# QUALITY MANUAL

GENOMIC DIAGNOSTICS LABORATORY

## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>PURPOSE</td>
<td>3</td>
</tr>
<tr>
<td>2.</td>
<td>GENERAL INFORMATION</td>
<td>3</td>
</tr>
<tr>
<td>2.1</td>
<td>Title of Laboratory</td>
<td>3</td>
</tr>
<tr>
<td>2.2</td>
<td>The Quality Manual</td>
<td>4</td>
</tr>
<tr>
<td>3.</td>
<td>QUALITY POLICY</td>
<td>4</td>
</tr>
<tr>
<td>4.</td>
<td>ORGANISATION, RESPONSIBILITIES AND AUTHORITIES</td>
<td>6</td>
</tr>
<tr>
<td>4.1</td>
<td>Relationship to the Host Organisation</td>
<td>6</td>
</tr>
<tr>
<td>4.2</td>
<td>Organisation and Responsibilities within the GDL</td>
<td>6</td>
</tr>
<tr>
<td>5.</td>
<td>ORGANISATION AND QUALITY MANAGEMENT SYSTEM</td>
<td>9</td>
</tr>
<tr>
<td>5.1</td>
<td>Organisation and management</td>
<td>9</td>
</tr>
<tr>
<td>5.2</td>
<td>Needs and requirements of users</td>
<td>9</td>
</tr>
<tr>
<td>5.3</td>
<td>Quality Policy</td>
<td>10</td>
</tr>
<tr>
<td>5.4</td>
<td>Quality management system</td>
<td>10</td>
</tr>
<tr>
<td>5.5</td>
<td>Quality objectives and plans</td>
<td>10</td>
</tr>
<tr>
<td>5.6</td>
<td>Quality manual</td>
<td>10</td>
</tr>
<tr>
<td>5.7</td>
<td>Quality Manager</td>
<td>10</td>
</tr>
<tr>
<td>5.8</td>
<td>Document Control</td>
<td>11</td>
</tr>
<tr>
<td>5.9</td>
<td>Control of process and quality records</td>
<td>11</td>
</tr>
<tr>
<td>5.10</td>
<td>Control of clinical material</td>
<td>11</td>
</tr>
<tr>
<td>5.11</td>
<td>Management review</td>
<td>12</td>
</tr>
<tr>
<td>6.</td>
<td>PERSONNEL</td>
<td>12</td>
</tr>
<tr>
<td>6.1</td>
<td>Professional Direction</td>
<td>12</td>
</tr>
<tr>
<td>6.2</td>
<td>Staffing</td>
<td>12</td>
</tr>
<tr>
<td>6.3</td>
<td>Personnel Management</td>
<td>13</td>
</tr>
<tr>
<td>6.4</td>
<td>Staff orientation and induction</td>
<td>13</td>
</tr>
<tr>
<td>6.5</td>
<td>Job descriptions and contracts</td>
<td>13</td>
</tr>
<tr>
<td>6.6</td>
<td>Staff records</td>
<td>14</td>
</tr>
<tr>
<td>6.7</td>
<td>Staff annual joint review</td>
<td>14</td>
</tr>
<tr>
<td>6.8</td>
<td>Staff meetings and communication</td>
<td>14</td>
</tr>
<tr>
<td>6.9</td>
<td>Staff training and education</td>
<td>15</td>
</tr>
<tr>
<td>7.</td>
<td>PREMISES AND ENVIRONMENT</td>
<td>15</td>
</tr>
<tr>
<td>7.1</td>
<td>Premises and environment</td>
<td>15</td>
</tr>
<tr>
<td>7.2</td>
<td>Facilities for staff</td>
<td>15</td>
</tr>
<tr>
<td>7.3</td>
<td>Facilities for storage</td>
<td>15</td>
</tr>
</tbody>
</table>
C5  Health and Safety .................................................................................................................. 16

8.  EQUIPMENT, INFORMATION SYSTEMS AND REAGENTS .................................................. 16
    D1  Procurement and Management of equipment .................................................................. 16
    D2  Management of data and information ........................................................................... 17
    D3  Management of reagents, calibration and quality control material ............................... 17

9.  PRE-EXAMINATION PROCESS ...................................................................................... 17
    E1  Information for users and patients ................................................................................. 17
    E2  Request forms ................................................................................................................ 18
    E3  Specimen collection and handling .............................................................................. 18
    E4  Specimen transportation .............................................................................................. 18
    E5  Specimen reception ...................................................................................................... 19
    E6  Referral to other laboratories ..................................................................................... 19

10.  EXAMINATION PROCESS ......................................................................................... 20
     F1  Selection and validation of examination procedure .................................................... 20
     F2  Examination procedures ............................................................................................ 20
     F3  Assuring the quality of examinations ........................................................................ 20

