**NW GLH Liverpool Quality Manual**

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# General Information

The genetics laboratory based at Liverpool Women’s NHS foundation Trust (LWH) forms part of the North West Genomics Laboratory Hub (NW GLH), managed by Manchester Centre for Genomic Medicine (MCGM), a directorate within St Mary’s Hospital Managed Clinical Service and an operational unit of the Manchester University NHS Foundation Trust (MFT). Laboratories from The Christie NHS Foundation Trust, Liverpool Clinical Laboratories and Lancashire Teaching Hospital NHS Foundation Trust also form part of the hub as local delivery partners. This allows the collaboration and combining of specialist knowledge from experts across the North West.

This change has been brought about due to national reconfiguration of genetics laboratories by NHS England in order to create a national NHS genomic medicine service. The laboratory based at Liverpool Women’s NHS Foundation Trust officially came under the management of MFT on 1st August 2019. The name of the genetics laboratory based at LWH was changed from The Cheshire and Merseyside Regional Genetics Laboratory to North West Genomics Laboratory Hub – Liverpool Site (NWGLH – Liverpool Site) and the legal entity has transferred to Manchester Foundation Trust (MFT) in August 2021.

A process of change has since been implemented and the two laboratories are currently working to align.

|  |  |
| --- | --- |
| The postal address is: | North West Genomics Laboratory Hub – Liverpool SiteManchester Centre for Genomic Medicine Liverpool Women’s NHS Foundation TrustCrown StLiverpool L8 7SS |

Information on the services provided and contact telephone numbers is available and on the hospital website *(*<https://mft.nhs.uk/nwglh>*).*

The North West Genomics Laboratory Hub – Liverpool Site is situated on the second floor of Liverpool Women’s Hospital and comprises of a combined Cytogenetics and Molecular Genetics Laboratory. The laboratory is divided into rare disease, cancer, and technical streams to deliver core and specialist genomic testing services as defined in the NHS England National Test Directories for rare disease and cancer. DNA banking is available for patients where no testing is currently available or for future testing.

Cancer testing is considered core service and is delivered from the hub for the North West region. Rare disease is subdivided into core and specialised services; specialised rare disease services are offered as part of the NHS Genomic Medicine Service on a national basis whereby Genetics Laboratory Hubs in England are responsible for specific specialist test groups ([https://www.england.nhs.uk/genomics/)](https://webmail.cmft.nhs.uk/owa/redir.aspx?C=_ZhlnWHw7OKhvO8TQk1eaN64ha9lrOoSaqs1kOffkP6M98M816PXCA..&URL=https%3a%2f%2fwww.england.nhs.uk%2fgenomics%2f)) for a designated geography (which can vary depending on the speciality). The test directory originated from an NHS Directory of Genetic Disorders/Genes previously established and validated via gene dossiers by the UK Genetic Testing Network (UKGTN).

The laboratory is a designated specialist Cytogenetics testing Centre for the Haematological Oncology Service (NICE IOG).

NWGLH Liverpool is accredited through external assessment by the United Kingdom Accreditation Service (UKAS) against the BSI standards ‘Medical laboratories - Requirements for quality and competence’ (ISO 15189) and is currently fully UKAS accredited under reference 9322 (DOC2252 UKAS ISO 15189 Accreditation Certificate).

# The Quality Manual

This Quality Manual describes the Quality Management System of the North West Genomics Laboratory Hub – Liverpool Site. Throughout the text there are references to ISO 15189:2022 Standards (in brackets) and to relevant information and documents written in fulfilment of these standards.

This Quality Manual fulfils two functions. It describes the Quality Management System for the benefit of the laboratory’s own management and staff, and it provides information for users and for inspection/accreditation bodies.

This Quality Manual can be regarded as the index volume to separate volumes of management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with the ISO 15189:2022 Standards; under the title of each standard there is a brief description of the way in which the laboratory seeks to comply with the particular standard and references are given to appropriate documents.

1. **ISO 15189:2022 headings**

ISO 15189:2022 Standards superseded the existing ISO 15189:2012 version and were published in December 2022. The laboratory will undergo transition to the newly published ISO Standards, with a timeframe of 3 years to meet compliance (December 2025).

The various clauses of the standard should be seen in relation to each other and are listed in full in ISO 15189:2022; the main clause headings are:

|  |  |
| --- | --- |
| Section in theQuality Manual | Section of ISO 15189:2022 Standard |
| 4 | General Requirements |
| 5 | Structural and Governance Requirements |
| 6 | Resource Requirements |
| 7 | Process Requirements |
| 8 | Management System Requirements |

# General Requirements

## Impartiality

Laboratory activities are undertaken impartially. Laboratory management is responsible for and committed to ensuring impartiality. Laboratory decisions are based on objective criteria and not biased by commercial, financial, or other influences.

Although NHS England dictate which tests genomics laboratory perform via the genomics test directories, the directories are reviewed annually and updates are overseen by a Genomics Clinical Review Group (see NHS policy/procedure [here](https://www.england.nhs.uk/publication/national-genomic-test-directory-supporting-material/)). Updates are based on policy decision (e.g., NICE guidelines) or are from the assessment of formal applications for changes to the directories.

All procurement is evaluated. Certain purchases (listed [here](https://intranet.mft.nhs.uk/content/corporate-services/finance-and-procurement/proc-and-ecommerce/proc-support); below £10K) are assessed via a prohibited discretionary spend exception approval process at Directorate level (Divisional Directorate Manager or Divisional Director). Business cases (to include options appraisals and/or quotes or identification of reasons for a waiver) are required for requisitions over £10K and are reviewed first at Directorate level and then at Managed Clinical Service (St Mary’s Hospital Senior Management) level. Those at high cost or waivered require Group level approval (refer to organisation charts). Business cases can be rejected if there is threat to impartiality.

There are safeguards to ensure personnel impartiality. All new staff members are required to declare any conflicts of interest prior to commencement at the Trust. All staff members complete annual Standards of Business Conduct and Hospitality core mandatory training, which includes all staff reading the Trust Standards of Business Conduct & Hospitality Policy [CORPS 001], and staff members above agenda for change Band 6 completing a declaration of interest form (at time of completing annual training and at any point when a conflict arises). Interests to declare include shareholding, outside employment, patents, hospitality, and gifts. These forms are reviewed and monitored by the office of the Corporate Director (ISO 4.1d). Potential breaches can be reported to the hospital Chief Executive for discussion with the Corporate Director (see Trust policy) and can result in disciplinary action.

## Confidentiality

### Management of information

Staff members adhere to Trust requirements to maintain confidentiality [Trust policy IG006 (ON4-3437) - Confidentiality Code of Conduct and Information Disclosure Policy; DOC2051 Confidentiality Policy] following staff induction and ongoing annual mandatory training schedule. Mandatory training includes relevant data protection laws, Freedom of Information, NHS Confidentiality – Code of Practice and Caldicott Principles.

Breaches of confidentiality (and potential breaches) are logged as Trust level incidents on Ulysses. Deliberate or repeated conduct causing breach of confidentiality is considered misconduct behaviour and subject to disciplinary measures as per Trust Disciplinary Policy.

Appropriately anonymised information may be shared to publicly available reputable clinical database/resources, only with appropriate patient consent. Transmission of reports and control samples to other NHS organisations is described in DOC2051 Policy and Procedures for Consent and Confidentiality.

### Release of information

The release of confidential information by law or contractual arrangement is described in DOC2051 Policy and Procedures for Consent and Confidentiality. Internal and external requests for genomic data are managed centrally by data analysts; all data requests are reviewed by a senior panel of governance, quality, and scientific representatives as per DOC6193 Guidance on Genomics Data Requests.

### Personnel Responsibility

Contractors, visitors, and other external individuals with access to laboratory information are made aware of the requirement for confidentiality and are required to sign a declaration (DOC6227 Visitors to the Genomics Laboratory – Appendix I). (For internal laboratory staff – see 4.2.1.)

## Requirements regarding patients

The laboratory has the following processes to ensure patient well-being, safety and rights are the primary considerations:

1. The NHSE Test Directory dictates the examination methods used for genetic testing, therefore patients and clinical users are unable to directly assist the laboratory in the selection of examination methods. The test directories are peer reviewed annually following a structured evidence-based review process implemented by NHS England (NHSE) and NHS Improvement (NHSI) to ensure they are up to date with the latest advances in science and technology. These reviews include applications for changes to the directories, evaluation of policy decisions, and horizon scanning. Genomic test evaluation working groups were set up to support directory updates; membership of the groups includes scientists, clinicians, health economists, **and patient and public representatives**. Applications for updates and changes to the test directories can be made to NHSE and NHSI by any stakeholders (see NHS policy/procedure [here](https://www.england.nhs.uk/publication/national-genomic-test-directory-supporting-material/)).

