

# NORTH WEST REGIONAL CYTOGENETICS LABORATORY QUALITY MANUAL

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## 1. CROSS REFERENCES

- QP000 001 Quality Policy

## 2. PURPOSE

This Quality Manual is in line with the requirements of the CPA Standard A6. It fulfils two functions. Firstly it describes the Quality Management System for the benefit of the laboratory's own management and staff, and secondly it provides information for users and for inspection/accreditation bodies

## 3. GENERAL INFORMATION

### 3.1 Title of Laboratory

The North West Regional Cytogenetics Unit is part of the *Central Manchester and Manchester Children's University Hospitals NHS Trust*. It is managed as part of St Mary's Division and the Genetics Natural Clinical Grouping (NCG).

The Unit provides services for the population of the former North-West Region of the NHS, comprising East Lancs., South Cumbria, Greater Manchester and, under a separate contract, North-East Cheshire. Cytogenetic analysis is undertaken on blood samples, prenatal samples including amniotic fluid, chorionic villus and fetal blood and post mortem samples from fetal tissue, paediatric and adult skin samples. These services encompass rapid aneuploidy screening using QF-PCR and, when appropriate, FISH and MLPA studies as well as conventional chromosome analysis.

### The postal address is:

Regional Cytogenetics Unit

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St Mary's Hospital  
Hathersage Road  
Manchester  
M13 0JH

**Tel:** +44 (0) 161 276 6553

**Fax:** +44 (0) 161 276 6238

Information on the services provided and contact telephone numbers are described in **the Regional Genetics Service 'Information for Referrers'** an information booklet which is sent to all Consultant Users of the Service. Information on the services provided and contact telephone numbers are available in the booklet and via the Regional Genetics Services for Manchester Website ([www.mangen.co.uk](http://www.mangen.co.uk)).

### 3.2 The Quality Manual

This Quality Manual describes the Quality Management System of the Regional Cytogenetics Unit. Throughout the text there are references to CPA (UK) Ltd Standards (in brackets) and to procedures (indicated by square brackets), written in fulfilment of these standards.

This Quality Manual can be regarded as the index volume to separate documents describing management, laboratory, clinical and quality procedures. The sections of the Quality Manual are arranged so that they equate with the CPA (UK) Ltd Standards (see table below). Under the title of each standard there is a brief description of the way in which the Regional Cytogenetics Laboratory seeks to comply with the particular standard and references are given to appropriate procedures.

The sections of the standards should be seen to relate to each other in the following manner; Section A describes the organisation of a laboratory and its quality management system which uses resources (Sections B, C and D) to undertake pre examination, examination and post examination processes (Sections E, F and G). The quality management system and the examination processes are continually evaluated and quality assured (Section F and H). The results feed back to maintain and, where required, improve the quality management process and to ensure that the needs and requirements of users are met.

Section in the Quality Manual	Section of CPA Standards
6	A Organization and quality management system
7	B Personnel
8	C Premises and environment
9	D Equipment, materials and reagents
10	E Pre-examination process
11	F Examination process
12	G Post-examination process
13	H Quality assurance and evaluation

## 4 QUALITY POLICY

The Quality Policy (A3 Quality Policy) of the Regional Cytogenetics Laboratory is given on the next page and published as a separate controlled document displayed within the laboratory and accessible on the laboratory database.

## Regional Cytogenetics Unit – Quality Policy

### QP000 001

The North West Regional Cytogenetics Laboratory is part of the Central Manchester University Hospitals and Manchester Children's Hospital NHS Trust's St Mary's Directorate and the Clinical Genetics Division and is committed to providing a service of the highest quality.

#### Our Mission Statement

This Laboratory exists to get the right cytogenetic diagnosis, with the right test carried out on the right patient in an appropriate timeframe using the most relevant technology, and to communicate that diagnosis to the right clinician in the most effective way.

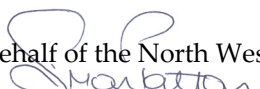
To ensure that our laboratory can deliver the service described above and meet the needs and requirements of our users we will:

- have a quality management system which brings together all areas of laboratory organisation, including documented procedures, the processes used by the laboratory to produce results and the resources available to deliver our service
- set annual quality objectives and institute plans to ensure the laboratory delivers the quality of service which this policy describes, within the resources available
- ensure that all the laboratory staff are familiar with this philosophy and committed to working to ensure our users receive the cytogenetic services they require and that their patients' deserve
- be committed to the health, safety and welfare of all our staff. Visitors to the department will also be treated with respect and we will seek to ensure their safety whilst they are on site.
- be committed to good professional practice and conduct as laid out in relevant national best practice guidelines and Trust procedures

The North West Regional Cytogenetics Unit will comply with standards set by CPA (UK) Ltd and is committed to:

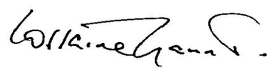
- both staff training and development and to staff recruitment and retention at all staff grades, in order to ensure that we can provide a full and effective service to our users.
- efficient and effective procurement and maintenance of equipment and other resources which are necessary for the delivery of our service.
- the handling of all specimens in ways which ensure the correct performance of tests is possible on all suitable samples received in the Laboratory.
- using procedures that will ensure the highest achievable quality in all of the tests we perform.
- reporting the results of all our tests in ways that are accurate, timely, clinically useful and which preserve patient confidentiality.
- participating in regular assessment of user satisfaction, external quality assessment and undertaking internal audit in order to produce continual quality improvement