11.  POST-EXAMINATION PROCESS ............................................................................. 20
     G1  Reporting results ......................................................................................................... 20
     G2  The report .................................................................................................................. 21
     G3  The telephoned report ............................................................................................... 21
     G4  The amended report .................................................................................................. 21
     G5  Clinical advice and interpretation ............................................................................ 21

12.  EVALUATION AND QUALITY ASSURANCE ............................................................. 21
     H1  Evaluation and improvement processes .................................................................... 22
     H2  Assessment of user satisfaction and complaints ....................................................... 22
     H3  Internal audit of quality management system .......................................................... 22
     H4  Internal audit of examination processes .................................................................. 23
     H5  External Quality Assessment .................................................................................... 23
     H6  Quality improvement ................................................................................................. 23
     H7  Identification and control of nonconformities ............................................................ 24

13.  Appendix ..................................................................................................................... 24
1. **PURPOSE**

This Quality Manual is consistent with the requirements of the Clinical Pathology Accreditation (UK) Ltd (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.

2. **GENERAL INFORMATION**

2.1 **Title of Laboratory**

The Genomic Diagnostics Laboratory (GDL) comprises two major laboratory sections –Biochemical Genetics (also known as the Willink Laboratory) and the joint Cytogenetics, Specialised Cell Culture Services and Molecular Genetics section. It is part of the Manchester Centre for Genomic Medicine, a directorate within St Mary’s Hospital, which is a division of the Central Manchester University Hospitals NHS Foundation Trust.

The laboratories provide services predominantly for the North-West population including East Lancs., South Cumbria, Greater Manchester and North–East Cheshire, but also provide some services nationally and internationally. Tests are undertaken on a variety of different tissues including blood samples, amniotic fluid, chorionic villus, post mortem samples, urine, skin samples, and tumour samples (see the Manchester Centre for Genomic Medicine website [www.mangen.org.uk](http://www.mangen.org.uk) for more details).

The laboratories also collaborate closely with two international EQA schemes which operate from within The Manchester Centre for Genomic Medicine; The European Molecular Genetics Quality Network, EMQN [www.emqn.org](http://www.emqn.org) and the European Research Network for evaluation and improvement of screening, Diagnosis, and treatment of Inherited disorders of Metabolism, ERNDIM [www.erndim.org](http://www.erndim.org).

The department has recently been rebranded and the website re-developed. Genetic Medicine is now known as the Manchester Centre for Genomic Medicine to reflect the collaboration between the NHS Trust and the University of Manchester. The Regional Genetics Laboratory Services (RGLS) is now known as the Genomic Diagnostics Laboratory (GDL).

**The postal address is:**

Genomic Diagnostics Laboratory,  
The Manchester Centre for Genomic Medicine,  
6th Floor, St Mary’s Hospital,  
Central Manchester University Hospitals NHS Foundation Trust,  
Oxford Road  
Manchester  
M13 9WL  

**Tel:**  
Molecular Genetics Lab: +44 (o) 161 276 6122  
Cytogenetics Lab: +44 (o) 161 276 6553  
Biochemical Genetics Lab: +44 (o) 161 701 2138
2.2 The Quality Manual

This Quality Manual describes the Quality Management System of the GDL. There are references to CPA (UK) Ltd Standards (in brackets) and to procedures (in square brackets), written in fulfilment of these standards.

This Quality Manual (including appendix) is the index volume to separate documents describing the management, laboratory, clinical and quality procedures. Sections 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 GDL seeks to comply with the particular standard and references are given to appropriate procedures.

The standards relate to each other; 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.

<table>
<thead>
<tr>
<th>Section in the Quality Manual</th>
<th>Section of CPA Standards</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>A Organization and quality management system</td>
</tr>
<tr>
<td>6</td>
<td>B Personnel</td>
</tr>
<tr>
<td>7</td>
<td>C Premises and environment</td>
</tr>
<tr>
<td>8</td>
<td>D Equipment, materials and reagents</td>
</tr>
<tr>
<td>9</td>
<td>E Pre-examination process</td>
</tr>
<tr>
<td>10</td>
<td>F Examination process</td>
</tr>
<tr>
<td>11</td>
<td>G Post-examination process</td>
</tr>
<tr>
<td>12</td>
<td>H Quality assurance and evaluation</td>
</tr>
</tbody>
</table>

3. QUALITY POLICY

The Quality Policy (A3 Quality Policy) of the GDL is given overleaf and published as a separate controlled document [DOC1018] displayed within the laboratory and accessible from the laboratory database.
QUALITY POLICY
GENOMIC DIAGNOSTICS LABORATORY

The Genomic Diagnostics Laboratory (GDL) comprises two major sections reflecting diverse workstreams - the Biochemical Genetics, section (also known as the Willink laboratory) and the joint Cytogenetics, Specialised Cell Culture Services and Molecular Genetics section. It is part of the Manchester Centre for Genomic Medicine– a directorate within St Mary’s Hospital which is part of Central Manchester University Hospitals NHS Foundation Trust. The GDL is committed to providing a service of the highest quality.

