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Author	Bryan Smith (Inactive), Harlovleen Bhachu, John Auld (Inactive), and Peter Jackson
Authorised By	Harlovleen Bhachu
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Contents

Procedure Amendments

	Date	Page	Amendment	Authorized By
1	29 Nov 17		Introduction of amendment page	JA
2	29Nov 17	21	Quality Policy is now a standalone document referenced in this manual	JA
3	29 Nov 17	Appendices	Various changes in Cell Path management structure	JA
4	29 Nov 17	11	Addition of reference to mortuary services	JA
5	29 Nov 17	53	Addition of reference to mortuary services TNT as a carrier	JA
6	29 Nov 17	23	Slight amendment to wording about quality objectives	JA
7	29 Nov 17	30	Clarification of the SLA procedure	JA
8	29 Nov 17	33	Clarification of the complaints procedure	JA
9	1 Aug 18	Various	Review document-Minor grammatical changes, updated departmental profiles and patient stats, updated quality policy.	JA
10	18 Oct 18	Various	Minor amendments and additions required by UKAS assessors following the Haem/BT SU visit. No material change to content	JA
11	05.11.19	Various	Minor amendments and additions required by UKAS assessors following the Histo visit.	JA
12	06.11.19	40	Cellular pathology TAT updated to reflect RCPath guidelines.	JA

All staff must be made aware of the change(s)

Procedure Amendments

	Date	Page	Amendment	Authorised by
13	29.5.2020	11	Responsibility for Antenatal Screening Programme & reference to organogram added	JA
14	29.5.2020	83	Change to named individual with responsibility for Pre-Analytics	JA
15	11.6.2020	13	Removal of role of Consultant Microbiologist as Associate Director of Infection Prevention & Control for WHAT.	JA
16	11.6.2020	77	Addition of Associated Document for Haematology (Audit Procedure)	JA
17	11.6.2020	12	Removal of Helena Aggram analyser from Haematology	JA
18	19/11/2020	12	Added HM-Jackarc analyser to Biochem,	LH
19	19/11/2020	23	Removed reference to GP locality meetings, added reference to user feedback form on website	LH
20	24/08/2021	14	Fine needle aspirate procedure within cellular pathology temporarily suspended	AP
21	24/08/2021	82	Organisational Chart updated	AP
22	29/09/2021	22	In the event of vacant laboratory director role	MC
23	29/09/2021	25	Updated quality policy 12.4 added Updated line …. and conforms to the standard and regulations of BS EN ISO 15189:2012	LKB
24	29/09/2021	12	4 DxH 900s 2 DxH 900s at the Alex rather than DxH800s	BBJ

25	29/09/2021	13	refers to TOSOH - should be SEBIA	BBJ
26	07/10/2021	24	Quality Policy Version number amended to 12.5	LKB
27	12/01/2022	81	Dr B Sethi lab director cellular pathology	A.Philo
28	31/01/2022	11,12 80,81	Update to Biochemistry instrumentation. Organisational chart updated.	NP
29	01/02/2022	80, 81	Update to both organisational charts Biochemistry – recent updated incorrect Replacement of Dr Sethi in Cellular Pathology	HKB
30	29/7/2022	80, 81	Update to cellular pathology organisational chart – DG lab manager, SWL deputy laboratory manager, KW training officer. Update to Biochemistry organisational chart: Jessica Patel laboratory manager. Update to pathology organisational chart: Helen Jarvie divisional director of operations.	A.Philo
31	29/7/2022	29	HTA DI updated	A.Philo
32	20/09/2023	23 & 81	Removal of Quality Policy now referenced as a stand-alone document , update to pathology organisational chart with AA added as Quality lead in Biochemistry, AD as Training officer in Cellular Pathology, JM as divisional medical director, TB Director of nursing, LW deputy director of nursing.	SJJ
33	31/05/2024	Whole Document	Review and re-write of Quality Policy in line with new ISO15189:2022 standard	PJJ
34	2/12/2024	18 28,29	Add line regarding patient sample/record's integrity during any merger Changes to competency and personnel records to reflect 15189:2022	PJJ

35	10/7/2025	21 26	amendment to Biochemistry instrument Re-wording of clinical and non clinical staff accountability	
36	18/06/2026	Various	Change SCSD to Diagnostics and Specialities Care Group Changed Job titles to reflect new Care Group Added Clinical Service Manager to Management Roles within Pathology	

1. Scope

This document, together with the specified documents, represents the Quality Management System (QMS) of the Pathology Directorate of Worcestershire Acute Hospitals NHS Trust (WAHT). It has been compiled to meet the requirements of UKAS (ISO 15189 2022), NHSLA, Human Tissue Authority and the Blood Safety and Quality Regulations 2005, Statutory Instrument 2005 No. 50. BSQR 2005 as amended.

The QMS is the process developed to support the generation of an efficient and effective, high quality and appropriate laboratory advice, testing and recommendation service.
It encompasses all elements of quality delivery, including management systems, quality assurance and quality control.

Throughout the text of the Quality Manual, there are references to the ISO Standard (ISO 15189 2022) and supplementary documents and to policies or procedures [indicated in square brackets].

This Quality Manual (ISO 15189 2022:8.2.4) [PO-U-GEN-QualityManual] fulfils two functions:-

(a) It describes the Quality Management System for the benefit of the Directorate management and staff.

(b) A copy of it is available on the pathology website to provide information for users and for external assessors.

The **scope of the service** provided by the Pathology Service is as follows:

An in-house routine diagnostic service for Haematology & Blood Transfusion and Clinical Biochemistry, Microbiology and Cellular Pathology services**.** All disciplines across the sites come under the same senior management and use the same quality management system. Pathology at Worcestershire Royal Hospital operates as the main facility, including Point of Care testing, where all routine primary care work is handled, with the facilities at the Alexandra Hospital operating as a satellite facility for inpatient, outpatients based at the Alexandra site and urgent work from this location. Some testing in Blood Sciences is done on a countywide basis either at the Redditch or Worcester site and in these cases the samples analysed would be from a variety of sources, both inpatient and outpatients. The service provided is of a routine nature with none of the facilities acting as a designated referral centre.

There are body stores on both sites with a post-mortem suite at Worcestershire Royal Hospital.

1.1 Laboratory background

Worcestershire Acute Hospitals NHS Trust Pathology Service
The Pathology Directorate is part of the Worcestershire Acute Hospitals NHS Trust. It has laboratories on two of the three Trust sites, located at Worcestershire Royal Hospital and Alexandra Hospital, Redditch. Any work from Kidderminster Hospital is transported by taxi to the Worcester site.

The Pathology service is provided to Worcestershire Acute Hospitals NHS Trust, The Herefordshire and Worcestershire Integrated Care System and The Worcestershire Health and Care NHS Trust. Other organisations are free to approach us to see if we are able to offer them specific elements of our service and these would be considered in line with our policy for Establishment and review of agreements, [MR-U-GEN-SLA], in order to assess capacity, skills and expertise. Currently Pathology has specific SLAs with a number of Private Hospitals, for pathology services including the supply of cross matched and flying squad blood components. Services are also provided to St Richards Hospice.

Phlebotomy is not within Pathology, this being within the Outpatient Department and managed as such by the relevant Outpatients manager on each of the three sites.

Transport services are provided by two separate organisations and are managed by their transport manager in each case. Samples from the South of Worcestershire and Wyre Forest including from Kidderminster Hospital are collected by a fleet of Acute Trust vehicles while those from the Bromsgrove and Redditch areas are collected by Health and Care Trust vehicles. Samples and pathology supplies are transported between the three sites by a different set of Acute Trust vehicles which constantly rotate between the three acute sites transporting a wide variety of items.

The four disciplines within the Pathology Directorate, alongside Point of care, provide a high quality evidence based service described below. Expert interpretation and advice from Consultant medical and scientific staff enhance the analytical service.

2 Normative References

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. ISO/IEC Guide 99:2007, International vocabulary of metrology — Basic and general concepts and associated terms (VIM) NOTE ISO/IEC Guide 99 is also known as the Joint Committee for Guides in Metrology (JCGM) 200. ISO/IEC 17000:2020, Conformity assessment — Vocabulary and general principles ISO/IEC 17025:2017, General requirements for the competence of testing and calibration laboratories

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 17000, ISO/IEC Guide 2 and ISO/IEC Guide 99 and the following apply.

3.1 Bias Measurement bias

Estimate of a systematic measurement error
Note 1 to entry: This definition only applies to quantitative measurements

3.2 Biological reference interval reference interval

Specified interval of the distribution of values taken from a biological reference population

Note 1 to entry: A reference interval is commonly defined as the central 95% interval. Another size or an
asymmetrical location of the reference interval could be more appropriate in particular cases.

Note 2 to entry: A reference interval can depend upon the type of *primary sample* (3.25) and the *examination procedure* (3.9) used.
Note 3 to entry: In some cases, only one biological reference limit is important, usually an upper limit, “x”, so that
the corresponding biological reference interval would be less than or equal to “x”.
Note 4 to entry: Terms such as ‘normal range’, ‘normal values’, and ‘clinical range’ are ambiguous and therefore discouraged.

3.3 Clinical Decision Limit

Examination (3.8) result that indicates a higher risk of adverse clinical outcomes, or is diagnostic for the presence of a specific disease
Note 1 to entry: Clinical decision limits for therapeutic drugs are called "therapeutic range".
Note 2 to entry: It is used to determine risk of disease, to diagnose or to treat.

3.4 Commutability of a reference material

Property of a reference material, demonstrated by the closeness of agreement between the relation among the measurement results for a stated quantity in this material, obtained according to two given measurement procedures and the relation obtained among the measurement results for other specified
materials
Note 1 to entry: The reference material in question is usually a calibrator and the other specified materials are usually routine samples.
Note 2 to entry: It is typical that there are more than two measurement procedures available and comparison among all applicable measurement procedures is desirable.
Note 3 to entry: Closeness of agreement of measurement results is defined in terms of fitness for purpose as appropriate for the intended use of the reference material.
Note 4 to entry: A commutability statement is restricted to the measurement procedures as specified in a particular comparison.

3.5 Competence

Demonstrated ability to apply knowledge and skills to achieve intended results

3.6 Complaint

Expression of dissatisfaction by any person or organization to a *laboratory* (3.20), relating to the activities or results of that laboratory, where a response is expected

3.7 Consultant

Person who provides expert advice professionally

3.8 Examination

Set of operations having the objective of determining the numerical value, text value or characteristics of a property
Note 1 to entry: An examination may be the total of a number of activities, observations or measurements
required to determine a value or characteristic.
Note 2 to entry: Laboratory examinations that determine a numerical value of a property are called "quantitative
examinations"; those that determine the characteristics of a property are called "qualitative examinations".
Note 3 to entry: Laboratory examinations are also called "assays" or "tests".

3.9 Examination Procedure

Specifically described set of operations used in the performance of an *examination* (3.8) according to a given method
Note 1 to entry: In the IVD medical device industry and in many laboratories that use IVD medical devices, an examination procedure for an analyte in a biological sample is commonly referred to as an analytical method, analytical procedure or test procedure

3.10 External Quality Assessment – EQA

Evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons
Note 1 to entry: Also known as proficiency testing (PT)

3.11 Impartiality

Objectivity with regard to the outcome of tasks performed by the *medical laboratory* (3.20)
Note 1 to entry: Objectivity can be understood as freedom from bias or freedom from conflicts of interest.
Note 2 to entry: Other terms that are useful in conveying the element of impartiality include “independence”, “lack of prejudice”, “neutrality”, “fairness”, “open-mindedness”, “even-handedness”, “detachment”, “balance”.

3.12 Interlaboratory comparison

Organisation, performance and evaluation of measurements or *examinations* (3.8) on the same or similar materials by two or more independent laboratories in accordance with pre-determined conditions

3.13 Internal Quality Control IQC – Quality Control QC

Internal procedure which monitors the testing process to verify the system is working correctly and gives confidence that the results are reliable enough to be released.

3.14 In Vitro Diagnostic Device – IVD

Device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic,monitoring or compatibility purposes and including reagents, calibrators, control materials, specimen receptacles, software, and related instruments or apparatus or other articles

3.15 Laboratory management

Person(s) with responsibility for, and authority over a *laboratory* (3.20)
Note 1 to entry: Laboratory management has the power to delegate authority and provide resources within the laboratory.
Note 2 to entry: The laboratory management includes the laboratory Director(s) and delegates together with individuals specifically assigned to ensure the quality of the activities of the laboratory

3.16 Laboratory User

Individual or entity requesting services of the *medical laboratory* (3.20)

Note 1 to entry: Users can include patients, clinicians, and, other laboratories or institutions that send samples
for examination.

3.17 Management System

Set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives
Note 1 to entry: This was formerly referred to and is synonymous with “quality management system”.
Note 2 to entry: The management system elements establish the organization’s structure, roles and responsibilities, planning, operation, policies, practices, rules, beliefs, objectives, and processes to achieve those objectives.

3.18 Measurement Accuracy

Closeness of agreement between a measured quantity value and a true quantity value of a measurand
Note 1 to entry: The concept ‘measurement accuracy’ is not a quantity and is not given a numerical quantity value. A measurement is said to be more accurate when it offers a smaller measurement error.
Note 2 to entry: The term “measurement accuracy” should not be used for measurement trueness and the term measurement precision should not be used for ‘measurement accuracy’, which, however, is related to both these concepts.
Note 3 to entry: ‘Measurement accuracy’ is sometimes understood as closeness of agreement between measured
quantity values that are being attributed to the measurand.

3.19 Measurement Uncertainty MU

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used
Note 1 to entry: MU includes components arising from systematic effects, as in the case of corrections to the assigned quantity values of measurement standards. Sometimes estimated systematic effects are not correctedfor, but instead, the associated MU components are incorporated.
Note 2 to entry: The parameter may be, for example, a standard deviation (SD) called standard MU (or a specified multiple of it), or the half-width of an interval, having a stated coverage probability.
Note 3 to entry: MU comprises, in general, of many components. Some of these may be evaluated by Type A evaluation of MU from the statistical distribution of the quantity values from series of measurements and can be characterized by SD. The other components, which may be evaluated by Type B evaluation of MU, can also be characterized by SD or evaluated from probability density functions based on experience or other information.
Note 4 to entry: In general, for a given set of information, it is understood that the MU is associated with a stated quantity value attributed to the measurand. A modification of this value may result in a modification of the associated uncertainty.
Note 5 to entry: All measurements have *bias* (3.1) and imprecision. For example, replicate measurements of a sample performed under repeatability conditions generally produce different values for the same measurand. Because the different values could all be reasonably attributed to the same amount of measurand, there is
uncertainty as to which value should be reported as the value of the measurand.

Note 6 to entry: Based on available data about the analytical performance of a given measurement procedure, an estimation of MU provides an interval of values that is believed to include the actual value of the measurand, with a stated level of confidence.
Note 7 to entry: Available data about the analytical performance of a given measurement procedure typically comprise uncertainty of calibrator assigned values and long-term imprecision of IQC materials.
Note 8 to entry: In medical laboratories, most measurements are performed in singleton, and are taken to be an acceptable estimate of the value of the measurand, while the MU interval indicates other results that are also possible.

3.20 Medical Laboratory

Entity for the *examination* (3.8) of materials derived from the human body for the purpose of providing information for the diagnosis, monitoring, management, prevention and treatment of disease, or assessment of health
Note 1 to entry: The laboratory can also provide advice covering all aspects of examinations including appropriate selection, the interpretation of results and advice on further examinations.
Note 2 to entry: Laboratory activities include *pre-examination* (3.24), *examination* (3.8) and *post-examination processes* (3.23).
Note 3 to entry: Materials for *examination* (3.8) include but are not limited to, microbiological, immunological, biochemical, immunohaematological, haematological, biophysical, cytological, tissue and cells, and genetic material.