Various regular multi-disciplinary team meetings are held, with laboratory staff in attendance, allowing discussion and interpretation of results with clinical user groups. Annual user surveys also capture important clinical user feedback and suggestions on services provision and testing. Patient feedback can be submitted via the procedure available on the NWGLH website ([here](https://mft.nhs.uk/nwglh/quality/queries-feedback-and-complaints-procedure/)), but due to the complex nature of genetic testing, patients do not assist in the interpretation of genetic results.

1. NHSE National Test Directories providing examination method information and testing criteria are available on the NHS website and via the NWLGH website [here](https://mft.nhs.uk/nwglh/test-information/rare-disease/genomics-tests/). Expected turnaround times are available on the laboratory NWGLH website [here](https://mft.nhs.uk/nwglh/quality/laboratory-test-service-turnaround-times/).
2. Examinations offered by the laboratory are dictated by NHSE National Test Directories. Eligibility and the appropriate testing method is specified in the directories and managed via sample receipt processes and trained duty scientist staff and duty scientist procedures. Sample numbers and testing are monitored at monthly quality meetings and formally trended as part of annual management review.
3. Incidents resulting in actual patient harm or that could have resulted in harm are recorded at Trust level on Ulysses system as per DOC5371 Incident reporting procedure and policy. High impact learning assessments and reviews (HILA/R) may be required for review by SMH Governance Team depending on the severity of the incident and level of harm. As part of this process the service user is informed, and patient duty of candour would be considered and actioned where necessary by relevant senior or clinical staff. Records of actions would be recorded via Q-Pulse/Ulysses records.
4. Laboratory policies for training and competency, and Trust mandatory training schedule ensures all staff are competent to handle patient samples and testing appropriately, with due care and respect. Trust values are reviewed annually at appraisal by all staff (Everyone matters, Working together, Dignity & care, Open & honest) and at quarterly lab meetings.
5. Consent information for testing is stated on the NWGLH website [here](https://mft.nhs.uk/nwglh/documents/consent/); the laboratory infers consent has been obtained by way of receipt of a patient sample and completed referral form. A standard consent form is available on the website for standard testing. Specific consent is required for whole genome sequencing, also available via the website. See DOC2051 Policy and Procedures for Consent and Confidentiality.
6. Storage facilities to maintain availability and integrity of samples and records are provided and maintained; see DOC5319 Clinical Material Control and DOC5649 Genetics Record Control Policy.
7. Laboratory enquiries are received and triaged by administrative staff via a central email account and telephone system. Contact details and information relevant to patients and service users are available on the NWGLH website. Reporting policies are available for cytogenetic and molecular testing [DOC5003 & DOC5147 respectively]. Patients can make a subject to access request via the Trust Medico Legal Department ([here](https://mft.nhs.uk/the-trust/other-departments/medico-legal-department/)).
8. Mandatory training schedule, laboratory induction, training and competency policies and engagement with Trust values ensure the rights of patients to care that is free from discrimination is upheld.

# Structural & Governance Requirements

## Legal entity

Manchester Foundation Trust (MFT) is legally responsible for the activities of the North West Genomics Laboratory Hub – Liverpool Site. The legal entity transferred from Liverpool Women’s Hospital Trust to MFT in 2021; UKAS were informed and accepted the change in legal entity upon its completion in August 2021.

## Laboratory Director

### Laboratory Director competence

The Laboratory Scientific Operational Director has the job role requirements and necessary qualifications as specified in the relevant job specification and job description. Ongoing competence is defined in DOC5112 Competency policy.

### Laboratory Director responsibilities

The laboratory has a strong management structure which feeds into the Head of Service and is led by the Scientific Operational Director who provides general management and strategic support.

The Scientific Operational Director for the North West Genomics Laboratory Hub is Dr Emma Howard who is ultimately responsible for the following issues where relevant:

* Professional
* Scientific
* Consultative/advisory
* Organisational
* Administrative
* Educational
* Quality

### Delegation of duties

The Laboratory Director can delegate duties and/or responsibilities to other qualified personnel (as described in MP000 008 Deputising for Director) but maintains the ultimate responsibility for the overall operation and administration of the laboratory.

On a day-to-day basis, at the Liverpool Site, responsibility and requirements are assumed by the Head of Service; the responsibilities are described within the job description and DOC5647 Quality Team Roles, which also details the delegation of these responsibilities, as per the organisational plans (5.4.1).

## Laboratory activities

### General

Accredited laboratory activities are documented on the UKAS schedule of accreditation document published on the UKAS website [here](https://www.ukas.com/wp-content/uploads/schedule_uploads/00007/9322-Medical-Single.pdf). Updates/additions to activities are made to UKAS via extension to scope applications.

There are no other external sites or POCT activities performed under the laboratory schedule.

### Conformance with requirements

Laboratory activities are carried out in such a way to meet the requirements of the ISO 15189 Standard, users (clinicians & patients), regulatory authorities and organisations providing recognition (including UKAS, NHS England, Care Quality Commission, MFT & LWH Trusts), with relevant policies and procedures in place.

### Advisory activities

The NW GLH website offers general information on the use of services, sample types and acceptance requirements (<https://mft.nhs.uk/nwglh/>) and contact details for the laboratory for advice and enquiries. The NHS England test directories and eligibility criteria ([here](https://www.england.nhs.uk/publication/national-genomic-test-directories/)) provide advice on the choice of examination.

The laboratory procedures for reporting results ensure that appropriate clinical advice and interpretation is included in the written report. Further clinical advice and report interpretation can be communicated by telephone as per reporting policies [DOC5147/DOC5003]. Clinical advice and interpretation is only given by appropriately trained scientific staff.

## Structure & Authority

###  General

The North West Genomics Laboratory Hub (NW GLH) is managed by Manchester Centre for Genomic Medicine (MCGM), a directorate within St Mary’s Hospital Managed Clinical Service and an operational unit of the Manchester University NHS Foundation Trust (MFT).

**The Host Organisation (MFT)**



The MFT Host Organisation

**Relationship to the Host Organisation**

The Liverpool site forms part of the NWGLH managed by MCGM which has a defined management structure that feeds into the host organisation management as shown below:

1. St Mary’s, MCGM and the NWGLH management structure.

Chairman (MFT)

NW Genomic Laboratory Hub (NW GLH) Manchester/

Biochemical (Willink) Laboratory

ERNDIM (EQA Provider)

Operations Scientific Director Genomics Division

Clinical Genetics

Chief Executive (MFT)

Director of Operations (SMH)

Clinical Director **(**MCGM)

NW Genomic Laboratory Hub (NW GLH) Liverpool

North West GLH

Manchester Centre for Genomic Medicine (MCGM)

With delivery partners

· Liverpool Clinical Laboratories

· Christie NHS Foundation Trust

· Lancashire Teaching Hospitals NHS Foundation Trust

1. The NW GLH senior management structure



The NWGLH – Liverpool Site Laboratory is broadly divided into:

* Technical
* Rare Disease
* Cancer
* Administration

Rare Disease and Cancer (formerly germline and acquired) teams are headed by a Scientific Programme Manager, and the Technical Team is headed by a Technical Programme Manager who report to the Head of the Service.

Cross professional cover is provided by these key members of staff. Teams are then broken down into further functional sections of Rare Disease, Cancer and Technical which are headed by Principal Clinical Scientists and Senior Technical Leads (please see organograms below; exact staff number, post/vacancy number and grade is not included in the organograms, but a complete staff structure list is maintained for payroll purposes by the Laboratory Director and Finance and is accessible as required).

A staff list of staff in post on the Liverpool site and their area of work and responsibilities is maintained on Q-Pulse (DOC5252 Staff List).

NW-GLH Liverpool Site Management Structure



\*NW-GLH Liverpool Site Technical Team Structure Breakdown



**Departmental committees and meetings (communication)**

The NWGLH has different methods and means for communicating with staff including meetings, newsletters, lunchtime seminars/education sessions, communication boards and staff suggestions. Meeting minutes are stored in the relevant folders on the Genetics Labs shared drive.

The NWGLH communicates with stakeholders via the NWGLH website, letters, complaints, and user satisfaction questionnaires. Stakeholders are informed of any significant changes to services.

Regular MCGM and GLH meetings, local team level to senior cross site level, are summarised and documented in DOC4969 NWGLH Meeting Structure & Diagram.

### Quality Management

The appointed GLH Quality Manager, based on the Manchester site of the NWGLH, is responsible for overseeing the implementation, development, and maintenance of all quality management activities across both sites. The Quality Manager oversees the quality management system and integration of this system into the Trust governance and risk management systems.

The day-to-day running of the quality management system on the Liverpool site is delegated to the Deputy Quality Manager with the support of the Quality Leads/Team and senior management. For full quality team roles/responsibilities see DOC5647 Quality Team Roles.