Commitment to Quality
The GDL is committed to providing the correct genetic diagnosis, with the correct test carried out on the correct patient in an appropriate timeframe using the most relevant technology, and to communicate that diagnosis to the correct 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:

- have a quality management system which brings together all areas of laboratory organisation, including documented procedures 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 genetic services they require and that their patients deserve,
- are committed to the health, safety and welfare of all our staff and visitors,
- are committed to good professional practice and conduct as laid out in best practice guidelines and Trust procedures,
- are committed to complying with current environmental legislation.

The GDL complies with standards set by CPA (UK) Ltd and;

- has a commitment to good practice in staff recruitment operating policies, offers continued training and development to staff of all grades, ensuring that we can provide a full and effective service to our users,
- operates an efficient and effective procurement and maintenance of equipment and other resources,
- implements policies for the handling of all specimens that ensure the correct performance of tests,
- uses procedures to ensure exceptional quality in the tests we perform,
- reports test results that are accurate, timely, clinically useful and that respect patient confidentiality,
- undertakes internal audit and regular assessment of user satisfaction and participate in external quality assessment to seek to identify areas of non compliance with standards or areas for improvement,
- maintains a commitment to continual quality improvement.

Signed on behalf of the GDL:

GDL Director

Date: 10.05.2013
4. ORGANISATION, RESPONSIBILITIES AND AUTHORITIES

4.1 Relationship to the Host Organisation
The GDL is part of the directorate of the Manchester Centre for Genomic Medicine within the Division of St Mary’s hospital and 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 (DOC893)
CMFT: Central Manchester University Hospitals NHS Foundation Trust; SMH: St Mary’s Hospital.

4.2 Organisation and Responsibilities within the GDL
A Clinical Scientist of consultant equivalent standing directs the GDL Laboratories (B1), supported by a senior management team of consultant and principal clinical scientists. The Manchester Centre for Genomic Medicine and the GDL have a management structure and participate in regular management meetings (A1.5).

Three laboratories (Regional Molecular Genetics, Regional Cytogenetics and Willink Biochemical Genetics) were brought into a single management structure in 2011, and in 2013 the Molecular and Cytogenetics services were merged and service delivery reorganised. Protocols and policies are under review and are being rationalised to reflect these changes.

a) The Genetics Executive Team (A1.5) meets bimonthly. Its membership is as follows:
- Clinical Director for Genetics
- Clinical Lead
- Director of GDL
- Directorate Manager
• Genetic Counsellor Lead
• University Lead
• Governance Lead

b) The Genetics Management Group meets bimonthly. Its membership is as follows:
• Clinical Director for Genetics
• Directorate Manager
• Director of GDL
• Clinical Lead
• Information Systems Manager
• Project Manager
• Chair of the Operations and Service Group
• Chair of the People Group

c) The Genetic Medicine Clinical Effectiveness Committee meets monthly. Its membership is as follows:
• Clinical Lead
• Genetics Risk Lead
• Divisional Clinical Governance Manager
• Clinical Representative for Biochemical Genetics
• Quality Lead – representatives from all three labs on a rotational basis
• Quality Manager(s) – GDL Laboratories
• Clinical Research Lead
• Office Manager – Clinical Genetics
• Clinical Audit Lead
• Genetic Counsellors’ Representative

Minutes of these meetings are circulated to members and appropriate actions taken. Minutes are also made available to members and are held by the PA to the Clinical Lead.

d) The Senior Management Team of the GDL Laboratories meets bi-monthly. Membership is as follows:
• Director of GDL
• Head of Laboratory sections, Consultant and Principal Clinical Scientists (named in figure 2 below)

Notes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are held by the Director of GDL Laboratories.

e) The Willink Biochemical Genetics Strategic Management Meeting meets bimonthly. Its membership is as follows:
• Director of GDL
• Head of Willink Biochemical Genetics
• Quality Manager for GDL Laboratories
• Business Manager for GDL Laboratories
• Sectional leads and deputies
Notes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are held by the Head of Willink Biochemical Genetics.

f) The Willink Biochemical Genetics **Operational Management Meeting** meets monthly. Its membership is as follows:
- Head of Willink Biochemical Genetics
- Sectional leads and deputies
- Quality and Risk Lead for Biochemical Genetics

Notes of the meetings are circulated to members of the team and appropriate actions taken. Minutes are made available to all members of staff via Q-Pulse.

g) The **laboratory strategy and development group** meets bimonthly. Its membership is:
- Clinical Director for Genetics
- Director of GDL
- SMH Manager
- Directorate Manager
- Academic Clinicians
- Consultant Clinical Scientists – Molecular Genetics
- Project Manager

Minutes of these meetings are circulated to members and appropriate actions taken. Minutes are also made available to members and are held by the PA to the Clinical Lead.

h) The **Quality Management Team** (relates to CPA standard A4) meets bi-monthly. Its membership consists of a Band 8 Quality Manager(s), Band 7 scientists and genetic technologists with speciality roles as follows:
- Quality Manager(s)
- Director of GDL
- Quality Lead /Risk Lead
- Document Control Lead
- Training Officer
- Audit Lead
- Manchester Centre for Genomic Medicine Health and Safety Officer
- Equipment Lead

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 Q-Pulse.
Figure 2: The organisation within the Genomic Diagnostics Laboratory.

