimens; Chlamydia and Gonococcal detection are also part of this sections service. Virology provides reference serology services to other pathology services within the local vicinity.

Mycology

This section is primarily concerned with the isolation, identification and susceptibility testing of fungal isolates. It is a designated 'Specialist Mycology laboratory' (UKCMN)

The postal address is:

Microbiology
William Harvey Hospital
Kennington Road,
Willesborough
Ashford, Kent
TN24 0LZ

Tel: 01233 633331
Ext: 723-6760

For further information on the services provided by any of the above disciplines; refer to the user guide available on the pathology page on the hospital website http://www.ekhuft.nhs.uk.

1.8 Antenatal and Newborn Screening

Pathology provides an antenatal and newborn screening service for EKHUFT including the NHS Fetal Anomaly Screening Programme (FASP) (Clinical Biochemistry external referrals), 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.

The Kent and Medway antenatal/ newborn screening programme board is attended by a clinical staff member from both haematology and microbiology. Both clinical and laboratory staff in microbiology (for IDPS) and haematology (for SCT) attend quarterly EKHUFT IDPS screening steering group meetings. A member of the haematology laboratory team also attends the haemoglobinopathy steering group bi-annually.

Microbiology communicates results as detailed in the Antenatal fail safe policy (MIC-MP-017).

Haematology communicate results for the SCT programme as per Electrophoretic separation of haemoglobins (HAE-LP-213) and Haemoglobinopathy processing (HAE-WI-15).

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 and screening incident reporting process for two or more Care Groups (DIR-EX-193).

2 The Quality Manual

This quality manual describes the QMS within EKHUFT pathology for the benefit of the laboratory'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 UKAS ISO 15189:2012 standards:

Section of Quality Manual	Section of ISO 15189: 2012 Standards
4	Section 4 Management Requirements
5	Section 5 Technical Requirements

Throughout the text there are references to UKAS ISO 15189:2012 standards, under the reference and title of each standard there is a brief description how pathology complies with this and reference is made to any corresponding procedure (where applicable).

Pathology policies and procedures are founded on EKHUFT policies (available on 4policies) e.g.

- Information Governance Policies (Data Protection, Information Governance, Information Sharing and Freedom of information)
- Waste management policy
- Incident management policy
- Management of complaints, concerns, comments and compliments
- Risk Management Strategy and Policy
- Social Media Policy
- Requisitioning, Purchasing and paying for non-stock goods and services Policy

3. QUALITY POLICY

The purpose of the quality policy (4.1.2.3) 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 of the three laboratory locations. Please refer to page 11 for EKHUFT pathology quality policy.

Quality Policy

East Kent Hospitals University NHS Foundation Trust (EKHUFT) pathology department provides a comprehensive clinical diagnostic and monitoring pathology service.

It is committed to providing a service of the highest quality and shall be aware and take into consideration the needs and requirements of its users.

The scope of the service comprises:-

Clinical Biochemistry (including Immunology), Haematology (including Blood Transfusion), Phlebotomy, Haemophilia, Cellular Pathology, Mortuary, Microbiology and Point of Care Testing. In order to ensure that the needs and requirements of users are met, the Department of Pathology will:

- Operate a quality management system to integrate the organisation, procedures, processes, and resources.
- Set quality objectives and plans in order to implement this quality policy, and seek to achieve continual quality improvement.
- Ensure that all pathology personnel are familiar with the quality manual and all procedures relevant to their work.
- Commit to health and safety and the welfare for all staff. Visitors to the department will be treated with respect and due consideration will be given to their safety while on site.
- Uphold professional ethics and values and be committed to good professional practice and conduct.
- Create and nurture a quality ethos based on continual improvement.
- Ensure that its activities have calculated and limited impact on the environment and comply with relevant environmental legislation.
- Ensure the suitability and effectiveness of this policy is reviewed as part of the annual management review.

Pathology will comply with standards set by ISO 15189:2012, the Human Tissue Authority (HTA), Screening Quality Assurance Service (SQAS) and the Medicines and Healthcare Regulatory Agency (MHRA), and is committed to:

- Staff recruitment, training, proficiency, development and retention at all levels to provide a full and effective service to its users.
- Appropriate procurement and maintenance of such equipment and other resources as are needed for the provision of the service.
- The assessment of user satisfaction, in addition to internal audit and external quality assessment, in order to produce continual quality improvement.
- Ensure that examinations and processes are designed and implemented with a focus on user and patient requirements, with performance monitoring applied to assure the required outcomes are delivered.
- The collection, transport and handling of all specimens to ensure the accuracy of laboratory examination.
- Undertake consistent analytical work so that systematic and random errors do not exceed specified limits; and these limits are in keeping with those considered as best laboratory practice.
- Report results of examinations in ways which are timely, confidential, accurate, and clinically useful including direct clinical advice and care.
- Provide a secure controlled archive for the storage of records and clinical material.

Signed on behalf of the Department of Pathology, EKHUFT:

…….. Dr Edmund Lamb PhD, FRCPath Clinical Director, Pathology on

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4 MANAGEMENT REQUIREMENTS

4.1 Organisation and management responsibility

Legal entity (4.1.1.2)

EKHUFT 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, and Executive Directors.

Ethical Conduct (4.1.1.3)

The ethical conduct expected of staff is outlined in the induction documents and within the equality and diversity training which is mandatory for all staff. All staff are bound by EKHUFT policies i.e. Anti-fraud, Bribery and Corruption Policy and the Gift and Hospitality Policy which clearly define the rules regarding conflict of interest and any undue pressures which may adversely affect their work. These are available on Q-Pulse see DIR-EX-130 and DIR-EX-148 which staff are tasked to read and acknowledge when they commence employment within the department.

Laboratory Director (Clinical Director) (**4.1.1.4)**

The pathology clinical director (CD) (4.1.1.4) is accountable to the clinical director of the CSS Care Group and is based at K&CH but works across all sites.

The CD for pathology has executive accountability and the overall responsibility for the service provided. Their responsibilities include, scientific, professional, consultative, advisory, organisational, administrative and educational activities relevant to the pathology service provided at EKHUFT. Selected duties and/or responsibilities are delegated to individuals with appropriate competence, such as discipline specific clinical leads, but the ultimate accountability for the overall operation, direction and regulatory compliance of the service lies with the CD.

Competence of the CD is assured by the General Medical Council (GMC) licence to practice or Health Care Professions Council (HCPC) and Fellowship of the Royal College of Pathologists (RCPath). Each individual discipline within pathology is under the professional direction of clinical leads (appropriate consultants), who are in possession of the FRCPath qualification or equivalent. (ISO 4.1.2.5)

CD duties (4.1.1.4 a- o) are fulfilled, with delegation as appropriate, as follows:

a) Provide effective leadership of the pathology service, including budget planning and financial management, in accordance with institutional assignment of such responsibilities (4.1.1.4a). Carried out in conjunction with the pathology GM.

b) Relate to and function effectively with applicable accrediting and regulatory agencies, appropriate administrative officials, the healthcare community, the patient population served and providers of formal agreements, when required (4.1.1.4b). Carried out in conjunction with QM.

c) Ensure that there are appropriate numbers of staff with the required education, training and competence to provide pathology services that meets the needs and requirements of users. (4.1.1.4c) Reviewed monthly at Pathology Management and Governance Committee (PMGC) with HBMS and heads of service.

d) Ensure the implementation of the quality policy (4.1.1.4d). Carried out in conjunction with QM.

e) Implement a safe laboratory environment in compliance with good practice and applicable requirements (4.1.1.4e). Carried out in conjunction with pathology H&S lead.

f) Serve as a contributing member of the medical staff for those facilities served, if applicable and appropriate. (4.1.1.4f). Contributes to appropriate clinical speciality as applicable and appropriate.

g) Ensure the provision of clinical advice with respect to the choice of examinations, use of the service and interpretation of examination results (4.1.1.4g). Accomplished with HBMS and heads of service at PMGC

h) Select and monitor laboratory suppliers (4.1.1.4h). Delegated to HBMS and GM

i) Select referral laboratories and monitor the quality of their service (4.1.1.4i). Delegated to HBMS and clinical heads of service

j) Provide professional development programmes for laboratory staff and opportunities to participate in scientific and other activities of professional laboratory organisations (4.1.1.4j). Delegated to HBMS and heads of service

k) Define, implement and monitor standards of performance and quality improvement of the pathology services. Carried out in conjunction with QM and reviewed at PMGC

l) Monitor all work performed in the laboratory to determine that clinically relevant information is being generated (4.1.1.4l). Carried out with HBMS and heads of service at PMGC

m) Address any complaint, request or suggestion from staff and/or users of laboratory services (4.1.1.4m). Delegated to HBMS, clinical heads of service, operations manager and QM.

n) Design and implement a contingency plan to ensure that the essential services are available during emergency situations or other conditions when laboratory services are limited or unavailable. (4.1.1.4n). Carried out with HBMS and heads of service at PMGC.

o) Plan and support research and development, where appropriate (4.1.1.4o). Carried out by CD and other clinical leads across the department and reviewed at PMGC.

The clinical lead (head of service, HoS**)** for each discipline has executive accountability and the overall responsibility for the service provided (5.1). The responsibilities of the HoS include, scientific, professional, consultative, advisory, organisational, administrative and educational activities, relevant to the pathology service provided at EKHUFT. 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 HoS. HoS are predominantly at one particular site, but will move across sites as and when necessary e.g. meetings, MDT's. There is currently no HoS for microbiology at present, the roles and responsibilities are shared between the consultant clinical staff.

A designated individual (DI), generally appointed from the consultant histopathology team or a practicing anatomical pathologist, supervises the licensed activity of the mortuary service. The primary (legal) responsibilities 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 license holder for the licensed mortuary activity is EKHUFT who can apply to the HTA to vary the license as appropriate and the contact is the medical director (MD).

The consultants in each discipline report to their respective clinical lead and are accountable through the pathology CD to the MD of EKHUFT. Where there are medical secretaries within disciplines, these predominantly to their individual consultants unless otherwise stipulated in organograms within this document.

Management commitment (4.1.2.1)

The general manager (GM) has responsibility for service delivery and financial balance as well as the operational management and modernisation of pathology services in line with local and national strategies (e.g. Kent STP). The GM works closely with the CD, head BMS and clinical leads to develop the service, manage its performance and plan for improvements.