Monthly local Quality meetings (attended by the Scientific Operations Director and Head of Service) and MFT Divisional Quality & Safety meetings allow monitoring of performance of the management system and laboratory activities, identifying deviations and non-conformances and initiating appropriate actions/mitigation or escalation as needed.

## Objectives & Policies

The laboratory is committed to providing a high-quality service that considers and aims to meet the needs and requirements of its clinical users and patients, commitment to good professional practice and compliance to ISO 15189 Standards. DOC5321 Quality Policy of the North West Genomics Laboratory Hub - Liverpool Site sets out the laboratory’s’ commitments and objectives and is reviewed biennially. The quality policy and other laboratory policies referenced within this document are implemented and accepted at all staff levels via Q-Pulse.

Laboratory objectives for all levels of the laboratory organisation and activities are considered at an annual strategy meeting attended by senior management. The Scientific Operations Director, Head of Service, Deputy/Quality Manager define measurable quality objectives of the laboratory (with timelines and responsibilities) and are responsible for ensuring that plans are made to meet these objectives. The management review that is undertaken on an annual basis determines whether the objectives have been successfully completed and provides an opportunity for revising such objectives and plans and the functioning of the quality management system. The management reviews can be found on Q-Pulse [DOC5310].

The laboratory has a change management procedure [DOC5318] to ensure planned changes to the management system are standardised and implemented appropriately.

Performance indicators to evaluate and monitor key aspects of pre-examination, examination and post-examination processes are defined in DOC5325 Performance Monitoring. Quality indicators are proactively reviewed at monthly quality meetings.

## Risk Management

The laboratories identify risks of harm to patients from examination processes and other laboratory activities (ISO 15189 5.6a). Risks are identified via:

* Validation/verification of processes prior to implementation of new or changed methods [DOC5366].
* Errors, incidents and other non-conformances or trends in non-conformances [DOC5371].
* Non-conformances or observations from internal audit activity [DOC5317]
* Risk assessments [DOC5042]
* Patient/service user complaints [DOC5308]
* Staff suggestions/complaints [DOC5308]
* Quality improvement projects [DOC5317] and change management [DOC5318]
* Equipment reviews of end-of-life, end-of-service-life (support) or repeated failures
* Discussion of services at laboratory meetings

When potential failures or risks are identified the process is risk assessed and appropriate control measures are put into place to reduce the risk and, if necessary, actions are undertaken to reduce/eliminate the risk (ISO 15189 5.6a). If a risk impacting patient service/care could not be mitigated sufficiently, users would be informed as appropriate (e.g., service delivery issues affecting turnaround time or the need to redirect testing to another centre as part of business continuity plans).

Risks are raised, assessed, actioned and monitored using the Trust procedures for recording risks [Trust ‘Risk Management Framework and Strategy’ Policy, Trust [risk guidance](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fintranet.mft.nhs.uk%2Fcontent%2Fpatient-safety-1%2Frisk-management-resources&data=05%7C02%7CAnna.Topping%40mft.nhs.uk%7Ce7e37dc5c3c04f9e780908dc21858590%7Cddc77078e8034eeb80cadd03ba7459c4%7C0%7C0%7C638422104543574842%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=ldtcFg1MDJm8bCoCdN6boBj%2FXjgITCtU5v93Sg52gsk%3D&reserved=0), and DOC5705]. The Trust uses a web-based risk register (Ulysses, Safeguard) to document, control, action and escalate risk. Laboratory risks are raised on Ulysses with oversight from the Laboratory Director (ISO 15189 5.6b). Risks are reviewed regularly at laboratory, divisional and hospital level depending on the risk level (ISO 15189 5.6b). Risks are graded based on likelihood and consequence; priority is given to high scoring risk.

# Resource Requirements

## General

See below 6.2 – 6.8.

## Personnel

### General

Laboratory activity/performance and staffing needs are monitored and managed by the Scientific Operational Director and senior management team to ensure sufficient and appropriate staffing. The laboratory uses relevant Trust policies and procedures issued by the Trust and HR/Recruitment Office for staff recruitment and selection. The Trust vision and values are included in recruitment in published job adverts and reviewed annually at staff appraisal; see also 8.1.3 Management system awareness for meeting patient/user needs and compliance to the Standards.

Each member of staff has a job description and contract of employment complying with current legislation and provides terms and conditions of service.

All staff participate in the Trust induction programme (described [here](https://intranet.mft.nhs.uk/content/corporate-services/mandatory-training)) including employee health & well-being, pension & payroll and mandatory training modules (evidenced on ESR). Trust mandatory training includes information governance and code of conduct. In addition, the laboratory has its own induction procedures and forms which are held on Q-Pulse including:

DOC5113 Induction Policy

DOC5106 Local Induction checklist

DOC5108 Genetic Laboratories Health & Safety Induction Document

DOC5908 Ethical Issues in Genomic Testing Presentation

### Competence requirements

Required qualifications are documented in the person specification of the job description for each role. All staff are suitably qualified to take up their position with appropriate education, experience, and skill. All staff employed at Clinical Scientist grades are HCPC registered. Genetic Technologists with sufficient experience are directed towards the voluntary state registration register.

There is a training programme for all members of staff outlined in the DOC5111 Genetics Laboratory Training Policy. Training is provided for all staff which includes training of specific work processes, health & safety requirements, quality management system, information management system, ethics, and confidentiality. Staff should not work unsupervised until they have been formally deemed competent on any given procedure, task, or process. The training and education needs of trained staff are identified through annual appraisal.

The NWGLH has an Education & Training Lead providing oversight and organisation of training needs across the sites, as well as site specific Scientific Educator Leads.

Training is organised into the following areas and covered by separate local training policies:

* DOC5114 Clinical Scientist training policy. This covers departmental training for State Registered Clinical Scientists, trainee Scientists (both STP and Route 2), and Higher Specialist Training for Scientists (HSST).
* DOC5118 Genetic Technologist training policy. This outlines current training arrangements for Healthcare Science Associates / Practitioners /Senior Practitioners.
* DOC5056 Liverpool Admin Training & Competency Form. This outlines training and competency specific to the administration team.

The laboratory process for assessing initial competency and monitoring ongoing competency is outlined in a separate policy (DOC5112 Laboratory Competency Policy). It also describes reassessment and/or retraining if indicated by a non-compliance or incident, or if the individual has not performed the task for over 6 months due to long term absence (i.e., sickness/maternity).

Various competency forms specific to laboratory activities covering pre-examination, examination, and post-examination processes relevant to staff roles and responsibilities are available on Q-Pulse and are used to record competence.

In addition, continued/ongoing competency or performance is monitored through day-to-day activities which may include oral assessment, examination of work records, or witness examination audits, and is reviewed annually at appraisal using the following forms:

* DOC5097 Registered Clinical Scientist PDR Competency Form
* DOC5101 Genetic Technologist PDR competency Form
* DOC5102 Competency review for Managers

### Authorisation

This clause requires the laboratory to have a process to authorise personnel to perform specific laboratory activities. These activities can include:

1. Selection, development, modification, validation, and verification of methods
2. Review, release, and reporting results
3. Use of laboratory information systems

The laboratory has training and competency documentation for its laboratory activities (including the review, release and reporting of results) and considers a signed competency document for individually named staff to fulfil the requirement for authorisation to perform the specified activity. The use of laboratory information systems is embedded into training and competence of laboratory activities (e.g., booking in referrals, reporting of results) and therefore authorised in the same way.

Test method selection and testing criteria eligibility is regulated by NHSE Test Directories for rare disease and cancer; therefore, the laboratory does not have a process for the selection or development of examination procedures/methods. However, the selection and authorisation of staff to perform method introduction or modification, and validation or verification is considered and agreed by senior management staff and is based on staff experience, knowledge, skills, and capacity.

Authorisation is also part of the laboratory’s change management procedure and change control form, whereby proposed changes to a laboratory system/process are reviewed and assessed by senior management and must obtain signed authorisation to proceed, if approved.

The requirement is fulfilled by the following:

DOC5112 Competency Policy

DOC5366 Validation & Verification

DOC5313 Change Control Form

### Continuing education and professional development

Each member of staff has an annual appraisal with their line manager to ensure continued competency, review staff performance, set individual objectives and identify learning/training needs and development, as required. A copy of the completed appraisal documentation, which includes an agreed personal development plan, is returned to staff to store electronically in staff folders on the shared drive or hard copy in a personal file.

All senior staff above Band 8b take part in the RCPath CPD scheme. All other scientific and technical staff take part in an internally organised CPD scheme. The Health and Care Professions Council (HCPC) performs checks on registered staff at registration renewal; staff must maintain good records of training and development to provide material to HCPC, if requested.