5. ORGANISATION AND QUALITY MANAGEMENT SYSTEM

A1 Organisation and management
The organisation and management of the GDL 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, results from which are uploaded to Q-pulse. 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 and consideration of the findings form part of the annual management review (A11 Management review).

The CPA standard A2.4 is fulfilled by DOC1192 - Developing and maintaining contracts for medical laboratory services.

The service profile of the GDL can be found on the Manchester Centre for Genomic Medicine website at www.mangen.org.uk.
A3 Quality Policy
The Quality Policy of the GDL is detailed in section 2.0 of this Quality Manual and available to all staff from Q-Pulse on the Genetics Server [DOC1018].

A4 Quality management system
The components and relationships within the Quality management system are described in section 5 of this Quality Manual under standards A5 to A11. The roles and responsibilities of laboratory quality management in ensuring compliance with the CPA standards are defined below:

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director of GDL Laboratories</td>
<td>Overseeing compliance with A to H standards</td>
</tr>
<tr>
<td>Consultant Clinical Scientists</td>
<td>Deputising for Director of Lab responsibilities</td>
</tr>
<tr>
<td>Principal Clinical Scientists /</td>
<td>Ensuring compliance with E to G standards</td>
</tr>
<tr>
<td>Section Leaders</td>
<td></td>
</tr>
<tr>
<td>Training Officer</td>
<td>Ensuring compliance with B9 standard</td>
</tr>
<tr>
<td>Quality Manager(s)</td>
<td>Implementing, maintaining and reporting on function and effectiveness of the</td>
</tr>
<tr>
<td></td>
<td>Quality Management System (including liaising with inspection bodies). A to H</td>
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<tr>
<td></td>
<td>standards.</td>
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<tr>
<td>Health &amp; Safety Officer</td>
<td>Ensuring compliance with C5 standard</td>
</tr>
<tr>
<td>Document Control Lead</td>
<td>Ensuring compliance with A8 standard</td>
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<tr>
<td>Audit Lead</td>
<td>Ensuring compliance with H3 and H4 standards</td>
</tr>
<tr>
<td>Equipment Lead</td>
<td>Ensuring compliance with D1</td>
</tr>
</tbody>
</table>

Table 1: Roles within the Quality Management system

A5 Quality objectives and plans
The GDL contributes to the Genetic Medicine service planning process. The Management Team (see section 4.2) defines the quality objectives within the GDL. This Team in conjunction with the Quality Team is responsible for ensuring that plans are made to meet these objectives. The quality objectives are available to all members of staff on Q-Pulse [DOC1343]. The management review (see A11 below), undertaken annually, 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 Quality Manual [DOC1191].

A7 Quality Manager
The Quality Manager for the GDL works with the Senior Management and Quality 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 raising awareness of the needs and requirements of users. The current post-holder is Dr Andrea Naughton.
There is are two Quality and Risk Leads who can deputise for the Quality Manager; Ms Natasha Leo, specific area of responsibility is the Molecular and Cytogenetics service and Mr Alistair Horman for Biochemical Genetics.

A8 Document Control
The GDL has 3 designated staff responsible for ensuring document control. They have specific areas of responsibility and report formally via the Quality Management team meetings.

Documents are controlled using Q-pulse software (Gael). Documents are approved for use by authorised personnel prior to use and are regularly reviewed and updated.

Q-pulse training is provided to all staff and there are guides within Q-pulse to enable its effective use.
- DOC842 - RGLS Document Template
- DOC843 - How to use the Q-Pulse document template
- DOC844 - A brief guide to document control
- DOC845 - Procedure for the preparation and control of documents
- DOC1196 - The role of the document controller
- MP 000 135 - How to review, approve and acknowledge documents on Q-Pulse

Trust documents can be accessed by all staff through the intranet. A separate document control process exists for documents relating to CMFT policies (CG01 Document Control Policy - located in Departments>Risk Management>Policies and Documents). Where there are forms in local use on a regular basis a copy may also be placed in the Q-Pulse database and regularly reviewed against the Trust form.

Other important documents from external sources relating to current practice are managed within the Q-Pulse document control system (DOC846 – Control of documents of external origin) and regularly reviewed to ensure the most up-to-date version is available.

A9 Control of process and quality records
The GDL has procedures to meet the requirements for controlling process records and quality records. The details of all documents, their storage and retention are detailed in the document DOC1279 - Control of process and quality records.

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

Process records are available to re-construct the process of any examination.