The GM provides management and operational leadership to the department, working with the head BMSs to ensure effective budget management, workforce management and planning and ensuring effective use of resources and equipment. The GM has overall responsibility for ensuring that the head BMSs manage ISO 15189:2012 compliance to ensure full UKAS accreditation is achieved and then maintained. The GM has direct management of the HBMS, PoC coordinator, blood transfusion coordinator, information and IT systems manager, operations and quality managers. The GM is based at the WHH but works across all sites.

The head BMS (HBMS) for each discipline reports to the GM and works closely with the relevant clinical lead and pathology CD. HBMS are responsible for the managerial direction and associated provision of the relevant pathology service including operational compliance with ISO 15189:2012, the pathology QMS and all other relevant standards and guidance. Where applicable, the HBMS works across all sites.

The head of quality, governance and risk management (4.1.2.7), otherwise known as the quality manager (QM), reports to the GM, and working alongside the HBMS/ discipline quality leads, is responsible for ensuring that the QMS process is implemented, maintained and continually improved to meet service users' needs and requirements in line with ISO 15189:2012 and all other relevant standards and guidelines. The QM also has responsibility to co-ordinate and oversee risk management (4.14.6) for pathology, including management of risks which may affect patient safety and potential failure of processes ensuring risks are reduced or eliminated

where possible. The role also includes clinical governance management overseeing issues, incidents, user interaction activities including investigating and responding to patient related complaints and compliments and assessment of users' needs and requirements.

The point of care (PoC) coordinator reports to the Head BMS for Clinical Biochemistry, Immunology and PoC and works closely with other disciplines. The role is responsible for the day to day planning and implementation of policies, procedures and guidance relating to PoC equipment and services across EKHUFT and associated sites where agreed. The PoC coordinator is responsible for ensuring user compliance with appropriate SOPs which reflect local and national standards of work practice. The PoC coordinator works across all sites with the PoC team based at both the QEQMH and WHH sites that travel across EKHUFT.

The blood transfusion (BT) coordinator reports to the GM and is responsible for the day to day planning and implementation of policies and procedures relating to the safe transfusion of blood components within EKHUFT. The blood transfusion coordinator is responsible for ensuring EKHUFT practice, policies and procedures are compliant with the Blood Safety and Quality Regulations (BSQR) and Good Practice Guidelines (GPG). The blood transfusion coordinator is also responsible for the blood budget within EKHUFT. The blood transfusion coordinator works across all sites with a transfusion practitioners based on each site.

Information and IT Systems Manager

The IT team comprises of an IT Manager, deputy and support staff who cover all sites with the IT manager and deputy based at K&CH. The IT Systems has the following roles:

- To be responsible for the IT development of the service and direct assessment of new software and hardware for the provision of effective IT solutions for the EKHUFT pathology service.
- To provide timely and accurate management and performance information as required by the CD, GM, HBMS, finance, CSS care group and users of the service.
- To collaborate with EKHUFT services with regard to EKHUFT and GP electronic ordering and reporting systems.

The operations manager supports management of staff welfare and HR activities alongside management of the administration team.

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 GM has no overall designated deputy, but will designate a HBMS to deputise in their absence; the individual is chosen on availability.
- All HBMSs are deputised by one of the Chief BMS within the discipline; the individual is chosen on availability.
- The clinical lead for clinical biochemistry is deputised by a fellow consultant clinical scientist.
- Other clinical leads are deputised by consultant colleagues as appropriate at the time of their absence.
- The IT manager is deputised by the IT deputy.
- Other key individuals including the QM (refer to DIR-NO-053: Competency requirement for quality leads including deputation for the quality manager), H&S lead and training lead designate a deputy as necessary to another member of the associated committee i.e. another quality lead, or H&S supervisor.

Needs of users (4.1.2.2)

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

- Providing statistical information to the EKHUFT, Kent and Medway CCG (Clinical Commissioning Group) and other external agencies.
- 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 Patient Safety Board (PSB)), 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 DATIX 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: DIR-QP-Q002; Complaints and Compliments DIR-MP-Q123: User satisfaction and 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 complaints and compliments received in the departmental PMGC meeting; consideration of the findings forms part of a dedicated pathology departmental annual management review (AMR) when business plans and objectives are set.

Quality objectives and planning (4.1.2.4)

Pathology determines objectives for each of the disciplines; 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 and discipline objectives is based on review of user interaction, consideration of EKHUFT strategy, consideration of the QMS, and business planning for the next year e.g. change in analytical platforms.

The determination of quality objectives occur at the same time as business plans are made and are updated to include any rolled over QO's following the AMR; these are included in the AMR reports and are distributed to all staff via use of Q-Pulse document module.

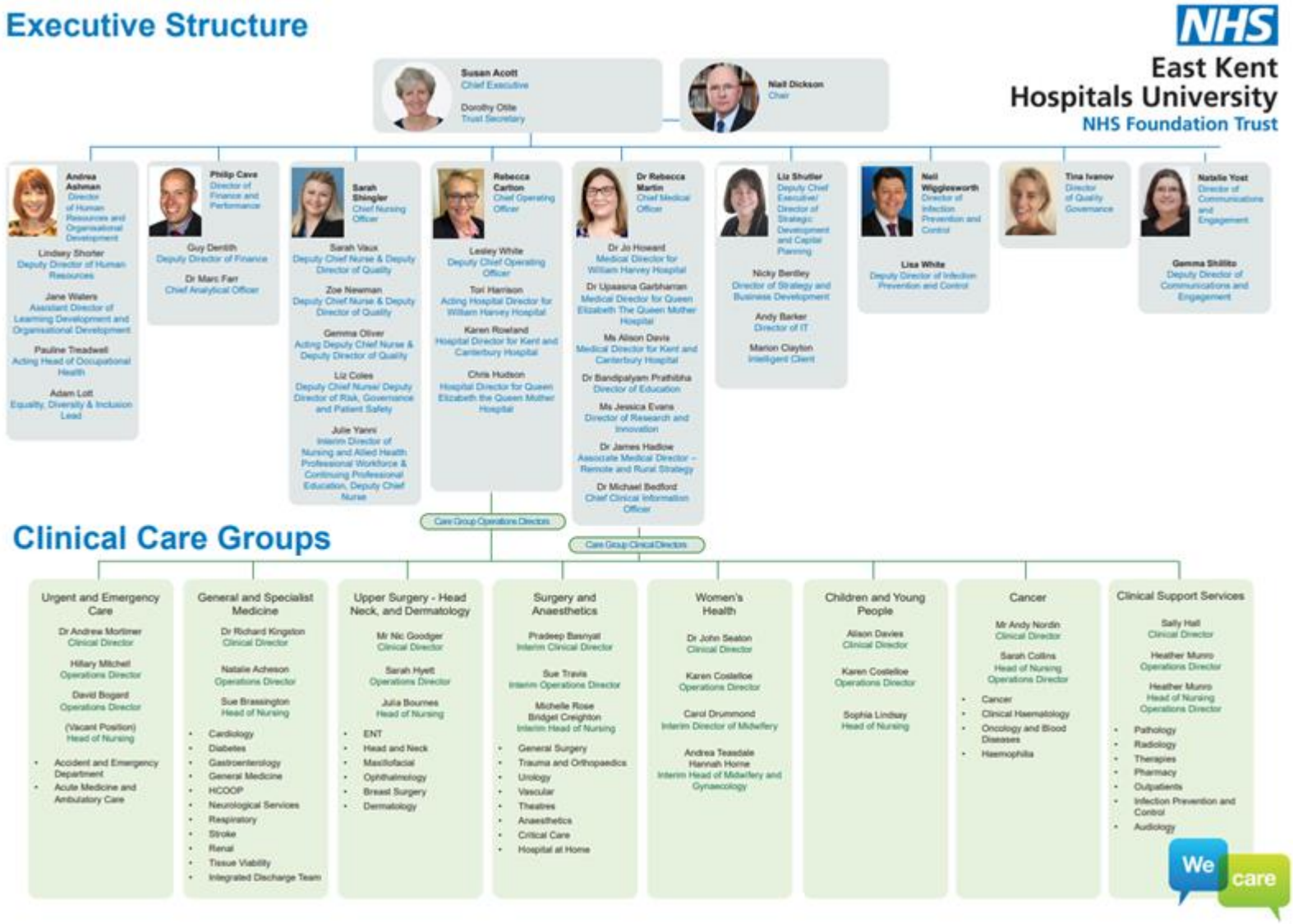
Review of the QOs occurs at a discipline specific level within monthly discipline quality meetings and at a senior level on a rotational basis between all disciplines after the PMGC.