There are Trust education courses as part of organisational development and training provided on the Kallidus Learning Hub, laboratory seminars/ education sessions are arranged weekly accessible to all staff, and other opportunities available for staff to enable continued education and professional development. The laboratory maintains a training budget including support for attendance at meetings and conferences. Participation in national meetings is encouraged, and feedback from these meetings is presented at cross site education sessions.

The laboratory is accredited by the National school of Healthcare Science in partnership with the Workforce Development sub-committee of the ACGS as a training centre for Clinical Scientists and Practitioners.

### Personnel records

Records of educational/professional qualifications, training, and competence (initial and ongoing) for staff are maintained, and accessible as needed, in staff personal folders, HR folders and training/competence folders on the shared drive. Additionally, hard copy personal staff folders are held in the admin office.

Generic job descriptions are held centrally in the HR folder on the shared drive, specific or individual job descriptions are held in staff personal folders.

## Facilities & Environmental conditions

### General

The NWGLH – Liverpool site is the main and only premises for laboratory activities accredited under UKAS no. 9322 (with no other facilities/sites, and no patient sample collection or POCT). It is located on the second floor of the Jeffcoate wing of the Liverpool Women’s NHS Foundation Trust Hospital. Separate office and laboratory space is provided with defined areas; laboratory space is further defined and separated suitable for the laboratory activities and sample types to ensure quality and safety. The laboratory site operates under the legal entity of Manchester NHS Foundation Trust with an SLA in place for maintenance of estates and facilities.

The site has a safe working environment, which is functional and well maintained, and in accordance with relevant legislation. Office areas are cleaned daily by the Trust Facilities Department and the laboratory areas are cleaned by laboratory staff with cleaning schedules in place. Please refer to DOC5040: Cleaning and Decontamination Policy and DOC5035 Laboratory Cleaning Record Forms.

Some areas are kept at optimal temperature using air conditioning units. Temperature/humidity dependent areas and equipment are monitored by Contronics monitoring system [DOC5201]; limited areas outside of Contronics monitoring for temperature are monitored by laboratory staff.

Regular Health & Safety audits are carried out by the Health & Safety lead.

### Facility controls

Access to the department is limited to authorised staff only using proximity cards. Laboratory information systems which contain patient information are access controlled using usernames and passwords and appropriate access/permission levels.

Temperature/humidity dependent areas and equipment are monitored by Contronics monitoring system; data is reviewed by a quarterly audit. Standard operating procedures and separated working areas for certain laboratory activities mitigate cross-contamination of samples/products where applicable.

Safety facilities and/or devices are provided and regularly tested:

* Fire alarms; weekly
* Fire extinguishers; annually
* Power systems (Trust Generator); monthly
* First Aid kits; monthly
* Eye Wash stations; 3 times a week
* PAT testing; annually

Regular Health & Safety audits are carried out by the Health & Safety lead to check and monitor environmental conditions and facilities which include estate condition, lighting, noise, ventilation, electrical safety, safety devices etc.

### Storage facilities

Storage and conditions to ensure integrity, prevent cross contamination (where applicable) and deterioration, of samples, equipment, reagents and consumables, and documents is provided, and details documented in DOC5319 Clinical Material Control, DOC5374 Laboratory Equipment Management Procedure, DOC5646 Receipt of Laboratory Consumables and Acceptance of Use, DOC845 Procedure for Preparation and Control of Documents, and DOC5649 Genetics Record Control Policy.

There is dedicated onsite storage facilities for flammable reagents, acids & solvents. The cultured cell bank is housed and maintained offsite at BioGrad Ltd. Secure offsite document storage to maintain retention of records for appropriate timescales is provided by Restore.

Storage and disposal of hazardous materials and waste are detailed in DOC5480 Health & Safety Local Rules and DOC5479 Waste Disposal Procedure.

### Personnel facilities

Suitable facilities are available for staff within the laboratory including male and female toilets, secure locker space and coat pegs (lab coats and personal), and a rest room with basic catering facilities and drinking water.

### Sample collection facilities

Not applicable to the laboratory.

## Equipment

### General

The requirement is fulfilled by:

DOC5374 Laboratory Equipment Management Procedures

DOC5414 Laboratory Ordering Procedure

DOC5133 Equipment Inventory Registration- Entry/Update form

DOC5651 Selection and Management of Suppliers

The purchasing of equipment and services is managed by the equipment leads. They ensure compliance with legislation, availability of service contracts and continued provision of spare parts etc. Assessment and selection of new equipment is carried out by senior and principal members of the department, in consultation with the Technical Programme Manager. Whenever possible, new equipment is evaluated and tested prior to selection and purchasing to ensure the equipment meets the specifications.

All information relating to equipment is kept on the shared drive, including a list of selected and approved suppliers, records of maintenance, service and repair, instrument failure and corrective action and potential replacement time/cost.

### Equipment requirements

The requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures and DOC5133 Equipment Inventory Registration- Entry/Update form.

An inventory of all equipment that includes name of manufacturer, serial number, date of purchase and a record of contracted maintenance is maintained on the shared drive. No equipment is used outside of the laboratory’s permanent control or equipment manufacturer’s functional specification.

### Equipment acceptance procedure

The requirement is fulfilled by:

DOC5374 Laboratory Equipment Management Procedures

DOC5133 Equipment Inventory Registration- Entry/Update form

DOC5816 Equipment acceptance of use following service form

DOC5366 Validation and Verification Policy

### Equipment instructions for use

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures. Instructions for use are incorporated into specific assay protocols and/or detailed in DOC5124 Molecular Laboratory Equipment Table. Full manufacturer instructions are available as external documents in Q-Pulse or hard copies stored in the Admin Office.

### Equipment maintenance & repair

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures, including relevant individual equipment notices and forms.

### Equipment adverse incident reporting

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures and DOC5371 Incident Reporting Procedure. When appropriate, adverse incidents relating to equipment are reported to the manufacturer/supplier or relevant external body.

### Equipment records

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures, and a complete equipment inventory is maintained on the Asset List.

## Equipment calibration & metrological traceability

### General

### Equipment calibration

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures and DOC5377 Uncertainty of Measurement Policy & Procedure.

### Metrological traceability of measurement results

This requirement is fulfilled by DOC5374 Laboratory Equipment Management Procedures and DOC5377 Uncertainty of Measurement Policy & Procedure.

## Reagents & consumables

### General

### Reagents & consumables – Receipt & storage

This requirement is fulfilled by DOC5416: Receipt and Distribution of Stock to Genetics Laboratories, and DOC5646: Receipt of Laboratory Consumables and Acceptance of Use.

Reagents and consumables are stored in defined areas within the laboratory working areas and follow manufacturer storage specifications. Fridges and freezers storing reagents within the laboratory are connected and temperature monitored by Contronics Laboratory Equipment Monitoring System.

### Reagents & consumables – Acceptance testing

This requirement is fulfilled by DOC5646: Receipt of Laboratory Consumables and Acceptance of Use.

### Reagents & consumables – Inventory management

This requirement is fulfilled by DOC5646: Receipt of Laboratory Consumables and Acceptance of Use and DOC5414 Ordering procedure – Genetics Labs and associated consumables spreadsheet.

### Reagents & consumables – Instructions for use

This requirement is fulfilled by DOC5646: Receipt of Laboratory Consumables and Acceptance of Use. Instructions for use of reagents are incorporated into relevant assay protocols, as appropriate. Modification to manufacturer instructions, or use is outside their intended purpose would require validation as per DOC5366 Validation & Verification Policy.

### Reagents & consumables – Adverse incident reporting

Incidents relating to reagents and consumables are reported to the manufacturer/supplier and/or appropriate authorities (e.g. MHRA), as required. This requirement is fulfilled by DOC5646 Receipt of Laboratory Consumables and Acceptance of Use and DOC5371 Incident Reporting Policy & Procedure.

### Reagents & consumables – Records

This requirement is fulfilled by DOC5646 Receipt of Laboratory Consumables and Acceptance of Use.

## Service Agreements

### Agreements with laboratory users

Each request for testing is considered an agreement with the service user. The requirements of the service user are indicated on the North West Genomic Laboratory Hub (<https://mft.nhs.uk/nwglh/>) website.

Genomic testing in England is commissioned via NHSE as directed by National Test Directories, therefore there are minimal regional service level agreements (SLA’s) outside of this arrangement. Under these circumstances specific contracts for medical laboratory services are put in place [DOC1192 Policy for developing and maintaining service level agreements for medical laboratory services and DOC5440 Service level agreement template]. Variations to SLA’s are required in writing and must be accepted and signed by both parties before a new contract is issued. There is also an agreement between the NW GLH Manchester and Liverpool sites for service processes [DOC5634 Agreement for service processes across Liverpool and Manchester sites]. Review of SLA’s forms part of the annual management review.

