Calderdale and Huddersfield NHS
NHS Foundation Trust

Pathology Quality Manual

Document ID	QP 100-125
Revision Number	8.0
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Authorised by	Dr Gavin Boyd. Director of Pathology

This document together with the processes and procedures specified in this represent the quality manual system of the Pathology Laboratory at Calderdale and Huddersfield NHS Trust.

It has been compiled to meet the requirements of ISO 15189. Consideration throughout this document is given to the requirements for compliance with the Human Tissue Act 2004 (HTA), Blood safety and Quality Regulations (MHRA) and the Guidelines for national screening programmes (QARC) and the Health and Social Care Act (CQC). Cross links to the different standards is presented in appendix 1 of this document.

All processes and procedures specified herein are mandatory within the Pathology Laboratory

Controlled versions of this document will be printed on blue paper and copy locations listed within Q-pulse as can the revision and document control history.

Amendment History

Date	Version Replaced	Pages Changed	Amendment
1.11.2014	1.0	all	Document cross references amended. Clinical lead for microbiology changed
4th May 2015	2.0	1,7 and 10	Author amended to Dr K.Mitchell, Trust organisation structure and Quality assurance structure of trust added in.
4th December 2015	3.0	19 and 21	Cross references added in for procedural documents – document control and corrective and preventive actions. S.Clenton replaces A.Cogan as gen manager in org charts.
9th September 2016	4.0		Frequency of Biochem huddle changed to at least once per week
25 November 2016	5.0	11	Chetan Mevada removed from org chart
14 December 2016		13	Transfusion huddles amended to weekly Amendment to quality policy Term head of department replaced by clinical lead throughout.
February 2017	6.0	13	Blood science quality and departmental meetings amended,
January 2018	7.0	8	Organisational charts removed from document and cross link to controlled documents added
		9	Blood sciences meetings amended and pathology business meeting added in
		various	Various cross references updated (trust policies)

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Section **Page**

0. GENERAL INFORMATION

This Quality describes the quality management system in Pathology at Calderdale and Huddersfield NHS Trust and to procedures written in fulfilment of these requirements.

All documentation relating to the quality management system is managed and held within the Q-Pulse compliance management system. Q-pulse document reference numbers are presented in tables at the end of each relevant section.

This quality manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures that constitute the quality management system. The sections of the manual are arranged so that they equate with the format of the management and technical requirements of ISO 15189. Under the title of each ISO 15189 sub clause there is a brief description of the way in which the Pathology Laboratories as part of the diagnostic and therapeutic services division of the Trust, seeks to comply with the particular sub clause, and references are given to appropriate Trust policies and procedures (black font), and any key Departmental supporting policies and procedures (blue font)

The Pathology Directorate of Calderdale and Huddersfield NHS Trust is managed by the Pathology Board within the Division of Diagnostic and Therapeutic Services.

The location of the laboratories:	Pathology Huddersfield Royal Infirmary Lindley Huddersfield West Yorkshire HD3 3EA	Telephone 01484 342000 (Trust switchboard)
	Pathology Calderdale Royal Hospital Salterhebble Halifax West Yorkshire HX3 0PW	Telephone 01422 357171 (Trust switchboard)
Main contacts	Director of Pathology General Manager- Pathology Enquiries	01484 355367 01484 355413 01484 345756 (Huddersfield) 01422 224315 (Calderdale)

Information on the services provided and further contact telephone numbers are available on both the Trust intranet site and on the hospital website www.cht.nhs.uk

The Pathology Directorate of Calderdale and Huddersfield NHS Trust provides an extensive range of services delivered by three main laboratory areas and Point of Care Testing, with the support of reference facilities. All areas are supported by comprehensive phlebotomy, reception and administration services.

Blood Sciences Department incorporates:

Clinical Biochemistry Department providing a diagnostic and clinical advisory service covering acute and general biochemistry, endocrinology, allergy, cardiac and tumour markers, toxicology and therapeutic drug monitoring.

Haematology Department providing a diagnostic and clinical advisory service for acute and general haematology tests, and specialized haemoglobinopathy tests.

Blood Transfusion provides blood and blood products to support the clinical services.

Medical Microbiology Department provides a diagnostic and clinical advisory service for all aspects of clinical microbiology and infection control. This includes bacteriology, mycology, parasitology, virology and serology.

Cellular Pathology Department providing the majority of aspects of cellular pathology including non-gynae cytology, histology and andrology. Mortuary facilities are provided at the Huddersfield Royal Infirmary and Calderdale Royal Hospital.

Point of Care Testing (POCT) provides multidisciplinary clinical and laboratory support to all clinical areas involved with near patient testing within the Trust.

1. QUALITY POLICY

The Quality policy below is reviewed annually by the Pathology Governance Board and distributed to all Pathology staff through Q-pulse as well as on the intranet site for service user access.

The Pathology Directorate of Calderdale and Huddersfield NHS Trust provides an extensive range of services delivered by three main laboratory areas and Point of Care Testing, with the support of reference facilities. All areas are supported by comprehensive phlebotomy, reception and administration services.

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Cellular Pathology Department providing the majority of aspects of cellular pathology including non-gynae cytology, histology and andrology. Mortuary facilities are provided at the Huddersfield Royal Infirmary and Calderdale Royal Hospital.
Point of Care Testing (POCT) provides multidisciplinary clinical and laboratory support to all clinical areas involved with near patient testing within the Trust.
Anticoagulation Service Providing testing and monitoring service for patients on oral anticoagulant therapy, with clinics in Outpatient departments at HRI, Phlebotomy suites HRI/CRH and a variety of community settings.