Signed on behalf of the North West Regional Cytogenetics Unit

  
(Quality Manager)

09/05/07

(Date)

  
\_\_\_\_\_

(Head of North West Regional Cytogenetic Unit)

09/05/07

(Date)

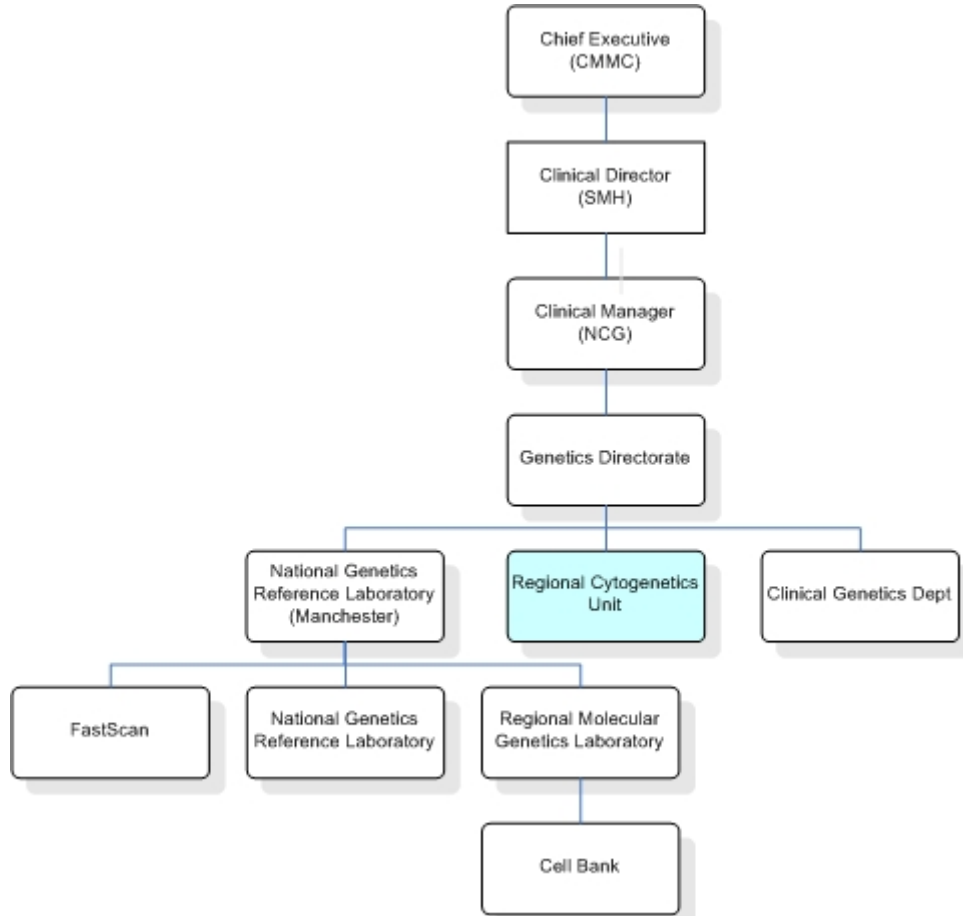
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5. ORGANISATION, RESPONSIBILITIES AND AUTHORITIES

5.1 Relationship to the Host Organisation

The North West Regional Cytogenetics Unit is part of *Central Manchester and Manchester Children’s University Hospitals NHS Trust*. The internal organisational relationships are shown below in figure 1 (A1.4):

Figure 1: The relationship to the Host Organisation



Key to figure:

CMMC: Central Manchester and Manchester Children’s University Hospitals NHS Trust; SMH: St Mary’s Hospital; NCG: Natural Clinical Grouping; NGRL: National Genetics Reference Laboratory (Manchester)

## 5.2 Organisation and Responsibilities within the North West Regional Cytogenetics Unit

A Clinical Scientist of consultant equivalent standing is in charge of the department (B1). The organisation and responsibilities with the North West Regional Cytogenetics Laboratory (B2.1) are shown below.

<b>Director</b>	Dr Lorraine Gaunt	0161 276 6553
<b>Secretary</b>	Mrs. Lynda Collantine	0161 276 6553
<b>Principal Cytogeneticists</b>	Ms Julia Tracey	0161 276 6553
	Mrs. Heather Ward	0161 276 6553
	Miss Susan Hamilton	0161 276 6553
<b>Quality Manager</b>	Dr Simon Patton	0161 276 6741
<b>Pre-natal enquiries</b>		0161 276 6118
<b>Solid tissue enquiries</b>		0161 276 6118
<b>Blood enquiries</b>		0161 276 6737 / 6771
<b>FISH enquiries</b>		0161 276 6737
<b>FAX</b>		0161 276 6238
e-mail	<a href="mailto:lorraine.gaunt@cmmc.nhs.uk">lorraine.gaunt@cmmc.nhs.uk</a> or <a href="mailto:lynda.collantine@cmmc.nhs.uk">lynda.collantine@cmmc.nhs.uk</a>	

a) **The Genetics Executive Team (A1.5)** meets once a month. Its membership is as follows:

- Clinical Director for Genetics
- Service Manager
- Head of Regional Cytogenetics Unit
- Head of National Genetics Reference Laboratory

b) **The Genetics Clinical/Laboratory Liaison group** meets once every two months. Its membership is as follows