Any new services are designed and developed with appropriate resources and staffing and validated appropriately.

### Agreement with POCT operators

Laboratory supported POCT is not performed; not applicable.

## Externally provided products & services

### General

Please see 6.8.2 & 6.8.3 below.

### Referral laboratories & consultants

This standard is met by the laboratory document DOC5460 Evaluation, selection, and monitoring of referral laboratories. Please note, the laboratory does not use advisory or interpretation services from external consultants.

All exported samples are recorded on the LIMS database and follow the DOC5641 Sample export procedure. Referral laboratories or hubs, external to the NWGLH, are expected as normal practice, to send the report directly back to the requesting consultant with a copy sent to the referral laboratory. The laboratory does not alter the report in any way and does not send out a report but logs receipt of the report on StarLIMS. External report returns are monitored (see DOC5147 Checking & Reporting Results Policy).

A list of referral laboratories is maintained (DOC5572).

### Review & approval of externally provided products & services

This requirement is fulfilled by:

DOC5651 Selection and management of suppliers

DOC5374 Laboratory equipment management procedure

DOC5414 Ordering Procedure – Genetics Labs

DOC5460 Evaluation, selection, and monitoring of referral laboratories

DOC5322 External Quality Assurance Policy

All licensed service providers are assessed annually using the DOC5134 Supplier Contract – Service provision, Consumables and Third Party Agreements including Maintenance Contracts’ form. A list of selected and approved suppliers is available on the shared drive. An inventory of all equipment that includes name of manufacturer, serial number, date of purchase and a record of contracted maintenance is maintained on the shared drive.

A list of referral laboratories is maintained (DOC5572) and is reviewed annually. External quality assurance (EQA) schemes and participation is also maintained and reviewed annually.

# Process requirements

## General

All procedures, pre-, examination and post-examination, are carried out by trained competent (authorised) staff who follow pre-defined validated procedures. Procedures have been assessed for clinical risk, health and safety, and measurement uncertainty consideration, with measures to mitigate identified risks (e.g., independent transfer, label or witness checks, use of personal protective equipment, internal quality control specification, analysis data checks, and report checks) implemented as appropriate.

The laboratory identifies risks and opportunities for improvement in examination processes via many routes including incident reporting and management, equipment & reagent management, performance monitoring (e.g., assay and culture failure rate, turnaround time, low resolution rate), EQA participation, staff competency assessment and internal audit schedule (e.g., vertical audit/sample journey).

Any risks are addressed by the appropriate personnel and controls or actions put in place to mitigate the impact and potential for recurrence. We ensure risks are reduced to an acceptable level. Where risks remain, they are reported on the risk register, monitored, and reviewed and actions put into place. Risks on the register are only closed when the level of residual risk is deemed at an acceptable level by laboratory management, such that it would not impact patient care, and therefore residual risk would not usually need to be communicated to clinical users. If a risk impacting patient service/care was in the process of risk management and not mitigated sufficiently, users would be informed as appropriate (e.g., service delivery issues affecting turnaround times).

Please also see 5.6 Risk Management, 8.5 Actions to address risks and opportunities for improvement, and 8.6 Continual Improvement.

## Pre-Examination processes

### General

All pre-examination processes are documented and are available to all staff via the Q-Pulse document module. Pre-examination information relevant to clinical users is also available on the NWGLH website.

### Laboratory information for patients and users

Information is available on the NWGLH website <https://mft.nhs.uk/nwglh> for 7.2.2 a) to g) as applicable/appropriate.

### Requests for providing laboratory examinations

#### General

Each request for testing is considered an agreement with the service user. The requirements of the service user are indicated on the North West Genomic Laboratory Hub (<https://mft.nhs.uk/nwglh/>) website.

Requests for examinations are made using an appropriate referral form; laboratory designed referral forms are available via the NWGLH website to users, however, other hospital specific referral forms are also accepted. Sample and minimum identifier criteria is stated on the website and laboratory referral forms. The laboratory communicates with users to clarify requests, where necessary.

#### Oral requests

Where a verbal request for testing is received, confirmation in writing is required and this is stated on the NWGLH website and Duty Scientist procedures [DOC5188, DOC5956 and DOC5014].

### Primary sample collection & handling

#### General

The laboratory is not directly involved in the collection of specimens but offers sample type, volume and collection & transportation guidance, and sample acceptance criteria available on the NWGLH website.

The risk to patient outcome due to rejection by the laboratory of a particular sample is considered on a case-by-case basis; in particular, samples of an urgent or precious nature may be accepted for processing which ordinarily would not (See 7.2.6.2).

The laboratory has a technical performance indicator for ‘unsuitable’ samples (DOC5325 Performance Monitoring) which do not meet sample acceptance requirements and require repeat sample request. The indicator allows periodic review of sample suitability and collection tubes; data is reported at the Quality Meeting and reviewed in the annual management review.

#### Information for pre-collection activities

Information for pre-collection activities is specified on the NWGLH website under general requirements link (sample requirements and sample acceptance criteria). Sample requirements and factors known to affect examination/interpretation are also stated on GLH referral form, also available on the website under Documents and Forms (test request forms e.g., DOC4900 Rare Disease referral form).

#### Patient consent

Informed consent is inferred by receipt of a sample accompanying a written request for testing (usually as a referral form) from a clinician; consent information is available on the NWGLH website.

The laboratory is not directly involved in the collection of specimens, or any special or invasive procedures to obtain samples, but offers sample type, volume, and collection & transportation guidance, available on the NWGLH website.

#### Instructions for collection activities

The laboratory is not directly involved in the collection of specimens; information for collection activities is specified on the NWGLH website under general requirements link (sample requirements and sample acceptance criteria). They are no requirements for primary samples to be separated or divided at collection. DOC5370 Sample Collection & Transportation Guidance and DOC5048 Buccal cell sampling (Cheek scrapes) for Molecular Genetic testing are available to users upon request, if required.

### Sample transportation

The laboratories do not control or manage the transport of specimens, however transport and packaging guidance is provided on the NWGLH website and guidance DOC5370 Sample Collection & Transportation Guidance is available to users upon request, if required.

The quality of sample preparations for chromosome analysis and/or FISH are known to be affected by prolonged time in transit and therefore adequacy of sample transportation is important. The laboratory monitors samples reported as low resolution and sample/culture failure via monthly key performance indicators (DOC5325 Performance Monitoring); time in transit is reviewed to identify if any delay in transit has been a contributory factor to quality issues.

Other errors relating to transport of samples should be recorded and investigated following DOC5371 Incident reporting policy & procedure.

### Sample receipt

#### Sample receipt procedure

This standard is fulfilled by:

DOC5400 Genetics Specimen Reception

DOC5178 Cyto Specimen Transport and Reception procedure

DOC5464 Specimen reception and booking in procedure

DOC5634 NWGLH Agreement for service processes across Liverpool & Manchester sites

#### Sample acceptance exceptions

This standard is fulfilled by:

As above for 7.2.6.1 and:

DOC5003 Cytogenetic checking, reporting and authorizing procedure

DOC5147 (Molgen) Checking and reporting results policy

### Pre-examination handling, preparation & storage

#### Sample protection

The laboratory has relevant procedures for pre-examination sample handling and appropriate facilities for securing samples that avoids deterioration, loss, or damage. Primary sample handling and storage is further described in DOC5319 Clinical Material Control Policy.

#### Criteria for additional examination requests

There is no time limit for requesting additional examinations on samples in long term storage, such as extracted DNA and cryogenic fibroblast culture. Cytogenetic cell suspension preparations are stored for approximately 6 months after culture/harvest and requests can be actioned in this time frame. If a stored sample or preparation is found to inadequate upon request for additional testing, a fresh sample will be requested.

#### Sample stability

Sample stability and times frames between collection and sample receipt are specified on the NWGLH website (Sample Types Accepted) and on relevant referral forms. See also 7.2.5 for monitoring of certain samples, in which the stability/quality is known to be affected by prolonged transit.

## Examination processes

### General

Technology used for specific examination procedures and testing criteria eligibility is regulated by NHSE Test Directories for rare disease and cancer; therefore, the laboratory does not have a process of selection or review of examination procedures for clinical utility. The tests given in these directories are peer reviewed annually by designated working groups (detailed [here](https://www.england.nhs.uk/genomics/the-national-genomic-test-directory/)). Laboratory senior management review and evaluate impact of the new revisions of the directories, when available and where necessary, prior to implementation.

Examination methods are validated or verified for their intended use prior to implementation into service (see 7.3.2 & 7.3.3). Standard operating procedures and other relevant documentation is controlled and available to staff via Q-Pulse (see 8.3). Personnel follow standard operating procedures and the identification of those carrying out activities as part of the examination process are recorded on relevant laboratory worksheets and StarLIMS.