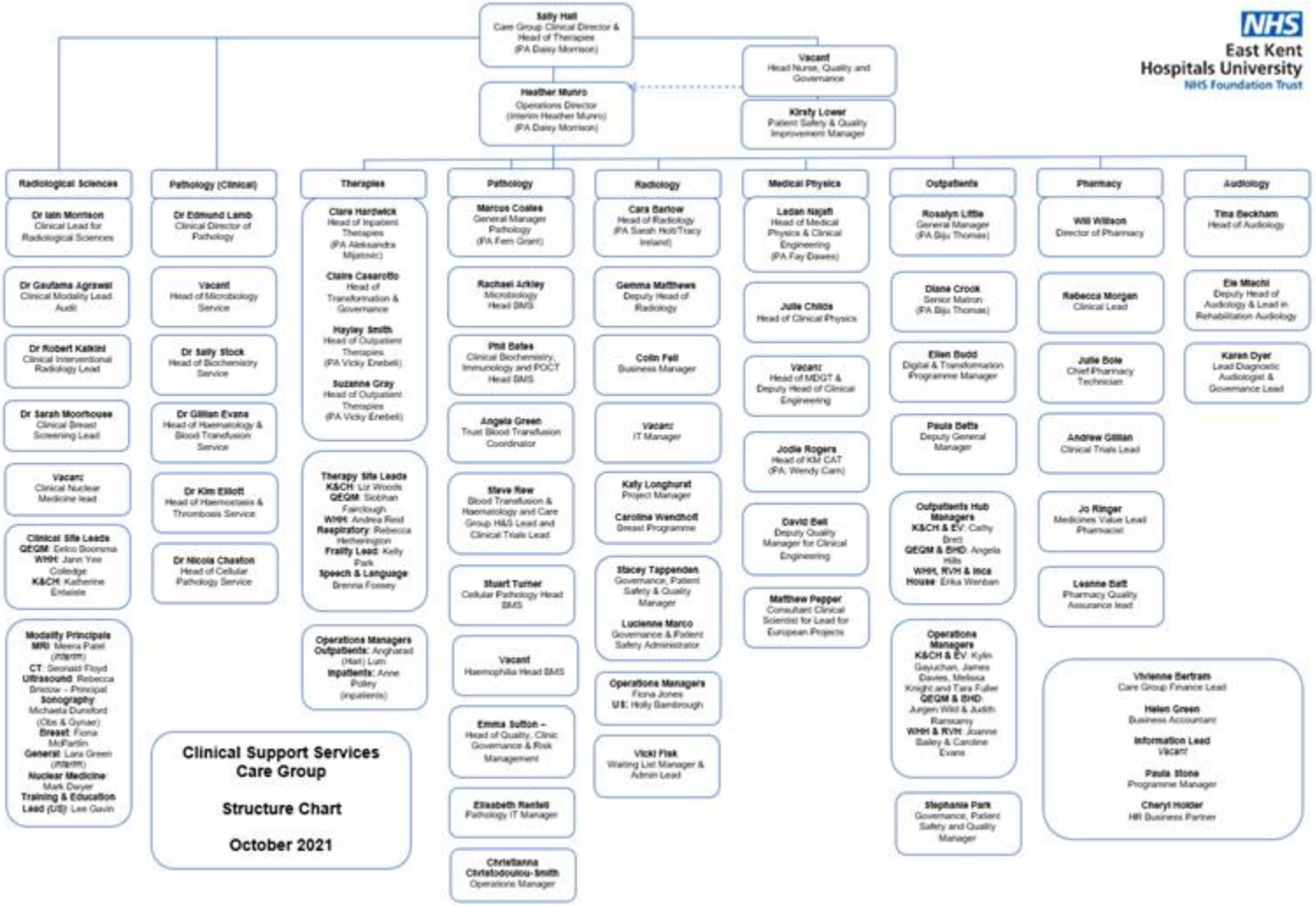
Responsibility, authority and interrelationships (4.1.2.5)

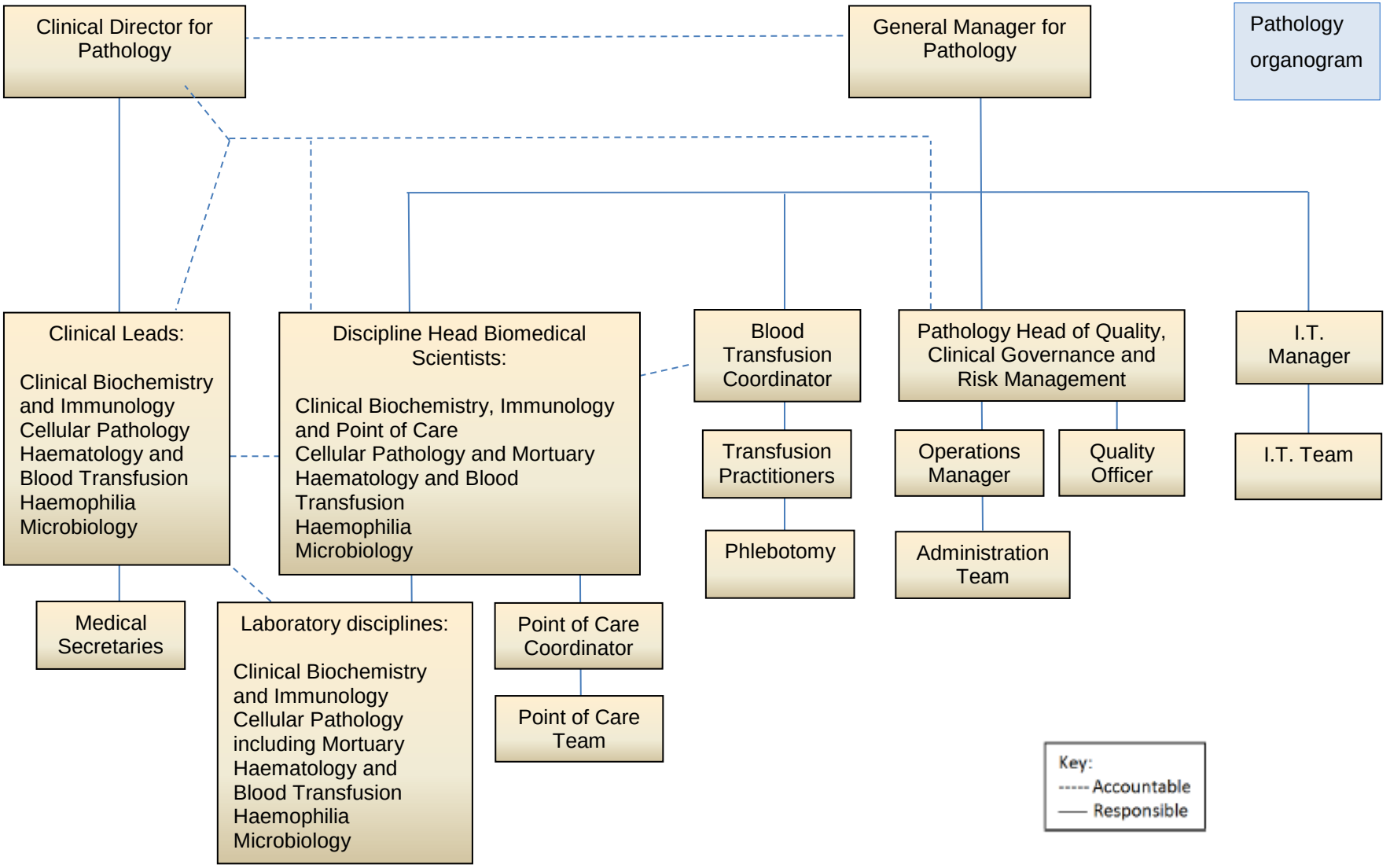
Pathology is part of the Clinical Support Services (CSS) Care Group (please see organogram on page 21) which sits within EKHUFT structure as depicted in the organogram on page 20.

The pathology department also interacts with the following external organisations:

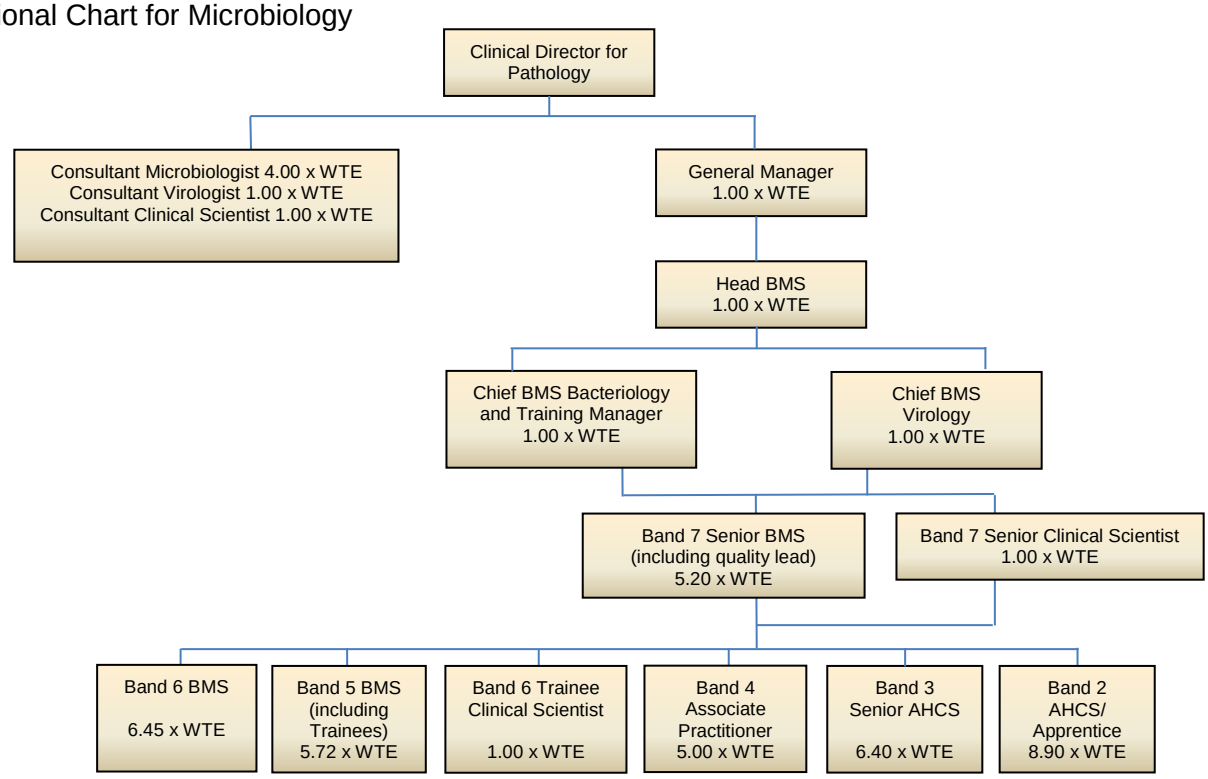
- United Kingdom Accreditation Services (UKAS)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Screening Quality Assurance Service (SQAS)
- Human Tissue Authority (HTA)
- National Health Service Blood and Tissue (NHSBT)
- Blood Safety and Quality Regulations (BSQR)
- National External Quality Assessment Service (NEQAS)
- Welsh External Quality Assessment Service (WEQAS)
- Quality Control for Molecular Diagnostics (QCMD)
- HM Coroner
- Kent County Council
- Kent Cancer Network