3.21 Patient

Person who is the source of material for an *examination* (3.8)

3.22 Point-of-care testing POCT near-patient testing

Examination (3.8) performed near or at the site of a *patient* (3.21)

3.23 Post-examination processes or post analytical phase

Processes following the *examination* (3.8) including review of results, formatting, releasing, reporting and retention of examination results, retention and storage of clinical material, *sample* (3.28) and waste disposal

3.24 Pre-examination processes or Pre-Analytical phase

Processes that start, in chronological order, from the user's request and include the *examination* (3.8) request, preparation and identification of the *patient* (3.21), collection of the *primary sample(s)* (3.25), transportation to and within the *laboratory* (3.20), ending when the *examination* (3.8) begins

3.25 Primary sample or specimen

discrete portion of a body fluid or tissue or other sample associated with the human body taken for *examination* (3.8), study or analysis of one or more quantities or characteristics to determine the character of the whole
Note 1 to entry: The International Medical Device Regulators Forum (IMDRF) uses the term specimen in its harmonized guidance documents to mean a sample of biological origin intended for examination by a *medical laboratory* (3.20).

3.26 Quality indicator

Measure of the degree to which a large number of characteristics of an object fulfils requirements
Note 1 to entry: Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

3.27 Referral laboratory

External *laboratory* (3.20) to which a sample or data is submitted for *examination* (3.8)
Note 1 to entry: A referral laboratory is one to which laboratory management chooses to submit a sample or subsample for examination, data for analysis or interpretation, or when routine examinations cannot be carried out.
Note 2 to entry: This differs from a laboratory to which submission of samples is required by regulation, or a so called reference laboratory, e.g. public health, forensic, tumour registry, or a central (parent) facility to which submission of samples is required by structure.

3.28 Sample

One or more parts taken from a *primary sample* (3.25)

3.29 Trueness measurement trueness

Closeness of agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value
Note 1 to entry: Measurement trueness is not a quantity and thus cannot be expressed numerically, but measures
for closeness of agreement are given in ISO 5725-1.
Note 2 to entry: Measurement trueness is inversely related to systematic measurement error, but is not related to random measurement error.
Note 3 to entry: ‘Measurement accuracy” should not be used for ‘measurement trueness’.
Note 4 to entry: For qualitative examinations, trueness of measurement (closeness of agreement) can be expressed in terms of concordance (i.e. percent agreement with a reference examination).
Note 5 to entry: Trueness is a property of the *examination procedure* (3.9) that reflects the *bias* (3.1) of the measurements from the expected or target value. It is described qualitatively as good or bad. An *examination procedure* (3.9) has good trueness if the *bias* (3.1) of the measurements is acceptable.

3.30 Turnaround time

Elapsed time between two specified points through *pre-examination* (3.24), *examination* (3.8), and *post examination processes* (3.23)

3.31 Validation

Confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled
Note 1 to entry: Objective evidence can be obtained through observation, measurement, examination or by other means.
Note 2 to entry: The word “validated” is used to designate the corresponding status.
Note 3 to entry: Specified requirements of an examination method may include the following performance specifications: measurement trueness, measurement precision including measurement repeatability, and measurement intermediate precision, analytical specificity,

including interfering substances, detection limit and quantitation limit, measuring interval, clinical relevance, diagnostic specificity and diagnostic sensitivity.

3.32 Verification

Confirmation of truthfulness, through provision of objective evidence, that specified requirements have been fulfilled

EXAMPLE 1 Confirmation that performance specifications of a measuring system are achieved.
EXAMPLE 2 Confirmation that a target measurement uncertainty can be met.

Note 1 to entry: Verification is the process by which the laboratory confirms that the established performance claims of a measuring system, e.g. trueness, precision, reportable range, can be replicated in the laboratory before human sample examination is performed. Note 2 to entry: The objective evidence needed for a verification can be the results of an inspection, or other forms of determination, such as performing alternative calculations or reviewing documents. Note 3 to entry: Verification may be sufficient to implement a new IVD device under circumstances where the examination (3.8) is performed and used in the manner as directed in the package insert. Note 4 to entry: The word “verified” is used to designate the corresponding status

4 General requirements

4.1 Impartiality

There are arrangements in place to always ensure the ethical conduct of staff.

A contractual commitment for both staff and the organisation through the commissioners of service ensures that there is no involvement in any activities that would diminish confidence in the laboratory’s competence, impartiality, judgement, or operational integrity.

All staff are governed by the Trust’s policies on Fraud, Bribery and Corruption and Standards of Business Conduct-Declaration of interests and acceptance of gifts and hospitality [ED-U-GEN-Declaration of interests and acceptance of gifts and hospitality] to ensure that management and personnel are free from any undue commercial, financial, or other pressures and influences that may adversely affect the quality of their work. This can be found on the Trust Intranet, under the Corporate, Finance Section.

At Induction staff will be given the opportunity to declare interests, with an Annual discussion as part of the PDR process. Where potential conflicts in competing interests may exist, they are openly and appropriately declared, with staff.

If an interest is declared, this is then managed within the Standards of Business Conduct policy which can be found on the Trust Intranet under Trust Clinical Policies and Guidelines

To uphold impartiality and avoid conflicts of interest in departmental processes, it is essential that local departments adhere to the following measures:

- **Excluding Staff from Tenders and Contracts with a Declared Interest**: Staff members must be excluded from participating in tendering and contracting processes if they have any personal, financial, or professional connection with the companies involved. This ensures transparency and fairness and avoids any undue influence on decision-making

- **Ensuring Companies Do Not Engage During the Contract Process**: Companies should be restricted from interacting with departmental staff or having any communication that might influence the tendering or contract award process. This helps maintain an objective and unbiased decision-making environment, free from pressure or influence.

- **Avoiding Involvement of Staff with Personal Connections in Certain Processes**:

  Recruitment: Staff members should not be involved in shortlisting, interviewing, or making hiring decisions for positions where they have a personal relationship or connection with the candidate. This is crucial for maintaining the integrity of the recruitment process and ensuring it is conducted based on merit.

  Authorising Leave: Employees should not be responsible for approving or managing leave requests for individuals with whom they have a personal connection. This helps prevent any potential favouritism or bias.

Staff always follow the retention and storage of pathological records and specimens (6th edition, 2025). Joint publication between the RCPath and IBMS [ED-U-GEN-The retention and storage of pathological records and specimens (6th edition, 2025)] when dealing with human samples, tissues or remains.

4.2: Confidentiality

Confidentiality of information is maintained by strict adherence to the Trust's Code of Conduct in respect of Confidentiality [ED-U-GEN-Code of Conduct in respect of Confidentiality]

4.3: Requirements for Patients

Within pathology we recognise that an essential prerequisite of a quality service is that the organisation and management of Pathology relates to the needs and requirements of its users. (ISO 15189 2022:6.7 and 8.4)

The needs and requirements of users are identified both at Department level and by the Pathology wide User Interaction Groups. The GP user group meets at least three times per year. Activities include: -

- Satisfaction surveys
- User Group Meetings
- MDTs
- Information for users and patients is available on the Pathology Website: Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) , is reviewed by the website group and is accessible from any internet enabled device.
- Other information, such as patient information leaflets are prepared by departments as appropriate and contain an explanation of the procedure and patient preparation details.

- **Specimen collection and handling:** The Pathology Website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) includes comprehensive information for users on specimen collection and handling including volume requirements. Laboratory staff also provide advice to users on request. (ISO 15189 2022:7.2.4)
- The scope of tests are regularly reviewed within each department for clinical relevance.
- To ensure patients samples or remains, are treated with due care and respect all staff are annually mandated to comply with Trust training for Information Governance (GDPR) and Equality and diversity training.
- When things go wrong, they are dealt with in an open honest manner in accordance with the Trust Duty of Candour, Patient Advice and Liaison Service (PALS)and Patient Safety Incident Reporting Policies, utilising Datix and non-conformance reporting (PR-U-GEN-Non-conformance)

- Ensures that the ongoing availability and integrity of retained patient samples and records during any closure, acquisition, or merger of a laboratory is maintained.

5: Structural and governance requirements

The Pathology Directorate is part of the Diagnostic and Specialities Care Group for Worcestershire Acute Hospitals NHS Trust which can be held legally responsible for its actions. (ISO 15189:2022:5.1) The Trust Establishment Order can be found at http://www.legislation.gov.uk/uksi/1999/3473/made

The management relationships with the Trust are through the Diagnostic and Specialities Care Group which is led by the Associate Chief Medical Officer and Associate Chief Operating Officer and is represented in the Trust organisational charts available on the Trust Intranet. The board members and a list of executive and non-executive directors can be found on the hospital website at: http://www.worcsacute.nhs.uk/about-us/trust-board-whos-who/

5.2: Laboratory Director

The Pathology Directorate is led by the Clinical Director, the Clinical Service Manager and the Directorate Manager who are all responsible to the Associate Chief Medical Officer and Associate Chief Operating Officer for all aspects of the pathology service.

Each individual Department of the Directorate is directed by a Laboratory Director lead who has executive accountability and the competence to assume responsibility for the services provided.

5.2.1: Laboratory Director competence

The duties and responsibilities of both the Clinical and individual laboratory Directors are documented within the individual job descriptions.

5.2.2 Laboratory Director responsibilities

The Laboratory Director(s) is(are) responsible for the leadership, communication and team working within the laboratory, providing advice to the Pathology Clinical Director, Associate Chief Medical Officer, Clinical Service Manager, Directorate Manager and others as required

on specialty issues. This includes accountability for all aspects of clinical governance, including quality assurance, accreditation, Risk Management and development of services.

5.2.3 Delegation of duties

The laboratory Director may delegate selected duties and/or responsibilities to persons with appropriate competence by mutual agreement (with specific reference to the Laboratory Manager) with the Laboratory Director(s) having ultimate Accountability and Responsibility for the overall operation and direction of the service

5.3: Laboratory activities

5.3.1: General

The service for Haematology, Blood Transfusion and Biochemistry is provided from two different Acute Trust sites. With respect to Kidderminster Hospital, there is a blood fridge in theatres, and weekly stock and fridge checks carried out by a member of the Blood Transfusion staff.

The IT system in use is common across both sites and information about any sample can be accessed from either site. Standardised analytical platforms are in use across the sites and where this is not the case progress is being made towards this. Comparison studies are done where tests are offered on both sites in order to ensure comparability of results irrespective of site of analysis. For those disciplines which operate from multiple locations staff are nominally assigned to the Worcestershire Royal Hospital site and the other site is staffed by rotating staff from this site. (Ref: GEN-1 Appendix C)

Worcestershire Royal Hospital **Charles** **Worcester** **WR5 1DD**	**Tel.** **Hastings**	**01905**	**763333** **Way**
Alexandra Hospital **Woodrow** **Redditch** **B98 7UB**	**Tel.**	**01527**	**503030** **Drive**

Information on the services provided and contact telephone numbers are available on the Pathology Website, Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)

Clinical Biochemistry

The Clinical Biochemistry service has its main site at Worcester with a satellite site at Redditch. The Worcestershire Royal hospital site has pre-analytical, automated, semi-automated and POCT sections.

The pre-analytical section is the core of the laboratory where all specimens are received and booked in to the Laboratory IT System, ready for analysis. The automated section consists of Total Laboratory Automation with a Beckman Coulter track system consisting of chemistry and immunoassay analysers providing results on serum, plasma, urines and fluids for a variety of common biochemical tests. The Semi-Automated section of the laboratory performs HbA1c analysis, electrophoretic, immuno-fixation techniques, quantitation of serum free light chains

and CSF spectrophotometry. All primary care samples are processed here as well as the Worcester hospital inpatient and outpatient work. The service is available 24 hours, 7 days per week, and is contacted via switchboard during out of routine hours. For a full test repertoire please consult the pathology website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)

The laboratory is also involved in the countywide management of Point of Care Testing (POCT) including test/equipment selection, training and external quality assurance for blood gas and glucose analysis.

The Alexandra hospital site at Redditch has pre-analytical, automated and manual sections. The automated section consists of Beckman Coulter chemistry and immunoassay analysers providing results on serum, plasma, urines and fluids for a variety of common biochemical tests. The manual section provides a countywide faecal calprotectin service as well as TTG and CCP analysis performed on the Werfen Bioflash at the Redditch laboratory. In addition, the laboratory also performs faecal haemoglobin (FIT) on the HM-Jackarc analyser. Other than for the countywide services only the Redditch hospital inpatient and outpatient samples are processed here as well as any urgent Primary care samples which are specifically delivered by local doctors/nurses. If there are any tests required on these samples that are not offered at this site, then the samples are sent on the next available transport to the Worcester site following analysis of the tests which are offered at this site. For a full test repertoire please consult the pathology website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) The service is available 24 hours, 7 days per week, and is contacted via switchboard out of routine hours.

POCT for the Redditch site is monitored daily by the laboratory staff but managed by the Worcester site. Although the majority of staff are based at the Worcester hospital, the Redditch laboratory is covered by a pool of cross site trained personnel.

Each biomedical scientist section lead has a team of staff under their supervision on both sites to ensure that all relevant tasks are completed. The department also has within its scope a pool of consultants and clinical scientists, providing clinical and quality oversight. The organisational structure for the Biochemistry Department is illustrated within the documentation - Biochemistry Staffing Structure (AD-U-CHM-Organisational chart chemistry).

Haematology

Haematology has its main site at Worcestershire Royal Hospital with a satellite site at the Alexandra Hospital at Redditch providing haematology and coagulation testing. The Worcester site processes all the GP samples as well as inpatient and out-patient samples. The Redditch site analyses only the Alexandra hospital inpatient and outpatient samples as well as any urgent Primary care samples which are specifically delivered by local doctors/nurses. The service at both Worcestershire Royal and Alexandra is available 24 hours, 7 days per week, and is contacted via switchboard out of routine hours. For a full test repertoire please consult the pathology website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)

At Worcestershire Royal Hospital the routine haematology section has 4 connected Beckman Coulter Unicel DxH 900 analysers for full blood count analysis, white (5 cell) differential and reticulocyte counting; with a connected Beckman coulter DxH (Automated) slidemaker stainer for blood samples. A semi-automated Hematek 3000 slide stainer is available for blood films

requiring urgent examination. Bone marrow slides are stained manually for Consultant examination. Automated ESR results are processed by one of two Alifax test1 BCL analysers using capillary stopped kinetic analysis.

The coagulation section provides routine INR, PTTR, Fibrinogen and D-Dimer results using two IL TOP 550 analysers, as well as Factor assays and screening for Lupus Thrombophilia, Factor VIII RCOF Antigen, Thrombophilia, Von Willebrand Factor Antigen.

The Haemoglobinopathy section has a Sebia Capillarys 3 Tera for identification of haemoglobin variants. The Countywide Antenatal Screening Service for Sickle Cell and Thalassemia is provided on the WRH site with referrals for counselling made to the Clinical Genetics Unit at Birmingham Women's Hospital, if necessary. Identified haemoglobin variants are referred for confirmation to New Cross Hospital and suspected thalassemia's sent to the National Haemoglobinopathy Reference Laboratory at Oxford. The Screening Service is overseen by the Clinical Lead Haematologist and organised daily by the Haematology Screening Lead BMS (ED-U-HAE-SCT Screening Organisation Chart).

The combined haematology and coagulation section at the Alexandra site provides full blood count analysis, white (5 Cell) differential and reticulocyte counting using two Beckman Coulter Unicel DxH 900 analysers. Routine INR, PTTR, Fibrinogen and D-Dimer tests are carried out on the IL TOP 350 analysers. Blood films are stained using the Hematek 3000 Slide stainer. Bone marrow slides are stained manually. Automated ESR results are obtained using the Alifax test1 BCL analyser

Blood Transfusion Services

A full acute blood transfusion service is provided from both Worcestershire Royal Hospital and Alexandra Hospital with a Blood Issue fridge being housed at Kidderminster Hospital. In addition an emergency blood fridge is available in A&E resus at Worcestershire Royal Hospital stocked with emergency O Negative and O Positive red cells.