The Directorate is committed to providing a high quality clinical laboratory service that makes a significant contribution to patient care, meets the needs of its users and is in compliance with ISO 15189 and all relevant national and international standards.
To achieve these aims the Directorate will:

- Operate a quality management system that integrates the organisation and its procedures, processes and resources
- Set quality objectives in order to implement this quality policy and to achieve continual quality improvement
- Ensure examinations are fit for their intended use
- Ensure that all personnel are familiar with this quality policy and are committed to ensuring user satisfaction.
- Ensure all personnel are familiar with the contents of the quality manual, and all procedures relevant to their work
- Commit to the health, safety and welfare of its entire staff and comply with all relevant environmental legislation
- Ensure that visitors to the department are treated with respect and that due consideration is given to their safety while on site.
- Uphold professional values and demonstrate commitment to good professional practice and conduct.

Document References	Q-pulse Reference
Pathology Quality Policy	QP 100-005

2. DEFINITIONS

For the purposes of this Quality Manual, the terms and definitions given in 15189:2012 apply.

3. ORGANISATIONAL OVERVIEW, RESPONSIBILITIES AND AUTHORITIES

Relationship to Calderdale and Huddersfield NHS Trust

The following charts illustrate the organisational structure of Calderdale and Huddersfield NHS Trust including the trust and pathology structures and current key posts.

Document References	Q-pulse Reference
Trust Governance Framework	MI 200-029
Trust Quality Committee	
Divisional Organisational Chart	
Pathology Directorate Structure	
Pathology Governance Framework	
Pathology Director- Delegated Duties	
Pathology Reporting Framework	
Pathology Current Staff in Post	
Blood Sceinces Organisational Chart	LI BS-2
Central Services Organisational Chart	LI BS-3
Microbiology Organisational Chart	LI 320-104
Cellular Pathology and Mortuaries Organisational Chart	LF 020-001

Department	Title	frequency	Membership
Pathology	Pathology Governance Board Meeting	Monthly	Director of Pathology (Chair) General Manager Pathology Clinical Leads Clinical Audit Lead Laboratory Departmental Managers Quality Manager IT Manager POCT Manager SPOT Directorate Clinical Governance Lead Directorate Management Accountant (attendance as required) Directorate Personnel Manager (attendance as required)
Pathology	Pathology Business Meetings	Monthly	Director Of Pathology (Chair) General Manager Pathology Quality Manager Clinical Lead Department Manager
Pathology	IT Group Meetings	6 times per annum	IT Manager (Chair) Department IT Officers
Pathology	Quality Group	Monthly	Quality Manager (Chair) Quality Administration Lead Departmental Quality Leads
Pathology	Health and Safety Group	6 times per annum	Health and Safety Manager (Chair) Laboratory Safety Officers Secretary
Pathology	Learning and Development Group	6 times per annum	Learning and Development Manager (Chair) Laboratory Training Officers Secretary
Microbiology			
Microbiology	Senior Staff Meeting	Monthly	Clinical Staff Department Manager (Chair) Senior Scientists Microbiology Secretary
Microbiology	Daily Huddle		Senior staff or BMS staff (Chair) All available staff on day
Cellular Pathology			
Cellular Pathology	Senior Staff Meeting	Monthly	Department Manager (Chair) Clinical Lead Senior Staff Mortuary Staff
Cellular Pathology	Huddle	Weekly	All available staff on day
Blood Sciences			
Blood Sciences	Management and Quality Meeting	Monthly	Department Manager (Chair) Department Senior Biomedical Scientists Phlebotomy Senior Staff Department Clinical Leads Departmental Senior Staff
Biochemistry	Huddle	Weekly	All available staff on day
Central Reception	Huddle	Weekly	All available staff on day
Haematology / Transfusion	Huddle	Weekly	All available staff on day
Phlebotomy			
Phlebotomy	Huddle	Twice monthly	Phlebotomy Managers Phlebotomists available on day
Phlebotomy	Management Team Meeting	Monthly	Department Manager (Chair) Phlebotomy Managers

4. MANAGEMENT REQUIREMENTS

4.1. ORGANISATION AND MANAGEMENT RESPONSIBILITY

4.1.1. Organisation

4.1.1.1. General Requirement

The Pathology Laboratories at Calderdale and Huddersfield NHS Trust are organised to operate in accordance with the requirements of ISO 15189.

4.1.1.2. Legal Entity

Calderdale and Huddersfield NHS Foundation Trust holds legal responsibility for the operation of Pathology Laboratories. The Trust is managed by a Board of Directors which is supported by a membership council made up of public, partners, staff and patient members.

The Pathology Laboratories adhere to corporate policies and procedures which are available on the Trust intranet and are linked to Q-Pulse as appropriate.

4.1.1.3. Ethical Conduct

The laboratory as part of Calderdale and Huddersfield NHS Trust has procedures in place to ensure that

- *there is no involvement in any activities that would diminish confidence in the laboratory's competence, impartiality judgement or operational integrity*
- *management and personnel are free from any undue pressures or influences that may adversely affect the quality of their work*
- *potential conflicts of interest are openly and appropriately declared*
- *staff treat human samples, tissues and remains according to relevant legal requirements*
- *confidentiality of information is maintained*

Document References	Q-pulse Reference
Trust Conflict of interest and Standards of Business Conduct	**TPOL-25**
Trust Fraud and Corruption Policy	**TPOL-26**
Trust Confidentiality Policy Statement	**TPOL-29**
Trust Standing Financial Instructions	**TPOL-189**
Trust Standing Orders- Council of Governors	**TPOL-188**
Trust Standing Orders- Board of Directors	**TPOL-187**
Trust- Constitution	**TPOL-190**
Confidentiality in Pathology	**MP 200-265**
HTA Licence	**LI M20-015**

4.1.1.4. Laboratory Director

The Pathology laboratory director is a medical consultant and has membership of the Royal College of Pathologists or equivalent. This person is accountable to the Divisional Director.