### Verification of examination methods

This standard is fulfilled by DOC5366 Validation and Verification Policy & Procedure.

Verification documentation is held on Q-Pulse (transferred from iPassport). Prior to this electronic system, hardcopies are kept in Room 2806. Data and progress files are also stored in S:\Genetic Labs\Quality management\validation & verification.

### Validation of examination methods

This standard is fulfilled by DOC5366 Validation and Verification Policy & Procedure.

Validation documentation is held on Q-Pulse (transferred from iPassport). Prior to this electronic system, hardcopies are kept in Room 2806. Data and progress files are also stored in S:\Genetic Labs\Quality management\validation & verification.

### Evaluation of measurement uncertainty (MU)

Overarching guidance is provided in DOC5377 Uncertainty of Measurement Policy and Procedure.

The NWGLH – Liverpool Site accepts the principle and requirement for measurement of uncertainty within our scope of practice; this has been considered for all processes, where applicable, within the laboratory activities.

### Biological reference intervals and clinical decision limits

Clinical decision values are described within specific diseases profiles (e.g., STR disorders) and relevant protocols where applicable. Biological reference intervals (distribution of values from a biological reference population) are not directly applicable to genetic testing; however, positive, and negative controls are used as biological references, as appropriate in all assays.

### Documentation of examination procedures

All examination procedures are carried out in accordance with the examination specific SOPs and policy documents. A full record of these is kept on Q-Pulse and legacy data is available on iPassport. All procedures and policies are reviewed regularly and are under full document control (DOC845 Procedure for the preparation and control of documents).

### Ensuring the validity of examination results

#### General

The laboratory has procedures to record and monitor the validity of results, see 7.3.7.2.

#### Internal quality control (IQC)

This standard is fulfilled by:

DOC5202 Internal quality control policy

DOC5324 Fails Procedure

DOC5325 Performance Monitoring

Examination procedures use appropriate controls and have defined acceptability criteria to ensure quality and validity of patient results. Assay protocols, worksheets, and/or disease profiles describe relevant information regarding acceptable data quality and controls, where applicable, e.g., DOC5642 Chromosome analysis and karyotyping procedure for chromosome QA score and DOC5397 Fluorescent DNA Sequencing protocol for sequencing trace scores.

Standards and controls supplied with manufactured reagent/assay kits are used where available, following manufacturer instructions for use and validation. The laboratory does not perform high throughput quantitative testing. Therefore, there is no concern regarding changing IQC material within the same day/run and manufacturer standards/controls are accepted via the acceptance of use procedure [DOC5646]. For a small number of assays (e.g., LAMP), the kit control results are monitored as part of the evaluation of ongoing assay performance [DOC6092].

For in-house validated tests or commercial kits provided without controls, the laboratory does not use third party IQC material, but instead uses appropriate retained positive/negative patient samples that are fit for their intended purpose and clinical application on each run (7.3.7.3a3/b/d). Certain tests do not require the use of IQC materials, e.g., karyotyping.

Control results or assay data metrics are recorded on relevant worksheets and LIMS. Performance indicators for examination processes are monitored and include assay failure rate, culture failure rate, low resolution results and FISH rehybridization rate [DOC5325, DOC5324].

Most genetic tests do not give a measurable numerical value and controls will produce an expected qualitative outcome (positive or negative) therefore there is no ability to check for trends and shifts in IQC material (7.3.7.2e). Exceptions are LAMP, short tandem repeat, and mitochondrial assays where measurement uncertainty is taken into account for the acceptability criteria and data is reviewed against expected values on every run (7.3.7.2f).

Where results do not meet expected outcome or meet acceptance criteria, the data is reviewed; if all acceptance criteria are not met the results are rejected and the run repeated. Where limited acceptance criteria are met results are reviewed by senior scientific staff, and results may be reported with suitable provisos.

#### External quality assessment (EQA)

The laboratory has a procedure for the enrolment, participation, and performance in interlaboratory comparisons and participates in recognised EQA schemes, relevant to the services provided. This standard is fulfilled by procedure DOC5322 External Quality Assurance Policy.

Where an EQA scheme is either not available, or not considered suitable, the laboratory will consider alternative approaches; decision making, and justification will be recorded.

The laboratory conducts formal review of EQA performance as results are returned via DOC5307 EQA review form and annually for the Annual Management Review. The laboratory will implement recommendations and/or improvements arising from review, where indicated. Errors resulting in poor performance outcomes will be recorded and investigated following DOC5371 Incident Reporting Procedure and Policy.

#### Comparability of examination results

All examination procedures are carried out on a single site. Where multiples of the same equipment exist or different workflows (e.g., manual and robotic) can be used as part of standard assay processing, these variations are incorporated into test validation (DOC5366 Validation and Verification Policy & Procedure). To provide assurance that interchangeable use of either equipment or workflow does not impact the validity of results, comparability studies are undertaken. Comparability is described in DOC5374 Equipment Management Procedure and DOC5322 External Quality Assurance Policy.

## Post-examination processes

### Reporting of results

#### General

NWGLH – Liverpool Site reports results accurately, clearly, unambiguously and in accordance with DOC5003 Cytogenetics checking, reporting & authorizing procedure and DOC5147 (Molecular) Checking and Reporting Results Policy.

Reports can be in an electronic format, paper format or both. Electronic reports are reported as PDF via secure email or transferred to the HODS database according to the above reporting policies.

#### Result review & release

This standard is fulfilled by procedures:

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

#### Critical result reports

This standard is fulfilled by procedures:

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

DOC6086 LAMP DPYD analysis and reporting procedure

DOC6027 DPYD Reporting Information by Hospital and Region

Some genetic test results are processed as urgent priority (with short target turnaround) but are not considered ‘critical’ (life threatening consequence requiring immediate action). Procedures for urgent result reporting (including preliminary and unexpected oncology results) are described; urgent reports are emailed where possible to relevant secure contact and group addresses.

All DPYD results are urgent (5-day turnaround) and inform chemotherapy treatment and patient management; DPYD reporting is described separately. If a variant is identified in a patient that reduces or abolishes DPYD function, the referring hospital is contacted by telephone to inform them; the report is distributed by email to the relevant contact and group address [DOC6027].

#### Special consideration for results

This standard is fulfilled by procedures:

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

Requesting clinical specialities for test referrals have been nationally agreed and are stated in the National Test Directories. Testing which has serious implications for the patient and/or requirement for special counselling will therefore be requested and accepted from the appropriate and stated speciality. Appropriate advice for onward patient management or specialist referral is provided in reports, as applicable.

For 7.4.1.4e anonymised release of results – see 4.2.1 Management of information and 4.2.3 Release of information. Furthermore, all staff complete mandatory training in information governance.

#### Automated selection, review, release & reporting of results

This clause is not applicable to NWGLH – Liverpool Site.

However, DPYD reporting of normal results has an element of semi-automation using a LIMS query to collate patient records with a n/n final result and mail merge function to populate a normal report template. Reports generated are checked and authorised by a competent clinical scientist and the procedure is documented in DOC6006 DPYD normal reports procedure.

#### Requirements for reports

This standard is fulfilled by procedures:

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

Report templates and statements have been designed to fulfil the criteria for these clauses.

#### Additional information for reports

This standard is fulfilled by procedures:

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

Referral laboratories or hubs, external to the NWGLH, are expected as normal practice, to send the report directly back to the requesting consultant with a copy sent to the referring laboratory. The laboratory does not incorporate or alter the report in any way and does not send out a report; receipt of the report is logged on StarLIMS. Interpretation and comments on results affected by sample quality (e.g., low resolution or suboptimal) and relevant result changes over time (e.g., relapse and remission status for oncology samples) are included in reports when applicable.

#### Amendments to reported results

Occasionally, amended reports are issued to service users following defined criteria in relevant sections of the reporting policies [DOC5003/5147].

### Post-examination handling of samples

This standard is fulfilled by the following documents:

DOC5319 Clinical Material Control

DOC5187 Receipt, disposal and return of solid tissue relating to pregnancy loss

DOC5410 DNA Storage Inventory

DOC5477 RCPath Guidance document; The retention and storage of pathological records and specimens

## Non-conforming work

The requirement is fulfilled using the following policies and forms:

DOC5371 Incident reporting policy & procedure

DOC5317 Laboratory Audit and Continual Improvement Procedures

DOC5312 Non-conformance report

DOC5428 Root Cause Analysis

DOC5003 Cytogenetics checking, reporting & authorizing procedure

DOC5147 (Molecular) Checking and Reporting Results Policy

Nonconforming work is any aspect of laboratory activity or examination result that does not conform to its own procedures, quality specification/criteria or user/patient requirement. Procedures are in place to ensure that non-conforming work is managed effectively. Formal errors and complaints (see also 7.7), equipment, internal quality control and IT failures impacting laboratory activities and service provision are raised and managed via the Q-Pulse non-conformance module, and the Trust Ulysses system, where necessary. Non-conforming work arising from other sources such as audit, key performance indicator monitoring, user surveys/feedback are recorded on the NC/QI register and non-conformance report [DOC5312].