- Clinical Director for Genetics
- Clinical Lead
- Head of Regional Cytogenetics Unit
- Head of National Genetics Reference Laboratory
- Innovation Manager for Molecular Genetics
- 2 Academic Clinical Geneticists
- 3 Academic Genetic Counsellors

c) The Genetics directorate **Clinical Governance Committee** meets once a month. Its membership is as follows:

- Clinical Lead
- Genetics Risk Lead
- Quality Lead – Cytogenetics
- Quality Manager – National Genetics Reference Laboratory (Manchester)
- Clinical Research Lead
- Office Manager – Clinical Genetics
- Clinical Audit Lead
- Genetic Counsellors' Representative

Minutes of the meetings are circulated to members and appropriate actions taken. Minutes are also made available to members and are held by the Directorate PA. Once approved minutes are also made available to all members of staff via the laboratory database

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d) **The Quality Management Team** (relates to standard A4) meets monthly. Its membership is as follows:

- Head of Regional Cytogenetics Unit
- Quality Manager
- Cytogenetics Quality Lead
- Health & Safety Officer
- Training Officer
- Document Controller
- Audit Manager
- Equipment Manager
- Other Senior Scientists as required

Minutes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are also made available to all members of staff via the laboratory database

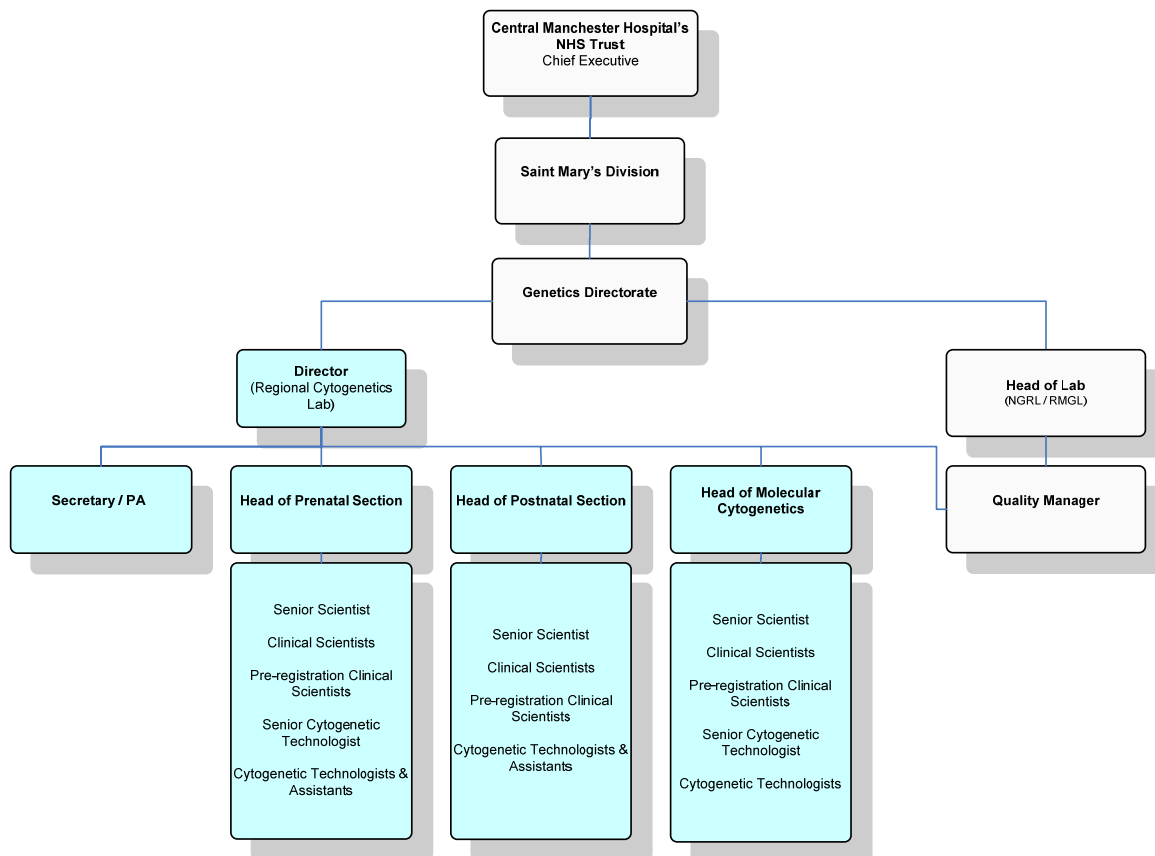
e) **The Training Committee** (relates to standard B9) meets regularly, the frequency being dependant on the training load within the department. Membership comprises:

- Training Officer
- Head of Regional Cytogenetics Unit
- Head of Prenatal Section
- Head of Postnatal Section
- A-Grade Trainers
- Technical Trainers

Minutes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are also made available to all members of staff via the laboratory database

f) **The 3 Sections** meet in their respective teams normally on a bi-monthly basis (relates to standard A1.5). Their membership consists of all current staff members within the respective team, and representatives from other sections as and when appropriate. Minutes of the meetings are circulated to members of the team and are available to all members of staff via the laboratory database.

Figure 2: The organisation and responsibilities within the Organisation



## 6. ORGANISATIONAL AND QUALITY MANAGEMENT SYSTEM

### A1 Organisation and management

The organisation and management of the North West Regional Cytogenetics Unit is detailed in section 5 of this Quality Manual

### A2 Needs and requirements of users

The needs of the users are kept under constant review. This is done proactively through the use of satisfaction questionnaires. Information is also gathered in response to comments or complaints regarding the service. These are translated into requirements, which form the focus of objective setting and planning (A5 Quality objectives and plans) within the quality management system. Assessment of user satisfaction and complaints (H1 Assessment of user satisfaction and complaints) is conducted on a regular basis and consideration of the findings form part of the annual management review (A11 Management review).