Each pathology laboratory discipline is professionally directed by a clinical lead who is a medical consultant or clinical scientist of equivalent status, and who has membership of the Royal College of Pathologists or equivalent. These are accountable to the Director of Pathology.

The responsibilities of the clinical leads are outlined in their individual job descriptions. Although the clinical lead has the ultimate responsibility for the overall operation and direction of the service including professional, scientific, consultative or advisory, organisational, administrative and educational matters, some duties may be delegated to other members of the laboratory management team and these will be included in these individual's job descriptions and an overall summary is presented in the Organisational chart document for Pathology.

All clinical staff participate in and hold evidence of continuing professional development in accordance with membership of the Royal College of Pathologists.

Document References	Q-pulse Reference
Organisational Charts and Current Positions	MI 200-029
General Manager Pathology Job Description	JD 010-018
Pathology Clinical Director Job Description	JD 010-017
IT Manager Job description	JD 010-016
Cellular Pathology Manager Job Description	JD 020-001
Microbiology Manager Job Description	JD 320-009
Microbiology Clinical Lead Job Description	JD 320-008
Blood Sciences Manager Job Description	JD BS-001
Haematology / Transfusion Clinical Lead Job Descriptopn	JD 620-001
Biochemistry Clinical Lead Job Description	JD 820 001
Quality Officer Job Description	JD 010-006
Health and Safety Officer Job Description	JD 010-004
Training Officer Job Description	JD 010-003

4.1.2. Management responsibilities

4.1.2.1. Management Commitment

Laboratory management's commitment to the development and implementation of the quality management system is demonstrated through compliance with 4.1.2.2.- 5.10 below.

4.1.2.2. Needs of Users

The Pathology Laboratories commitment to meeting the needs and requirements of users is demonstrated by the establishment of the quality policy (Section 1) and quality management system (see 4.2).

The requirements of service users are defined and documented as part of service agreements (see 4.4). The laboratory has an on-going programme for user surveys and findings are captured within Q-pulse for any relevant improvement actions to be documented and implemented.. Users of the service are encouraged to contact the laboratory at any time with any concerns or improvement suggestions with a feedback link available in the intranet site. See also 4.4 and 4.14.3

Document References	Q-pulse Reference
Pathology Policy-Complaints, compliments and assessment of user satisfaction	MP 200-034
SLA Pro-forma	MF 200 100
Technical Agreement for the provision of blood components by Calderdale and Huddersfield NHS Trust to a site without a current Service Level Agreement in place	LF 720 040

4.1.2.3. Quality policy

The quality policy of the Pathology directorate detailed in Section 1 of this quality manual. This policy is reviewed annually at the management review and then approved and signed by the director of pathology. Personnel are made aware of any updates to the quality policy through Q-Pulse distribution and on various notice boards throughout the department as well as on the Pathology intranet site

Document References	Q-pulse Reference
Pathology Quality Policy	QP 100-005

4.1.2.4. Quality objectives and planning

Quality objectives are formulated annually and are designed to map to those of the parent organisation as well as the Pathology quality policy and the needs and requirements of service users. Objectives are agreed in Pathology Governance Board meeting and then transcribed into capa records within Q-

pulse enabling the effective management of timescales and responsibilities for implementation. See also 4.2

4.1.2.5. Responsibility, authority and interrelationships

Responsibilities, authorities and interrelationships are defined and outlined in the following document. Also see 4.1.1.4 for reference to job descriptions for key managerial and technical staff.

Document References	Q-pulse Reference
Organisational Charts and Current Positions	MI 200-029

4.1.2.6. Communication

Regular meetings are held across both the Trust and Division, and within departments to maintain good communication and exchange of information on organisational issues or aspects of the laboratory service. Details of regular meetings are shown in Section 3 , and a range of departmental meetings take place according to defined schedules. Records, usually in the form of minutes, are kept at Divisional or departmental level as appropriate. Action points are recorded accordingly, with progress on or discharging of these being undertaken at the subsequent meeting. All laboratory personnel have access to the minutes of the relevant meetings. All staff have internet and email access in accordance with Trust policy.

Higher level meeting details are found within the trust governance procedure. Minutes are available to staff on the intranet where relevant.

Staff are encouraged to raise quality improvement notes in Q-pulse and this is an option for all staff to use when first inducted into Pathology. A paper format of the quality improvement note is also available for staff wishing to remain anonymous. The paper records are transcribed into Q-pulse by quality leads or the quality manager. (See also 4.14.4).

The Laboratory intranet site contains links to all relevant information and the junior medical staff induction process communicates pre-examination requirements to stakeholders, to help ensure the effectiveness of examination, post examination processes and quality management system. Where changes to examination procedures result in changes to reference ranges or differences in interpretation of results, users are informed in advance of the change.

Laboratory staff are actively encouraged to communicate effectively with users at all times.

User meetings take place with local service commissioners and with Trust membership council to understand the needs and requirements of users Membership councillors are also approached consulted on all relevant proposed changes to service and leadership walk-rounds by key trust and membership personnel take place as a means of continually improving services for users.

Document References	Q-pulse Reference
Trust Policy- Engaging with Membership Council	**TPOL-67**
Pathology Policy – Continual Improvement Incorporating Preventive/ Corrective Action and The Identification and Control Of Non-Conformities	**MP 200-310**
Complaints, Compliments and Assessment of User Satisfaction in Pathology- (Incorporating staff suggestions and surveys)	**QP 100-014.**
Pathology Policy- Communicating With Service Users	**MP 200-309**
Communicating With Service Users- Microbiology	**SOP 320-729**
Communicating With Service Users- Cellular Pathology	**SOP 020-004**
Communicating With Service Users – Blood Sciences	**SOP BS-007**
Communicating with Service Users- Phlebotomy	**SOP P20-007**

4.1.2.7. Quality Manager

Responsibilities and reporting arrangements are detailed in the quality managers job description referenced in section 4.1.1.4. The Quality Manager chairs the quality group meeting, attends the pathology governance board and the divisional patient safety and quality board meetings.