Executive Structure
NHS
East Kent Hospitals University
NHS Foundation Trust
Susan Acott
Chief Executive
Dorothy Otile
Trust Secretary
Niall Dickson
Chair
Andrea Ashman
Director of Human Resources and Organisational Development
Lindsey Shorter
Deputy Director of Human Resources
Jane Waters
Assistant Director of Learning Development and Organisational Development
Pauline Treadwell
Acting Head of Occupational Health
Adam Lott
Equality, Diversity & Inclusion Lead
Philip Cave
Director of Finance and Performance
Guy Dentith
Deputy Director of Finance
Dr Marc Farr
Chief Analytical Officer
Sarah Shingler
Chief Nursing Officer
Sarah Vaux
Deputy Chief Nurse & Deputy Director of Quality
Zoe Newman
Deputy Chief Nurse & Deputy Director of Quality
Gemma Oliver
Acting Deputy Chief Nurse & Deputy Director of Quality
Liz Coles
Deputy Chief Nurse/ Deputy Director of Risk, Governance and Patient Safety
Julie Yanni
Interim Director of Nursing and Allied Health Professional Workforce & Continuing Professional Education, Deputy Chief Nurse
Rebecca Carlton
Chief Operating Officer
Lesley White
Deputy Chief Operating Officer
Tori Harrison
Acting Hospital Director for Willam Harvey Hospital
Karen Rowland
Hospital Director for Kent and Canterbury Hospital
Chris Hudson
Hospital Director for Queen Elizabeth the Queen Mother Hospital
Dr Rebecca Martin
Chief Medical Officer
Dr Jo Howard
Medical Director for William Harvey Hospital
Dr Upasana Garbharran
Medical Director for Queen Elizabeth The Queen Mother Hospital
Ms Alison Davis
Medical Director for Kent and Canterbury Hospital
Dr Bandipalyam Prathibha
Director of Education
Ms Jessica Evans
Director of Research and Innovation
Dr James Hadlow
Associate Medical Director – Remote and Rural Strategy
Dr Michael Bedford
Chief Clinical Information Officer
Liz Shutler
Deputy Chief Executive/ Director of Strategic Development and Capital Planning
Nicky Bentley
Director of Strategy and Business Development
Andy Barker
Director of IT
Marion Clayton
Intelligent Client
Neil Wigglesworth
Director of Infection Prevention and Control
Lisa White
Deputy Director of Infection Prevention and Control
Tina Ivanov
Director of Quality Governance
Natalie Yost
Director of Communications and Engagement
Gemma Shillito
Deputy Director of Communications and Engagement
Care Group Operations Directors
Care Group Clinical Directors
Clinical Care Groups
Urgent and Emergency Care
Dr Andrew Mortimer
Clinical Director
Hillary Mitchell
Operations Director
David Bogard
Operations Director
(Vacant Position)
Head of Nursing
Accident and Emergency Department
Acute Medicine and Ambulatory Care
General and Specialist Medicine
Dr Richard Kingston
Clinical Director
Natalie Acheson
Operations Director
Sue Brassington
Head of Nursing
Cardiology
Diabetes
Gastroenterology
General Medicine
HCOOP
Neurological Services
Respiratory
Stroke
Renal
Tissue Viability
Integrated Discharge Team
Upper Surgery - Head Neck, and Dermatology
Mr Nic Goodger
Clinical Director
Sarah Hyett
Operations Director
Julia Bournes
Head of Nursing
ENT
Head and Neck
Maxillofacial
Ophthalmology
Breast Surgery
Dermatology
Surgery and Anaesthetics
Pradeep Basnyat
Interim Clinical Director
Sue Travis
Interim Operations Director
Michelle Rose
Bridget Creighton
Interim Head of Nursing
General Surgery
Trauma and Orthopaedics
Urology
Vascular
Theatres
Anaesthetics
Critical Care
Hospital at Home
Women's Health
Dr John Seaton
Clinical Director
Karen Costelloe
Operations Director
Carol Drummond
Interim Director of Midwifery
Andrea Teasdale
Hannah Horne
Interim Head of Midwifery and Gynaecology
Children and Young People
Alison Davies
Clinical Director
Karen Costelloe
Operations Director
Sophia Lindsay
Head of Nursing
Cancer
Mr Andy Nordin
Clinical Director
Sarah Collins
Head of Nursing
Operations Director
Cancer
Clinical Haematology
Oncology and Blood Diseases
Haemophilia
Clinical Support Services
Sally Hall
Clinical Director
Heather Munro
Operations Director
Heather Munro
Head of Nursing
Operations Director
Pathology
Radiology
Therapies
Pharmacy
Outpatients
Infection Prevention and Control
Audiology
We care