### A3 Quality Policy

The Quality Policy of the North West Regional Cytogenetics Unit is detailed in section 2.0 of this Quality Manual and available in the document module of Q-Pulse on the Genetics Server QP000 001

### A4 Quality management system

The components and relationships within the Quality management system are described in section 6 of this Quality Manual under standards A5 to A11

### A5 Quality objectives and plans

The Regional Cytogenetics Unit contributes to the NCG and Unit service planning process.

The Senior Management Team (comprised of the Head of Department, all Section Heads and Deputy Section Heads) defines the quality objectives within the North West Regional Cytogenetics Unit, involving all other team members This Team is responsible for ensuring that plans are made to meet these objectives. The management review (see A11 below), which is undertaken on an annual basis, determines whether the objectives have been successfully completed and provides an opportunity for revising both objectives and plans and the functioning of the quality management system.

### A6 Quality manual

This standard is fulfilled by the production of this Quality Manual QP000 002

### A7 Quality manager

The Quality Manager for the North West Regional Cytogenetics Unit works with the Quality Management Team to ensure the quality management system is implemented and maintained. The Quality Manager is also responsible for reporting on the functioning and effectiveness of the quality management system and for coordinating awareness of the needs and requirements of users.

The Quality Manager post for the Regional Cytogenetics Unit is shared with the Regional Molecular Genetics Laboratory and National Reference Laboratory.

The current post-holder is Dr Simon Patton

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**A8 Document Control**

This standard is fulfilled by procedures:

- [MP000 029 A brief guide to Document Control](#)
- [MP000 025 Q-Pulse Quick Start Guide](#)
- [MP000 041 How to acknowledge a document distribution on Q-Pulse](#)
- [MP000 042 How to create a document distribution list on Q-Pulse](#)
- [MP000 048 How to use the Q-Pulse Template](#)
- [MP000 049 How to use Q-Pulse for documents](#)
- [MP000 050 Q-Pulse Template](#)
- [MP000 058 How to print a list of all documents stored in Q-Pulse for the Regional Cytogenetics Unit](#)

**A9 Control of process and quality records**

The Regional Cytogenetics Unit has procedures to meet the requirements for controlling process records and quality records. These include:-

- [QP000 003 Procedure for internal audit](#)
- [LF110 010 AF & CVS Audit Trail Forms](#)
- [LP 000 025 Audit trail - Delivery record](#)
- [LP100 001 Cryogenic Storage of Sample](#)
- [LP000 005 Disposal and Storage \(Biological Specimens\)](#)
- [LP000 009 Inappropriately Labelled Samples](#)
- [LP000 010 Leaking Samples](#)
- [LP000 025 Audit trail - Delivery record](#)
- [LP100 001 Cryogenic Storage of Samples](#)
- [LP110 020 Audit Trail - Amniotic Fluid Samples](#)
- [LP120 018 CVS - Audit trail](#)
- [LP130 008 Audit trail- Solid Tissue Samples](#)
- [LP300 023 FISH Audit Trail](#)
- [LP500 007 QF-PCR Audit Trail](#)
- [MP000 036 Design, Development and Validation of new tests or services](#)
- [MP000 054 Guidance on consent for the processing and analysis of clinical samples](#)
- [MP000 056 The Human Tissue Act 2004](#)
- [MP000 057 The retention & storage of pathological records & archives \(2005\)](#)
- [MP000 064 CMMC Trust Data Protection Policy](#)
- [MP000 066 Departmental Security](#)
- [MP000 067 Administrator tasks in Cytovision](#)

The laboratory complies with current legislation, regulations and guidelines determining the timescales for retention and storage of such records.

**A10 Control of clinical material**

This standard is fulfilled by the following procedures

- [H&S000 007 Decontamination of Biological Material](#)
- [H&S000 012 High Risk Samples](#)
- [H&S000 020 Transport of Biological Specimens](#)
- [LP000 005 Disposal and Storage \(Biological Specimens\)](#)
- [LP000 007 Expected Samples](#)
- [LP000 019 Specimen Reception and Handling](#)
- [LP000 021 Slide and Referral Card Locating](#)
- [LP000 023 Sending Fixed cell suspensions to other laboratories](#)

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- LP100 001 – Cryogenic Storage of samples
- LP100 007 Exporting Prenatal Samples for Testing in Other Laboratories
- LP100 008 Reagents and Stock Solutions - Amniotic Fluid, CVS, Fibroblasts and Cystic Hygroma Fluids
- LP200 015 Transfer of Blood samples between Molecular Genetics and Cytogenetics
- MF000 007 Telephone Record for Expected Samples
- MF000 008 Telephone Record for Ongoing Cases
- MP000 012 General Use of Shire Database
- MP000 072 Transportation of Sample Material to Other Laboratories

#### A11 Management review

The Quality Team conducts an annual review, which considers the following items of information:

- a) reports from Quality Team, Prenatal and Postnatal Team review of Objectives
- b) assessment of user satisfaction and complaints (H2)
- c) internal audit of quality management system (H3)
- d) internal audit of examination processes (H4)
- e) external quality assessment reports (H5)
- f) reports of assessments by CPA (UK) Ltd, NEQAS (UK)
- g) status of preventive, corrective and improvement actions (H6)
- h) major changes in organisation and management, resource (including staffing) or process.
- i) review of the minutes and matters arising from the previous annual management review

Records are kept and key objectives for subsequent years defined and plans formulated for their implementation. An annual report containing an executive summary is produced and a copy sent to CPA (UK) Ltd.