The quality manager is supported by quality officers and deputies within each section of the laboratory.

4.2. QUALITY MANAGEMENT SYSTEM

4.2.1. General Requirements

The pathology department at Calderdale and Huddersfield NHS Trust has implemented a quality management system in accordance with the requirements of ISO 15189 and other relevant national and international standards. This quality manual outlines the key documents and the key interactions and processes that comprise the quality management system.

4.3. DOCUMENT CONTROL

Systems are in place to ensure that all required elements of good document control are in place and effectively managed for all policies, procedures, records, and reference materials that comprise the quality management system.

Document References	Q-pulse Reference
Pathology Policy- Production and Control of Documents	**MP 200-315**
Pathology Procedure- Production and Control of Documents	**QP 100-012**

4.4. SERVICE AGREEMENTS

The laboratory has implemented procedures for the establishment and on-going review of service level agreements. The service agreement provides for the monitoring and reviewing of the service and sets out arrangements for performance management. Once established service agreements are reviewed on an annual basis or as need requires. Any required amendments and deviations are agreed and communicated to all affected parties

Document References	Q-pulse Reference
Service Level Agreements	MP 200-040
SLA pro-forma	MF 200-100
Technical Agreement for Sites without SLA- Transfusion	LF 720-040

4.5. EXAMINATION BY REFERRAL LABORATORIES

The laboratory has procedures for the selection and evaluation of referral laboratories and consultants providing opinion and interpretation of complex testing and for the provision of results of referred tests.

Document References	Q-pulse Reference
Pathology Policy- Selection and Purchasing of External Services, Equipment, Reagents and Consumables	MP 200-307
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Cellular Pathology	SOP 020-010
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Microbiology	SOP 320-734
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Blood sciences	SOP BS-015

4.6. EXTERNAL SERVICES AND SUPPLIES

The laboratory as part of Calderdale and Huddersfield NHS Trust has documented procedures for the selection and purchasing of external services, equipment, reagents and consumable supplies that affect the quality of its service

Document References	Q-pulse Reference
Trust Policy- Medical devices Management	TPOL-42
Trust- reps Protocol	TPOL-50
Pathology Policy- Selection and Purchasing of External Services, Equipment, Reagents and Consumables	MP 200-307
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Cellular Pathology	SOP 020-010
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Microbiology	SOP 320-734
Selection and Purchasing of External Services, Equipment, Reagents and Consumables-Blood sciences	SOP BS-015

4.7. ADVISORY SERVICES

The laboratory has documented and implemented procedures for communicating with users including;

- *Advice on choice of examinations and the use of services,*
- *Clinical indication and limitations of procedures*
- *Frequency of requests*
- *Clinical advice*
- *Effective utilisation of services*
- *Failures of samples to meet acceptance criteria*

Document references	Q-pulse reference
Pathology Policy- Communicating With Service Users	MP 200-309
Communicating With Service Users- Microbiology	SOP 320-729
Communicating With Service Users- Cellular Pathology	SOP 020-004
Communicating With Service Users – Blood Sciences	SOP BS-007
Communicating With Service Users- Phlebotomy	SOP P20-007

4.8. RESOLUTION OF COMPLAINTS

The laboratory has in place documented procedures for the management of complaints and other forms of feedback from clinicians, patients laboratory staff and other parties.

Document References	Q-pulse Reference
Trust Policy- Complaints and Concerns	TPOL-177
Pathology Policy-Complaints, compliments and assessment of user satisfaction	MP 200-034
Removing Units of Blood from Bank After Notification of Withdrawal by NBS	SOP 720-042
Withdrawal of Blood and Blood Products from Use	SOP 720-045

4.9. IDENTIFICATION AND CONTROL OF NON-CONFORMITIES
4.10. CORRECTIVE ACTION
4.11. PREVENTIVE ACTION
4.12. CONTINUAL IMPROVEMENT

The laboratory has in place documented procedures to identify preventive and corrective actions and management of non-conformances including but not limited to :

- *Authorities and responsibilities*
- *Remedial actions are defined and implemented in timely manner*
- *The grading of the non-conformance*
- *Procedures to maintain patient safety*
- *Trending*

- *Preventive actions to prevent occurrence.*
- *Corrective action to prevent recurrence.*

Document references	Q-pulse reference
Pathology Policy – Continual Improvement Incorporating Preventive/ Corrective Action and The Identification and Control Of Non-Conformities	**MP 200-310**
Preventive / Corrective Action and Continual Quality Improvement- incorporating Quality Indicators	**QP 100-011**

4.13. CONTROL OF RECORDS

The laboratory has documented and implemented procedures for identification, collection, indexing, access, storage, maintenance, amendment and safe disposal of quality and technical records.