A10 Control of clinical material
The GDL has procedures to meet the requirements for the control of clinical material. The details of all biological materials, their storage and retention are detailed in the documents below.
- DOC1464 – RGLS – Retention and storage of Biological Material
- MP000 057 - The Retention & Storage of Pathological Records & Archives
This document is supplemented by the following procedures:
- DOC1417 - Procedure for Leaking Samples
- DOC1419 - Transport of Biological Specimens
- DOC2044 - High Risk Samples

A11 Management review

The Quality Team and Management representatives conduct an annual review, which considers the following items of information:

a) A report from the Head of Department
b) A report from the Quality Team including a review of laboratory performance for the year against Key Performance Indicators and a review of annual Objectives (A11.1).
c) A review of the quality policy (A11.1)
d) Assessment of user satisfaction and complaints (H2)
e) Internal audit of quality management system (H3)
f) Internal audit of examination processes (H4)
g) External quality assessment reports (H5)
h) Reports of assessments by CPA (UK) Ltd\(^1\), UKNEQAS\(^2\), EMQN\(^3\), ECFN\(^4\), ERNDIM\(^5\) and CDC\(^6\).
i) The status of preventive, corrective and improvement actions (H6)
j) Major changes in organisation and management, resource (including staffing) or process.
k) 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. The annual management review is available to all members of staff on Q-Pulse [DOC1020].

6. PERSONNEL

B1 Professional Direction

A Clinical Scientist of consultant equivalence (GDL Director) is responsible for the GDL Laboratories [DOC433]. The organisation and responsibilities within the laboratory are shown in figure 2 of section 4.0 of this quality manual. Consultant Clinical Scientists with specific team responsibilities are responsible for the management of the Laboratory in the absence of the GDL Director.

B2 Staffing

The GDL carries out a regular review of the repertoire, workload and staffing levels of the Laboratory and employs an appropriate number of qualified staff to deal with the workload of the department.

\(^1\) Clinical Pathology Accreditation (UK) Ltd
\(^2\) United Kingdom National External Quality Assessment Schemes for Molecular Genetics
\(^3\) European Molecular Genetics Quality Network
\(^4\) European Network for Cystic Fibrosis
\(^5\) European Research Network for evaluation and improvement of screening, Diagnosis, and treatment of Inherited disorders of Metabolism
\(^6\) Centres for Disease Control
All staff employed as Clinical Scientist grades are HCPC state registered. Trained Genetic Technologist staff are directed towards the voluntary state registration register. There is a documented line of accountability for all staff detailed in figure 2 of section 4.0.

Staffing includes individuals with roles in quality management, training and education, and health and safety (see table 1, section A4 in this quality manual). The officer/leads for these roles are:
- Quality Management - Andrea Naughton.
- Training Officer – Heather Ward
- Health & Safety – Stuart Bayliss.

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 site http://intranet.cmht.nwest.nhs.uk/policies) or within the GDL via the Q-Pulse database as appropriate:

a) staff recruitment (CMFT policies)
b) staff orientation and induction (B4)
c) job descriptions and contracts (B5)
d) staff records (B6)
e) staff joint review (B7)
f) staff meetings and communication (B8)
g) staff training and education (B9)
h) Grievance/Disputes Procedure (CMFT policy)
i) Disciplinary Procedure (CMFT policies)
j) Performance Capability (CMFT policy)
k) Dignity at work (CMFT policy)

B4 Staff orientation and induction
All new staff are required to attend the induction programme provided by the Trust on their first day of employment with the Trust. Additionally they undertake a specific induction to the laboratory. 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. A record of the areas of induction undertaken is kept in the personal records of each member of staff.

- DOC772 - New Starters Induction Logbook – Regional Genetics Laboratories
- DOC775 - Local Induction Policy and Guide - Regional Genetics Laboratories

Together these satisfy the requirements of standard B4

B5 Job descriptions and contracts
Each member of staff has a job description and contracts of employment with CMFT, 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 Director of the GDL to which they are entitled to see on request. The files contain:

a) personal details  
b) employment details  
c) job description  
d) terms and conditions of employment  
e) a record of staff induction and orientation  
f) relevant education and professional qualifications  
g) certificate of registration, if relevant  
h) record of return to work following absence  
i) accident record  
j) a record of annual appraisal and personal development plan  
k) record of disciplinary action  
l) a record of competency (also held on the Q-Pulse database and in paper format by some staff).  
m) a record of attendance at fire lectures (held by the Health & Safety Officer)  
n) a record of courses and scientific conferences attended (part of CPD, held on the Q-Pulse database and in paper format by some staff).

An occupational health record is held by the Occupational Health Department within the Trust.

Each member of staff has a Training & Development Portfolio which they are required to keep up to date with information and data relating to their personal professional development. Clinical Scientists hold a CPD Training Record and/or are registered for the Royal College of Pathologists CPD Scheme.