An electronic blood tracking system and electronic issue are utilised at both the Worcestershire Royal site and Alexandra sites and manual techniques are used for red cell compatibility testing when the rules for EI are not met. Platelets, plasma and cryoprecipitate are issued on named patient basis. The departments also issue other blood products including Anti-D immunoglobulin, Fibrinogen concentrate (Riastap) and FEIBA (Factor VIII) for haemophilia. Kleihauer testing is done manually on the WRH site only with any identified positive foetal bleeds above 2 ml being referred to Heartlands Hospital (weekdays) or NHS BT Liverpool (weekends) for quantitation by flow cytometry. The department also performs manual transfusion reaction investigations.

Both the Worcestershire Royal and Alexandra departments each have 2 Ortho Clinical Diagnostic Vision analysers for processing group & screen samples, direct agglutination tests, performing antibody identification panels and red cell phenotyping. An Antenatal blood group serology screening service is provided with sample referral to NHS Blood and Transplant if antibody titration is required. HLA tissue typing, HLA B27 and Foetal Genotyping tests are sent to the NHS Blood and Transplant service for processing.

There is a blood issue fridge at Kidderminster Hospital which contains 4units of emergency O Rh D negative red cell units which are supplied from WRH. The laboratory at Worcester also sends blood and platelets to KTC on a named patient basis, primarily to support oncology and

community transfusion services (approximately 10 patients per week). All blood transfusion samples from KTC are sent to WRH for processing.

The lead consultant for Transfusion chairs the Monthly Transfusion Team Meetings and Quarterly Trust Transfusion Committee. The implementation of National Guidelines and development of service provision are agreed at these meetings.

The Blood Transfusion department also supplies blood and blood products on a supply only basis to community and private hospitals within the locality.

Cellular Pathology Service

Cellular Pathology has its main site at Worcestershire Royal Hospital, with a satellite facility for frozen sections (must be pre-booked) at the Alexandra Hospital

Redditch. There is no Cellular Pathology service at Kidderminster Hospital. Cellular Pathology also manages Mortuary services at both Redditch and Worcester.

The Worcestershire Royal Hospital site provides a full Histology service, from dissection of formalin fixed tissue through processing, sectioning and staining. A limited range of tinctorial special stains are carried out on this site and all immunohistochemistry and Breast HER2 slides are prepared and stained onsite here using the Roche Ultra immunostaining platform.

Frozen section facilities exist within the laboratory for rapid diagnosis where necessary and for specialist investigations such as immunofluorescence.

MOHS:

This service is managed by the Dermatology department. Cellular Pathology offers technical assistance – BMS assistance for specimen preparation and Consultant assistance for reporting the samples. The samples are processed within the Dermatology area and the sections are brought to the Cellular Pathology Laboratory for reporting. The reporting procedure involves one consultant pathologist from Cellular Pathology alongside the consultant dermatologist.

Fine Needle Aspiration assistance (FNA)

The laboratory offers assistance with preparation of slides to any clinics. This service should be directly requested through the laboratory.

An adequacy assessment service is also provided for Head and Neck FNA samples at the Worcester one-stop Head and Neck Clinic.

Mortuary Services

The mortuary services are HTA accredited on both sites. The Worcester site has facilities for post mortems and body storage. The Redditch site acts as a body store only. One of the Consultant Pathologists acts as the HTA Designated Individual for the Trust.

For more details see website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)

Microbiology

The Microbiology laboratory is situated at Worcestershire Royal Hospital. It provides a diagnostic service for Bacteriology, Mycology, Parasitology and Virology. The department has a wide repertoire of tests that are listed on the Pathology Website. Wherever possible these assays are performed on automated systems but where limitations exist conventional manual cultures, manual identification and antimicrobial susceptibility testing are performed.

The automated identification system used by the department is Matrix assisted laser desorption/ionization technology (MALDI-TOF) and the automated identification / antimicrobial susceptibility system is a VITEK 2 using micro dilutions and an advanced expert rules system.

The department also deploys an automated optical system combining bright-field and phase contrast microscopy and Mast Uri semi- automated identification and sensitivity system to assist in the analysis of urinary tract infections.

Tuberculosis screening is also undertaken by bacteriology under Containment Level 3 conditions using an automated liquid methodology in conjunction with a manual solid media culture method allowing for greater sensitivity. The Cepheid GeneXpert is available for rapid confirmation of the presence of *Mycobacterium Tuberculosis*.

Virology provides a wide range of serological and molecular tests using a variety of automated and manual methods as stated on the pathology website.

There are automated molecular methods for the detection of viral loads for HIV and HCV viruses and Sexual health screening for HSV, Chlamydia and Neisseria gonorrhoea that are carried out on Roche and Cepheid platforms.

Molecular detection for SARS-COV2 is performed using a variety of platforms, using Roche, Cepheid and Biofire platforms.

All routine serological analytical processing has recently been re-patriated into Microbiology and is performed on the Diasorin Liaison, and Biomerieux VIDAS 3 platforms.

Microbiology also maintains links with outside bodies including Public Health England and has an active role in monitoring patterns of infection in the community.

5.3.2: Conformance with requirements

To provide a high-quality Pathology service including Cellular Pathology Services, Clinical Biochemistry, Haematology & Blood Transfusion and Microbiology that meets the expectations agreed with its users, and conforms to the standard and regulations laid down by UKAS (ISO 15189: 2022) and other relevant legislation and regulatory bodies.

UKAS must be informed of any Significant changes to Service/ Personnel.

5.3.3: Advisory activities

The laboratory has various established arrangements for communicating with users as detailed earlier in the section about the needs and requirements of users on the following:

- advising on choice of examinations and use of the services, including required type of sample, clinical indications and limitations of examination procedures and the frequency of requesting the examination:

- advising on individual clinical cases:
- professional judgments on the interpretation of the results of examinations:
- promoting the effective utilization of laboratory services:
- consulting on scientific and logistic matters such as instances of failure of sample(s) to meet acceptance criteria

These arrangements work in a variety of ways: formal and informal, extending from formal user group meetings through informal lunchtime meetings to individual conversations between clinical staff and senior laboratory staff or Consultants.

Clinical advice and interpretation can be obtained directly from a relevant Pathology Consultant during normal working hours or outside of these hours via switchboard as part of the on-call Pathology service.

5.4: Structure and authority

5.4.1a: General

Directorate organisational chart structures are shown at the end of this document [AD-U-GEN-DirectorateOrgChart]. (ISO 15189:2022:8.2.1)

Each individual department within Pathology is responsible for the maintenance and storage of a current department specific organisational chart. (BSQR 2005, as amended 4.b.i) These are linked in iPassport to the Directorate organisational chart [AD-U-GEN-DirectorateOrgChart].

- A Biomedical Scientist (BMS) for each individual department acts as laboratory manager and as such has Trust wide managerial responsibility for non-medical staff of that department and manages and co-ordinates services between laboratories within their discipline. This managerial responsibility covers the areas of personnel, quality and Health and Safety as well as being the budget manager for their area. The Pathology Directorate Manager is the Budget Holder, whilst budgetary and finance issues are dealt with on a day to day basis by the Laboratory Manager in their role as budget manager. (See post holder form at end of this document for more detail including deputies)

- Each department has its own Quality Manager/Lead who may be supported by a quality team.

- There are deputies for all key functions of the Laboratory Clinical Director role as detailed on the Post Holder form at end of this document.

- Non-Medical staff are accountable to the Clinical Service Manager and the Directorate Manager for Pathology through the Departmental Manager

- Pathology Clinical staff are accountable directly to the relevant Clinical Director as per core Job Description, who is then accountable to the Trust Chief Medical Officer via the Associate Chief Medical Officer for Diagnostics and Specialities Care group.

Departmental Quality Managers/Leads are responsible to the Directorate Clinical Service Manager for Pathology, the Pathology Quality Manager and their Departmental Manager for issues relating to quality and the maintenance of the QMS.

Departmental H&S Officers are responsible through their Departmental Manager to the Directorate Clinical Service Manager for Pathology who has ultimate responsibility for ensuring the Health, Safety and Welfare of staff and visitors within Pathology.

Departmental Training Officers are responsible through their Departmental Manager to the Pathology Training Lead and the Directorate Manager for Pathology who has ultimate responsibility for ensuring compliance with National and Trust training requirements.

All Senior Biomedical Scientist staff have proven technical competencies appropriate to the post held. They are registered with the HCPC and have relevant qualifications such as Licentiate, Member or Fellowship of the Institute of Biomedical Sciences (IBMS) or be HCPC registered Clinical Scientists. Senior Biomedical Scientists are expected to complete a Management Qualification

In the absence of key managerial staff, the appropriate appointed deputy fulfils the role of the absent member of staff.

All staff are issued with a job description detailing the general extent and limitations of their responsibilities. These are reviewed annually at Personal Development Reviews (PDR) meetings for laboratory and clerical staff and at appraisals for medical staff.

On a day-to-day basis, specific duties relating to these responsibilities are discharged through the member of staff with direct responsibility for the supervision of any given individual.

- It is the responsibility of all employees to become familiar with and participate in Quality Management and the requirements of the Pathology QMS.
- Staff must at all times follow documented and approved SOPs.
- Staff must become familiar with the contents of this Quality Manual.
- Staff must record non-conformances on iPassport (PR-U-GEN-Recording of Non-Conformances on iPassport) as soon as possible after they arise and if patient/staff harm or potential harm has been caused this must also be recorded on the Trust Datix system in order that prompt and appropriate action can be taken to control the problem.
- Staff must participate in annual appraisal.
- BMS staff must record self-assessments and Continuing Professional Development (CPD) activities within their personal portfolios and ensure that their competency records are kept up to date.

5.4.1b Communication

- Laboratory management communicates with staff through a variety of means including departmental staff meetings and daily huddles, e-mails, notice boards and one to one meetings. Staff suggestions are actively encouraged (ISO 15189 2012:4.14.4). Records are kept of items discussed in communications and meetings. Minutes of all pathology wide meetings are readily available for all staff to read.

- Laboratory management ensures that appropriate communication processes are established between the laboratory and its stakeholders through a variety of mechanisms including user interaction meetings, surveys, e-mails and individual interactions ensuring that communication takes place regarding the effectiveness of the laboratory's pre-examination, examination, post-examination processes and quality management system

5.4.2: Quality management

Each department has a Quality Manager and or quality lead(s) that have, irrespective of other responsibilities, delegated responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented, and maintained.

They also submit detailed reports to laboratory management through Pathology Quality and Accreditation Committee (PQAC), on the performance of the quality management system and any need for improvement. If necessary, these can be raised to Pathology Executive Management Committee(PEMC)

User needs and comments are fed through PQAC ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organisation.

5.5: Objectives and policies

The Laboratory management has described the purpose of its quality management system in the following quality policy.

The quality policy:

a) includes a commitment to good professional practice, examinations that are fit for intended use, compliance with the requirements of ISO 15189, and continual improvement of the quality of laboratory services.

b) provides a framework for establishing and reviewing quality objectives.

c) is communicated to and understood by all staff via iPassport and the pathology website as well as being displayed in all areas of the department.

d) is reviewed bi-annually or more frequently if required, by the Pathology Executive Management Committee (PEMC) using feedback from departmental management review meetings for continuing suitability.

Each discipline establishes specific quality objectives which allow their department to meet the needs and requirements of the users, and these are approved at PQAC. The quality objectives are measurable and consistent with achieving the aims of the quality policy.

The Quality Policy (ISO 15189:2022: 5.5) of the Pathology Directorate is described in document WI-U-GEN-Quality Policy and a copy is displayed within each laboratory, and Specimen Reception at Worcestershire Royal Hospital and in Blood Transfusion and Biochemistry at the Alexandra Hospital

The Trust decides upon its strategic objectives on an annual or biennial basis. These are fed through the Diagnostics and Specialities Care Group (of which Pathology is a part) to the Pathology Executive Committee who then ensure that Directorate and Departmental objectives are measurable, consistent with achieving the aims of the quality policy and link to these are then determined. The individual departments conduct their management reviews in sufficient depth to meet the requirements of ISO 15189 throughout the year in a manner that ensures all topics are covered on at least an annual basis. They also determine whether the objectives have been successfully completed which provides an opportunity for revising such objectives and plans and the on-going functioning and integrity of the QMS.

5.6: Risk management

The laboratory evaluates the impact of work processes and potential failures on examination results as they may affect patient safety. [MR-U-GEN-Process Risk management]
The monitoring and review of this procedure is the responsibility of the Quality manager.
Implementation of this procedure is the responsibility of the Laboratory Clinical Director
All qualified BMS staff must follow this procedure.
Every member of staff has a duty to alert laboratory management of any potential risks identified so these can be acted upon appropriately.
Processes are then modified as appropriate to reduce or eliminate the identified risks and decisions and actions taken are documented. (ISO15189:2022 8.5)

Risks are discussed at Departmental Quality meetings and taken to the Pathology Quality & Accreditation Committee with presence from Trust Governance,

6: Resource requirements

6.1: General

The laboratory has a documented procedure for personnel management [PR-U-GEN-PersonnelManagement: Personnel Management Procedure] which details how personnel are managed and what records are maintained to indicate compliance with requirements.

6.2: Personnel

6.2.1: General

All staff are required to attend a Trust induction prior to or at commencement of post. [PO-U-GEN-PathologyindPolicy] Staff also undergo a departmental induction which starts on their first day in the department. The documents' describing this process are linked to the above named policy in iPassport and once completed and signed a copy of this induction checklist is stored in the individual's personal file, held by the Department Manager.

6.2.2: Competence requirements

a) The laboratory shall specify the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, re-training, technical knowledge, skills and experience.

b) The laboratory shall ensure all personnel have the competence to perform laboratory activities for which they are responsible.

c) The laboratory shall have a process for managing competence of its personnel, that includes requirements for frequency of competence assessment.

d) The laboratory shall have documented information demonstrating competence of its personnel

The personnel qualifications required for each position are identified in the person specification used during the selection process. The qualifications reflect the appropriate education, training, experience and demonstrated skills needed, and are appropriate to the tasks performed. This is highlighted in all process SOPs under 'personnel/training requirements'

Any personnel in a position to make judgments with reference to examinations carry suitable qualifications and have registration by appropriate professional/legal bodies.

As the range of competences required across pathology is far reaching it is impossible to identify all of the competency documents here but these can be accessed in the individual departments as required.

6.2.3: Authorisation

The level of authorisation an individual has with the remit of their job is determined by the level of competence achieved as laid down within the Pathology Competence assessment policy [PO-U-GEN-Competence assessment policy pathology], Pathology reporting results [PO-U-GEN-ReprtingResults] and compliant with the Trust Information Governance policy [Data Protection Policy WAHT-IG-004]

6.2.4: Continuing education and professional development

Continuing education and professional development is dealt with in a variety of ways. Lunchtime meetings or seminars are held by individual disciplines with an open invite to all staff if the subject matter is appropriate. Various educational meetings are held within the trust to which all staff are again invited. Senior staff are constantly reviewing the effectiveness of these meetings and looking for innovative ways to provide this training in a format which is acceptable to both the staff member and the smooth running of the department.
Individually the IBMS offer regular CPD opportunities which many staff partake in.
When re-registering with HCPC each registered member must sign a declaration that they are actively partaking in CPD and if requested produce their portfolio for independent scrutiny.

6.2.5: Personnel records

Confidential personnel records are kept securely by department managers. (ISO 15189 2022:6.2.5) These records are readily available to relevant personnel and as a minimum include:

The laboratory shall have procedures and retain records for:

a) determining the competence requirements specified in 6.2.2 a);

b) position descriptions;

c) training and re-training;

d) authorization of personnel;

e) monitoring competence of personnel

NOTE: The records listed above should be stored in secure office and locked when not in use and remain accessible as needed.