Document references	Q-pulse reference
Trust Policy- Records Management	**TPOL-58**
Policy on Storage, Retention and Disposal of Records and Clinical Samples	**MP 200-022**
Storage, Retention and Disposal of Records and Clinical Samples- Cellular Pathology	**SOP 020-003**
Storage, Retention and Disposal of Records and Clinical Samples-Microbiology	**SOP 320-735**
Storage, Retention and Disposal of Records and Clinical Samples-Blood Sciences	**SOP BS-011**

4.14. EVALUATION AND AUDITS

4.14.1. General

The laboratory has planned and implemented procedures for evaluation and internal audit to:

- *demonstrate that the pre-examination, examination and post-examination and supporting processes are being conducted in a manner that meets the needs and requirements of users;*
- *ensure conformity to the quality management system;*
- *continually improve the effectiveness of the quality management system.*

Document References	Q-pulse Reference
Pathology Policy-Laboratory Audit	MP 200-316
Pathology Policy – Continual Improvement Incorporating Preventive/ Corrective Action and The Identification and Control Of Non-Conformities	MP 200-310
Laboratory Audit- Cellular Pathology	SOP 020-016
Laboratory Audit- Blood Sciences	SOP BS-008
Laboratory Audit- Microbiology	SOP 320-740
Audit – in Phlebotomy	SOP P20-005

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

Authorized personnel periodically review the examinations provided by the laboratory, to ensure that they are clinically appropriate for the requests received.

The laboratory periodically reviews its 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.

The annual review of the above takes place as part of the Pathology Governance Board Meeting calendar.

Document References	Q-pulse Reference
Pathology Governance Board Agenda	MF 200-023

4.14.3. Assessment of user feedback

See 4.1.2.6.-Communication

4.14.4. Staff suggestions

See 4.1.2.6.-Communication

4.14.5. Internal audit

See 4.14.1

4.14.6. Risk management

The laboratory evaluates the impact of work processes and potential failures on examination results as they affect patient safety, and modifies processes to reduce or eliminate the identified risks and documents the decisions and actions taken.

Document References	Q-pulse Reference
Trust Risk Management Policy	TPOL-176
Managing risks in Pathology-Incorporating risk assessment.	SP 010-001

4.14.7. Quality indicators

The laboratory has established quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.
The process of monitoring quality indicators is planned, which includes establishing the objectives, methodology, interpretation, limits, and duration of measurement.
The indicators are reviewed annually as part of the Pathology Governance Board meeting calendar using a standardised template.

Document References	Q-pulse Reference
Pathology KPI Dashboard and Outcome Measures	**QF 100-098**
Pathology Governance Board Agenda	**MF 200-023**

4.14.8. Reviews by external organisations

When reviews by external organizations indicate the laboratory has nonconformities or potential nonconformities, the laboratory takes appropriate immediate actions and, as appropriate, corrective action or preventive action to ensure continuing compliance with the requirements of the relevant standard. Records are kept of the reviews and of the corrective actions and preventive actions taken.

Document References	Q-pulse Reference
Pathology Policy-Laboratory Audit	**MP 200-316**
Pathology Policy – Continual Improvement Incorporating Preventive/ Corrective Action and The Identification and Control Of Non-Conformities	**MP 200-310**

4.15. Management review

4.15.1. General

Laboratory management reviews the quality management annually to ensure continuing suitability, adequacy and effectiveness and support of patient care. The annual review is part of the Pathology Governance Board meeting calendar. Processes include:

- *Review input (4.15.2)*
- *Review activities (4.15.3)*
- *Review output (4.15.4)*

Document References	Q-pulse Reference
Pathology Governance Board Agenda	**MF 200-023**

5. TECHNICAL REQUIREMENTS

5.1. PERSONNEL

5.1.1. General

The laboratory has documented procedures for personnel management and maintenance of all relevant records that includes:

- *Personnel qualifications (5.1.2)*
- *Job descriptions (5.1.3)*
- *Personnel introduction to the organizational environment (5.1.4)*
- *Training (5.1.5)*
- *Competency assessment (5.1.6)*

Reviews of staff performance (5.1.7)
Continuing education and professional development (5.1.8)
Personnel records (5.1.9)

Document References	Q-pulse Reference
Trust Mandatory Training Policy	**TPOL-60**
Trust Induction Policy	**TPOL-61**
Trust Policy-Probationary Periods	**TPOL-39**
Trust Policy-Managing the Work Performance of Staff	**TPOL-54**
Trust Policy-Attendance Management	**TPOL-57**
Trust Policy-Special Leave	**TPOL-31**
Trust Policy-Disciplinary Procedures	**TPOL-53**
Trust Policy-Recruitment and Selection	**TPOL-38**
Trust Policy-Appraisal- Medical Staff	**TPOL-155**
Trust Policy-Flexible Working	**TPOL-156**
Trust Policy- Workforce mediation	**TPOL-19**
Trust Policy-Bullying and Harassment	**TPOL-37**
Trust Policy- Equality of Opportunity	**TPOL-55**
Trust Policy – Grievance Procedures	**TPOL-171**
Management of Personnel and Records in the Pathology Directorate	**MP 200-020**
Pathology Training Policy	**MP 200-030**
Training and Assessment of Competence in Cellular pathology	**TP 020-001**
Training and Competency assessing in Microbiology	**TP 320 001**
Training and Assessment of Competence in Blood Sciences	**TP BS-001**
Training and Assessment of Competence in Phlebotomy	**TP P20-002**

5.2. ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

5.2.1. General

The laboratory management ensures that there is space allocated for the performance of its work that is 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 within the primary laboratory and at sample collection and testing sites under laboratory control. All proposed changes to facilities are subject to change management and impact assessment to ensure on-going adequacy of facilities including:

- *Laboratory and office facilities (5.2.2)*
- *Storage facilities(5.2.3)*
- *Staff facilities (5.2.4)*
- *Patient sample and collection facilities (5.2.5)*
- *Facility maintenance and environmental conditions (5.2.6)*

Document References	Q-pulse Reference
Trust –Management of Estates Policy	**TPOL-158**
Trust –Pest Control Policy	**TPOL-159**
Pathology Policy-Control of Accommodation and Environment.	**MP 200-031**
Pathology Policy- Change Management	**MP 200-032**
Management of Accommodation and Environment-Cellular Pathology	**SOP 020-017**
Management of Accommodation and Environment-Blood Sciences	**SOP BS-009**
Management of Accommodation and Environment-Microbiology	**SOP 320-741**
Management of Accommodation and Environment-Phlebotomy	**SOP P20- 008**