B7  Staff annual joint review
Each member of staff has an annual appraisal with their line manager using the CMFT Appraisal documentation and Guidance which is available on the Trust intranet. The Trust provides training for all staff undergoing review and those conducting the review. This process includes the review of:

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

A copy of the completed Appraisal documentation which includes an agreed personal development plan is placed in the appropriate personal file. The Trust maintains a record of appraisal dates for all staff and monitors compliance.

B8  Staff meetings and communication
Laboratory Meetings are held regularly, generally in the form of team meetings. Minutes of the meetings are documented on Q-Pulse and circulated to all relevant members of staff (Lab meetings) and appropriate actions taken.
B9 Staff training and education

The GDL Laboratories are authorised by the National School for Healthcare Science to provide training for both Clinical Scientists and Practitioners using national training programmes.

All staff undertake in induction when appointed (see B4). Training and education needs for all trained staff are identified through annual appraisal (see B7), and in the interim period in accordance with the laboratory system for risk management and continuing professional development [E&T000 019 - Staff Training and Education]. The GDL has a Training Officer (see A4) to develop policies and procedures, provide an oversight of training needs, to organise training within the laboratory. The current post holder is Mrs Heather Ward.

There are regular GDL and Genetic Medicine seminars with both internal and external speakers presenting diagnostic, research, journal article appraisal and technical workshops. All staff are invited to attend.

7. PREMISES AND ENVIRONMENT

C1 Premises and environment

The Manchester Centre for Genomic Medicine occupies the 6th floor of the CMFT major hospital building. It is designated as part of St Mary’s Hospital. Access to the department is restricted via swipe cards.

Specimens are delivered to the Manchester Centre for Genomic Medicine Mail Room or via a pneumatic pod system to the pre-analytical laboratory for molecular genetic and/or cytogenetic tests. Pre- and post- analytical laboratories and offices are clearly defined.

C2 Facilities for staff

Suitable facilities are provided for staff within the GDL including secure locker space, sufficient toilet and shower facilities, basic catering facilities with a staff room and access to the hospital cafeteria, cafes and shops [DOC473].

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
d) hazardous substances (C5)
e) reagents (D3)
f) waste material for disposal
C5  **Health and Safety**

The GDL provides a safe working environment for staff in accordance with current legislation. Details of the Health and Safety of the host institution (CMFT) can be found via the CMFT intranet. The Manchester Centre for Genomic Medicine has a Health and Safety Officer, Stuart Bayliss. Each laboratory within the GDL has an appointed Health and Safety Lead who works with the Health and Safety Committee to ensure that all areas of this standard are met.

Procedures relating to this standard are available to all members of staff via the Q-Pulse database. All laboratory procedure documents include any relevant risk assessments. CoSHH documentation is available on Q-Pulse for all chemicals used in the GDL. The system of CoSHH documentation is currently being updated on Q-Pulse with individual assessment checklist forms in preparation for all substances.

All staff are given information about the Health and Safety procedures within the laboratory during their induction. Any issues relating to Health and Safety are discussed in Quality Team Meetings and in regular team meetings. Model rules exist for visitors to the department [DOC1420] outlining relevant Health and Safety matters.

- **DOC1420** – Visitors to Genetic Medicine
- **DOC2020** – Health and Safety – General Guidelines
- **DOC2021** – RGLS- Health and Safety Policy
- **DOC1418** – Safety Equipment
- **DOC2014** – Genetic Medicine Safety Policy – CoSHH
- **DOC2064** – RGLS Waste Disposal

8. **EQUIPMENT, INFORMATION SYSTEMS AND REAGENTS**

D1  **Procurement and Management of equipment**

The laboratory has equipment which is sufficient and appropriate to provide the laboratory service. Procurement of equipment above £5000 is acquired via the acceptance of a suitable business case. Several sources of equipment, services or works are considered before purchase.

Items of equipment are either serviced, repaired or calibrated by Sodexo or are contracted to external sources. Information about equipment suppliers, a record of laboratory assets (including manufacturer, serial number, date of acquisition, location) 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. Adverse incidents involving equipment are reported via the non-conformance module of the Q-Pulse database, a risk assessment made and the equipment placed on the risk register.

There is no point-of-care testing carried out within the GDL.

There are individual protocols detailing the correct use and maintenance of equipment on a day-to-day basis, these are drawn up in line with manufacturer’s recommendations.
D2  **Management of data and information**

The GDL has a number of data systems in use; in each case procedures exist to ensure:

a) Security  
b) Access  
c) Confidentiality and data protection  
d) Back-up systems  
e) Storage, archive and retrieval

The Trust has a Data Protection Policy to which the Laboratory adheres which can be found on the Trust intranet (and as MP000 064 - CMFT Trust Data Protection Policy). Supporting documents include:

- DOC2051 - RGLS Confidentiality Policy  
- DOC310 – Genetic Medicine – data storage, back up/recovery and archiving strategy  
- MP 000 080 – Procedure for off-site storage of records

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

The GDL operates a system for the management and regular monitoring of stock of reagents and materials to ensure sufficient supply is available to maintain the service. Stock levels are replaced based on both usage and the likely time taken for replacement orders to be delivered. All procedures have a risk assessment carried out before any processing begins and this includes evaluation of any new chemicals required being assessed by the relevant Health and Safety Lead for their COSHH regulations prior to any order being placed. Suppliers are evaluated as part of the procurement process (D1). Disposal of materials is regulated by the Trust Health and Safety Officer in conjunction with the Health and Safety Officer who will advise on whether waste chemicals can be disposed of safely using means available to the laboratory or whether specialist removal is required.