6.3: Facilities and environmental conditions

6.3.1: General

Laboratory facilities on both sites are and were designed to ensure the quality, safety and efficacy of the service provided to the users and the health and safety of laboratory personnel, patients, and visitors. As processes and ways of working have changed over the years laboratory management have evaluated the sufficiency and adequacy of the space allocated for the performance of the work carried out and made what changes can be reasonably done to make the most efficient and safe use of the space and facilities available.

Health and safety**:** The following policies ensure the health, safety, and welfare of all personnel: -

- Trust Health & Safety Policies, available on the intranet. [Health and Safety Policy WAHT-CG-125]
- A Pathology Health& Safety Policy [HS-U-GEN-Path Health &Safety policy]
- A Pathology COSHH Policy [HS-U-GEN-COSHHPol&Procedures]
- Local departmental SOPs including risk assessments

Laboratory containment facilities conform to the requirements of the Advisory Committee on Dangerous Pathogens (ACDP) Guidelines.

All staff are informed of their responsibilities relating to Health & Safety through appropriate training, notices and labelling.

All adverse incidents or near misses resulting or potentially resulting in harm to patients, staff or visitors and the associated actions arising are reported using DATIX as well as being recorded in iPassport as a non-conformance. Serious incidents are recorded on the Pathology Risk Register in DATIX and discussed at the PEMC and Pathology Quality and Accreditation meetings. Datix incidents are monitored by the Trust Clinical Risk Department.

Chemical waste for all of Pathology is disposed of via Cellular Pathology. This is collected from their stores by Genta Medical Ltd, who are registered with the environment agency for waste collection/disposal.

6.3.2: Facility controls

The laboratory and associated office facilities on both sites provide an environment suitable for the tasks to be undertaken with the following conditions being met:

a) Access to laboratory premises is restricted to authorised personnel
b) Once in the department access to any IT system containing medical or personal information is controlled by individual passwords with different and appropriate levels

of access to different grades of staff. Patient samples and other associated data are always treated confidentially and retained for the length of time and temperature appropriate to the item(s) in question.

c) The facilities provided including energy sources, lighting, ventilation, noise, water, waste disposal and environmental conditions are appropriate to allow for correct performance of examinations.
d) Communication systems e.g. telephones, electronic links etc. meet the needs and requirements of users.
e) Safety facilities and devices including alarm systems for cold rooms, eyewash stations and emergency showers are provided and their function regularly verified.

The WRH site facilities are managed by our PFI partners, Equans, Siemens and ISS with regular input from laboratory managers when issues are identified. The trust estates department manages the Redditch site again with regular input from laboratory managers when issues are identified. Both sites are kept maintained in a functional and reliable condition. Work areas are kept clean and well maintained, with Monthly Cleaning Audits conducted by ISS.

Where the environmental conditions may influence the quality of results of examinations and or the health of staff then attention is given to monitoring, controlling, and recording these as required with relevant policies being itemised in the associated documents list at the end of this document.

Within departments adequate space has been allocated for the use of all equipment and separation of incompatible activities. Procedures are in place to prevent cross-contamination where examination procedures pose a hazard or where work could be affected or influenced by not being separated.

Where it is needed the laboratory provides a quiet and uninterrupted work environment.

6.3.3: Storage facilities

Storage space is provided in the way of store rooms, fridges, cold room, freezers, etc. to ensure the continuing integrity of sample materials, documents, equipment, reagents, consumables, records, results, and any other items that could affect the quality of examination results. Where necessary the temperature in these areas is monitored.

Clinical material is stored according to policy [PO-U-GEN-CtrlClinMat]. Materials used in examination processes are normally stored separately. If both samples and materials used in examination procedures must be stored together then the samples are always stored below the materials in order to avoid cross contamination.

Hazardous substances are managed in accordance with the COSHH policy [HS-U-GEN-COSHHPol&Procedures].

6.3.4: Personnel facilities

The following facilities are provided for staff:

- Sufficient toilets within access of the laboratories on each site.

- Rest areas are available with limited catering facilities. There is also a restaurant where hot food and drinks are available. Drinking water is always available.
- Secure storage for personal effects is provided. Suitably sited hangers are available within each department for laboratory coats
- Swipe-card or keypad access to all laboratory areas, with security staff or alarm systems where appropriate for lone workers. (ISO 15189 2022:6.3.4)
- Rooms or Pods are available on all three hospital sites for staff activities such as meetings and interviews, or Quiet Study.

6.3.5: Sample collection facilities

Patient Facilities are no longer required within Pathology on the Worcestershire Royal or Alexandra Hospital sites.

6.4: Equipment

6.4.1: General

Laboratory Management ensures that equipment is sufficient and appropriate to provide the service. Procurement and management of equipment is in accordance with Trust Standing Financial Instructions, the Trust Medical Devices Policy: [Medical Devices policy including Education and Training: WAHT-CG-022] and Pathology Procurement and Management of Equipment Procedure [MR-U-GEN-ProcMgtEquip] and takes account of energy usage and disposal requirements.

A list of selected and current approved suppliers of equipment, reagents and consumables can be obtained from iPassport on demand at any time which includes evidence that the performance of suppliers is monitored to ensure that purchased services or items consistently meet the stated criteria. [MR-U-GEN**-External** Services and supplies] (ISO15189:2022:6.2)

6.4.2: Equipment requirements

The laboratory selects and approves suppliers using relevant criteria based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's and end user's requirements. This is done in collaboration with the procurement department who ensure that purchasing information describes the requirements for the product or service to be purchased.

The inventory of equipment supplied through the PFI is held by Siemens (on the WRH site) although Laboratory Managers can obtain a complete list of all equipment in their department(s), irrespective of funding source, from iPassport on demand at any time.

All assets on the PFI schedule have an expected lifetime determined on installation but should there be a requirement to replace earlier or later than this, for example, due to technological change, then this can be negotiated between the PFI, finance and the pathology management.

The Trust assets are replaced as required to ensure the quality of examination results normally by production of a business case.

6.4.3: Equipment acceptance procedure

Equipment once obtained is subject to validation and verification as per the pathology wide policy: [PO-U-GEN-Validation and Verification Policy]. Information about the equipment including its unique identifiers is entered onto iPassport where the verification data is also stored. Further re-verification is then carried out when changes are made, repairs or any other interventions are carried out or if other concerns are raised and this data is added to the entry in iPassport.

This process would apply equally to equipment used in the laboratory, equipment on loan or equipment used in associated or mobile facilities by others authorized by the laboratory.

6.4.4: Equipment instructions for use

Anyone using equipment unsupervised would have been trained in its use and have a completed competence form for it.

Current instructions for use would normally be in the form of an SOP on iPassport and any relevant manuals would be indexed as external documents again on iPassport and listed as either links or attachments on the relevant iPassport file for that particular piece of equipment.

Most equipment used in the laboratory is fixed so transport and storage is not normally an issue.

6.4.5: Equipment maintenance and repair

Because of the diverse nature of the equipment used across the various areas of pathology the documented procedure for the programme of preventive maintenance would be specific to that analyser and as such would form part of the SOP.
Procedure: [MR-U-GEN-ProcMgtEquip] details how the preventive maintenance contracts would be set up as well as the procedures to be carried out in the event of defective equipment, decontamination and post repair performance verification.
The safe handling and disposal of chemical and biological materials is also detailed in the individual SOPs and would only be carried out by authorized persons

6.4.6: Equipment adverse incident reporting

Procedure: [MR-U-GEN-ProcMgtEquip] details how equipment adverse incident reporting would be carried out.

6.4.7: Equipment records

Equipment Records are maintained on iPassport for each item of equipment that contributes to the performance of examinations and as a minimum includes:

a) identity of the equipment;

b) manufacturer’s name, model and serial number or other unique identification;

c) contact information for the supplier or the manufacturer;

d) date of receiving and date of entering into service;

e) location;

f) condition when received (e.g. new, used or reconditioned);

g) manufacturer's instructions;

h) records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;

i) maintenance carried out and the schedule for preventive maintenance;

j) equipment performance records that confirm the equipment's on-going acceptability for use;

k) damage to, or malfunction, modification, or repair of the equipment.

These records are maintained, updated as appropriate and are readily available for the lifespan of the equipment as specified in the laboratory's Control of Records procedure [PO-U-GEN-ControlProcessQualRec] although the records would in fact be available for as long as the QMS system was operational

6.5: Equipment calibration and metrological traceability

6.5.1: General

Because of the diverse nature of the equipment used across the various areas of pathology the documented procedure for the calibration of equipment that directly or indirectly affects examination results would be specific to that particular type of assay or analyser hence the recording of the information required by this standard would all be itemised within the individual SOPs.

6.5.2: Equipment calibration

In relation to equipment calibration the following must be considered:

a) Conditions of use and the manufacturer's instructions.
b) Recording the metrological traceability of the calibration standard and the traceable calibration of the item of equipment.
c) Verifying the required measurement accuracy and the functioning of the measuring system at defined intervals;

6.5.3: Metrological traceability of measurement results

All calibration material utilised will have appropriate documentation recorded on ipassport

a) recording the calibration status and date of recalibration;
b) ensuring that, where calibration gives rise to a set of correction factors, the previous calibration factors are correctly updated, and any amendments made to current Procedures

c) safeguards to prevent adjustments or tampering that might invalidate examination results.

Metrological traceability will always be to a reference material or reference procedure of the highest metrological order available.

6.6: Reagents and consumables

6.6.1: General

The management of reagents, calibration and quality control material is in accordance with the pathology wide Management of Materials Policy [PO-U-GEN-ManagementMaterials] and external services and supplies [MR-U-GEN-External Services and Supplies] specific departmental procedures which are linked in iPassport to this policy.
This includes both the process for selecting an appropriate supplier and the acceptance criteria once goods have been received.
- Before putting any goods into use they would be subject to appropriate verification as per departmental procedures.

6.6.2: Reagents and consumables - Receipt and storage

Deliveries of goods to the laboratory normally occur through the loading bays at either WRH or the Alexandra Hospital. While there are no specific storage facilities in either of these areas the goods are delivered to the department as soon as possible. Audits are carried out to confirm this and any issues arising from these would be dealt with by both the loading bay and the laboratory management.

Once received in the laboratory received reagents and consumables are stored according to manufacturer's specifications.
Environmental monitoring is carried out to ensure appropriate storage conditions.

6.6.3: Reagents and consumables - Acceptance testing

Due to the diverse nature of the various reagents and consumables used across the various areas of pathology the process for acceptance testing of both reagents and consumables is specific to each discipline and ensures in all cases that each new formulation of examination kits with changes in reagents or procedure, or a new lot or shipment, is verified for performance before use in examinations. The same applies to consumables that can affect the quality of examinations. As detailed above these documents can be found on iPassport and are linked to the Management of Materials Policy [PO-U-GEN-ManagementMaterials]

6.6.4: Reagents and consumables - Inventory management

Within the acceptance testing processes detailed above each discipline within pathology has specific procedures for inventory control of reagents and consumables which ensures that uninspected and unacceptable reagents and consumables are segregated from those that have been accepted for use.

6.6.5: Reagents and consumables - Instructions for use

Instructions for the use of reagents and consumables, including those provided by the manufacturers are retained as per the Document Control policy: [MO-U-GEN-Document Control] and are readily available.

6.6.6: Reagents and consumables - Adverse incident reporting

Adverse incidents and accidents would always be recorded as non-conformances on iPassport and fully investigated. If it was found that the incident can be attributed directly to specific reagents or consumables then this would be reported to the manufacturer and appropriate authorities, as required.

6.6.7: Reagents and consumables - Records

Records are maintained as required to comply with ISO 15189 for each reagent and consumable that contributes to the performance of examinations as part of the individual discipline's stock control and acceptance testing policies.

There are now very few reagents prepared or completed in-house but where this is the case the records include, in addition to the basic information required, reference to the person or persons undertaking their preparation and the date of preparation.

6.7: Service agreements

6.7.1: Agreements with laboratory users

The laboratory has documented procedures for the establishment and review of agreements for providing medical laboratory services both internally to the Trust and externally to other healthcare organisations. [MR-U-GEN-SLA] [MR-U-GEN-Service agreement internal]

By following these we ensure compliance with the ISO 15189 standard as outlined below.

Agreements to provide medical laboratory services consider the complete sample pathway including the request, examination and the report. The agreement specifies the information needed on the request to ensure appropriate examination and result interpretation.

Each request accepted by the laboratory for examination(s) is considered to constitute an agreement.

The following conditions are met when the laboratory enters into an agreement to provide medical laboratory services.

- The requirements of the customers and users, and of the laboratory services, including the examination processes to be used, are defined, documented, and understood (see ISO 15189 2022: 7.2.2 and 7.3).
- The laboratory management ensures that it has the capability and resources to meet the specified requirements including:
- The laboratory personnel have the skills and expertise necessary for the performance of the intended examinations.
- Examination procedures selected are appropriate and able to meet the customer's needs (see ISO 15189 2022:7.3).

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

6.7.2: Agreements with POCT operators

The Pathology wide multidisciplinary POCT committee meets quarterly, and reports to the Trust Medical Devices Committee which is attended by one of the Clinical Scientists.

6.8: Externally provided products and services

6.8.1: General

The laboratory has a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline. [MR-U-GEN-Examination by referral labs and consultant. The procedure ensures that the following conditions are met.

- The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance and ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.
- Arrangements with referral laboratories and consultants are reviewed and evaluated periodically using the scheduled review process in iPassport where appropriate documentation and evidence can be recorded in iPassport to ensure that the relevant parts of ISO 15189 are met.
- A register of all referral laboratories and consultants from whom opinions are sought along with approval status can be obtained by discipline from iPassport on demand at any time.
- Requests and results of all samples referred are kept for a pre-defined period as defined in the control of records and control of clinical material policies. **[**PO-U-GEN-ControlProcessQualRec; PO-U-GEN-CtrlClinMat]

Unless otherwise specified in the agreement, we as the referring laboratory (and not the referral laboratory) accept responsibility for ensuring that examination results of the referral laboratory are made available to the person making the request.

Reports from referral laboratories include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation and indicate which examinations were performed by a referral laboratory or consultant with the author of any additional remarks also being clearly identified.

Where possible both requests and results are transmitted electronically to and from the referral laboratories using N-PEX to reduce both the risk associated with transcription processes and turnaround times. In all other cases, there are processes in place to ensure the efficient and accurate transcription or onward transmission of referred results to the requestor in order to avoid any unnecessary delays.

6.8.2: Referral laboratories and consultants

Where collaboration is needed between clinicians and specialists from both referring and referral laboratories for the correct interpretation and application of examination results, this process is not hindered by commercial or financial considerations.

6.8.3: Review and approval of externally provided products and services

A policy exists [MR-U-GEN**-External** Services and supplies] that defines how the laboratory selects and approves suppliers using relevant criteria that have been established, based on their ability to supply external services, equipment, reagents and consumable supplies in accordance with the laboratory's and end user's requirements. This is done in collaboration with the procurement and supplies department who ensure that purchasing information describes the requirements for the product or service to be purchased. Reviews are carried out regularly using the scheduled review process in iPassport where appropriate documentation and evidence can be recorded to ensure that the relevant parts of ISO 15189 are met.

A list of selected and current approved suppliers of equipment, reagents and consumables along with their review status can be obtained by discipline from iPassport on demand at any time.

7: Process requirements

7.1: General

The laboratory evaluates the impact of work processes and potential failures on examination results as they may affect patient safety. [MR-U-GEN-Process Risk management] Processes are then modified as appropriate to reduce or eliminate the identified risks and decisions and actions taken are documented.