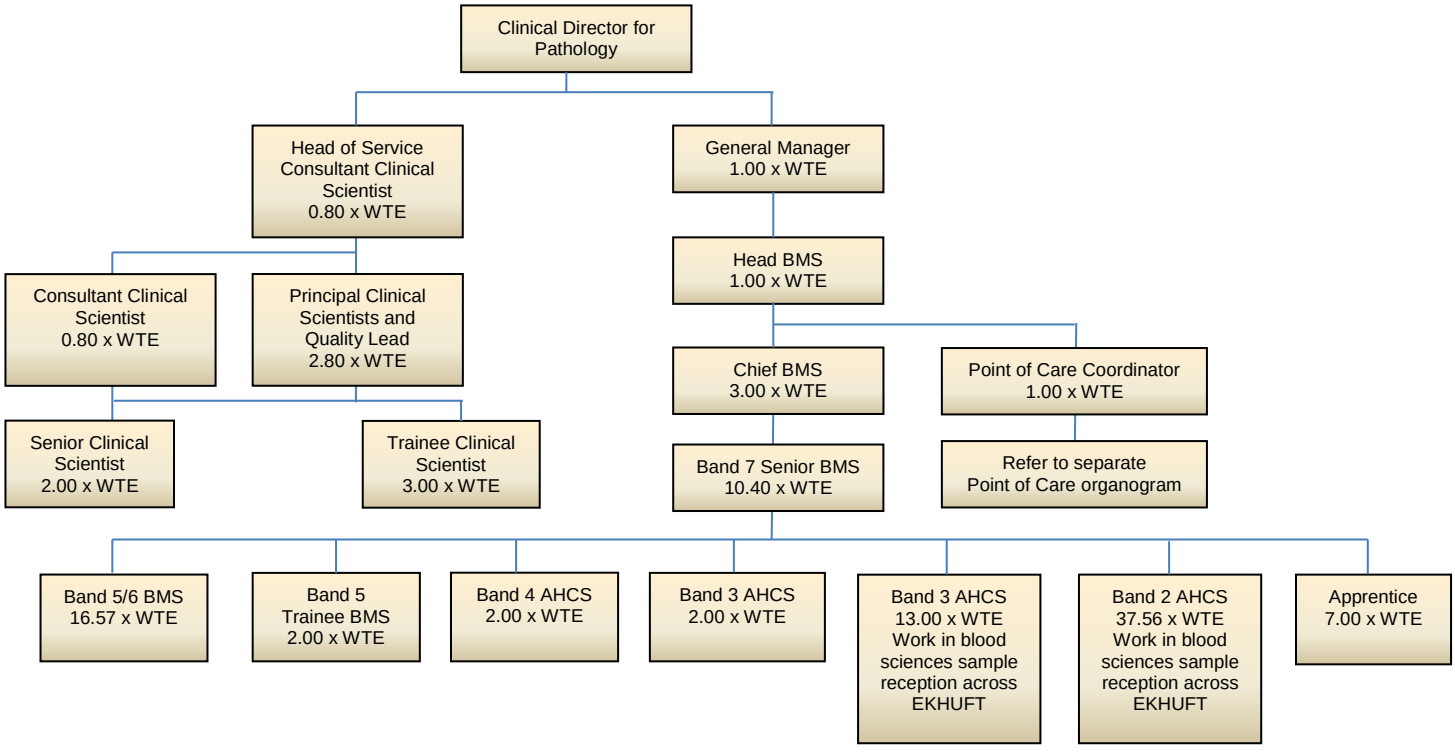

Sally Hall
Care Group Clinical Director & Head of Therapies
(PA Daisy Morrison)
Vacant
Head Nurse, Quality and Governance
Heather Munro
Operations Director
(Interim Heather Munro)
(PA Daisy Morrison)
Kirsty Lower
Patient Safety & Quality Improvement Manager
NHS East Kent Hospitals University NHS Foundation Trust
Radiological Sciences
Dr Iain Morrison
Clinical Lead for Radiological Sciences
Dr Gautama Agrawal
Clinical Modality Lead Audit
Dr Robert Kalkini
Clinical Interventional Radiology Lead
Dr Sarah Moorhouse
Clinical Breast Screening Lead
Vacant
Clinical Nuclear Medicine lead
Clinical Site Leads
QEQM: Eelco Boonsma
WHH: Jann Yee Coltedge
K&CH: Katherine Entwistle
Modality Principals
MRI: Meera Patel (Interim)
CT: Seonaid Floyd
Ultrasound: Rebecca Bristow - Principal Sonography: Michaela Dunsford (Obs & Gynae)
Breast: Fiona McPartlin
General: Lara Green (Interim)
Nuclear Medicine: Mark Dwyer
Training & Education Lead (US): Lee Gavin
Pathology (Clinical)
Dr Edmund Lamb
Clinical Director of Pathology
Vacant
Head of Microbiology Service
Dr Sally Stock
Head of Biochemistry Service
Dr Gillian Evans
Head of Haematology & Blood Transfusion Service
Dr Kim Elliott
Head of Haemostasis & Thrombosis Service
Dr Nicola Chaston
Head of Cellular Pathology Service
Therapies
Clare Hardwick
Head of Inpatient Therapies
(PA Aleksandra Miljatovic)
Claire Casarotto
Head of Transformation & Governance
Hayley Smith
Head of Outpatient Therapies
(PA Vicky Enebeli)
Suzanne Gray
Head of Outpatient Therapies
(PA Vicky Enebeli)
Therapy Site Leads
K&CH: Liz Woods
QEQM: Siobhan Fairclough
WHH: Andrea Reid
Respiratory: Rebecca Hetherington
Frailty Lead: Kelly Park
Speech & Language: Brenna Fossey
Operations Managers
Outpatients: Angharad (Hart) Lum
Inpatients: Anne Polley (inpatients)
Clinical Support Services Care Group
Structure Chart
October 2021
Pathology
Marcus Coates
General Manager Pathology
(PA Fern Grant)
Rachael Arkley
Microbiology Head BMS
Phil Bates
Clinical Biochemistry, Immunology and POCT Head BMS
Angela Green
Trust Blood Transfusion Coordinator
Steve Rew
Blood Transfusion & Haematology and Care Group H&S Lead and Clinical Trials Lead
Stuart Turner
Cellular Pathology Head BMS
Vacant
Haemophilia Head BMS
Emma Sutton –
Head of Quality, Clinic Governance & Risk Management
Elisabeth Rantell
Pathology IT Manager
Christianna Christodoulou-Smith
Operations Manager
Radiology
Cara Barlow
Head of Radiology
(PA Sarah Holt/Tracy Ireland)
Gemma Matthews
Deputy Head of Radiology
Colin Fell
Business Manager
Vacant
IT Manager
Katy Longhurst
Project Manager
Caroline Wendthoft
Breast Programme
Stacey Tappenden
Governance, Patient Safety & Quality Manager
Lucienne Marco
Governance & Patient Safety Administrator
Operations Managers
Fiona Jones
US: Holly Bambrough
Vicki Fisk
Waiting List Manager & Admin Lead
Medical Physics
Ladan Najafi
Head of Medical Physics & Clinical Engineering
(PA Fay Dawes)
Julie Childs
Head of Clinical Physics
Vacant
Head of MDGT & Deputy Head of Clinical Engineering
Jodie Rogers
Head of KM CAT
(PA: Wendy Carn)
David Bell
Deputy Quality Manager for Clinical Engineering
Matthew Pepper
Consultant Clinical Scientist for Lead for European Projects
Outpatients
Rosalyn Little
General Manager
(PA Biju Thomas)
Diane Crook
Senior Matron
(PA Biju Thomas)
Ellen Budd
Digital & Transformation Programme Manager
Paula Betts
Deputy General Manager
Outpatients Hub Managers
K&CH & EV: Cathy Brett
QEQM & BHD: Angela Hills
WHH, RVH & Inca House: Erika Wenban
Operations Managers
K&CH & EV: Kyln Gayuchan, James Davies, Melissa Knight and Tara Fuller
QEQM & BHD: Jurgen Wild & Judith Ramsamy
WHH & RVH: Joanne Bailey & Caroline Evans
Stephanie Park
Governance, Patient Safety and Quality Manager
Pharmacy
Will Willson
Director of Pharmacy
Rebecca Morgan
Clinical Lead
Julie Bole
Chief Pharmacy Technician
Andrew Gillian
Clinical Trials Lead
Jo Ringer
Medicines Value Lead Pharmacist
Leanne Batt
Pharmacy Quality Assurance lead
Audiology
Tina Beckham
Head of Audiology
Ela Machi
Deputy Head of Audiology & Lead in Rehabilitation Audiology
Karen Dyer
Lead Diagnostic Audiologist & Governance Lead
Vivienne Bertram
Care Group Finance Lead
Helen Green
Business Accountant
Information Lead
Vacant
Paula Stone
Programme Manager
Cheryl Holder
HR Business Partner


Clinical Director for Pathology
General Manager for Pathology
Pathology organogram
Clinical Leads:
Clinical Biochemistry and Immunology
Cellular Pathology
Haematology and Blood Transfusion
Haemophilia
Microbiology
Discipline Head Biomedical Scientists:
Clinical Biochemistry, Immunology and Point of Care
Cellular Pathology and Mortuary
Haematology and Blood Transfusion
Haemophilia
Microbiology
Blood Transfusion Coordinator
Transfusion Practitioners
Phlebotomy
Pathology Head of Quality, Clinical Governance and Risk Management
Operations Manager
Quality Officer
Administration Team
I.T. Manager
I.T. Team
Medical Secretaries
Laboratory disciplines:
Clinical Biochemistry and Immunology
Cellular Pathology including Mortuary
Haematology and Blood Transfusion
Haemophilia
Microbiology
Point of Care Coordinator
Point of Care Team
Key:
----- Accountable
—— Responsible

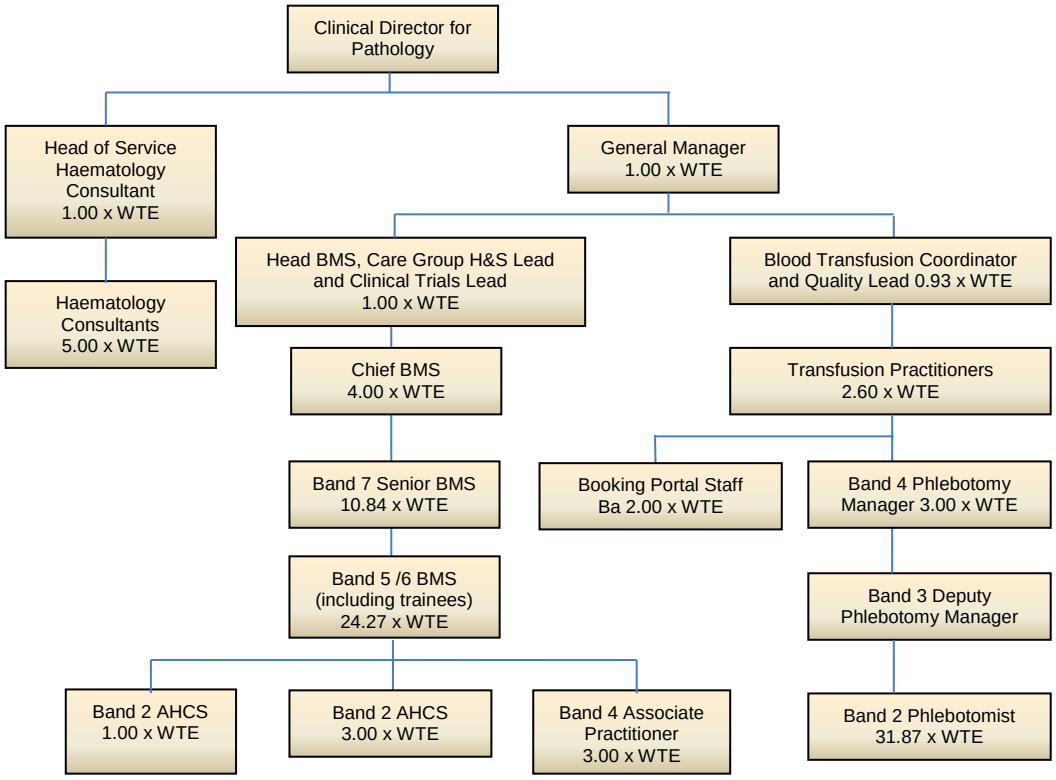
Organisational Chart for Microbiology



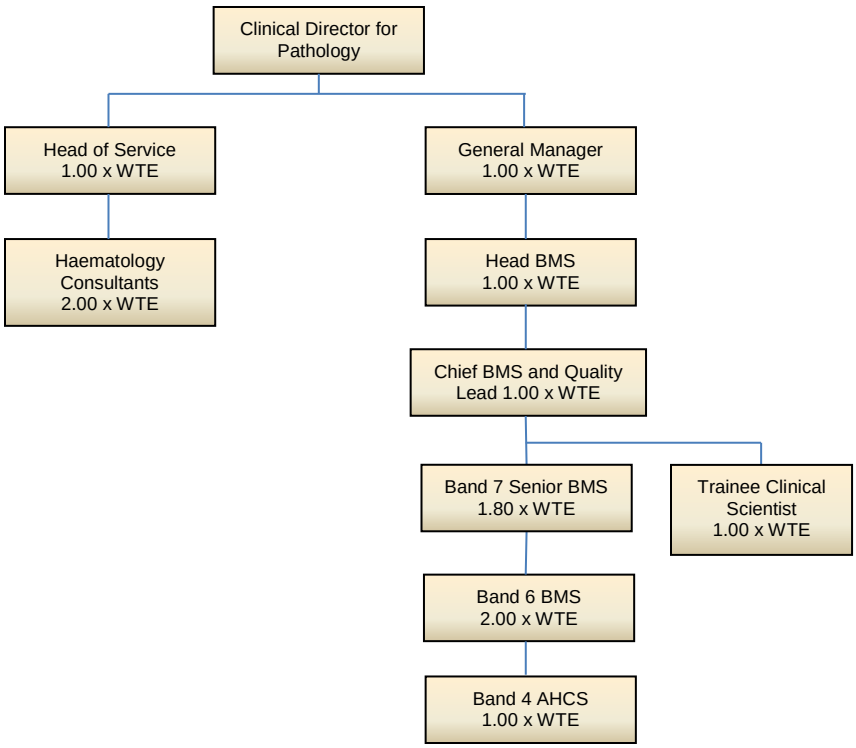
Organisational Chart for Clinical Biochemistry Including Immunology