## 7. PERSONNEL

### B1 Professional Direction

A Clinical Scientist of consultant equivalent is in charge of the North West Regional Cytogenetics laboratory. The organisation and responsibilities within the laboratory are shown in figure 2 of section 3.0 of this quality manual. The Heads of Sections with the support of the Consultant Clinical Geneticists have responsibility for the running of the Laboratory in the absence of the Head of the Regional Cytogenetics Unit. Additional arrangements exist to ensure the continued running of the Laboratory with appropriate supervision and support in the absence of suitably qualified staff

- MP000 008 Deputising for Head of Department.
- MP000 004 Authorisation of Reports

### B2 Staffing

The North West Regional Cytogenetics Unit carries out regular review of the repertoire, workload and staffing levels of the Laboratory and seeks to employ an appropriate number of qualified staff to deal with the workload of the department.

All staff on scientific grades are state registered or working towards state registration. There is a documented line of accountability for all staff detailed in figure 2 of section 3.0. This demonstrates that someone appropriately qualified supervises all unqualified staff. The following procedures fulfil this standard

- LP110 019 Role of the Prenatal Duty Scientist
- LP200 013 Blood samples – Specimen Reception and Booking in
- MP200 001 Role of the Blood Culture Scientist

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- [MP000 002 Annual Leave](#)
- [MP000 006 Bank Holidays and Out of Hours Service](#)

### B3 Personnel management

Procedures exist for the following areas of personnel management and are available to all members of staff either through the host organisation (via the Trust intranet <http://intranet.cmht.nwest.nhs.uk/policies>) or within the Regional Cytogenetics Unit (using the Q-Pulse database) as appropriate:

- staff recruitment and selection (CMMC policies)
- staff orientation and induction (B4)
- job descriptions and contracts (B5)
- staff records (B6)
- staff joint review (B7)
- staff meetings and communication (B8)
- staff training and education (B9)
- Grievance/Dispute Procedure (CMMC policy)
- Disciplinary Procedure (CMMC policies)
- Capability Procedure (CMMC policy)
- Fair Treatment Policy (CMMC policy)

### B4 Staff orientation and induction

All new staff are required to attend the induction programme provided by the Trust. In addition they are required to undertake a general induction to the laboratory [E&T000 003- Induction Document E&T000 018 – Induction Information](#) and a Health and Safety induction [E&T000 002 – Training Checklist \(H&S\)](#). Induction and mandatory training specific to the section and position in which they will be working is also given using the appropriate documents which are available in the Q-Pulse document register in the Cytogenetics –Education and Training Section.

- [E&T000 007 Induction Programme - MTO3](#)
- [E&T000 008 Induction programme - temporary staff](#)
- [E&T000 011 Induction Programme - Post basic, pre-registration training](#)
- [E&T000 012 Re-induction to a New Team](#)
- [E&T000 014 Validation of Induction](#)
- [E&T000 016 Cytovision Induction Audit](#)
- [E&T000 018 Induction Information](#)

A record of the areas of induction undertaken is kept in the personal records for each member of staff

### B5 Job descriptions and contracts

Each member of staff has a job description and contracts of employment with CMMC, which are in compliance with current legislation and provide clear terms and conditions of service.

### B6 Staff records

Each member of staff has a personal file kept by the Head of the Regional Cytogenetics Unit to which they are entitled to gain access on request ([MF000 012 Personnel File Checklist](#)). The files contain:

- personal details
- employment details
- job description
- terms and conditions of employment
- a record of staff induction and orientation

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- f) relevant education and professional qualifications
- g) certificate of registration, if relevant
- h) absence record
- i) accident record
- j) a record of annual KSF Review and personal development plan
- k) (*occupational health record – this is held by the Occupational Health Department within the Trust*)
- l) record of disciplinary action

In addition, Clinical Scientists hold a Training Record using the proforma produced by the Royal College of Pathologists including registration for the College CPD Scheme where appropriate.

#### **B7 Staff annual joint review**

Each member of staff has an annual KSF Review with their line manager using the CMMC KSF Review documentation and Guidance which is available on the Trust intranet.. This process includes the review of:

- a) team objectives
- b) job description
- c) personal objectives
- d) training and development needs

A copy of the completed KSF review documentation which includes an agreed personal development plan is placed in the appropriate personal file.

#### **B8 Staff meetings and communication**

Minutes of meetings of the laboratory teams and committees (see 3.2) are documented, circulated to participating staff and available to all staff via the “shared documents” folder (Y:\Shared Documents\Memos & Minutes) via the Genetics Server with access via the desktop of all PCs in Cytogenetics.