5.3. LABORATORY EQUIPMENT, REAGENTS AND CONSUMABLES

The laboratory has implemented documented procedures the reception, storage, acceptance testing and inventory management of equipment reagents and consumables including:

5.3.1. Equipment

- *Acceptance testing (5.3.1.2)*
- *Instructions for use (5.3.1.3)*
- *Calibration and metrological traceability (5.3.1.4)*
- *Maintenance and repair (5.3.1.5)*
- *Adverse incident reporting (5.3.1.6)*
- *Records (5.3.1.7)*

5.3.2. Reagents and consumables

- *Reception and storage (5.3.2.2.)*
- *Acceptance testing (5.3.2.3)*
- *Inventory management (5.3.2.4)*
- *Instructions for use (5.3.2.5)*
- *Adverse incident reporting (5.3.2.6)*
- *Records (5.3.2.7)*

Document References	Q-pulse Reference
Trust-Medical Devices Policy	**TPOL-42**
Pathology Policy Management of Laboratory Equipment Reagents and Consumables in Pathology	**MP 200-033**
Pathology Policy – Continual Improvement Incorporating Preventive/ Corrective Action and The Identification and Control Of Non-Conformities	**MP 200-310**
Management of Equipment, Reagents and Consumables in	**SOP 320-061**

Microbiology	
Management of Equipment, Reagents and Consumables in Cellular Pathology	**SOP 020-005**
Management of Equipment, Reagents and Consumables in Blood Sciences	**SOP BS-014**
Management of Stock, Consumables, Calibration and Quality Control Material in Phlebotomy	**SOP P20-006**

5.4. PRE-EXAMINATION PROCESSES

5.4.1. General

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

- *Information for patients and users (5.4.2)*
- *Request form information (5.4.3)*
- *Primary sample collection and handling (5.4.4)*
- *Sample transportation (5.4.5)*
- *Sample Reception (5.4.6)*
- *Pre-examination handling, preparation and storage (5.4.7)*

Document References	Q-pulse Reference
Pathology Minimum Dataset Policy- (Laboratory Request Form Completion and Specimen Labelling)	**TPOL-48**
Infection Control Policy- Specimen Collection and Handling	**TPOL-11**
Infection Control – Blood Culture Policy	**TPOL-14**
Pathology Policy- Pre-Examination Processes	**MP 200-037**
Pre-Examination Processes in Cellular Pathology	**SOP 020-012**
Pre-Examination Processes in Microbiology	**SOP 320-736**
Pre-Examination Processes in Blood Sciences	**SOP BS-**
Collection and Handling of Samples in Phlebotomy	**SOP P20-001**

5.5. EXAMINATION PROCESSES

5.5.1. Selection, verification and validation of examination procedures

The laboratory has procedures in place to ensure it selects examination procedures which have been validated for their intended use and that validated examination procedures used without modification are subject to independent verification before being introduced into routine use.
The laboratory validates examination procedures derived from the following sources:

- *non-standard methods;*
- *laboratory designed or* developed methods;
- standard methods used outside their intended scope;
- validated methods subsequently modified.

See also:
Verification of examination procedures (5.5.1.2)
Validation of examination procedures (5.5.1.3)

Document References	Q-pulse Reference
Pathology Policy for the Selection, Validation and Verification of Examination Procedures	MP 200-023
Selection, Validation and Verification of Examination Procedures in Microbiology	SOP 320-730
Selection, Validation and Verification of Examination Procedures in Cellular Pathology	SOP 020-006
Selection, Validation and Verification of Examination Procedures in Blood Sciences	SOP BS-020

5.5.1.1. Measurement uncertainty of measured quantity values

5.5.2. Biological reference intervals or clinical decision values

The laboratory has implemented procedures to determine measurement uncertainty for each measurement procedure in the examination phase used to report measured quantity values on patients' samples.
The laboratory considers measurement uncertainty when interpreting measured quantity values.
Upon request, the laboratory makes available its estimates of measurement uncertainty.

The laboratory has implemented procedures to determine, where relevant, the biological reference intervals or clinical decision values, document the basis for the reference intervals or decision values and communicate this information to users.

Document References	Q-pulse Reference
Policy on Establishing Measurement Uncertainty and Biological Reference Intervals- Pathology	MP 200-024
Measurement Uncertainty and Biological Reference Intervals in Microbiology	SOP 320-731
Measurement Uncertainty and Biological Reference Intervals in Cellular Pathology	SOP 020-007
Measurement uncertainty- Blood Sciences	SOP 620-764
Biological Reference Intervals in Blood Sciences	SOP BS-025

5.5.3. Documentation of examination procedures

The laboratory has procedures for the production and control of documents that ensure

- *examination procedures shall be written in a language commonly understood by the staff in the laboratory and be available in appropriate locations.*
- *all documents that are associated with the performance of examinations, including procedures, summary documents, condensed document format and product instructions for use, are subject to document control.*
- *examination procedure documentation include all the requirements of the international standard.*

Document References	Q-pulse Reference
Policy and Procedures for the Production and Control of Documents in Pathology	QP 100-012

5.6. ENSURING QUALITY OF EXAMINATION RESULTS

5.6.1. General

The laboratory ensures the quality of examinations by performing them under defined conditions. Appropriate pre and post-examination processes are implemented

5.6.2. Quality control

5.6.2.1. General

The laboratory has quality control procedures that verify the attainment of the intended quality of results.