7.2: Pre-examination processes

7.2.1: General

Pathology discusses with users of the service the way requests are communicated to the laboratory, either through the User Interaction groups or other less formal routes. Requests and results reporting are now almost exclusively done using the Sunquest ICE system. Where there are technical or practical difficulties in achieving this Worcestershire Acute Hospitals NHS Trust supplies various departmental specific pathology request forms for both hospital and GP use.

There is a pathology wide policy which is used on all sites for the patient sample and request form identification criteria [PO-U-GEN-ReqCriteria] as well as a policy for the acceptance and rejection of specimens [PO-U-GEN-PolSpecAcceptance]. (ISO 15189 2022:7.2.3)

There is detailed information on the pathology website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) for each individual test indicating any particular requirements for pre-examination activities in order to ensure the validity of the results of examinations.

7.2.2: Laboratory information for patients and users

Information for users and patients is available on the Pathology Website: Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) This is reviewed by departmental designated staff along with management of the site by Trust Communications, following changes, audit findings and actions from non-conformance. It is accessible from any internet enabled device.

Other information, such as patient information leaflets are prepared by departments as appropriate and contain an explanation of the procedure and patient preparation details.

Specimen collection and handling: The Pathology Website Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk) includes comprehensive information for users on specimen collection and handling including volume requirements. Laboratory staff also provide advice to users on request. (ISO 15189 2022:7.2.4)

Specimen transportation**:** A courier service is provided for specimen transportation between the hospitals, GP surgeries and the pathology departments. In the Bromsgrove and Redditch areas this is provided by Worcestershire Health and Care NHS Trust and elsewhere across the county, and between the various trust sites, by Worcestershire Acute Hospitals NHS Trust (ISO 15189 2022:7.2.5).

Between 7pm and 7am Monday to Thursday and 7pm Friday to 7am Monday and all day on bank holidays we use a voluntary organisation called Severn Freewheelers to transport samples between sites and across the area. If this service is not available, for whatever reason, contracted private hire vehicles (Taxis) are used via arrangement through switchboard.

Specimens referred to other laboratories are transported in accordance with current legislation using Trust transport, Royal Mail, TNT, Hayes DX Network Services, PDP and private hire vehicles.

There is a policy [PO-U-GEN-SpecTransport] for the transport of specimens to which appropriate departmental procedures are linked detailing specific instructions for packaging, labelling and despatch of specimen types which have specific requirements.

7.2.3: Requests for providing laboratory examinations

7.2.3.1: General

Wherever possible we encourage the use of ICE electronic requesting, or where this is not possible hard copy request forms, which ensures that at a minimum the following information is given:

a) patient identification, including gender, date of birth, and the location/contact details of the patient, and a unique identifier;

b) name or other unique identifier of clinician, healthcare provider, or other person legally authorized to request examinations or use medical information, together with the destination for the report and contact details;

c) type of primary sample and, where relevant, the anatomic site of origin;

d) examinations requested;

e) clinically relevant information about the patient and the request, for examination performance and result interpretation purposes;

f) date and, where relevant, time of primary sample collection;

The date and time of sample receipt are recorded on the LIMS system when the request is booked in.

The format of this requesting system has evolved over the years following feedback from users particularly around the use of specific disease related testing profiles.

If there is any doubt or concern about the clarity of the user's request this will be dealt with either by the Biomedical Scientist dealing with the issue of if necessary one of the clinical staff.

7.2.3.2: Oral requests

The pathology website documents the procedure concerning verbal requests for examinations for each department where applicable, with timeframes for submission, sample and test dependent, and that includes providing confirmation by written request

7.2.4: Primary sample collection and handling

7.2.4.1: General

The pathology website has details about the proper collection and handling of primary samples including any special requirements for specific tests. The website is freely available to all on any internet enabled device.

Where the user requires deviations and exclusions from, or additions to, the documented collection procedure, these are recorded and included in all documents containing examination results and communicated to the appropriate personnel on the report.

Before carrying out any special procedures, including more invasive procedures, or those with an increased risk of complications to the procedure, a more detailed explanation is given to the patient and where necessary written consent is obtained and the consent form retained.

As part of the review process authorised personnel periodically review the examinations provided by the laboratory to ensure that they are clinically appropriate for the requests received. As well as looking at the clinical significance other areas are also reviewed including sample volume, collection device and preservative requirements for blood, urine, other body fluids, tissue and other sample types, as applicable, to ensure that neither insufficient nor excessive amounts of sample are collected and the sample is properly collected to preserve the measurand.

7.2.4.2: Information for pre-collection activities

The laboratory's instructions for pre-collection activities are available test by test on the pathology website and include the following:

a) preparation of the patient (e.g. instructions to caregivers, phlebotomists, sample collectors and patients);

b) type and amount of the primary sample to be collected with descriptions of the primary sample containers and any necessary additives;
c) special timing of collection, where needed;
d) clinical information relevant to or affecting sample collection, examination performance or result interpretation (e.g. history of administration of drugs).

Instruction on completion of electronic requests is included when trained in use of ICE and on-line guides are also available within ICE.

7.2.4.3: Patient consent

For most routine laboratory procedures, consent can be inferred when the patient willingly submits to the sample collecting procedure, for example, venipuncture.
Where obtaining consent is not possible in emergency situations, the laboratory may carry out necessary procedures, provided they are in the patient's best interest.

7.2.4.4: Instructions for collection activities

The instructions for collection activities are documented in procedures devised by the Out-Patients manager, who is responsible for phlebotomy with additional information being available on the pathology website and include the following:
a) determination of the identity of the patient from whom a primary sample is collected;
b) Verification that the patient meets pre-examination requirements (e.g. fasting status, medication status (time of last dose, cessation), sample collection at predetermined time or time intervals, etc.);
c) instructions for collection of primary blood and non-blood samples, with descriptions of the primary sample containers and any necessary additives;
d) in situations where the primary sample is collected as part of clinical practice, information and instructions regarding primary sample containers, any necessary additives and any necessary processing and sample transport conditions;
e) instructions for labelling of primary samples in a manner that provides an unequivocal link with the patients from whom they are collected;
f) recording of the identity of the person collecting the primary sample and the collection date, and, when needed, recording of the collection time;
g) instructions for proper storage conditions before collected samples are delivered to the laboratory;
h) safe disposal of materials used in the collection.

7.2.5: Sample transportation

The laboratory's instructions for post-collection activities can be found on the pathology website [PO-U-GEN-SpecTransport] and include packaging of samples for transportation.

As part of the pre-analytical process a regular audit (RADT) is done of the journey time of the sample to confirm they have been transported:
a) within a time-frame appropriate to the nature of the requested examinations and the laboratory discipline concerned;
b) within a temperature interval specified for sample collection and handling and with the designated preservatives to ensure the integrity of samples;
c) in a manner that ensures the integrity of the sample and the safety for the carrier, the general public and the receiving laboratory, in compliance with established requirements.

As this laboratory is not involved in primary sample collection and transportation we would always contact the sender immediately when, upon receipt of a sample, we discovered that the integrity was compromised or it could have jeopardized the safety of the carrier or the general public and inform them about what measures need to be taken to eliminate recurrence of the issue.

7.2.6: Sample receipt

7.2.6.1: Sample receipt procedure

At Worcestershire Royal Hospital there is a pathology sample receipt area where all pathology samples, from transport couriers or personal callers, i.e. Doctors, Nurses, Patients, etc. are handed over to reception staff. Staff and resources in this area are managed by the Blood Sciences Pre-Analytics manager who is also responsible for all aspects of the pre-analytical components of the work in Blood Sciences on both this and the Redditch site. Microbiology and Cellular Pathology samples are placed in their labelled receptacles and then handed over to staff from these disciplines that then perform any necessary pre-analytical work on these samples under the direction and guidance of the laboratory manager for their own discipline. Blood Sciences samples with their associated request forms are sorted from their outer transport bags and are transferred into receptacles for delivery to the appropriate departmental specimen reception area, for example: Haematology, Biochemistry and the Urine bench where the bags are opened and the appropriate checks done on the sample and form.
Samples arrive via the air tube system to Blood Sciences, there are two delivery systems feeding to Pathology, one from the Emergency Department, the other from the remainder of the hospital site.

At Redditch, the samples are delivered either by hand to a table inside an access controlled area, but out with of the main secure laboratory area, where they are collected by Blood Science MLA staff or in the case of hospital patients by air tube directly into the main blood sciences specimen reception area where they are then appropriately dealt with. Samples for Microbiology arrive in separate marked bags and are picked up regularly by the transport staff and delivered to Worcestershire Royal Hospital along with Cellular Pathology samples and blood science samples requiring assays not offered on this site where they are dealt with as explained above.

At Kidderminster, the samples are transported in a safe and timely manner to Worcestershire Royal Hospital.

Additional information about this aspect of the work is detailed in the Pre-Analytical Department Information procedure: [LP-U-CHM-Pre-Analytical department information]. It is not until the samples arrive within the designated department specimen reception area that the samples are removed from the sample pouch in line with the individual departmental specimen reception procedures, identified in the associated documents list at the end of this document, that identify the processes for:

- Accurate matching of the request form and specimen including any subsequent sample aliquots with the unique identifying number
- Data entry of request form and specimen information onto the Laboratory Information System
- Recording of date and time of receipt of specimens.

- Handling urgent specimens
- Ensuring staff safety (e.g. H&S procedures)

7.2.6.2: Sample acceptance exceptions

A Pathology Policy [PO-U-GEN-PolSpecAcceptance] exists in combination with local procedures which are linked in iPassport to this policy for:

- Criteria for rejection of specimens
- Recording of rejected specimens.
- Notification of the user concerning rejected specimens.

As part of the regular management review process authorised personnel regularly review requests and samples and decide examinations to be performed and methods used. (ISO 15189 2022:7.2.6)

7.2.7: Pre-examination handling, preparation, and storage

7.2.7.1: Sample protection

The laboratory is equipped with appropriate facilities for securing patient samples and avoiding deterioration, loss or damage during pre-examination activities and during handling, preparation and storage.

7.2.7.2: Criteria for additional examination requests

Laboratory procedures and the pathology website indicate time limits for requesting additional examinations or further examinations on the same primary sample.

7.2.7.3: Sample stability

Laboratory procedures and the pathology website indicate stability of analytes and the time frame for collection to examination to ensure validity of result.

7.3: Examination processes

7.3.1: General

Selection and verification of examination procedures is carried out according to the pathology wide policy [LP-U-GEN-Selection and Verification of Examination Procedures.]

The identity of persons performing activities in examination processes can be determined by reference to past work rotas or by the various audit trails in use across the department.

7.3.2: Verification of examination methods

All examination procedures are subject to validation and verification prior to introduction. Validated examination procedures used without modification are subjected to independent verification by the laboratory before being introduced into routine use. If the procedure was

not a 'preferred procedure' used without modification then a full validation would have to be carried out before any verification could proceed.
The laboratory would obtain information from the manufacturer/method developer confirming the performance characteristics of the procedure and using the form: [LF-U-GEN- Verification of Examination procedures] would confirm and record through obtaining objective evidence (in the form of performance characteristics) that the performance claims for the examination procedure have been met.
The performance claims for the examination procedure confirmed during this verification process would be those which were relevant to the intended use of the examination results.
Evaluation of procedures is performed using "in-house" or nationally recommended methods, i.e. ACB guidelines. The method, results and conclusions and any associated paperwork are recorded and stored in iPassport following review by staff with the appropriate authority.
When changes to examination procedures significantly affect the results or their interpretation, full information on these changes is provided to users through the user interaction groups and by letter prior to the introduction of the change alongside appropriate comments on the reports.

As part of the regular management review process examination procedures are reviewed to ensure they continue to meet the needs and requirements of users.

7.3.3: Validation of examination methods

If an examination procedure was derived from any of the following sources:
a) non-standard methods;
b) laboratory designed or developed methods;
c) standard methods used outside their intended scope;
d) validated methods subsequently modified.

A full validation would be carried out and would be as extensive as is necessary in order to confirm, through the provision of objective evidence (in the form of performance characteristics), that the specific requirements for the intended use of the examination have been fulfilled.
The laboratory would then document the procedure used for the validation and record the results obtained on iPassport following review by staff with the appropriate authority. Once validated the examination procedure would be subjected to verification as detailed above.
When changes are made to a validated examination procedure, the influence of such changes would be documented and, when appropriate, a new validation carried out.

7.3.4: Evaluation of measurement uncertainty (MU)

All areas of the laboratory have determined measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples. The laboratory has defined performance requirements for the measurement uncertainty of each measurement procedure and regularly reviews estimates of measurement uncertainty. This data is readily available and could be supplied to users who requested it.

7.3.5: Biological reference intervals and clinical decision limits

The laboratory has defined the biological reference intervals or clinical decision values and documented the basis for the reference intervals or decision values on the website which is available to all users.

If a particular biological reference interval or decision value was no longer relevant for the population served, appropriate changes would be made and this information would be communicated to the users.
Whenever a change occurs to either an examination procedure or pre-examination procedure, the laboratory reviews the associated reference intervals and clinical decision values, as applicable and notifies users accordingly.

7.3.6: Documentation of examination procedures

The format of Standard Operating Procedures is in accordance with the Document Control Policy and Procedure [MO-U-GEN-Document Control]. All examination procedures are readily available on the electronic document control system (iPassport) with controlled hard copies being available where required on the relevant benches

When changes to examination procedures significantly affect the results or their interpretation, full information on these changes is provided to users through the user interaction groups and by E-mail and Trust Communications prior to the introduction of the change alongside appropriate comments on the reports.

7.3.7: Ensuring the validity of examination results

7.3.7.1: General

There are departmental procedures which are itemised in the associated documents list at the end of this document for selection, use and interpretation of internal quality control (IQC), performed under controlled conditions, for all examinations to ensure the quality of laboratory examinations. These include:

- Implementation of appropriate pre-examination processes
- Provision of trained staff, appropriate premises and environmental conditions, equipment and materials information systems, and the use of documented procedures.
- Use of internal quality control
- The determination of uncertainty
- Calibration of measuring systems
- Verifying the comparability of results
- Participating in external Proficiency Testing Schemes
- Records of date, source and storage requirements of IQC material
- The process of validation of IQC material prior to routine use
- Appropriate statistical procedures and acceptance criteria for results where applicable.
- All IQA results are regularly recorded, evaluated and any remedial or corrective actions recorded on the individual evaluation sheets.

The laboratory determines the uncertainty of results, where relevant and appropriate using methods appropriate to the nature of the results concerned, i.e. quantitative/qualitative.

The laboratory uses material for calibration of measuring systems and verification of trueness which has defined metrological traceability designed to ensure that results are traceable, where possible, to SI units or to a stated reference material.

Where examinations are performed using different procedures or equipment or at different sites the departments involved have mechanisms in place, itemised in the associated documents list at the end of this document, to ensure that results are comparable throughout clinically appropriate intervals. (ISO 15189 2022:7.3.7 and UKAS supplementary document (GEN-1 Assessment of CAB's by UKAS- Appendix C)

7.3.7.2: Internal quality control (IQC)

The laboratory ensures that there are quality control procedures in place that verify the attainment of the intended quality of results.

The laboratory always strives to use quality control materials that react to the examining system in a manner as close as possible to patient samples. Given the amount of substances added to most QC materials to achieve values around clinical decision levels this can sometimes be difficult to achieve.

Each area of the laboratory examines Quality control materials with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.

Wherever possible independent third-party control materials are used, either instead of, or in addition to, any control materials supplied by the reagent or instrument manufacturer.

Across pathology there are many ways in which the release of patient results in the event of quality control failure is avoided. In some cases, the release of patient results is blocked until all quality control results are acceptable and in others this is a manual process. In any case good laboratory practice dictates that patient samples are not analysed until there is clear indication that the method is under control.