#### **B9 Staff training and education**

All staff are involved in induction on arrival in the laboratory (see B4) All Clinical Scientist staff and Medical Technical Officers will also be given further induction on rotation onto a different section within the laboratory. Training and education needs for all trained staff are identified through annual KSF Review (see B6), and in the interim period in accordance with the laboratory system for risk management and continuing professional development [E&T000 010 CPD](#). Completed Course Evaluation Forms ([E&T000 001 Course Evaluation Form](#)) are reviewed by the Training Officer and also at the annual KSF Review. The laboratory makes every effort to notify staff of training and education opportunities and facilities and facilitate their participation as appropriate. The Regional Cytogenetics Unit identifies a budget for training and education and has a training officer to develop policies and procedures, provide an oversight of training needs, to organise training within the laboratory and to lead the Laboratory Training committee. All staff are encouraged to make use of the library and electronic facilities to access literature and training information relevant to their work. The following procedures fulfil this standard:

- [E&T000 004 Completion Of Training Form For MTO2s](#)
- [E&T000 005 Staff Re-Training Record Form](#)
- [E&T000 006 Training Program for Grade A Trainees](#)
- [E&T000 015 Competences for Clinical Scientist State Registration](#)
- [E&T110 001 Cytogenetic Assistant Logbook - MTO2 Amnio Section](#)

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- [E&T110 002 Cytogenetics Assistant Logbook - MTO1 Amniotic Fluids](#)
- [E&T130 001 MTO2 Competences and Logbook - Solid Tissue Section](#)
- [E&T200 001 MTO2 Competences and Logbook - Blood team](#)
- [E&T200 002 Assistant Cytogenetics Technologist Logbook – Bloods](#)
- [E&T200 003 Breakage Syndrome Training Programme](#)
- [E&T200 004 Breakage Syndrome training form](#)
- [E&T300 002 FISH team Cytogenetics Technologist Logbook](#)
- [E&T300 003 Validation of FISH practical competence](#)
- [E&T500 001 Cytogenetics Technologist Competences and Log Book - QF-PCR Section](#)

## 6. PREMISES AND ENVIRONMENT

### C1 Premises and environment

The North West Regional Cytogenetics Unit is located on the first and second floors of the Gynaecological block of St Mary's Hospital, Manchester, which is part of the host institution (CMMC). Separate areas are provided for administrative functions/cytogenetic analysis, designated as office space and technical/laboratory functions, designated as laboratory space. Access to the department is limited to the door nearest the reception area.

### C2 Facilities for staff

Suitable facilities are provided for staff within the Regional Cytogenetics Unit including secure locker space, sufficient toilet facilities and basic catering facilities with access to the hospital cafeteria.

### C3 Facilities for patients

This standard does not apply to the Regional Cytogenetics Unit as patients do not attend the laboratory.

### C4 Facilities for storage

Facilities exist within the laboratory for storage in accordance with national legislation, regulations and guidelines of:

- a) patient records, process records and quality records in secure office space (A9)
- b) clinical material (A10)
- c) blood and blood products(A10)
- d) hazardous substances (C5)
- e) reagents (D3)
- f) waste material for disposal(A10)

### C5 Health and safety

The Regional Cytogenetics Unit provides a safe working environment for staff in accordance with current legislation. Details of the Health and Safety of the host institution (CMMC) can be found in the yellow folder on the Health and Safety documentation shelf in Room 213 and via the CMMC intranet.

The Laboratory has an appointed Health and Safety Officer who works with the Health and Safety Committee to ensure that all areas of this standard are met. The current post holder is Mr Philip Smith.

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- Procedures relating to this standard are available to all members of staff via the Q-Pulse database various procedures in the document archive with the H&S suffix. All laboratory procedure documents include any relevant risk assessments

## 7. EQUIPMENT, INFORMATION SYSTEMS AND REAGENTS

### D1 Management of equipment

Information about equipment suppliers, a record of laboratory assets and audit of equipment service and maintenance are stored in the Equipment module of the Q-Pulse database. The module also has the facility to record equipment breakdowns

A policy for equipment procurement exists:

- [MP000 061 Procurement of Equipment and the Ordering of Supplies](#)
- [MP000 037 How to use the equipment module on Q-Pulse](#)

### D2 Management of data and information

The Regional Cytogenetics Unit has a number of data systems available.

- The Shire System stores information on patient samples and results of examinations carried out
- The Cytovision database stores captured images of metaphase spreads used in determining patient karyotypes
- The Q-Pulse database stores information concerning the quality management system
- The GeneMapper database stores information on microsatellite analysis for QF-PCR

For each system procedures exist to ensure:

- a) security
- b) access
- c) confidentiality and data protection
- d) back-up systems
- e) storage, archive and retrieval

The Information Technology department within CMMC ensures that all computers for disposal are wiped of any confidential information prior to disposal

### D3 Management of reagents, calibration and quality control material

The following procedures and forms meet the requirements of this standard:

- [LF000 004 Record of Curatorship/Stock Control/Cleaning](#)
- [LF000 006 Stock Control Form](#)
- [H&S000 002 Chemicals – storage](#)
- [LP000 002 Banding - Reagents and Stock Solutions](#)
- [LP100 008 Reagents and Stock Solutions - Amniotic Fluid, CVS, Fibroblasts and Cystic Hygroma Fluids](#)
- [LP200 014 Stock and Working Solutions for Blood Referrals](#)
- [LP300 016 Stock Solutions](#)
- [LP500 003 Preparation of primer mixes for QF-PCR](#)
- [LP500 004 Preparation of PCR Reactions for QF-PCR](#)

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## 8. PRE-EXAMINATION PROCESS

### E1 Information for users and patients

Information for users and patients is available via the following sources

- The Regional Genetics Services for Manchester Website: <http://www.mangen.org.uk>
- A hard copy of the User Information guide is sent out to all users following its regular review