5.6.2.2. Quality control materials

5.6.2.3. Quality control data

The laboratory has implemented procedures that includes:

- *the use of quality control materials that react to the examining system in a manner as close as possible to patient samples.*
- *Controls are examined with a frequency that is based on the stability of the procedure and the risk of harm to the patient from an erroneous result.*
- *procedures to prevent the release of patient results, as deemed clinically necessary, in the event of quality control failure.*
- *Data is reviewed at regular intervals to detect trends and instigate preventive actions as necessary*

Document References	Q-pulse Reference
Policy on Internal Quality Control- Pathology	MP 200-025
Internal Quality Control- in Cellular Pathology	SOP 020-015
Internal Quality Control- in Microbiology	SOP 320-739
Internal Quality Control- Blood Sciences	SOP BS-016

5.6.3. Interlaboratory comparisons

The laboratory has procedures for participation in an interlaboratory comparison programme(s) such as an external quality assessment programme or proficiency testing programme, appropriate to the examination and interpretations of examination results including:

5.6.3.1. Participation (5.6.3.1)

Alternative approaches (5.6.3.2)

Analysis of interlaboratory comparison samples (5.6.3.3.)
Evaluation of laboratory performance (5.6.3.4)

Document References	Q-pulse Reference
Policy on Interlaboratory Comparison- Pathology	MP 200-026
Interlaboratory Comparison- Cellular Pathology	SOP 020-013
Interlaboratory Comparison- Microbiology	SOP 320-737
Interlaboratory Comparison- Blood Sciences	SOP BS-019

5.6.4. Comparability of examination results

The laboratory has defined procedures for comparing procedures, equipment and methods used and establishing the comparability of results for patient samples throughout the clinically appropriate intervals, applicable to same or different:

- *procedures*
- *equipment*
- *sites*

Document References	Q-pulse Reference
Policy on Comparability of Results - Pathology	MP 200-027
Comparability of Results Cellular Pathology	SOP 020-014
Comparability of Results - Microbiology	SOP 320-738
Comparability of Results – Blood Sciences	SOP BS-017

5.7. POST-EXAMINATION PROCESSES

5.7.1. Review of results

The laboratory has procedures to ensure that authorized personnel review the results of examinations before release and evaluates them against internal quality control and, as appropriate, available clinical information and previous examination results.

Document References	Q-pulse Reference
Policy on Reviewing and Reporting and Release of Results in Pathology	MP 200-029
Reviewing and Reporting and Release of Results in Microbiology	SOP 320-732
Reviewing and Reporting and Release of Results in Cellular Pathology	SOP 020-008
Reviewing and Reporting and Release of Results in Blood Sciences	SOP BS-021

5.7.2. Storage, retention and disposal of clinical samples

The laboratory shall has documented procedures for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples that include;

- *length of time clinical samples are to be retained.*
- *Safe disposal of samples shall be carried out in accordance with the Trusts waste management policies*

Document References	Q-pulse Reference
Policy on Storage, Retention and Disposal of Records and Clinical Samples	**MP 200-022**
Storage, Retention and Disposal of Records and Clinical Samples-Cellular Pathology	**SOP 020-003**
Storage, Retention and Disposal of Records and Clinical Samples-Microbiology	**SOP 320-735**
Storage, Retention and Disposal of Records and Clinical Samples-Blood Sciences	**SOP BS-011**

5.8. REPORTING OF RESULTS

5.9. RELEASE OF RESULTS

The Laboratory has in place, procedures for the reporting and release of results that include:

- *Report attributes (5.8.2)*
- *Report content (5.8.3);*
- *Automated selection and reporting of results (5.9.2)*
- *Revised reports (5.9.3)*

Document	Q-pulse Reference
Policy on Reviewing and Reporting and Release of Results in Pathology	**MP 200-029**
Reviewing and Reporting and Release of Results in Microbiology	**SOP 320-732**
Reviewing and Reporting and Release of Results in Cellular Pathology	**SOP 020-008**
Reviewing and Reporting and Release of Results in Blood Sciences	**SOP BS-021**

5.10. LABORATORY INFORMATION MANAGEMENT

The laboratory as part of Calderdale and Huddersfield NHS Trust has procedures in place for the management of information that meets the needs and requirements of users, including

- *Authorities and responsibilities (5.10.2)*
- *Information system management (5.10.3)*

Document References	Q-pulse Reference
Trust- Network Security policy	TPOL-165
Trust- Information Governance Policy	TPOL-169
Trust Information Security Policy	TPOL-170
Pathology Policy- Information Management	MP 200-038
Management of IT Systems in Pathology – Incorporating Change Control	SOP 010-017

Appendix 1:	Related standards and regulations			
Section of Manual and ISO 15189 Clause	**ISO 15189 UKAS/CPA**	**Human Tissue Act Human Tissue Authority**	**GMP**	**Health and Social Care Act Care Quality Commission**
0. General information				
1. Quality Policy				
2. Definitions				
3. Organisational Overview, responsibilities and Authorities				
4. Management Requirements				
4.1. Organisation and Management Responsibility				
4.1.1. Organisation				
4.1.1.1. General				
4.1.1.2. Legal entity				
4.1.1.3. Ethical conduct		C1,C2,C3, GQ6		
4.1.1.4. Laboratory director	4.5, 4.14.3, 4.14.4			
4.1.2. Management responsibility				
4.1.2.1. Management commitment	4.1.2.2, 4.1.2.3, 4.1.2.4, 4.1.2.5, 4.1.2.6, 4.1.2.7,4.15, 5.1.6, 5.1, 5.2, 5.3, 5.4, 5.5, 5.7			E3, W1
4.1.2.2. Needs of users	4.4, 4.14.3	C2		E2, C1, C2,R3, R4, W4
4.1.2.3. Quality policy				W1
4.1.2.4. Quality objectives and planning	4.2			E1,R1,W5
4.1.2.5. Responsibility, authority and interrelationships				W2,W3