When the quality control rules are violated after patient results have been released and there are indications that examination results are likely to contain clinically significant errors immediate action is taken to reject the results and to contact users if necessary to advise them. Relevant patient samples would then be re-examined after the error condition has been corrected and within-specification performance is verified. A process would then be put into place as per individual disciplines procedures to evaluate the results from patient samples that were examined after the last successful quality control event in order to identify at what point results became invalid. Once determined all results would be repeated from this point. At all stages of this process the Laboratory Clinical Director would be kept aware so that they could deal with any clinical issues arising from the problem.

Quality control data is reviewed at regular intervals to detect trends in examination performance that may indicate problems in the examination system. When such trends are noted, preventive actions are taken and recorded.

7.3.7.3: External quality assessment (EQA)

All departments participate in approved External Quality Assurance/Proficiency Testing (EQA/PT) Schemes appropriate to the examinations and interpretations provided, most of which are now ISO17043 compliant or working towards it. TPS47 is used to guide the selection and interpretation of the results.
Departments have documented procedures, itemised in the associated documents list at the end of this document, for inter-laboratory comparison participation that includes defined responsibilities and instructions for participation, and any performance criteria that differ from the criteria used in the inter-laboratory comparison programme.
The inter-laboratory comparison programme(s) chosen by the laboratory, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-examination procedures, and post-examination procedures.

A record of results against agreed performance criteria in approved schemes is maintained by departments and performance is reviewed by competent staff and action plans devised where necessary to determine what corrective actions need to be implemented to come within the agreed performance criteria. Decisions taken are recorded, monitored, and acted upon in accordance with departmental procedure. Information on Proficiency Testing (PT) results are regularly communicated to staff within each department and discussed at PQAC.

Across pathology we would not attempt to accredit an assay unless there was a proven EQA Scheme available. If an assay was required whereby there was no proven EQA Scheme available, then arrangements would be made to facilitate some sort of interim inter-laboratory comparison and the assay would have to be offered as an assay which was outside of the scope of the laboratories accreditation process until such times as a proven EQA scheme became available.

The laboratory integrates inter-laboratory comparison samples into the routine workflow in a manner that follows, as much as possible, the handling of patient samples. Samples are examined by personnel who routinely examine patient samples using the same procedures as they use for patient samples.
The laboratory does not communicate with other participants in the inter-laboratory comparison programme about sample data until after the date for submission of the data and does not refer inter-laboratory comparison samples for confirmatory examinations before submission of the data, although this would routinely be done with patient samples.

The performance in inter-laboratory comparisons is reviewed and discussed with relevant staff.
When predetermined performance criteria are not fulfilled (i.e. nonconformities are present), staff participate in the implementation and recording of corrective action. The effectiveness of corrective action is monitored and any further necessary corrective actions implemented. The returned results are evaluated for trends that indicate potential nonconformities and preventive action is taken.

7.3.7.4: Comparability of examination results

There are defined means within individual departments, itemised in the associated documents list at the end of this document, for comparing procedures, equipment and methods used and

establishing the comparability of results across platforms and across sites for patient samples throughout the clinically appropriate intervals.

The laboratory would notify users of any differences in comparability of results and discuss any implications for clinical practice when measuring systems provide different measurement intervals for the same measurand (e.g. glucose) and when examination methods are changed.

The laboratory documents, records and, as appropriate, expeditiously acts upon results from the comparisons performed. Problems or deficiencies identified are acted upon and records of actions retained.

7.4: Post-examination processes

7.4.1: Reporting of results

Individual departments within the directorate have specific procedures, itemised in the associated documents list at the end of this document, to ensure that competent authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

When the procedure for reviewing results involves automatic selection and reporting, review criteria have been established, approved and documented

7.4.1.1: General

There is a procedure that has been established in collaboration with users for reporting results [PO-U-GEN-ReportingResults] which includes:

- Electronic transmission via the GP link and the ICE electronic reporting system
- Telephoned (verbal)
- Amended reports
- Clinical advice and interpretation

  The results of each examination are reported accurately, clearly, unambiguously and in accordance with any specific instructions in the examination procedures.
- There is a pathology wide policy which gives guidance on transcription of results: Correctness of transcription of laboratory data, [PO-U-GEN-Correctness of transcription] and individual departments within pathology have details within individual SOPs to ensure the correctness of transcription of laboratory results.
- Reports include the information necessary for the interpretation of the examination results.
- The laboratory through the individual departments has processes in place for notifying the requester when an examination is delayed that could compromise patient care.

7.4.1.2: Result review and release

The procedure for reporting results [PO-U-GEN-ReportingResults] includes telephoning results. Specific departmental SOPs give more detail relevant to the type of information they need to transmit if necessary. These include:

- Circumstances for phoning reports.
- Staff authorised for giving or receiving reports.
- Methods for mutual identification, confirmation, and maintenance of confidentiality.
- Recording mechanisms.
- Requirements for sending a follow-up report.

7.4.1.3: Critical result reports

The laboratory through the individual departments has processes in place for notifying the requester when an examination falls within established critical decision limits
The Pathology Website has details of staff to contact for emergency or out of hours

7.4.1.4: Special considerations for results

In order to effectively communicate laboratory results and meet the users' needs the laboratory ensures that on the report

- Comments are made on sample quality where this might compromise examination results
- Comments are made regarding sample suitability with respect to acceptance/rejection criteria:
- Critical results, where applicable are highlighted:
- Interpretive comments on results are added where applicable, which may include the verification of the interpretation of automatically selected and reported results in the final report.

7.4.1.5: Automated selection, review, release and reporting of results

The laboratory implements a system for automated selection and reporting of some results from some departments and has established procedures to ensure that:

a) The criteria for automated selection and reporting are defined and approved by relevant and appropriately qualified staff within that department and are available and understood by the staff

b) The criteria mentioned above are used by the relevent Departmental IT Lead liaising with the Pathology IT manager to set up rules within the various systems ,which are validated for proper functioning before use and verified after changes to the system that might affect their functioning.

c) The process for indicating the presence of sample interferences (e.g. haemolysis, icterus, lipaemia) that may alter the results of the examination is part of the data manager linked to the main analysers and ensures that data received by the host computer system already

contains relevant information about these interferences. In many cases the results are automatically removed before getting to the LIMS if the interference level is such that the result could be adversely affected.

d) The process for incorporating analytical warning messages from the instruments into the automated selection and reporting criteria is part of the data manager linked to the main analysers and ensures that data received by the host computer system already contains relevant information about these warnings:

e) Results selected for automated reporting are identifiable on the auto-authorisation PC at the time of review before release and include date and time of selection:

f) Should the automated selection and reporting of results need to be suspended this could be rapidly achieved by the Departmental IT lead in conjunction with the Pathology IT Manager, changing the rules on the pathology computer system, in agreement with Lab Clinical Director and Managers.

7.4.1.6: Requirements for reports

The reports are designed to comply with the needs of the users and the requirements of the local medical records system.

In order to effectively communicate laboratory results and meet the users' needs the laboratory ensures that on the report

- Comments are made on sample quality where this might compromise examination results:
- Comments are made regarding sample suitability with respect to acceptance/rejection criteria:
- Critical results, where applicable are highlighted

7.4.1.7: Additional information for reports

The reports include the following (where available):

- Laboratory name
- Unequivocal patient identification information on each page of the report.
- Requester name and address for delivery where supplied
- Type of specimen, date and time of collection where supplied
- Time and date of reporting
- Results, including reasons if no examination is performed
- Reference intervals where appropriate
- Interpretative comments where appropriate.

- Highlighting of abnormal results and/or inclusion of critical limits
- A comment if the test is/is not accredited to the ISO 15189 standard
- Status of report as appropriate.
- Page number to total number of pages (e.g. “Page 1 of 5”, “Page 2 of 5”, etc.).
- Where possible identification of person(s) verifying and authorising the release of the report.

There is a Pathology referral to other laboratories policy [MR-U-GEN-Examination by Referral Labs and Consultants].

Reports issued following receipt of the results from referral laboratories or Consultants additionally include:

- Identification of the referral laboratory. Where a laboratory is identified by a code, the name and address of the referral laboratory is available on request
- All the results
- A comment if the test is/is not accredited to the ISO 15189 standard
- Appropriate interpretative comments received from the referral laboratory.

7.4.1.8: Amendments to reported results

The procedure for reporting results [PO-U-GEN-ReportingResults] includes the process for amended reports and includes:

- The criteria and reason for issuing an amended report.
- The process of staff authorisation to amend reports.
- Identification to the user of amended reports.
- Recording of amendments made to reports as well as evidence of the original results via the computer audit trail.
- The instigation of corrective and preventive action, if required. (ISO 15189 2022:7.4.1.8)

7.4.2: Post-examination handling of samples

The laboratory has a documented procedure [PO-U-GEN-CtrlClinMat] along with linked departmental procedures, itemised in the associated documents list at the end of this document, for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples which is based on the current edition of: *The retention and storage of pathological records and specimens – The Royal College of Pathologists and the Institute of Biomedical Science*

Individual departments procedures also define the length of time clinical samples are to be retained with retention time being defined by the nature of the sample, the examination and

any applicable requirements with processes being in place for those instances where legal liability concerns regarding certain types of procedures (e.g. histology examinations, genetic examinations, paediatric examinations) require the retention of certain samples for much longer periods than for other samples.

Safe disposal of samples is carried out in accordance with individual departments procedures in a way which is commensurate with the risk involved with the specific sample type.

7.5: Nonconforming work

There is a procedure for Identification and control of non-conformities (PR-U-GEN-Non-conformance procedure) which includes determining appropriate Preventive and Corrective Action and ensures that nonconformities identified from pre-examination, examination or post-examination processes are effectively managed. There is also a procedure for recording these and any necessary actions on iPassport (PR-U-GEN-Recording of Non-Conformances on iPassport)

It is appreciated that nonconforming examinations or activities occur in many different areas and can be identified in many ways, including clinician complaints, internal quality control indications, instrument calibrations, checking of consumable materials, inter-laboratory comparisons, staff comments, reporting and certificate checking, laboratory management reviews.

The procedure therefore ensures that the requirements of the ISO 15189 standard are met in that:

- the responsibilities and authorities for handling nonconformities are designated:
- the immediate actions to be taken are defined:
- the extent of the nonconformity is determined:
- examinations are halted and reports withheld as necessary:
- the medical significance of any nonconforming examinations is considered and, where appropriate, the requesting clinician or authorised individual responsible for using the results is informed:
- the results of any nonconforming or potentially nonconforming examinations already released are recalled or appropriately identified, as necessary:
- the responsibility for authorization of the resumption of examinations is defined:
- each episode of nonconformity is documented and recorded, with these records being reviewed at regular specified intervals to detect trends and initiate corrective action.

There are also procedures for recalling blood components associated with internal and external notification and reporting of adverse transfusion incidents and events to the MHRA via SABRE and where appropriate SHOT.

7.6: Control of data and information management

7.6.1: General

Laboratory Management ensures the availability of data and information required to provide a service that meets the needs and requirement of users. The Laboratory Information Management System is WinPath and was procured from CliniSys in 2006.

There is an electronic document control system used for quality management (iPassport) and this is administered by the Departmental Laboratory Managers and Quality Managers.

SGSS (formally CoSurv) is jointly managed by the Office of the Regional Epidemiologist and the Trust IT Department.

ComputaCentre maintains all hardware and networks Trust wide.

There is a procedure [MR-U-GEN-Data&InfoManagement] for the management of data and information.

Managers, the Trust Information Security Officer and the Caldecott Guardian are responsible for implementation of The Trust Information Governance Policy [WAHT-CG-579] to ensure compliance with current national legislation and regulations in relation to data protection. There is also a Pathology Policy [PR-U-GEN-TrustComputerUse] which supports the Trust Information Governance Policy (ISO 15189 2022:7.6).

There are procedures [PO-U-GEN-ReportingResults] for ensuring that the reports are handled and transmitted confidentially according to Trust Information Governance Policy [WAHT-CG-579]**.** Access to the computer is password controlled, transmitted electronic data is encrypted and hard copies of reports are treated as confidential. (ISO 15189 2022:7.6.1)

7.6.2: Authorities and responsibilities for information management

The authorities and responsibilities for the management of the information system are defined, [MR-U-GEN-Data&InfoManagement] including the maintenance and modification to the information system(s) that may affect patient care. There are various levels of access which are determined by laboratory managers and then set up on the system by the Pathology IT Manager.

7.6.3: Information systems management

The system(s) used for the collection, processing, recording, reporting, storage or retrieval of examination data and information is validated by the supplier and verified for functioning by the laboratory before introduction with any subsequent changes to the system being similarly authorized, documented and verified before implementation;

Documentation has been produced including that for day to day functioning of the system and is readily available to authorized users;

The system is password protected with an automatic timeout and mandatory password changes to protect it from unauthorized access;

The hardware is secured against tampering or loss;

The system is operated in an environment that complies with supplier specifications.

Regular maintenance is carried out on the system to ensure the integrity of the data and information and system failures are recorded along with the appropriate immediate and corrective actions.

The system complies with national or international requirements regarding data protection.

Systems are in place to verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information (e.g. computer systems, e-mail, website, personal web devices). When a new examination or automated comments are implemented, the laboratory verifies that the changes are accurately reproduced by the information systems external to the laboratory intended to directly receive information from the laboratory.

7.6.4: Downtime plans

The laboratory has documented contingency plans to maintain services in the event of failure or downtime in information systems that affect the laboratory's ability to provide service. [PO-U-GEN-PathologyITBusinessContinuityPolicy]

7.6.5: Off site management

Laboratory management maintains responsibility for ensuring that the provider or operator of the system complies with all applicable requirements of this International Standard for the parts of the information system(s) which are managed and maintained off-site or sub-contracted to an alternative provider.

7.7: Complaints

7.7.1: Process

Feedback received from clinicians, patients, laboratory staff or other parties is dealt within pathology following the pathology wide policy, [PO-U-GEN-Userfeedback] or in the event of a specific complaint this would be dealt with by the pathology wide complaints policy [MR-U-GEN-Complaints]. As detailed in that policy anything that was a formal complaint would then be managed using the Trust Complaints Process flowchart, [ED-U-GEN-Trust Complaints Process flowchart].

7.7.2: Receipt of complaint

Records are maintained in the complaints section of iPassport of all complaints, formal or informal, their investigation, including investigation of the root cause, and the action taken by both the laboratory and the Trust complaints department, where appropriate.

7.7.3: Resolution of complaint

Any other feedback would be dealt with by the Laboratory Clinical Director/Lab manager who would investigate, raise non-conformances as appropriate and take what action was possible to resolve the highlighted issues. Communicating the outcome to the appropriate personnel.

7.8: Continuity and emergency preparedness planning

Each Pathology laboratory has documented Business Continuity plans to maintain services in the event of failure or downtime, with a separate Pathology LIMs Continuity plan [PO-U-GEN-PathologyITBusinessContinuityPolicy]

8: Management system requirements

8.1: General requirements

8.1.1: General

Laboratory management is committed to the development and implementation of the quality management system and continually improves its effectiveness.

This is achieved through;

- Each department having a Quality Manager and quality lead(s) that have, irrespective of other responsibilities, delegated responsibility and authority as detailed previously above.
- User needs and comments being fed through PQAC to PEMC ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.
- The roles which are responsible for the quality management system (QMS) are described below, and defined within Departmental/discipline specific individual Job Descriptions (see AD-U-GEN-DirectorateOrgChart and post holder form)
- The Quality Manager/Lead has responsibility for implementation and maintenance of the QMS but not for undertaking all the tasks involved. They may be engaged full-time or part-time on quality management.
- Laboratory management through PQAC ensures that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. Quality manual: The Pathology Quality Manual is reviewed at least annually by PQAC, updated as required and any changes communicated to all personnel concerned. This document includes the Quality Policy, description of the scope of the QMS, organisational structure, roles and responsibilities of laboratory management, quality management structure and documentation and is accessible to all staff. (ISO 15189 2022:8.2.1)

8.1.2: Fulfilment of management system requirements

The following groups/committees are responsible for the creation, implementation, review and amendment of the QMS used across Pathology in Worcestershire.