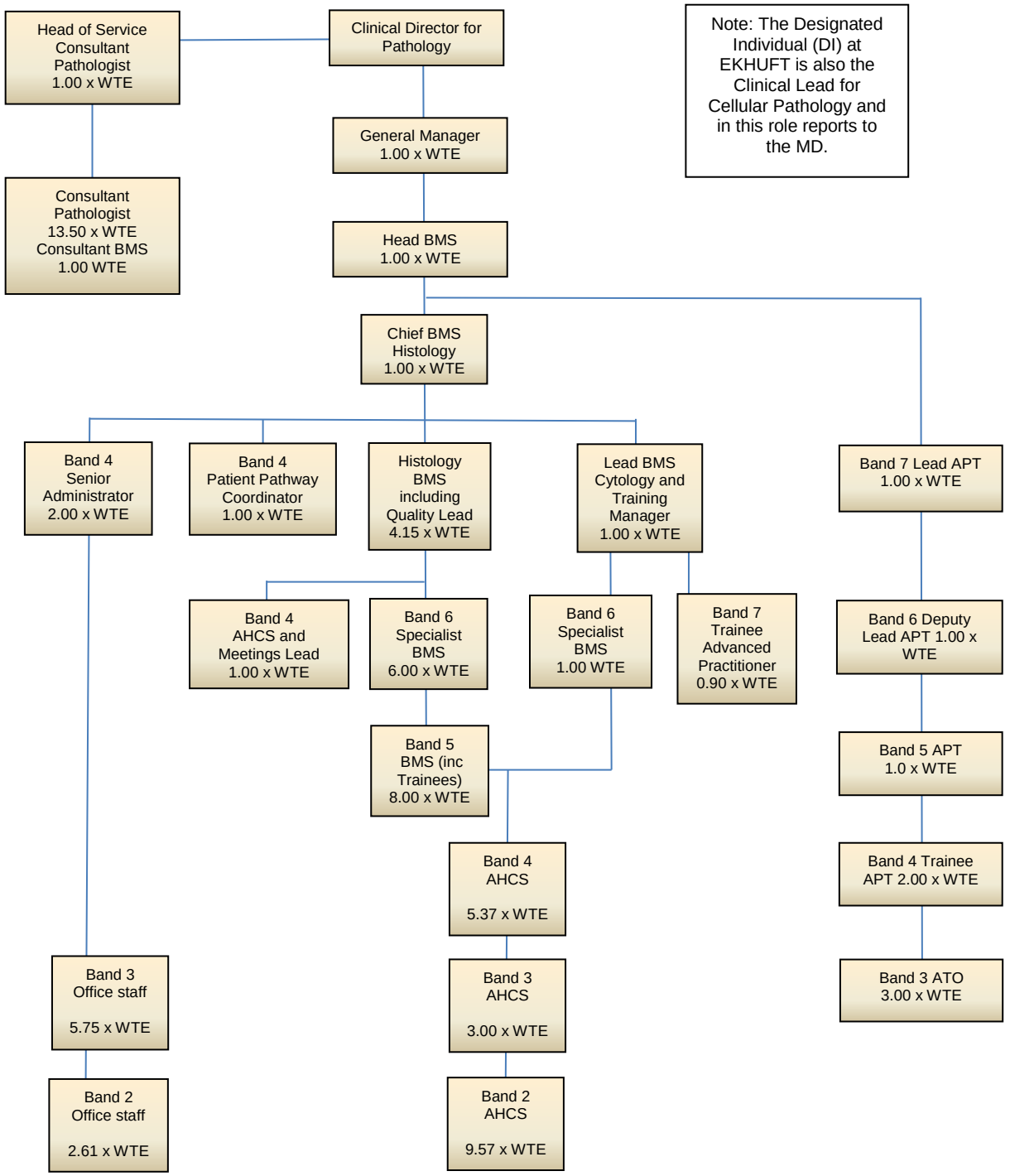
Organisational Chart for Haematology and Blood Transfusion



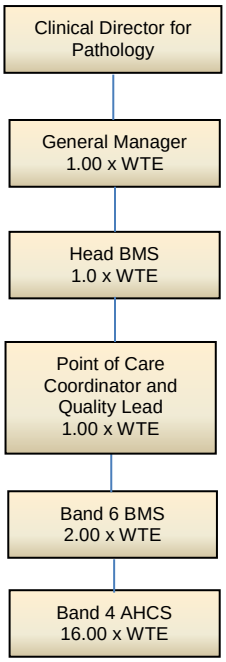
Organisational Chart for the Haemostasis & Thrombosis laboratory



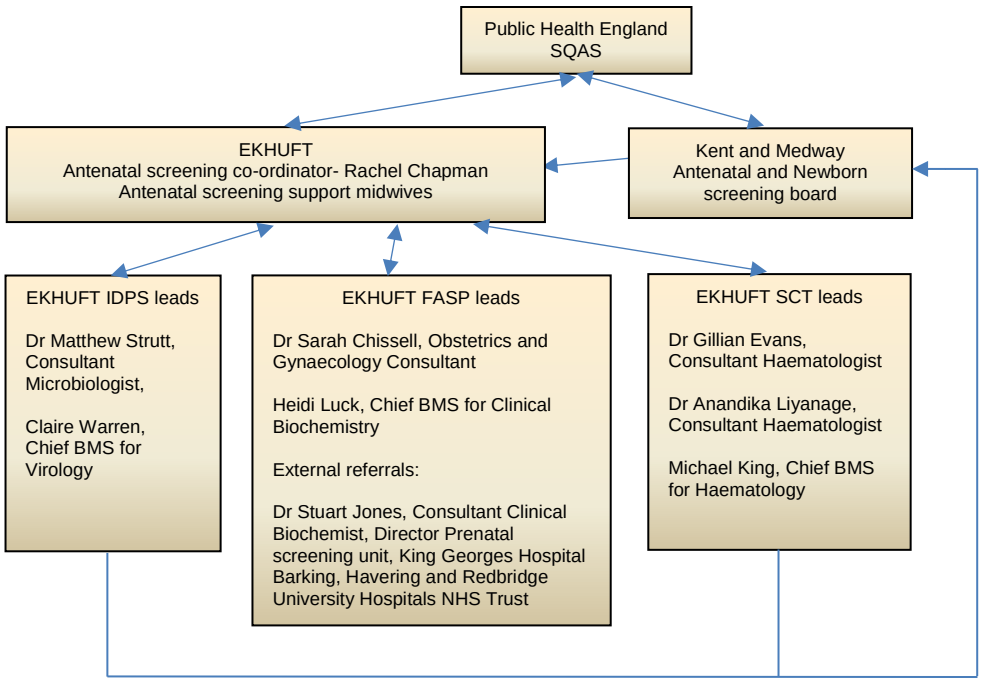
Organisational Chart for Cellular Pathology



Organisational Chart for the Point of Care



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



Communication (4.1.2.6)

The PMGC meets once a month.

The meeting is attended by the CD (chairperson), GM, all disciplines' HoS and HBMS; QM, blood transfusion coordinator, IT manager and operations manager.

Pathology quality forum meets once a month.

The meeting is attended by the QM (chairperson) and is attended by the discipline quality leads; discipline HBMS, GM and CD are welcome to attend but are not part of the key membership.

Key agenda items are to discuss discipline and overarching QMS processes and activities including review of CAPA, document review, compliance to audit schedule, quality improvements and governance.

Pathology senior management team aims to meet fortnightly.

The meeting is attended by the GM (chairperson), all disciplines' HBMS; QM, blood transfusion coordinator, pathology health and safety lead, IT manager and operations manager. Key agenda items are to discuss pathology operational issues along with innovation, training and improvement; terms of reference are reviewed annually.

Health and Safety forum meets once a month:

The meeting is attended by the pathology health and safety lead (chairperson), all disciplines' health and safety leads, if available the Union health and safety representative and as required the quality manager and site health and safety officers

Training and Education forum aims to meet alternate months

The meetings are chaired by the overall training lead for Pathology. Each discipline is represented by their Training Officer and one or more of the Mortuary APTs attend. The Head of Quality may attend as required.

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

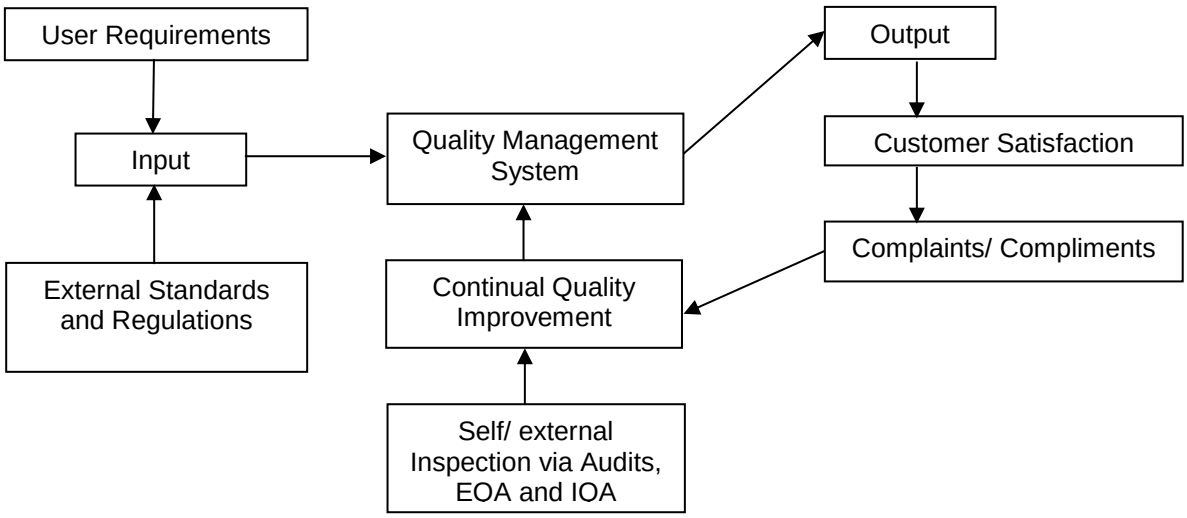
Discipline communication forms include huddles, diary meetings, team briefs (general staff meetings), senior, quality, training and education and health and safety to communicate information regarding the pathology service and QMS to staff which aims to occur once a month. Meeting minutes are recorded for each meeting and are available to staff to read (on Q-Pulse or via use of handwritten notes e.g. huddle).

Communications between EKHUFT and pathology occur via:

- Weekly global e-mails used to distribute trust news and information.
- Weekly updates sent via e-mail from the chief executive officer (CEO).
- Communications stream via the CSS care group pathway (via meetings or clinical and/ or operations director to pathology CD and GM).

4.2 Quality management system

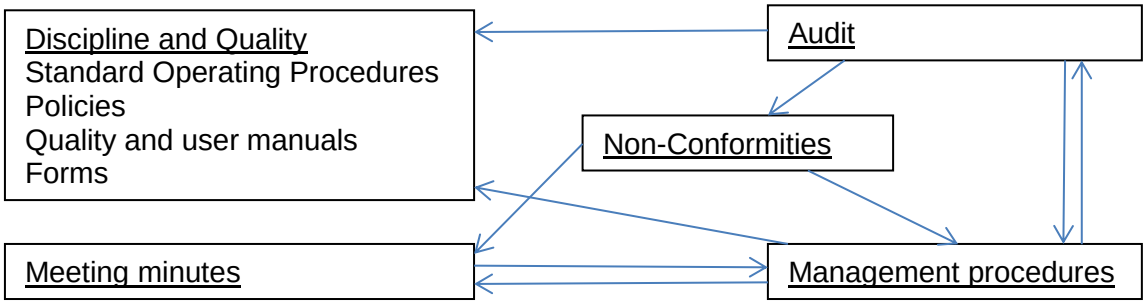
The laboratory has established a QMS which is documented and maintained to continually improve the quality of the service and ensure it meets the needs and requirements of its users. The following diagram depicts the sequence and interaction of maintaining the QMS including continual evaluation from 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 a procedure DIR-MP-Q205 which details the policy on using the UKAS logo and symbol.