4.1.2.6. Communication				W3
4.1.2.7. Quality manager				
4.2. Quality management system		GQ2	Chapter 1	
4.2.1. General requirements				
4.2.2. Documentation requirement				
4.2.2.1. General	4.1.2.3, 4.1.2.4, 4.2.2.2, 4.13,			
4.2.2.2. Quality manual	4.1.2.3			
4.3. Document control		GQ1	Chapter 4	
4.4. Service agreements	5.4.2, 5.5,		Chapter 7	
4.4.1. Establishment of service agreements	5.5.1			
4.4.2. Review of service agreement				E2
4.5. Examination by referral laboratories				
4.5.1. Selecting and evaluating referral laboratories and consultants				
4.5.2. Provision of examination results				
4.6. External services and supplies	5.3			
4.7. Advisory services	5.1.2, 5.1.6			
4.8. Resolution of complaints	4.14.3	GQ2	Chapter 8	R4, W4
4.9. Identification and control of non-conformities	4.1	GQ2, GQ7		S2, R4,W4,W5
4.10. Corrective action	4.13, 4.14.5			
4.11. Preventive action	4.13			
4.12. Continual improvement	4.14.5			
4.13. Control of records	5.8.6, 5.2.6, 5.9.4, 4.15	GQ3		
4.14. Evaluation and audit		GQ2	Chapter 9	
4.14.1. General	4.15, 4.10,4.11, 4.12			

4.14.2. Periodic review of requests, and suitability of procedures and sample requirements				
4.14.3. Assessment of user feedback				E2, C1
4.14.4. Staff suggestions				
4.14.5. Internal audit	4.13, 4.10			
4.14.6. Risk management		GQ8		S4, S5
4.14.7. Quality indicators	4.12			
4.14.8. Reviews by external organisations				
4.15. Management review			Chapter 1	W5
4.15.1. General				
4.15.2. Review input	4.14.2, 4.14.3, 4.14.4, 4.14.5, 4.14.6, 4.14.7, 4.14.8, 5.6.3,4.8, 4.6, 4.9, 4.12, 4.10, 4.11			
4.15.3. Review activities				
4.15.4. Review output				
5. Technical requirements				
5.1. Personnel	GQ3		Chapter 2	
5.1.1. General				
5.1.2. Personnel qualifications				
5.1.3. Job descriptions				
5.1.4. Personnel introduction to the organisational environment				
5.1.5. Training				
5.1.6. Competence assessment				
5.1.7. Review of staff performance				
5.1.8. Continuing education and professional development				

5.1.9. Personnel records				
5.2. Accommodation and environmental conditions	PFE1, PFE2,PFE3		Chapter 3	E3
5.2.1. General				
5.2.2. Laboratory and office facilities				
5.2.3. Storage facilities				
5.2.4. Staff facilities				
5.2.5. Patient sample collection facilities				
5.2.6. Facility maintenance and environmental conditions				
5.3. Laboratory equipment, reagents and consumables				E3
5.3.1. Equipment		PFE5	Chapter 3, Annexe 15	
5.3.1.1. General				
5.3.1.2. Equipment acceptance testing	5.5.1			
5.3.1.3. Equipment instructions for use				
5.3.1.4. Equipment calibration and metrological traceability				
5.3.1.5. Equipment maintenance and repair	4.1			
5.3.1.6. Equipment adverse incident reporting				
5.3.1.7. Equipment records	4.13			
5.3.2. Reagents and consumables			Chapter 6	
5.3.2.1. General				
5.3.2.2. Reagents and consumables-reception and storage				
5.3.2.3. Reagents and consumables- acceptance testing				
5.3.2.4. Reagents and consumables- inventory management				
5.3.2.5. Reagents and consumables- instructions for use				
5.3.2.6. Reagents and consumables- adverse incident reporting				
5.3.2.7. Reagents and consumables- records				

5.4. Pre-examination processes				
5.4.1. General				
5.4.2. Information for patients and users				
5.4.3. Request for information				
5.4.4. Primary sample collection and handling				
5.4.4.1. General				
5.4.4.2. Instruction for pre-collection activities				
5.4.4.3. Instructions for collection activities				
5.4.5. Sample transportation		PFE4		
5.4.6. Sample reception				
5.4.7. Pre-examination handling, preparation and storage				
5.5. Examination processes				
5.5.1. Selection, verification and validation of examination processes				
5.5.1.1. General				
5.5.1.2. Verification of examination procedures				
5.5.1.3. Validation of examination procedures				
5.5.1.4. Measurement uncertainty of measured quantity values				
5.5.2. Biological reference intervals or clinical decision values				
5.5.3. Documentation of examination procedures	5.5.1.2, 5.5.1.3			
5.6. Ensuring the quality of examination results			Chapter 6	
5.6.1. General				
5.6.2. Quality control				
5.6.2.1. General				
5.6.2.2. Quality control materials				
5.6.2.3. Quality control data				

5.6.3. Interlaboratory comparisons				
5.6.3.1. Participation				
5.6.3.2. Alternative approaches				
5.6.3.3. Analysis of interlaboratory comparison samples				
5.6.3.4. Evaluation of laboratory performance				
5.6.4. Comparability of examination results				
5.7. Post- examination processes				
5.7.1. Review of results	5.9.1			
5.7.2. Storage, retention and disposal of clinical samples		D1,D2		
5.8. Reporting of results				
5.8.1. General				
5.8.2. Report attributes	5.9.1			
5.8.3. Report content				
5.9. Release of results				
5.9.1. General	4.5, 4.9			
5.9.2. Automated selection and reporting of results				
5.9.3. Revised reports				
5.10. Laboratory information management			Annexe 11	
5.10.1. General				
5.10.2. Authorities and responsibilities				
5.10.3. Information system management				