### E2 Request forms

Requests for examinations are made using North West Regional Cytogenetics request forms, which are available for prenatal and postnatal samples. These forms are available directly from the laboratory. Within the Trust, postnatal forms can be submitted via the Patient Administration System (PAS) or in electronic form via the intranet. Request forms can be downloaded from the Regional Genetics Services for Manchester Website [www.mangen.co.uk](http://www.mangen.co.uk) Space is available for the following information to be completed by the user:

- the necessary information required for unique and unequivocal patient identification
- date of specimen collection
- type of specimen
- clinical reason for the request (investigation requested)
- full consultant details
- details of referring hospital

Space is available for the laboratory to complete the following information:

- date of arrival in the laboratory
- identification of priority status
- laboratory accession number

Users are encouraged to complete the request forms fully. Attention is drawn in the final report to incomplete information on referral cards. Procedures exist for dealing with incomplete information that may affect onward processing of samples:

- [LP110 006 – Booking in \(AF\)](#)
- [LP120 011 – CVS Booking in Samples](#)
- [LP130 002 – Solid Tissue – Booking In](#)
- [LP200 013 – Blood samples – Specimen Reception and Booking in](#)
- [LP000 009 Inappropriately Labelled Samples](#)

### E3 Specimen collection and handling

Information concerning specimen collection and handling is available on the reverse of the North West Regional Cytogenetics Unit referral cards, in the information for referrers booklet and via the electronic systems used (the Regional Genetics Services for Manchester Website [www.mangen.co.uk](http://www.mangen.co.uk), PAS or the CMMC intranet).

### E4 Specimen transportation

The protocol [H&S000 020 Transport of Biological Specimens](#) meets this standard.

### E5 Specimen reception

There is a dedicated sample reception area within the Regional Cytogenetics Unit on the second floor. The following procedures and forms meet this standard:

- [H&S000 012 High Risk Samples](#)

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- [LF110 004 Amniotic Fluid Cell Culture Daybook](#)
- [LF120 001 CV Daybook](#)
- [LF130 002 Tissue Culture Daybook](#)
- [LF200 003 Blood Lymphocyte Culture Daybook](#)
- [LP000 010 Leaking Samples](#)
- [LP000 019 Specimen Reception and Handling](#)
- [LP110 013 Receipt of Samples for Prenatal FISH](#)
- [LP120 007 CVS Booking In](#)
- [LP130 002 Solid Tissue – Booking In](#)
- [LP200 013 Blood sample – Specimen Reception and Handling](#)

## E6 Referral to other laboratories

All samples for onward referral to other laboratories are entered into the Laboratory Database and a written report issued to the referring clinician, except when a request card for another laboratory accompanies the sample from the referring clinician (e.g. EDTA blood samples for FRAX testing). This standard is met by the following laboratory procedures:

- [H&S000 020 Transport of Biological Specimens](#)
- [LF100 001 Cytogenetic Laboratory Request for Cryogenic Storage Form](#)
- [LP100 001 Cryogenic Storage of Samples](#)
- [LP100 007 Exporting Prenatal Samples for Testing in Other Laboratories](#)
- [LP100 010 Uniparental Disomy Studies in Prenatal Diagnosis](#)
- [LP200 015 Transfer of Blood samples between Molecular Genetics and Cytogenetics](#)
- [LP130 009 Solid Tissues- Exporting Samples](#)

## 9. EXAMINATION PROCESS

### F1 Selection and validation of examination procedure

All examination procedures are validated prior to introduction or following a change in technique. Validation is achieved either by acceptance of manufacturers' data or by in-house validation. This standard is met by the following protocol:

- [MP000 036 Design, Development and Validation of new tests or services](#)

### F2 Examination procedures

Procedures are available for the conduct of all examinations within each section of the department and are located on the Q-Pulse database in the Laboratory Procedures section of the document register. All laboratory procedures are signified by the letters LP, followed by 3 numbers which denote the sample type and by a further 3 numbers which give the document a unique identification as described below:

#### 1. All Sections

- [Laboratory Protocols with the prefix LP000](#)

#### 2. Prenatal Section

Laboratory protocols concerning examination procedures on the prenatal section are numbered as follows:-

- [LP100 prefix for general long term culture protocols](#)
- [LP110 prefix for examination procedures related to amniotic fluid samples](#)
- [LP120 prefix for examination procedures related to chorionic villus samples](#)
- [LP130 prefix for examination procedures related to Solid Tissue samples](#)
- [LP140 prefix for examination procedures related to Cystic Hygroma and Pleural effusion fluids](#)

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### 3. Postnatal Section

Laboratory protocols concerning examination procedures relating to blood samples are numbered with the prefix [LP200](#)

### 4 Molecular CytogeneticsSection

Laboratory protocols concerning examination procedures relating to FISH testing are numbered with the prefix [LP300](#)

Laboratory protocols concerning examination procedures relating to QF-PCR testing are numbered with the prefix [LP500](#)

Laboratory protocols concerning examination procedures relating to MLPA testing are numbered with the prefix [LP600](#)

These procedures are reviewed regularly by examination and vertical audit and changed in the light of team objectives and new methods as appropriate.

### F3 Assuring the quality of examinations

Regular audit of analytical quality data is conducted by checking scientists and at report authorisation to ensuring that all samples meet the required quality for issue of unqualified results. Procedures are available for the use and acceptance of internal quality control systems for all molecular cytogenetic examinations for which such control systems are required. For these tests, IQC results are recorded, regularly evaluated and subsequent corrective and/or preventive actions taken recorded.