The clinical significance of patient care/harm as a result of any nonconforming work is evaluated (7.5d). The acceptability of the nonconforming work is established through the investigation process, is led by the most appropriate staff member (e.g., incident/stage owner, line manager/team lead) and reflected in the remedial and corrective actions (7.5e).

In some instances, acceptability of nonconforming work may be defined in relevant procedures (e.g., IQC failures where duplicate controls and/or patient samples mitigate the IQC failure and maintain validity of the assay data).

If nonconforming work has or could have a direct impact on patient care (i.e., results and reports) it must be escalated to the relevant Team/Programme Lead to agree appropriate actions and acceptability of work e.g., isolating/withholding samples, reports, or halting services. A decision to resume service, processing and/or release of results, following necessary investigations, must be made by an appropriate senior staff Team/Programme Lead or above (7.5c,d,e,g).

Records of nonconforming work include immediate (remedial) and long-term (corrective) actions based on cause and risk analysis, and are reviewed and approved by appropriately trained staff (7.5a,b).

## Control of data & information management

### General

NWGLH- Liverpool site uses a number of data management systems and software applications. There are documented procedures in place to ensure data security, access, back-up of data, storage, archive, and retrieval (overarching policy DOC5191 Data Management & Storage Policy). Archive and retrieval of data is described in DOC5425 Archived Records Databases.

Storage of hardcopy paperwork (non-computerised) resulting from laboratory processing (e.g., LIMS worksheets), are stored securely (short term) in chronological order in box files in GT office (room 2834) and Restore offsite storage (long term) as per DOC5649 Genetics Record Control Policy.

### Authorities & responsibilities for information management

The IT Service Manager and StarLIMS Administrators are jointly responsible for maintaining the main laboratory information system and as such have administrator rights in conjunction with the software provider StarLIMS UK. An authority for access to data and various data analysis is controlled by the permissions system linked to individual login usernames and passwords, as appropriate to their laboratory role and grade and described in DOC5599 StarLIMS Administrator User Guide.

DOC5191 Data Management & Storage Policy specifies authorities and management of other information systems and software used as part of examination processes.

### Information systems management

Laboratory data management systems and software applications used for the collection, processing, recording, reporting, storage and retrieval of examination data will be appropriately verified or validated as per DOC5366 Validation and Verification Policy.

Changes to information systems are managed through change management procedure [DOC5318] where necessary. Changes or upgrades to software are verified and recorded using DOC5199 Software Verification Proforma.

Documented procedures are available for the day-to-day use of StarLIMS, and other information management systems/software (e.g., Metasystems, Alamut, and Congenica) including archived databases (DOC5425 Archived Records Databases). Staff members are appropriately trained in their use.

Laboratory computer hardware and networks are hosted and supported by Liverpool Women’s Hospital NHS Foundation Trust and Manchester University NHS Foundation Trust Informatics departments. As NHS organisations both Trusts adhere to industry standards, best practice, and continuous improvement; dedicated cyber security teams are embedded within the Informatics departments.

All PCs in the Trust are password protected and all staff members have their own username and password credentials. Other software applications are also password protected to ensure patient data security.

Databases and information systems are operated in an environment that complies with supplier specification and maintained to ensure data access and integrity. All non-conformances or failures associated with data systems and software (affecting laboratory activities and impacting patient care) are recorded on Q-Pulse and/or Ulysses and investigated appropriately.

Data transfers and transfer checks are detailed in relevant operating procedures, where applicable.

### Downtime plans

The laboratory has a contingency plan to maintain operations/services in the event of failure or prolonged downtimes of information management systems [DOC6001/DOC5421]. Automated reporting is not applicable.

### Off site management

The information system management and data storage are provided in part by Liverpool Women’s NHS Foundation Trust (external provider), as per service level agreement, and Manchester Foundation Trust (access via VPN); plans are in process to fully transfer databases from LWH servers to MFT in due course. As NHS organisations both Trusts adhere to industry standards, cyber security best practice and continuous improvement.

The LWH servers are fully virtualized UCS Mini Blade chassis and are located in the LWH Trust Data Centre. The centre is only accessible to authorised Trust IT and Estates staff. The centre is environmentally controlled and temperature monitored to ensure the integrity of data and information on the servers. All Trust servers are backed up nightly and copied over to a failover site in at AIMES Tier 3 Data centre, ensuring the safety of all Trust data in the event of an incident onsite.

## Complaints

### Process

The standard is fulfilled by DOC5308 Assessment of complaints, compliments, and user feedback and DOC5371 Incident Reporting Procedure & Policy. All formal complaints are referenced and discussed at local quality meetings and Quality & Safety Committee meetings. Complaints and outcomes are summarised in the annual management review.

Details of how patients and clinical users can make formal or informal complaints to the laboratory and the complaint handling process are publicly available on the NWGLH webpage for ‘Queries, Feedback & complaints procedure’ [here](https://mft.nhs.uk/nwglh/quality/queries-feedback-and-complaints-procedure/).

### Receipt of complaint

The standard is fulfilled by DOC5308 Assessment of complaints, compliments, and user feedback and DOC5371 Incident Reporting Procedure & Policy.

### Resolution of complaint

The standard is fulfilled by DOC5308 Assessment of complaints, compliments, and user feedback and DOC5371 Incident Reporting Procedure & Policy.

## Continuity & emergency preparedness planning

Trust and local site level business continuity plans for emergency situations or conditions affecting laboratory activities are defined in DOC6001 Trust Business Continuity Plan and DOC5421 (Local) Business Continuity Plan. Business continuity plans activated as part of mitigation to an identified risk impacting patient service/care will be communicated to users as appropriate (e.g., temporarily redirecting testing to another GLH/centre).

Plans should be tested, and response capability exercised where practicable; exercising plans will be scheduled (Quality Yearly Planner) and recorded.

# Management systems requirements

## General requirements

### General

The laboratory maintains a robust quality management system, as evidenced by UKAS accreditation to ISO 15189:2012 and transition process ongoing to ISO 15189:2022. Fulfilment of the system to clauses 8.1-8.9 as a minimum, please see specific sections.

### Fulfilment of management system requirements

The laboratory quality management system supports and demonstrates fulfilment of the requirements of ISO 15189:2022 clauses 4 to 7 and 8.2-8.9. The laboratory does not use ISO 9001 certification to demonstrate compliance of the management system.

### Management systems awareness

The laboratory quality policy [DOC5321], quality manual [DOC5320], annual management review [DOC5310] and other laboratory policies are available on Q-Pulse to all staff. Following review or update, these documents are distributed to all staff requiring an acknowledgment to be entered by individual staff on Q-Pulse, ensuring an awareness of relevant objectives and policies. Staff are required to follow all relevant laboratory policies and procedures.

Meeting agendas are designed to promote management system awareness and include agenda items for ‘Quality’, ‘Staff suggestions’ and ‘Incidents’. ‘Quality’ is a standard meeting agenda item across all meetings to engage staff at all levels with the management system and included in induction training.

Important communications from the Quality Team, Quality & Safety Committee and Joint Laboratory meetings are displayed and shared regularly via email and communication boards regarding effectiveness of the management system and/or consequence of non-conformances/errors to patient care.

## Management systems documentation

### General

The components and relationships within the quality management system are described in section 4-8 of this Quality Manual. Laboratory management system documentation, including objectives and policies, and the quality manual are distributed and acknowledge by all staff at all levels via Q-Pulse.

### Competence & quality

The quality policy [DOC5321] and laboratory objectives as defined in the annual management review [DOC5310] address competence, quality, and operation of laboratory activities.

### Evidence of commitment

Laboratory management is committed to the development and implementation of the (quality) management system and its continual improvement as evidenced by: laboratory communication and communication processes, the quality policy, quality objectives developed from strategy and operational management meetings, staff responsibilities, the appointment of a quality manager and quality team, annual management reviews, audit schedule, monitoring of key performance indicators, non-conformance and quality improvement register, staff competency, and management of resources necessary for pre-examination, examination and post-examination activities.

### Documentation

Documentation and records relating to laboratory processes and management system are managed and available to all staff via Q-Pulse. The main quality management system documentation consists of the following:

* DOC5321 Quality Policy NWGLH Liverpool
* Quality objectives agreed and documented in the annual management review [DOC5310]
* A quality manual [DOC5320]
* A copy of ISO 15189, accessible in hard copy
* All other laboratory procedures, documents, and forms, controlled and reviewed on Q-Pulse

### Personnel access

All laboratory documentation is managed, controlled, and held within Q-Pulse; all staff are provided with a login and access to the software and read access (as a minimum) to stored documentation. ISO 15189:2022 is available in hard copy (room 2830) to all staff as required.