Documentation is controlled through the use of an electronic document control system supplied by Genial Genetics called iPassport.

Pathology Executive Management Committee (PEMC)

The Pathology Executive Management Committee meetings are held monthly. There is a defined constitution and terms of reference [MR-U-GEN-ExeMeetConst]. Its principal function is to define the strategy for Pathology and monitor performance.

The Committee includes the Pathology Clinical Director, Clinical Service Manager, Directorate Manager, Laboratory Clinical Directors, Laboratory Managers, Pathology IT Manager, other Band 8 pathology staff, Human Resources representative and a finance representative.

Chairman: Pathology Clinical Director / Clinical Service Manager/ Directorate Manager

Secretary: Personal Assistant to directorate

Pathology Quality and Accreditation Committee (PQAC)

The Directorate Quality & Accreditation Committee meets monthly. It has a defined constitution and terms of reference [MR-U-GEN-PQACMeetConst]. Its principal function is to oversee and steer the quality management system and accreditation issues for Pathology. This group reviews risk reporting incidents and advises on clinical governance. PQAC is also responsible for the management of pathology wide documents including the development and updating of the pathology web pages.
The Committee includes the Clinical Service Manager, Directorate Manager, Pathology Quality Manager, Individual Laboratory managers, Clinical Directors, Quality Managers/Quality Leads and IT Lead.

Chairman: Quality Manager / Clinical Service Manager

Secretary: Personal Assistant to directorate.

PQAC oversee subgroups which deal with specific aspects of the quality agenda

User Interaction Groups

This group co-ordinates interaction, consultation and feedback with users. It has a defined constitution and terms of reference [MR-U-GEN-PQACMeetConst]. Because of the differing needs of internal and external users the group meets with Hospital staff and Primary Care representatives separately, 3 times per year

The group includes User representatives which may be clinical or managerial, Pathology General Manager, Individual Laboratory Managers, Pathology IT Manager, Laboratory Directors and Pathology Consultant staff, as well as specific individuals relevant to the agenda items.

Chairman: Principal Clinical Scientist.

Secretary:

In addition to the User Interaction Group, additional subgroups are formed as appropriate, i.e. Policies & Procedures and report to the PQAC on the specific areas they have been set up to deal with.

HTA Governance committee

The HTA Governance committee meets quarterly. Its purpose is to ensure the HTA DI is aware of any issues across the two sites, raise awareness of HTA and make the staff groups aware of any new legislation. It is also a forum for mortuary / hospital staff to raise any suggestions.

The committee includes: HTA DI (chair), Mortuary manager, Clinical Service Manager, Directorate Manager, Laboratory manager or deputy, Mortuary staff – all or representative, Hospital representatives – Family Health, A&E

Chairman: Dr W Haddadin, Consultant Histopathologist

Secretary: Minutes are taken by the lab manager

HTC committee

The Hospital Transfusion Committee (HTC) meets quarterly and acts as an expert forum of the Clinical Governance Group. It has been established to ensure safe and appropriate transfusion practice within the organisation using local protocols based on national guidelines.

Its remit includes:

- Implementation of national guidelines into trust practice
- Implementation of Serious Hazards Of Transfusion recommendations into the trust
- Monitoring transfusion incidents and risk
- Monitoring blood usage and wastage within the trust and benchmarking against other trusts usage and wastage
- Monitoring training of staff involved in transfusion practise
- Developing contingency plans in case of blood shortages
- Ensuring compliance with Blood Safety and Quality Regulations 2005.

The committee includes: Haematology Clinical Director, Blood Bank manager, Lead Transfusion Practitioner, Consultant physician, Consultant anaesthetist, Consultant surgeon, Consultant paediatrician, Consultant Obstetrics and Gynaecology, A&E consultant, Worcester Health and Care trust (HACW) representative.

Chairman: The Haematology Clinical Director will chair the meetings. In the absence of the chair an alternative consultant haematologist will be nominated.

Secretary: Secretarial support will be through the Transfusion Practitioners and pathology.

Antenatal & Newborn Screening Steering Group

New national guidance to support providers in addressing inequalities throughout the antenatal and newborn (ANNB) screening pathway.

The guidance was developed by a national PHE Screening team that included representatives from each of the 6 ANNB screening programmes:

- foetal anomaly screening

- Infectious diseases in pregnancy screening
- sickle cell and thalassaemia screening
- newborn and infant physical examination (NIPE)
- newborn blood spot screening
- newborn hearing screening

The Antenatal and Newborn Screening Steering group meets quarterly to ensure safe and appropriate practice within the organisation through the use of local protocols based on national guidelines.

Attendees from Microbiology and Blood Sciences produce and present reports for the group.

8.1.3: Management system awareness

Each department has a Quality Manager and or quality lead(s) that have, irrespective of other responsibilities, delegated responsibility and authority that includes ensuring that processes needed for the quality management system are established, implemented, and maintained.

They also submit detailed reports to laboratory management through PQAC, on the performance of the quality management system and any need for improvement. If necessary, these can be raised to PEMC.

User needs and comments are fed through PQAC to PEMC ensuring the promotion of awareness of users' needs and requirements throughout the laboratory organization.

Individual staff members are introduced to Quality Management at induction, staff must demonstrate competence in Quality, and are involved in Quality Management within Laboratory Meetings

8.2: Management system documentation

8.2.1: General

The quality management system documentation includes:

a) statements of a quality policy (see 5.5) and

b) a quality manual (see 8.2)

c) quality objectives (see 5.5); determined by each individual department to align with the achievement of the above.

d) procedures, documents and records determined by the laboratory as required to comply with both ISO 15189 and to ensure the effective planning, operation and control of its processes;

e) copies of applicable regulations, standards and other normative documents.

8.2.2: Competence and quality

Key Performance Indicators; the Directorate uses an agreed template for monitoring departmental performance indicators as described below.

The following KPI's are reported to the Specialised Clinical Services Division monthly Performance and Planning meeting.

Turn Around Time performance against target for:

Cellular Pathology

All Cellular pathology requests (70% within 10 days)

All Cytology requests (70% within 10 days)

Clinical Biochemistry

- Creatinine for Emergency Department (90% within90 mins)
- Creatinine for GP (90% within 24 Hours)
- Troponin-T for Emergency Department (90% within 90 minutes)

Haematology

- Full Blood count for Emergency Department (both sites) (90% within 1 hour)
- Full Blood Count for GPs (both sites) (90% within 24 hours)

Blood Transfusion

Foetal Genotyping 95% in 10 working days

Kleihauer testing 95% in 24 hours

Microbiology

- MRSA for Acute Trust (95% within 2 Days)
- Urine M&CS for GP (95% within 3 Days)
- Covid-19 urgent tests (within 4 hours)
- C. difficile for acute and primary care (100% 24 hrs)

The above turnaround times have been chosen as they provide assurance that Pathology supports patient flow within the Trust (A&E times and MRSA reporting), meets standards for Bowel Cancer screening programme and provides timely reports for primary care.

Accreditation status with UKAS, MHRA and HTA are reported together with IBMS portfolio Training status for all Departments.

The numbers of incidents which require reporting to SABRE or HTA are monitored.

These performance indicators provide the Trust with information on a range of key areas. (ISO 15189 2022:5.5)

In addition to this the disciplines within pathology can record other quality indicators which can be used internally to facilitate continuous quality improvement. LP-U-HAE.TRA Procedure for

Establishing and Monitoring Quality Indicators; MR-U-HIS-Quality Indicators Procedure; LP-U-CHM-Performance Indicators; DP-U-MIC-QPIProcedure

Laboratories have established turnaround times for each examination that reflects clinical needs. These are monitored through PQAC where remedial or corrective action is discussed. Other performance indicators which are regularly audited include IQA and EQA performance, sickness absence, mandatory training and complaints. Departments and the Directorate participate fully in the evaluation of clinical effectiveness, audit, and risk management activities of the parent organisation, and have close links with the Risk and Clinical Governance team. The PQAC reviews clinical incidents and any high risks are added to the Trust Risk Register. (ISO 15189 2022:8.6.2/8.9)

8.2.3: Evidence of commitment

Laboratory Management through the Pathology Executive Management Committee is committed to the development, implementation and continual improvement of its quality management system (QMS). This requirement is achieved by:

- Ensuring that all laboratory personnel are aware of and comply with regulatory and accreditation requirements.
- Ensuring that all laboratory personnel are aware of and comply with the needs and requirements of service users.
- Establishment of the Directorate Quality Policy (see below).
- Ensuring that quality objectives and plans to achieve these objectives are in place.
- Defining the responsibilities, authorities and interrelationships of all personnel
- Establishment of effective communication processes with staff and also with the service stakeholders.
- Establishment and appointment to the role of Quality Manager
- Ensuring that management reviews are carried out on a regular basis to the depth required by the ISO 15189 standard.
- Ensuring that staff are competency assessed to provide assurance that they are competent to perform their assigned activities.
- Ensuring that there are adequate resources to enable the proper conduct of pre-examination, examination, and post-examination activities.

8.2.4: Documentation

The laboratory management have established and maintain this quality manual that includes:

a) the quality policy (5.5)

b) a description of the scope of the quality management system;

c) a presentation of the organization and management structure of the laboratory and its place in the parent organization including a description of the roles and responsibilities of laboratory management (including the laboratory clinical Director and quality manager)

d) Information about the structure and relationships of the documentation established for the quality management system and reference to the managerial and technical activities that support them.

8.2.5: Personnel access

All laboratory staff have access to and are instructed on the use and application of the quality manual and the referenced documents.

8.3: Control of management system documents

8.3.1: General

Documents are prepared both on a pathology wide basis and within individual departments. Every opportunity is taken to harmonise these documents across pathology to reduce duplication and ensure single ways of working. Irrespective of whether the document is department specific or pathology wide the same process is followed so that both the preparation and control of documents is in accordance with the document control policy and procedure [MO-U-GEN-Document Control].

8.3.2: Control of documents

The first 3 parts of the title of any document thus prepared indicate the type of document, site or 'U' if universal and department or 'GEN' if pathology wide. Authorisation of these documents is carried out by senior staff within the discipline for department specific documents while pathology wide ones are authorised by the Pathology Clinical Service Manager, if non-clinical, and the Clinical Dierctor, if clinical. Once authorised, documents are available for everybody to use on iPassport and reading records are stored on the system. Superseded protocols are then not widely visible but are retained by the system.

a) All documents issued as part of the quality management system are reviewed and approved by authorized personnel before issue.
b) All documents are identified to include:
   — a title;
   — a unique identifier on each page;
   — the date of the current edition and/or edition number;
   — page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5,");
   — authority for issue.
c) Current authorized editions and their distribution can be identified on demand by producing a list from iPassport.
d) The minimum amounts of hard copy documents are used but where this is the case only current, authorized editions of applicable documents are available at points of use.
e) Documents remain legible.
f) Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.
g) Obsolete controlled documents are removed and made inaccessible to all but senior staff on iPassport.
h) All previous versions of obsolete controlled documents are retained in iPassport for as long as the system is live.

8.4: Control of records

8.4.1: Creation of records

- The control of process and quality records is governed by the Pathology wide policy [PO-U-GEN-ControlProcessQualRec] and similar departmental procedures which cover those items specific to individual areas are linked in iPassport to this policy.
- Notice is taken of current legislation, regulations and guidelines including those provided by the IBMS/Royal College of Pathologists [ED-U-GEN-The retention and storage of pathological records and specimens (6th edition, 2025)] in determining which process and quality records (including quality records of external origin) are to be retained and for how long.
- The control of clinical material is governed by the Pathology wide policy [PO-U-GEN-CtrlClinMat] and similar departmental procedures which cover those items specific to individual areas are linked in iPassport to this policy.
- One of the Consultant Pathologists is the HTA Designated Individual for the Trust. (ISO 15189 2022: 6.3.3/7.4.2)

8.4.2: Amendment of records

Where documents are amended by hand, pending the re-issue of documents, the procedures and authorities for such amendments are defined, amendments are clearly marked, initialled and dated, and a revised document is issued within a specified time period in compliance with [MO-U-GEN-Document Control].

Changes to documents are identified either by change sheets attached to each document and or with change information attached to each version of the document within iPassport.

8.4.3: Retention of records

Documents are periodically reviewed and updated at a frequency that ensures that they remain fit for purpose.

Obsolete controlled documents are removed and made inaccessible to all but senior staff on iPassport.

All previous versions of obsolete controlled documents are retained in iPassport for as long as the system is live in line with PO-U-GEN-ControlProcessQualRec

8.5: Actions to address risks and opportunities for improvement

8.5.1: Identification of risks and opportunities for improvement

It is recognised that preventive action is a proactive process for identifying opportunities for improvement rather than a reaction to the identification of problems or complaints (i.e. nonconformities). For this reason, it can result from several sources, in addition to review of the operational procedures, including analysis of data, trend and risk analyses and external quality assessment (proficiency testing).

The detail of how this is carried out can be found in the procedure: PR-U-GEN-Non-conformance procedure

The laboratory determines actions to eliminate the causes of potential nonconformities to prevent their occurrence utilising [MR-U-GEN-Process risk management] ensuring that any preventive actions taken are appropriate to the effects of the potential problems and are fully documented on iPassport

Once this has all been done the effectiveness of the preventive action taken is reviewed and modified as necessary.

8.5.2: Acting on risks and opportunities for improvement

The laboratory determines actions to eliminate the causes of potential nonconformities to prevent their occurrence utilising [MR-U-GEN-Process risk management] ensuring that any preventive actions taken are appropriate to the effects of the potential problems and are fully documented on iPassport

Once this has all been done the effectiveness of the preventive action taken is reviewed and modified as necessary.

8.6: Improvement

8.6.1: Continual improvement

The department has a procedure: [PO-U-GEN-Continuous Quality Improvement] which identifies the many ways that we as a provider of laboratory services strive to ensure that we aim for continual improvement in everything we do.
Individual disciplines within pathology carry out management and other reviews on a regular basis covering all aspects of the service provided. These other reviews include such things as corrective and preventive actions resulting from non-conformances, evaluation of IQC and EQA, staff suggestions as well as changes imposed by methodology or system changes. The purpose of these reviews is to ensure that there is continual improvement in the way work is performed and a constant strive to maintain a service of the highest quality as stated in our quality policy. Improvement activities are prioritised at senior staff meetings based on the effect of the issue(s) identified obviously giving issues affecting patient outcome the highest priority and communicated to staff through the daily huddles that occur in each department. As per: [PR-U-GEN-Non-conformance procedure] all non-conformances are recorded on iPassport where the action plans are developed, documented, and implemented as appropriate. The procedure also identifies that: In all cases it is vital that any corrective actions are determined, implemented and along with any remedial or preventive actions which were put into place are monitored by subsequent re-audit or by other appropriate means to ensure the actions have corrected the cause of the non-compliance and have not resulted in any deleterious effects elsewhere. This whole process is monitored by Laboratory management at the monthly Pathology Quality and Accreditation (PQAC) meetings where data is submitted by discipline of outstanding non-conformances, audits and documents due for review. As well as these other issues are also reviewed including compliments/complaints, NICE guidance, items on risk register or anything else which has the potential to affect our ability to provide a high-quality service

8.6.2: Laboratory patients, user, and personnel feedback

The laboratory seeks information relating to user perception as to whether the service has met their needs and requirements through a variety of means including regular user group

meetings, surveys and individual meetings ensuring confidentiality is maintained to other users at all times. Records are kept of this information collected and actions taken. [PO-U-GEN-UserFeedback]

Laboratory management encourage staff to make suggestions for the improvement of any aspect of the laboratory service. [LF-U-GEN-Staff Suggestion for Improvement Form]. Suggestions are evaluated, implemented as appropriate and feedback provided to the staff. Records of suggestions and action taken by the management are maintained within each individual department. There is also a facility on iPassport whereby any member of staff who wishes to suggest an amendment to a policy, procedure, SOP, etc. can register this on passport at any time and this is then passed to the document owner who can do one of three things:

1) Reject it as not appropriate,

2) Accept it for immediate incorporation into the document,

3) Accept it to be incorporated into a future version of the document.