- DOC2025 - Delivery and Receipt of Reagents and Consumables  
- DOC2014 - Genetic Medicine Safety Policy – CoSHH  
- MP000 061 - Procurement of Equipment and the Ordering of Supplies  
- DOC1464 - RGLS - Retention, Storage and Disposal of Biological Material  
- DOC1279 - Control of Process and Quality Records  
- DOC2064 – RGLS Waste Disposal

9.  **PRE-EXAMINATION PROCESS**

E1  **Information for users and patients**

Information for users and patients is available via the Manchester Centre for Genomic Medicine website and involves a real time update to ensure information is kept up-to-date.

- The Manchester Centre for Genomic Medicine Website: [http://www.mangen.org.uk/](http://www.mangen.org.uk/) or [http://www.mangen.co.uk/](http://www.mangen.co.uk/)

The website is currently being re-developed and the department rebranded. Genetic Medicine is now known as the Manchester Centre for Genomic Medicine to reflect the collaboration between the NHS Trust and the University of Manchester. The Regional Genetics Laboratory Services (RGLS) is now known as the Genomic Diagnostics Laboratory (GDL).
E2 Request forms
Requests for the majority of examinations are made either using a joint Molecular Genetics/Cytogenetics test request form (DOC19 – Genetics laboratories referral form), Cell Bank request for cell line/storage form (LF160 001 - Cell Bank referral card) and/or specific test request form for the Willink Biochemical Genetics laboratory (DOC512 – Biochemical Genetics laboratory referral form). Specific forms are required for stratified medicine services. Request forms are available:
- directly from the laboratory
- as postnatal requests via the Patient Administration System (PAS) within CMFT
- from the Genetic Medicine website: www.mangen.org.uk.

The following information is requested from the user:
1. the necessary information required for unique and unequivocal patient identification
2. date of specimen sent to lab
3. type of specimen
4. clinical reason for the request and investigation requested
5. full consultant details
6. details of referring hospital
7. urgency of the test
8. other information when appropriately required (consent, high infection risk, gestation and date of delivery).

Space is available for the laboratory to complete the following information:
1. Date of arrival in the laboratory
2. identification of priority status
3. laboratory accession number

The date of arrival of a sample request in the laboratory is recorded directly onto the relevant laboratory database. Users are encouraged to complete the request forms fully. Incomplete information is requested where necessary by telephone (urgent cases) or letter. Procedures exist for dealing with incomplete information that may affect onward processing of samples (DOC1563 - Inappropriately Labelled RGLS Samples).

E3 Specimen collection and handling
Information concerning specimen collection and handling is available on the reverse of the Genetic Medicine – Genetic Test Request forms, or via the Genetic Medicine website (www.mangen.org.uk). The laboratory is not directly involved in specimen collection for any of its sample types.

E4 Specimen transportation
The Genetic Medicine website (www.mangen.org.uk) contains model rules and detailed information for the transportation of specimens to the laboratory. Some samples are exported from the laboratory. The protocols governing these are:
- DOC1419 - Transport of biological specimens
- LP 000 007 - Export procedure - UK specialist genetic testing network
- LF 000 141 - Sample export form
- MP000 072 - Transportation of Samples or Materials from the Cytogenetics Laboratory to Other Laboratories
- LP100 007 - Prenatal Section - Exporting Samples for Testing in Other Laboratories

E5 Specimen reception
Specimens for GDL are delivered to the reception point close to the Lift and Stairs in Core Lift Junction 8 in the Royal Manchester Children’s Hospital (L.6.CV.220). Samples for Molecular Genetic or Cytogenetic tests are transferred prior to unpacking to the Specimen Reception in the Pre-analytical laboratory located in room L.6.CV.123. Alternatively, samples are received via the pneumatic pod system to room L.6.CV.221 or directly to room L.6.CV.123. Samples for Biochemical tests are transferred prior to unpacking to the appropriate laboratory area in room L.6.CV.287 or room L.6.CV.289. Sample referrals are date and time stamped at receipt and the urgent samples dealt with promptly.

There is a standard procedure for the rejection of specimens including those where the request and specimen are not linked (DOC1563 - Inappropriately Labelled RGLS Samples).