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



4.3 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 discipline quality leads. Documentation held on Q—Pulse includes information pertinent to the QMS or specific examination processes within a discipline (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.
- Ownership of documentation.

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 DIR-MP-Q002: Use of document module in Q-Pulse.

4.4 Service agreements

Pathology services are supplied to EKHUFT, GPs, other NHS organisations (use of EKHUFT pathology as a referral laboratory) and on individual bases to requestors/ patients on submission

of test requests and forms. Services to GP's are agreed via contracts with the Kent and Medway CCG (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.

4.5 Referral to other laboratories

When required, pathology refers samples to referral laboratories for additional/ specialised testing. The choice of the referral laboratory utilised is assessed by formal evaluation including review of accreditation to ISO 15189:2012, 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 DIR-MP-Q201: Process for Selection and Review of Suppliers (including referral laboratories).

The referral laboratories utilised are listed within discipline specific handbooks and are managed as suppliers using the supplier module on Q-Pulse with annual review to ascertain continuing suitability.

4.6 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 DIR-MP-Q201: Process for Selection and Review of Suppliers (including referral laboratories) and DIR-MP-Q108: Management of Reagents and Consumables. If necessary, EKHUFT procurement team 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.

4.7 Advisory services

Pathology provides relevant advisory service via the issue and maintenance of discipline specific user handbooks/ guides which are available to all users on EKHUFT webpages which detail information pertinent to the test repertoire offered by the disciplines.

Advisory services are also available from interpretative comments and ranges issued on reports and availability of clinical advice from all disciplines' clinical leads and consultant teams.

Assessment of advisory information is reviewed in the annual user survey issued to all pathology users.

4.8 Resolution of complaints

All complaints are investigated, documented and responded to within pathology as part of good governance; these are discussed within discipline specific communications, at the pathology quality forum, PMGC meeting and collated at 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 DIR-QP-Q002; Complaints and Compliments DIR-MP-Q123: User satisfaction and engagement.

4.9 Identification and control of nonconformities

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 DIR-MP-Q130: Identification and management of non-conformities and quality improvement.

4.10 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. See DIR-MP-Q130: Identification and management of non-conformities and quality improvement.

4.11 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. After the

preventive action has been implemented, its effectiveness must be reviewed. See DIR-MP-Q130: Identification and management of non-conformities and quality improvement.

The status of non-conformities, corrective and preventive actions are monitored and reported monthly at discipline specific quality meetings and the pathology quality forum are and collated for review at the AMR.

4.12 Continual improvement

Pathology employs a continuous quality improvement system, which involves the continual assessment, evaluation and evolution of the service; this is documented within DIR-MP-Q130: Identification and management of non-conformities and quality improvement.

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.

4.13 Control of quality 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 DIR-MP-Q001- The management and control of process documents & DIR-MP-Q102 Control of process and quality records and archive. These procedures include: identification and

indexing. security, retention, storage and retrieval, disposal, compliance with BSQR (2005) and the HTA conditions of license.

4.14 Evaluation and audits

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, discipline specific and department quality indicators and reviews of external organisations alongside continual quality improvement mechanisms. These are reviewed monthly at the pathology quality forum and disciple quality meetings and when significant escalated to the PMGC. 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 or quality improvement (QI) CAPA wizard on Q-Pulse.

All disciplines throughout pathology 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 disciplines e.g. transport, phlebotomy and organisational requirements. Non-conformities identified as part of internal audit programme are managed as per DIR-MP-Q130: Identification and management of non-conformities and quality improvement. The process for planning, conducting, evaluating, monitoring and reviewing the audit are described in DIR-QP-Q125: Internal audit.

All processes within pathology (pre-examination, examination and postexamination stages) are risk assessed using EKHUFT template to identify potential pitfalls and put in place effective mitigation steps. Risks that cannot be successfully mitigated are placed on discipline risk

registers and are reviewed until agreed residual risk rating (usually classed as between 1-3) has been achieved. This is monitored at the quality forum, PMGC and CSS care group meeting.

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 discipline performance and therefore the relationship to effective patient care. These are monitored on a monthly basis within disciplines and any identified issues are managed as risks and where appropriate are discussed with users.

The pathology department is subject to assessment through a variety of external organisations i.e. assessment bodies (both regulatory and accreditation). Annual assessment occurs from the HTA 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 discipline. 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 DIR-MP-Q130: Identification and management of non-conformities and quality improvement 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).

4.15 Management review

Pathology conducts an annual review of the QMS in each discipline including review of trends of incidents, quality improvements, the quality policy and QO set the previous year. Discipline 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
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
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

Reports are written by disciplines and are reviewed formally with records comprising of these reports and minutes of the meetings. 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 (4.15.4) are discussed at discipline quality meetings and are monitored and reported at PMGC mid-year.

5 TECHNICAL REQUIREMENTS

5.1 Personnel

Staffing

Pathology employs staff with the appropriate level of qualifications, training and experience relevant to the post held, this information is held within personnel files (5.1.2). Scientific and technical posts include those registered with the Health Care Professions Council (HCPC) 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)

Personnel management

For further details regarding personnel management within pathology please refer to DIR-MP-Q104 Personnel and Site Management.

Job descriptions and contracts (5.13)

All staff are issued with a contract of employment (which provides clear terms and conditions of service), job description and a person specification, on application for a post; job descriptions are reviewed and may be revised at personal development reviews (PDRs) or following organisational change; this document encompasses:

a) Job role
b) The location within the organisation
c) Accountability
d) The main purpose of the job
e) The main duties and responsibilities
f) A requirement for participation in staff annual joint review.

Personnel introduction to the organisational environment (5.14)

EKHUFT ensures all staff undertakes trust induction as the first working days as an EKHUFT employee by coordinating start date with the induction sessions. At this event; each new starter is issued a trust induction booklet to provide information on EKHUFT as an organisation including trust values and actions to do in working area:

- Introduction to department or area in which the person will work

- Terms and condition of employment
- Staff facilities
- Health and safety requirements (including fire and emergency)
- Occupational health services

Records of staff orientation and induction are kept in the individual's personnel file.

Training (5.15)

Pathology provides training to all new starters on the following:

a) Quality management system (staff tasked to read this manual and undergo training regarding QMS with the quality manager)
b) Assigned work processes and procedures (undertaken within discipline for each activity)
c) Applicable laboratory information system (undertaken within discipline)
d) Health and Safety (staff tasked to read(DIR-LP-105a: Health and safety handbook)
e) Ethics (staff tasked to read DIR-EX-130: Anti-fraud and bribery policy and DIR-EX-148 Gifts and hospitality policy)
f) Confidentiality of patient information (encompassed within mandatory annual information governance training and assessment)

All staff have access to the hospitals libraries, the internet, intranet (provides a range of e-learning tools, including all mandatory training modules) and Q-Pulse.

For further information refer to DIR-MP-600 Education and Training Policy and discipline specific training manuals/ protocols which describe the training of pathology staff.

Each discipline has designated training officer(s) who coordinates the training and education of all staff, including mandatory training; records of attendance are kept by the discipline specific training officers/ HBMS. Records of staff training are kept on Q-Pulse (audit trails i.e. copyholder lists for acknowledgement, within personal training files and online personnel files).

Pathology has created a level 3 modern apprenticeship working with Canterbury College to educate and train individuals to work as assistant healthcare scientists. Our vision is to create a training program using the modern apprenticeship framework across bands 2-4. Higher apprenticeships may be explored at a future date once further guidance is given from Health Education England and the Health Care Science Program Board.

Competence assessment (5.1.6)

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 (5.1.6) 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. The training officer's co-ordinate the training of all trainee BMS which includes laboratory based training and the completion of appropriate portfolios.

Reviews of staff performance (5.1.7) (non-medical staff)

Reviews of staff performance (also known as annual joint reviews/ appraisal/PDRs) are conducted in accordance with EKHUFT guidelines and follow the standards set in the Knowledge and Skills Framework (KSF) document. Appraisal occurs at a minimum once a year (at three month period for new starters) to discuss the needs of the laboratory and of the 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

Staff appraisal records are kept in their personnel files, and copies supplied to the individual.

Continuing Professional Development (CPD) (5.1.8)

All staff are encouraged to undertake CPD with each discipline organising CPD sessions for staff to attend predominantly during break times or as scheduled sessions throughout the work day. External courses can be attended to but require applications made for training time and budget which are not guaranteed; review is made of potential benefits to the department (or specific discipline) and consideration given to other requests.

Staff records (5.1.9)

Each member of staff has a personnel file which can comprise of hard and electronic copies of the information listed below;

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 an appropriate discipline office. Information may also be held by EKHUFT HR team from initial applications.

5.2 Accommodation and Environmental conditions

Laboratory and office facilities (5.2.1)

Access to pathology is restricted to authorised personnel only via a FOB &/or coded locking system on the doors leading into the department areas. Staff issued with a FOB are recorded and limited to only those requiring entry to areas that they need to gain access for; porters have access as appropriate. All visitors at any site are required to contact pathology reception to gain entry 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 laboratory personnel (5.2.2). The laboratory areas are separated so as to reduce and eliminate cross contamination where appropriate. Environmental conditions such as temperature are routinely monitored (5.2.6). In areas of lone working man down alarms are routinely used. 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.

Facilities for Storage (5.2.3)

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

Facilities for staff (5.2.4)

Facilities for staff are provided by the department and include: male and female toilets, secure lockers for storage of personal items; rest room with drinking water; facilities for making hot drinks and a wash-up area. There are also areas available within pathology on each site for private/ quiet study and meetings.

Facilities for patient sample collection facilities (5.2.5)

Phlebotomy at EKHUFT is under the management of pathology and suitable space has been provided for each phlebotomy clinic within their designated areas, at pathology entrance in both K&CH and QEQMH, and in the out patients department at WHH. There is also adequate provision at BHD and RVHF for phlebotomy patients. There is provision to maintain privacy for patients with sufficient clinical support if required; dedicated paediatric bays have been identified.

Facilities maintenance and environmental conditions (5.2.6)

Pathology ensures that there is a safe working environment in accordance with current safety guidelines and legislation with continuous audit using EKHUFT toolkits to assess compliance to trust policy. A pan-pathology health & safety handbook is in place to ensure a safe environment for staff, patients and visitors (DIR-LP-105a Health & Safety Handbook) with the GM holding overall responsibility for departmental health and safety. Day to day management of health and safety issues is delegated to a health and safety supervisor within the disciplines with support from the pathology health and safety lead.