## Control of management systems documents

### General

NWGLH documents, including some relevant external documents, are controlled by Q-Pulse. NWGLH Liverpool site onboarded to Manchester site’s Q-Pulse server in December 2020. Prior to the transfer, Liverpool site document control had been operated and managed by iPassport electronic quality management system; ongoing access to all document control history and legacy data is still accessible in iPassport via two read only licenses.

Trust documents can be accessed by all staff through the intranet.

### Control of documents

Document control to fulfil clause 8.3.2 a) to i) is detailed in DOC845 Procedure for the Preparation and Control of Documents.

Use of the document module in Q-Pulse is included in induction training for all staff and recorded by DOC841 Document Training Checklist (Q-Pulse document module). There are designated trained staff responsible for ensuring document control [DOC1196].

## Control of records

NWGLH Liverpool has procedures to meet the requirements for controlling process and quality records. This standard is fulfilled by DOC5649 Genetics Record Control.

### Creation of records

Appropriate and legible records relating to relevant laboratory activities are created and retained as required.

### Amendment of records

This standard is fulfilled by:

DOC5649 Genetics Record Control

DOC5003 Cytogenetic checking, reporting and authorizing procedure

DOC5147 (Molgen) Checking and reporting results policy

### Retention of records

This standard is fulfilled by:

DOC5649 Genetics Record Control

MP000 057 RCPath Retention & Storage of Pathological Records & Specimens

## Action to address risks and opportunities for improvement (was preventive action)

### Identification of risks & opportunities

The laboratory identifies risk and finds opportunity for improvement associated with laboratory activities to mitigate risks to patient care, improve services and fulfil laboratory objectives. This is achieved in a number of ways and includes incident reporting (DOC5371) and other non-conformance sources (DOC5312), risk assessments (DOC5042), user survey (DOC5314), feedback and suggestions, audit (DOC5317), equipment review, performance monitoring (DOC5325), EQA review (DOC5307) and external assessment. See also 5.6 and 8.6.

### Acting on risks and opportunities for improvement

Formal risks are raised, assessed, actioned, and monitored using the Trust procedures for recording risks using a web-based risk register (Ulysses; see 5.6). Other identified risks and opportunities are captured and recorded on the NC/QI register, change control, objective setting, and management review. Risks are graded based on likelihood and consequence; priority is given to high scoring risks.

Appropriate control measures are put in place to reduce or prevent undesired impacts and potential failures that have been identified. Improvements are achieved where actions are taken to reduce or eliminate a risk or by acting on a new opportunity (e.g., technology advance/transfer); actions must be proportional to the benefit and the impact on the patient or activity. Audit, performance monitoring (internal and external), trend analysis and management review provide assurance that the management system continues to achieve its intended results and that implemented actions and changes are effective.

## Improvement

### Continual improvement

The laboratory will identify opportunities for improvement and will develop and implement any actions as necessary. Improvement activities will be prioritised based on service needs, risk, and patient care outcome. Opportunities for improvement can include those identified via the following: risk assessment, review of polices and operational procedures, objective setting, management reviews, incident reporting, feedback and suggestions, and from various internal and external evaluations.

This requirement is fulfilled by DOC5317 Laboratory Audit and Continual Improvement Procedures. Actions or changes relating to opportunities for improvement will be recorded via change management forms [DOC5313] and quality improvement forms [DOC5311]. The effectiveness of actions taken can be evaluated by audit and re-audit, existing or new key performance monitoring (e.g., improvements in turnaround time or failure rates) and management review. Improvement activities are shared with staff via various laboratory meetings and through the management review.

### Laboratory patients, user, & personnel feedback

User feedback is received via various routes, e.g., multi-disciplinary team meetings, email correspondence, complaints/compliments and via the use of user satisfaction surveys. Patient feedback can be submitted to the laboratory via the PALS procedure available on the NWGLH website. User and patient feedback are recorded, assessed, and acted upon where appropriate. When possible and appropriate, feedback is acknowledged, and any actions communicated to the user or patient. Feedback is compiled and presented in the Annual Management Review.

NWGLH encourages all staff to make suggestions for the improvement of any aspect of the laboratory service. Decisions and outcomes from the staff suggestions are fed back to all staff at relevant meetings or via email. All suggestions made throughout the year are compiled and presented in the Annual Management Review.

This standard is fulfilled by procedures:

DOC5314 User Satisfaction Policy

DOC5317 Laboratory Audit and Continual Improvement Procedure

DOC5308 Assessment of Complaints, Compliments and User Feedback Procedure

## Nonconformities and corrective actions

### Actions when nonconformity occurs

This requirement is fulfilled by:

DOC5371 Incident reporting policy & procedure

DOC5317 Laboratory Audit and Continual Improvement Procedures

DOC5312 Non-conformance report

DOC5428 Root Cause Analysis

Immediate action is taken in response to any incident or non-conformance to control and correct the event. An investigation is carried out to establish and understand cause(s) and contributing factors and to determine the extent and impact. Appropriate and proportionate actions to correct the cause(s), address any potential consequences, and eliminate or reduce risk of recurrence of the nonconformity are made and recorded. Appropriately trained staff review non-conformance actions for their effectiveness and approve non-conformance records. Trend analysis is performed at regular intervals to monitor underlying themes and evaluate effectiveness of corrective actions. The investigation of incidents and non-conformances may uncover other potential risks or highlight areas for improvement.

### Corrective actions effectiveness

See above 8.7.1

### Records of nonconformities & corrective actions

See above 8.7.1

## Evaluations

### General

The laboratory conducts various evaluations of laboratory activities and management systems at planned intervals to ensure that there is continued compliance to the ISO 15189:2022 standards and that the needs of patients and users are met.

This requirement is fulfilled by:

DOC5317 Laboratory Audit and Continual Improvement Procedures

DOC5308 Assessment of complaints, compliments and user feedback procedure

DOC5314 User Satisfaction Policy

DOC5310 Annual Management Review.

NWGLH Liverpool is accredited by external assessment by the United Kingdom Accreditation Service (UKAS) conforming to the requirements for quality and competence for medical laboratories (ISO 15189) and is currently fully UKAS accredited under reference 9322 (DOC2252 UKAS ISO 15189 Accreditation Certificate). Assessment plans, findings and reports are stored in the relevant inspection folders on the shared drive Quality Management System folder. Further details can be found in DOC4165 UKAS accreditation process.

### Quality indicators

Key quality indicators are recorded and monitored as per policy DOC5325 Performance Monitoring to evaluate performance throughout critical aspects of pre-examination, examination, post-examination, and quality management. Indicators are presented and reviewed at monthly quality meetings and form part of the annual management review. The policy is regularly reviewed to ensure the continued appropriateness of quality indicators.

There are requirements to provide Patient Level Contract Monitoring (PLCM) data to NHS England for the assessment of laboratory activity and turnaround times ([here](https://www.england.nhs.uk/publication/patient-level-contract-monitoring-plcm-user-guidance/)).

### Internal audits

The laboratory plans an annual schedule of audits to ensure continued compliance with the ISO 15189:2022 standards, that the requirements of the laboratory’s policies and procedures are met, and that the management systems is implemented and maintained effectively. The requirements of this clause are fulfilled by DOC5317 Laboratory Audit and Continual Improvement Procedure.

Other internal audits agreed on an informal basis may arise from incidents and non-conformances, identified risks, complaints, findings from external reviews or previous audits, and changes to laboratory activities. Those audits with the greatest potential for risk to patients (e.g., from incidents and risks) are given the greatest priority over other informal incidents, which are given priority over those audits on the annual schedule.

## Management reviews

### General

The Quality Management and Senior Team conduct an annual management review [DOC5310] and produce a report. It considers the items detailed in the agenda template DOC5309 Annual Management Review Template.

In addition to the full annual review report, regular quality and service-related meetings are held throughout the year to monitor and evaluate workload, turnaround times, staffing, non-compliances/incidents against performance indictors to ensure quality and safety of services and patient care (both local and cross site meetings).

### Review input

The Annual Management Review template is currently structured to include information and evaluation of the required elements as defined by ISO 15189:2012 standard 4.15.2 points a) to o). Prior to the next management review, the template will be revised to reflect ISO 15189:2022 standard 8.9.2 a) to j).

Annual objectives and improvement outcomes are reviewed and new objectives for the upcoming year are defined with plans formulated for their implementation and measurable outcome.

### Review output

Requirements for review output are included on the agenda template DOC5309 Annual Management Review Template, and therefore included in the full report. The Annual Management Review report is shared with all staff via Q-Pulse.