This information is then fed back to the sender so that they know what has happened with their suggestion.

8.7: Nonconformities and corrective actions

8.7.1: Actions when nonconformity occurs

As per the above named procedure all nonconformities are reviewed as soon as possible after they are found by a senior member of staff to determine the severity and effect which then helps to determine the management route for that particular non-conformance. Once any immediate remedial action felt to be needed has been carried out then:

- The root cause is determined using one of the standard techniques, i.e. 5 whys, fishbone analysis or any other system felt to be appropriate to the particular circumstance. Once this is done it is then possible to:

- evaluate the need for corrective action to ensure that nonconformities of this sort do not recur and then:

- the appropriate corrective action needed is determined, implemented and recorded: Once this has all been done:

8.7.2: Corrective action effectiveness

The effectiveness of the corrective action taken is reviewed and modified as necessary.

8.7.3: Records of nonconformities and corrective actions

Records of non-conformities and actions relating to the nonconformity are recorded in iPassport. All non conformities are discussed at Departmental Quality meetings

8.8: Evaluations

8.8.1: General

There are a number of ways in which we as Pathology and individual disciplines demonstrate that the pre-examination, examination, post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users. This helps to ensure conformity to the quality management system and where deficiencies are identified allows us to continually improve the effectiveness of the quality management system.

These include but are not limited to:

- Assessment of user satisfaction and complaints
- Internal audit of the quality management system
- Internal audit of examination processes
- External quality assessment
- Reports from external assessment bodies.
- Quality improvement, including corrective and preventive action and the monitoring of quality indicators
- Identification and control of nonconformities

The results of these evaluations and subsequent improvements are made available to staff through the daily huddles or staff meetings and to users through the minutes of meetings as required. This information is also analysed and entered into the management review process.

8.8.2: Quality indicators

The process of monitoring quality indicators (5.5) are planned to establish Service efficiency. These are discussed at Department Quality Meetings, PQAC, PEMC and at Quality Management Reviews to determine appropriateness

8.8.3: Internal audits

The laboratory has a documented procedure to define the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records. [PO-U-GEN-Audit policy and procedure]

The audit programme considers the status and importance of the processes and technical and management areas to be audited, as well as the results of previous audits.

Audit training forms part of the programme identified within this document. All such training is carried out by competent peer auditors within departments.

The audit criteria, scope, frequency and methods are defined in individual departments audit calendars.

Audit activities, nonconformities found and time scales for corrective and preventive actions are recorded.

The results of internal audit are regularly evaluated by departmental quality managers, quality leads and by the PQAC and escalated to the Pathology Executive Management Committee (if appropriate). Decisions and actions taken are documented, monitored and communicated to personnel as appropriate.

8.8.3.1 QMS

Internal audit of the quality management system is conducted as part of the Pathology audit policy [PO-U-GEN-Audit policy and procedure], planned and scheduled as part of the audit calendar and conducted against agreed criteria.

8.8.3.2 Examination Processes

The internal audit processes for pre-examination, examination and post examination processes [PO-U-GEN-Audit policy and procedure], are part of the scheduled internal audit calendar which is specific to each discipline, these are given priority as there is a patient risk involvement assigned to Laboratory activities. As with internal audits of the quality management system, audit is conducted against agreed criteria and performed by individuals with appropriate training.

Personnel responsible for the area being audited ensure that appropriate action is promptly undertaken when nonconformities are identified. Any necessary remedial actions are taken and then corrective action is taken without undue delay to eliminate the causes of the detected nonconformities, once the root cause analysis has been conducted. These are then recorded and any further changes needed implemented and the process re-audited.

8.9: Management reviews

8.9.1: General

Each department in Pathology conducts regular reviews of the laboratory's quality management system to ensure its continuing suitability, adequacy and effectiveness and support of patient care. LF-U-HAE.TRA-Quality management meeting TOR; LP-U-HIS-QMRTOR; LP-U-CHM-QMRTOR; MP-U-MIC-MQAC MeetiConst

8.9.2: Review input

The review includes all that is required by ISO 15189 and key quality objectives identified from this review are defined and plans formulated for their implementation with agreed timeframes (ISO 15189 2022:5.5). These documents are then stored on iPassport.

In addition to the above, the blood transfusion department submits an annual report to the MHRA that includes a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with BSQR 2005, as amended, and provides details of how these systems ensure such compliance. (BSQR 10.1.a/b). These documents are also stored on iPassport.

The review analyses the input information for causes of nonconformities, trends and patterns that indicate process problems particularly where these could or have affected the laboratory's contribution to patient care.
Once identified these issues are used as opportunities for improvement [PO-U-GEN-Continuous Quality Improvement] and if necessary the need for changes to the quality management system, including the quality policy and quality objectives.

8.9.3: Review output

The output from the management review is incorporated into a record documenting any decisions made and actions taken during the management review related to:

a) improvement of the effectiveness of the quality management system and its processes;
b) improvement of services to users;
c) resource needs.

Any findings and actions arising from management reviews are recorded and reported to laboratory staff through the various methods detailed earlier in this document and are also made available on iPassport for all to see at any time.

Laboratory management also ensures that any actions arising from management review are completed within a defined and reasonable timeframe which is appropriate to the importance of the issue identified and that these are reviewed at subsequent review meetings.

Associated Documents

Pathology - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)	Pathology Website
Our board Archive - Worcestershire Acute Hospitals NHS Trust (worcsacute.nhs.uk)	Trust Board
AD-U-GEN-DirectorateOrgChart	Directorate Organisational Chart
AD-U-MIC-DepartOrgChart	Microbiology Organisational Chart
AD-U-CHM-Organisationalchartchemistry	Biochemistry Organisational Chart
AD-U-HIS-DepartmentalOrganisationalChart	Cell Path Organisational Chart
AD-U-GEN-HaematologyandBloodTransfusionorganisationchart	Haematology and Blood Transfusion organisational chart
MR-U-GEN-ExeMeetConst	Executive Management Committee
MR-U-GEN-PQACMeetConst	Pathology Quality & Accreditation Committee Terms of Reference
ED-U-GEN-Declarationofinterestsandacceptanceofgiftsandhospitality	Standards of Business Conduct-Declaration of interests and acceptance of gifts and hospitality
ED-U-GEN-Code of Conduct in respect of Confidentiality	Code of Conduct in respect of

	Confidentiality
ED-U-GEN-Trust Complaints Process flowchart	Trust Complaints Process flowchart
PO-U-GEN-Userfeedback	User Feedback
MR-U-GEN-Complaints	Complaints procedure
ED-U-GEN-Pneumatic tube policy	Pneumatic tube transfer service operational policy
MO-U-GEN-Document Control	Document Control Policy and Procedure
PR-U-GEN-PersonnelManagement	Personnel Management
PO-U-GEN-PathologyIndPolicy	Pathology Induction Policy
PO-U-GEN-Training Policy	Training Policy
LP-U-GEN-Personal Development review process	Personal Development review process
PO-U-GEN-CtrlClinMat	Control of Clinical Materials
LP-U-HAE.TRA Control, Retention and Storage of Records and Clinical Materials	Control, Retention and Storage of Records and Clinical Materials
LP-U-MIC-CtrlCliMat	Procedure for the control of clinical material
LP-U-CHM-Control of Clinical Material	Procedure for the Control of Clinical Material
LP-U-HIS-CtrlCliMat	Procedure for the control of clinical material
PO-U-GEN-ControlProcessQualRec	Control of Process & Quality Records
LP-U-MIC-CtrlProcQualRec	Control of microbiology process & quality records
MO-U-HIS-Control of Process and Quality Records	Control of Process and Quality Records
LP-CHM-ControlProcessRecords	Control of Process and Quality Records
LP-U-HAE.TRA Control, Retention and Storage of Records and Clinical Materials	Control, Retention and Storage of Records and Clinical Materials
MR-U-GEN-External Services and Supplies	External Services and supplies
MR-U-GEN-ProcMgtEquip	Procurement and Management of Equipment
Medical Devices policy including Education and Training: WAHT-CG-022	Trust Medical Devices policy
PO-U-GEN-ManagementMaterials	Management of Materials Policy

LP-U-CHM-8000 Automated Section Stock Control and Pre Acceptance	Automated Section Stock Control & Pre Acceptance
LP-W-CHM-SEMI-AUTOMATED SECTION STOCK CONTROL & PRE-ACCEPTANCE	Semi-automated Section Stock Control & Pre-acceptance
LP-U-MIC-StockControlandOrdering	Stock Control and Ordering
LP-U-HAE-STOCK CONTROL	Stock control Haematology
LP-U-HIS-Acceptance testing and receipt of goods	Acceptance testing and receipt of goods
LP-U-MIC-ConsumableAcceptanceProcedure	Consumable Acceptance procedure
LP-U-COAG-PROCEDURE FOR RECEIPT AND PRE-ACCEPTANCE TESTING IN COAGULATION	Procedure for Receipt and Pre Acceptance Testing in Coagulation
LP-U-HAE-Reagentacceptanceandverificationhaematology - Reagent acceptance and verification haematology	
LP-U-TRA-Reagent pre acceptance testing	Reagent pre acceptance testing
LF-W-HAE-Receipt and pre-acceptance testing for TOSOH G8 reagents	Receipt and pre-acceptance testing for TOSOH G8 reagents
LP-W-CHM-TOSOH G8 Stock acceptance	TOSOH G8 Stock delivery and Pre-Acceptance
LP-U-GEN-Selection and Verification of Examination Procedures	Procedure for selection and Verification of Examination Procedures
LF-U-GEN-Verification of Examination procedures	Verification of Examination procedures form
PO-U-GEN-Validation and Verification Policy	Validation and Verification Policy
MR-U-GEN-Process Risk management	Process Risk management
MR-U-GEN-Examinationbyreferrallabsandconsultants -Examination by referral labs and consultants	
ED –U-HAE.TRA ExternalSuppliers & Referral Laboratory Reviews	
MR-U-GEN-SLA	Procedure for Establishment & Review of Agreements to Provide Services to External Users

MR-U-GEN-Service Agreement Internal	Procedure for Establishment & Review of Agreements to Provide Services to Internal Users
PO-U-GEN-PolSpecAcceptance	Policy for acceptance and rejection of specimens
LP-U-CHM-Pre-Analytical department information	Pre-Analytical department information
LP-U-CHEM-Rejected samples	Rejected sample policy
LP-U-MIC-VirolSpecRecep	Procedure for receiving specimens in virology
LP-U-HIS-Cut up-receipt of Histology specimens	Cut up-receipt of Histology specimens
LP-A-HAE.TRA-Specimen Reception	Specimen Reception, Staffing Levels and Workflow
LP-U-MIC-SpecRecep	Specimen reception procedures
LP-W-BSC : Front Reception Procedures	Front Reception Procedures
PO-U-GEN-ReqCriteria	Requesting Criteria
PO-U-GEN-SpecTransport	Specimen Transport Policy
PO-U-GEN-Correctness of transcription	Procedure for the Correctness of transcription of laboratory data
PO-U-GEN-Continuous Quality Improvement	Continuous Quality improvement Policy
LP-U-TRA-Recall procedure	Recalling blood components/products
PO-U-GEN-ReportingResults	Policy for reporting results
PR-U-GEN-Non-conformance procedure	Non-conformance procedure
PR-U-GEN-RecordingofNon-ConformancesoniPassport - Recording of Non-Conformances on iPassport	
PO-U-GEN-Audit policy and procedure	Audit policy and procedure
LP-U-HAE.TRA Audit Procedure for Haematology	Departmental Audit Procedure & Blood Transfusion
LF-U-GEN-Staff Suggestion for Improvement Form	- Staff Suggestion for Improvement Form
ED-U-GEN-The retention and storage of pathological records and specimens (6th edition, 2025)	Retention and storage of pathological records and specimens
HS-U-GEN-COSHHPol&Procedures	Control of Substances Hazardous to Health

HS-U-GEN-Path Health &Safety policy	Pathology Health and Safety Policy
Health and Safety Policy WAHT-CG-125	Trust Health and Safety Policy
PO-U-GEN-Competenceassessmentpolic	pathology - Competence assessment policy pathology
PR-U-GEN-TrustComputerUse	Trust Computer Use Policy
MR-U-GEN-Data&InfoManagement	Data & Information Management
PO-U-GEN-PathologyITBusinessContinuityPolicy	Pathology IT Business Continuity
Trust Information Governance Policy [WAHT-CG-579]	Trust Information Governance Policy

TPS47 UKAS policy on participation in proficiency testing

GEN-1 Assessment of CAB's by UKAS

The following documents exist within individual departments as mentioned in the main text of this document.

Selection, use and interpretation of internal quality control (IQC)

LP-U-CHM-IQC validation procedure

LP-U-HIS-Internal Quality Control In Histopathology and Cytology

LP-U-COAG-COUNTYWIDE IQC PROCEDURE IN BLOOD COAGULATION

LP-U-HAE-Countywide IQC procedure

LP_U_MIC_IQCProc

LP-U-TRA-Procedure for using the automated blood group analyser Interlaboratory comparisons

LP-U-CHEM-EQA-CONTENTS

LP-U-MIC-EQA: EQA PROCEDURE

LP-U-HAE-EQAprocessing

MP-U-HIS-External Quality Assurance and Reports from external bodies

LP-U-TRA-Proficiency Testing in Blood Transfusion

Where examinations are performed using different procedures or equipment or at different sites the departments involved have mechanisms in place to ensure that results are comparable throughout clinically appropriate intervals
LP-U-CHM-QC-SAMPLE COMPARISON
LP-U-HAE-HAEMComparisons: Comparisons countywide Haematology
LD-U-TRA-Blood transfusion inter-analyser comparison
LP-U-MIC-EquipmentComparison

Procedures to ensure that competent authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.
LP-U-CHM-Clinical Validation
LP-U-HAE-Authorisation of FBC results
LP-U-HIS-HistoRptAuth (WRH)
LP-U-HIS-Reporting Procedure of NG Specimens
LP-U-HIS-Reporting of synovial fluids
LP-U-MIC-Winpath reporting

Safe disposal of samples is carried out in accordance with either the individual departments procedures or the pathology wide one in a way which is commensurate with the risk involved with the specific sample type.
LP-U-GEN-Waste disposal
LP-U-CHM-waste disposal in the automated section
DP-U-HIS-Disposal of Laboratory waste
LP-U-MIC-WasteDisposal

Environmental testing is done according to:
LP-U-HIS-FormaldehydeMon:
P-U-HIS-Weekly Airflow AFOS Monitoring
LP-U-HIS-Xylene monitoring
LP-U-HIS-Temperature Log
LP_U_MIC_TempMonitoring
LP-U-MIC-AnemometerOperationMaintenanceProc
LP_U_MIC_SterileFluidsEnvMonitoring

Departments have the following processes in place for notifying the requester when an examination is delayed that could compromise patient care.
AD-U-CHM-AS-Quick Reference Manual: Winpath
LP-U-HAE-Contingency Planning HaematologyDepartmental

Induction procedures:
LP-U-CHM-Lab Induction
LF-U-HIS-Cellular Pathology Induction
LF-U-MIC-Departmental Induction Orientation
LF-U-MIC-MicrobiologyLaboratoryInduction
LP-U-HAE.TRA Haematology Departmental Induction Programme for New Employees
TR-U-MIC-Medical Microbiology Consultant Induction
LP-U-CHM-Pre-Analytical Departmental Induction