For information on related processes i.e. cleaning, decontamination, spillages and waste refer to these pan-pathology documents:

DIR-LP-105a- Pathology Health and Safety handbook

DIR-LP-105b- Disinfectants used and their preparation

DIR-LP-105c- Procedure for Dealing with Laboratory Biological & Chemical Spillages

DIR-LP-105e- Cleaning and decontamination of centrifuges

DIR-LP-105f- Directorate Waste Management policy and procedure

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 EKHUFT (e.g. patient harm, security, health and safety or non-pathology error) are made using DATIX, see DIR-LP-Q122: Adverse Incidents (DATIX). This facilitates non-pathology staff i.e. EKHUFT governance and anyone who is allocated as part of the report or investigation team access to the incident form to review and update.

5.3 Laboratory equipment, reagents and consumables

Pathology has a procedure for the management of equipment and associated records (see DIR-MP-Q106 Procurement and Management of Equipment) which adhere to EKHUFT 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 DIR-QP-Q008 Validation/ Verification Procedure). Q-Pulse is utilised to hold equipment and supplier records:

a) Identity of equipment (5.3.1.7a) (Asset module)
b) Manufacturer, model and serial number (5.3.1.7b) (Asset module)
c) Contact information for supplier or manufacturer (5.3.1.7c) (Supplier module)
d) Date of receipt and date entered into service (5.3.1.7d) (Asset module)
e) Location (5.3.1.7e) (Asset module)
f) Condition when received (5.3.1.7f) (Asset module)

g) Manufacturer's instructions (5.3.1.7g) (Document module via use of manual)
h) Validation documentation (5.3.1.7h) (Asset module)
i) Equipment maintenance records (5.3.1.7i) (Asset module)
j) Acceptance for use records (5.3.1.7j) (Asset and/or document module)
k) Details of damage or repair (5.3.1.7k) (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).

EKHUFT Estates 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).

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 measurement of uncertainty (DIR-LP-Q514: Determination of Uncertainty) procedure provides details on traceable calibration for these.

Reagents and consumables (5.3.2)
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. The department 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 DIR-MP-Q108 Management of Reagents and Consumables. Specific instructions for acceptance testing and storage, use and disposal can be found in the discipline SOP's.

Any non-conformity that is directly due to any reagent, consumable or equipment will be reported as a CAPA; see DIR-MP-Q130: Identification and management of non-conformities and quality improvement.

5.4 Pre-examination processes

Information for patients and users (5.4.2)

Pathology provides information regarding the services it provides to users (both internal and external to EKHUFT) via the EKHUFT webpages for pathology. The pathology pages include information on the pathology department, user guides for the different disciplines, and links to specific discipline webpages (including phlebotomy) where the scope of accreditation to ISO 15189:2012 is available.

The web pages contain information for each of the diciplines regarding instructions to patients for phlebotomy; such as fasting instructions, presemen analysis preparation and phlebotomy opening hours on site and for outreach clinics. User guides available online provide more in depth information regarding the specific discipline including test repetoire, contact details for the pathology service (routine and out of hours), turnaround times, sample requiremetns, reference ranges, referral laboratories used and factors known to affect test.

Clinical advice is available as stipulated within the user handbooks outlining how to contact the laboratory or clinical staff for general advice or aide in interpretation of results. Clinical biochemistry and microbiology run duty desks which are available throughout daytime working hours (Monday to Friday) to give clinical advice within one hour. During the evenings, overnight and at weekends there is an on call clinical scientist (clinical biochemistry), or consultant microbiologist available via telephone. Haematology and haemophilia have an on call haematologist and specialist registrar (SpR) available for clinical advice and interpretation as necessary. Histologists in cellular pathology are available throughout working hours to give clinical advice.

Request form information (5.4.3)

Pathology provides three mechanisms for ordering pathology tests which include a manual request form and two forms of electronic order comms. Internally to EKHUFT; the electronic order comms system using PAS is used to order tests and review results; externally all GPs have access to use DART OCM to make requests. In addition, cellular pathology utilises nationally approved gynaecological cytology request forms and blood transfusion has specific request forms for sample and blood product requests. For anticoagulant clinics; patient anticoagulant monitoring books can be utilised in place of a request form or order comm.

Request forms / order comms provide space for:

- Sufficient information to allow unequivocal identification of the patient (5.4.3a)
- Identification of the location and of the requesting individual (5.4.3b)
- Type of specimen and anatomical site of origin if relevant. (5.4.3c)
- Investigation required (5.4.3d)
- Relevant clinical information (5.4.3e)
- Date and time of specimen collection (5.4.3.f)
- Date and time of receipt of sample by the laboratory (5.4.3g)

Pathology provides information regarding acceptance criteria for samples and request forms to users available on the pathology webpage (see DIR-LP-Q113 Sample and request form acceptance policy); where this criteria is not met; the request will be rejected.

Pathology accepts verbal requests and will log these for full audit trail using a verbal request log/ form and add this onto electronic requests (see BLS-IP-252 Apex Laboratory Computer: Inputting Requests for Clinical Biochemistry, Haematology and Haemophilia and Blood transfusion have a telephone request document: BLT-LP-033 Telephone requests).

Primary Specimen collection and handling (5.4.4)
Discipline specific user guides provide information regarding transport arrangements for sample and whether particular assays have specific criteria (e.g. require rapid transport to the laboratory).

DIR-LP-112a Specimen postal regulations and transport and DIR-LP-Q516: Sample transportation within EKHUFT procedures details the processes to be undertaken for all sample transportation methods i.e. by porters, phlebotomists, couriers and the pneumatic tube system including how this is audited.

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.

Specimen transportation (5.4.5)

Transportation of samples within EKHUFT is undertaken by a variety of methods and staff including porters, phlebotomy, nurses, doctors, drivers, health care assistants, allied health professionals and pathology staff or can be transported by the Aerocom (UK) pneumatic tube system. Samples referred to EKHUFT pathology are transported using the network inter-trust transport system, which is timetabled, whereby samples are sent between network pathology laboratories. 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 logistics service or by courier service.

Specimen reception (5.4.6)

There is a centralised sample reception area on each site which performs initial sorting of all pathology samples, under the management of clinical biochemistry. As samples are received into pathology they are sorted into the various sections and sent to the relevant disciplines for processing. At the WHH site there are separate reception areas for both cellular pathology and microbiology where samples are further sorted once received from central reception.

Pre-examination handling, preparation and storage (5.4.7)

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.

5.5 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. DIR-MP-Q106 Procedure for the Procurement and Management of equipment and DIR-QP-Q008 Validation/ Verification Procedure 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 DIR-MP-Q001 The management and control of process documents to meet requirements set in ISO 15189:2012 5.5.3. 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 DIR-LP-Q514: Determination of Uncertainty or individual assay's calculated uncertainties held by specific disciplines.

5.6 Ensuring quality of examination results

There are discipline specific procedures in place in each discipline 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 have been adopted including exchanging samples with other laboratories (inter laboratory comparisons). Performance is reviewed within discipline quality meetings and at the pathology quality forum; any poor performance arising from either method are logged and managed as described in DIR-MP-Q130 Identification and management of non-conformities and quality improvement.

These procedures are within discipline specific SOPs:

Clinical Biochemistry- BIO-LP-430 Quality assessment procedure, BIO-LP-431, Quality Control procedure

Cellular Pathology- CEL-LP-511 EQA review

Haematology and Blood Transfusion- HAE-LP-304 Internal Quality Assurance, HAE-LP-139a-Haematology External and Internal QA

Haemophilia- HPA-LP-173 Procedure for the Testing, Resulting and Reporting of National External Quality Assurance Samples

Microbiology- MIC-QP-126 External Quality Assessment, MIC-QP-003a Quality Control Bacteriology, MIC-QP-001 IQA Microbiology

5.7 Postexamination processes

Results for all examinations are reviewed by appropriately authorised personnel as per discipline 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 disciplines:
Clinical Biochemistry- BIO-LP-618b- Control of Clinical Material
Cellular Pathology- CEL-LP-404- Retention Storage of Cellular Pathology Samples and Slides CEL-LP-406- And Block Retention / Discard
Haemophilia- HPA-LP-179- The disposal and retention of samples
Microbiology: MIC-MP-006- Management, Retention, Storage and Disposal of Clinical Material
Haematology and transfusion incorporate this information within their individual examination SOPs.

5.8 Reporting results

Results are authorised in accordance with procedural documents and are electronically generated; electronic reports are available using DART for both internal and GP users; EKHUFT staff can also access results using PAS or Vital Pac. Hard copy results are sent out where no electronic link is available or else as agreed with users (both internal and external) via the EKHUFT 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 (5.8.3a)
- The name of the laboratory issuing the report (5.8.3b)
- Identification of the laboratory that issued the report (5.8.3c)
- Unequivocal identification of the patient and location on each page (5.8.3d)
- Name and contact details of requestor (5.8.3e)

- Date of sample collection (5.8.3f)
- Type of sample (5.8.3g)
- Measurement procedure (5.8.3h)
- SI units (5.8.3i)
- Biological reference intervals and clinical decision values (especially critical results) (5.8.3j)
- Result interpretation (5.8.3k)
- Additional cautionary or explanatory notes (5.8.3l)
- Identification of examinations undertaken by research where no measurement performance is available (5.8.3m)
- When possible, the identity of the authorizer (s) of the report
- Date of report (5.8.3n)
- Page number to total number of pages (5.8.3o)

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

5.9 Release of results

Results may be released automatically or manually; autovalidation is determined by the configuration of rules written into the respective software. 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 (DIR-LP-Q118 Communicating results by telephone or e-mail (including critical)).

Where interim reports are issued these are highlighted as interim and it is advisable where possible to wait final report before making clinical decisions (DIR-LP-Q117 Provisional and revised reports). DIR-LP-Q117 Provisional and revised reports also ensures 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 shows 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).

5.10 Management of data and information

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 DIR-MP-Q107: 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. Pathology complies with the Caldicott principles, the Freedom of Information Act, General Date Protection Regulation (GDPR) and Data Protection Act.