## 10 POST-EXAMINATION PROCESS

### G1 Reporting results

The following laboratory procedures meet this standard:

- [MP000 004 Authorisation of Reports](#)
- [MP000 007 The Checking Procedure](#)
- [MP000 022 Reporting By Telephone or Fax](#)
- [MP000 024 Written Results](#)

### G2 The report

Reports in the Regional Cytogenetics Unit are produced using the Shire Management database and conform to requirements of NEQAS and CPA (UK) Ltd (G2.1, G2..2 & G2.3). Laboratory procedures listed above (G1) detail factors that need to be considered and included in the written report if appropriate.

### G3 The telephoned report

The management procedure [MP000 022 Reporting By Telephone or Fax](#) meets the requirements of this standard.

### G4 The amended report

Authorised reports are finalised in the Shire database [MP000 004 Authorisation of Reports](#). This process, undertaken by the Head of the Unit or a Head of Section (or in exceptional circumstances other senior

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members of staff [MP000 008 Deputising for Head of Department](#)) requires password authorisation. Once finalised, reports can only be amended by removing the password protected "final" status [MP000 026 Issuing Amended Reports](#) describes the process for issuing an amendment report and directs the issuer to other protocols where corrective and/or preventive action are required.

## G5 Clinical advice and interpretation

The laboratory procedures for reporting results (see list in standard G1) ensure that appropriate clinical advice and interpretation is included in the written report or communicated in the telephoned report.

Clinical advice and interpretation is available from the scientific staff when the Laboratory is open and during routine working hours on Bank Holidays (with the exception of Christmas Day and most Boxing Days). Such advice is provided by staff with appropriate training.

## 11. EVALUATION AND QUALITY ASSURANCE

### H1 Evaluation and improvement processes

Procedures for evaluation and quality improvement processes are detailed in section 11 of this quality manual (H1.1). These procedures include:

- a) assessment of user satisfaction and complaints (H2)
- b) internal audit of the quality management system (H3)
- c) internal audit of examination processes (H4)
- d) external quality assessment (H5)
- e) reports from external assessment bodies, CPA (UK) Ltd, UK NEQAS
- f) quality improvement (H6)

The results of these evaluation and quality improvement processes are available to all staff via the Cytogenetics network and available to users upon request (H1.2). Analysis of the data collected forms part of the annual review (H1.3 & A11)

### H2 Assessment of user satisfaction and complaints

The Regional Cytogenetics Unit;

- a) has established processes for obtaining and monitoring data on user satisfaction and complaints
- b) seeks to meet performance targets in all areas
- c) assesses the clinical relevance of molecular genetic investigations performed and the reliability of interpretive reports in conjunction with users.
- d) participates in the evaluation of clinical effectiveness, audit and risk management activities within CMMC (H2.1) via the Directorate Clinical Governance Group.

### H3 Internal audit of quality management system

The Regional Cytogenetics Unit has established a procedure for internal audit of the quality management system. The internal audit process is:

- a) planned and scheduled
- b) conducted against agreed criteria
- c) carried out by personnel trained in internal audit

The record of internal audit includes:

- a) the activities, areas or items audited
- b) nonconformities or deficiencies found

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- c) the recommendations and time scales for corrective and preventative action

The results of internal audit are regularly evaluated and the decisions taken documented monitored, reviewed and acted upon by the Quality Management Team. There are forms and policies dealing with this held in the Q-Pulse document register:

- [MP000 038 How to report an audit using Q-Pulse](#)
- [MP000 039 How to create and approve an audit schedule on Q-Pulse](#)
- [MF000 013 Non-Compliance Form](#)
- [MF000 014 Examination Audit Form](#)
- [MF000 015 Vertical Audit Checklist Form](#)

#### H4 Internal audit of examination processes

Internal audit of pre examination, examination and post-examination processes (H4.1) are planned and scheduled using the Audit Module of the Q-Pulse database. Examination, Vertical and Horizontal audits are conducted following laboratory procedures [MF000 014 - Examination Audit](#) & [MF000 015 - Vertical Audit Checklist Form](#) (H4.2). Records of audits carried out are recorded in the Audit Module of the Q-Pulse Database. The results of all internal audits are evaluated by the Audit Officer who ensures that corrective and preventative actions are undertaken in a timely fashion and communicated to all members of staff via Quality team meetings and e-mail (H4.4)

#### H5 External quality assessment

The Regional Cytogenetics Unit participates in the UK National External Quality Assessment Scheme for Cytogenetics (H5.1). A record of the performance of the Regional Cytogenetics Unit against the performance indicators measured by the UK NEQAS Cytogenetics is kept on the Cytogenetics area of the Genetics server and is available to all staff on the desktops of networked PCs in Y:\Shared Documents\Quality\NEQAS & CPA Reports\NEQAS (H5.2 & H5.3).

## H6 Quality improvement

The Quality Management Team is responsible for ensuring continual quality improvement occurs. Results of scheduled audits and regular review of adverse incidents and internally recorder errors occurs in the meetings of the Quality Management Team. These include discussion of corrective action, preventative action and improvement processes. Information from these meetings is available to all staff via the minutes of the meeting and is discussed as part of regular team meetings. The results of the quality improvement programme form a part of the development, training and education of all staff.

Minutes of the meetings of the Quality Management Team Meetings are documented, circulated to participating staff and available to all staff via the "shared documents" folder (Y:\Shared Documents\Memos & Minutes) via the Genetics Server with access via the desktop of all PCs in Cytogenetics.

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