The relevant personal protective equipment is available for use. Leaking samples are treated appropriately, receipt recorded and a Trust incident logged. High risk samples are treated appropriately.
- DOC1418 - Safety equipment
- DOC1417 - Procedure for Leaking Samples
- DOC2044 - High Risk Samples

E6 Referral to other laboratories

Biochemical Genetics Samples: These are handled by the Willink laboratory which periodically refers samples to external laboratories when a biochemical genetics test is required that is not available locally. The laboratory maintains a list of referral laboratories for routinely requested tests (DOC613 - Samples to Send Away). More unusual requests are dealt with by a clinical scientist as it may be necessary to first identify a suitable provider. All referred samples are booked into the sendaway database. When the report is received from the external lab the results are entered on to the database and the original report sent out to the clinician (although some labs also send a copy of the report directly to the clinician).

Molecular Genetics Samples: The GDL will extract DNA and export samples on behalf of external and internal (Clinical Genetics) referrers (LP 000 007 - Export procedure - UK specialist genetic testing network). The lab will give advice on the most appropriate laboratory to choose. In order to meet regulatory requirements we will always choose UKGTN testing laboratories (http://www.ukgtn.nhs.uk/gtn/Home) where possible and Orphanet (http://www.orpha.net/consor/cgo-bin/index.php) and Genetests (http://www.ncbi.nlm.nih.gov/sites/GeneTests?db=GeneTests) where not.
Where samples are exported for research purposes the referring clinician must take responsibility for the testing credentials of the recipients. A full audit trail for exported samples is maintained on the laboratory LIMS.

Cytogenetic Samples: Referrals for karyotype analysis are not referred to third party testing laboratories. Prenatal samples may be received for processing and/or culture prior to testing in
another laboratory outside the Trust (MP000 072 - Transportation of Samples or Materials from the Cytogenetics Laboratory to Other Laboratories).
This standard is met by specimen transportation procedures (E4) and by the laboratory procedure:
- QP 000 008 - Assessing the suitability of sample referral labs.

10. EXAMINATION PROCESS

F1 Selection and validation of examination procedure
All new examination procedures are validated prior to introduction. Validation is achieved by acceptance of manufacturers’ data and by in-house verification. Copies of validation information are kept on Q-Pulse. Paper copies of other validation documents are available. Any significant changes to examination procedures are reported to relevant users prior to implementation. Users are asked for their views regarding examination procedures via user surveys (H2). This standard is met by the following procedures:
- DOC2063 - Design, Development and Validation of New Tests or Services and Retrospective Validation of Existing Tests
- DOC1566 - Validation Project for RGLS

F2 Examination procedures
Procedures are available for the conduct of all examinations within the GDL and are located on the Q-Pulse database in the relevant Laboratory Procedures section of the document register and are available to all staff. These procedures are reviewed regularly by examination and vertical audit and changed in the light of objectives and new methods as appropriate. All procedures include the requirements of CPA standard F2.1 where applicable.

F3 Assuring the quality of examinations
Clinical Scientists and senior technologists ensure that the appropriate processes are developed, validated and implemented by all staff. Staff are trained in the use of documented procedures and regular audit of analytical quality data is conducted by checking and reporting procedures and authorisation to ensure that all tests meet the required quality for issue. Procedures are available for the use and acceptance of internal quality control systems for all genetic laboratory examinations for which such control systems are required. All laboratory test standard operating procedures are IQC risk assessed. For these tests, IQC results are recorded, regularly evaluated and subsequent corrective and/or preventive actions taken recorded. This standard is met by the following procedure:
- DOC1564 - Policy for internal quality control (IQA) and participation in external quality assessment (EQA)

11. POST-EXAMINATION PROCESS

G1 Reporting results
The laboratories have defined reporting criteria.
The GDL aims to achieve the national guidelines for the reporting time for all examinations, where such guidelines exist. Where applicable the laboratory turnaround times reflect the clinical needs of the user. Turnaround times are monitored and reviewed at laboratory team and quality meetings and action plans introduced if reporting times are not being met. Target turnaround times are published on the Manchester Centre for Genomic Medicine website http://www.mangen.org.uk. Laboratory reporting times are collected and reported quarterly via the Trust Audit department for specialised services quality dashboards. http://www.specialisedservices.nhs.uk/info/specialised-services-quality-dashboards.

The following laboratory procedures meet this standard:
- DOC2066 – RGLS Reporting Procedures

G2 The report
Reports in the GDL are produced using the Molecular Genetics laboratory database and/or Shire Management database (Cytogenetics tests) or a combination of Lotus Approach and Access databases (Biochemical Genetics tests). The Willink is in the process of acquiring a comprehensive LIMS. Reports are clear, unambiguous and conform to requirements of professional best practice, CPA (UK) Ltd (G2.1, G2.2 and G2.3). The report contains all the requirements specified in the CPA (UK) standards G2.3 and G2.4. Reports are validated (authorised) by trained staff before issue by post, telephone, fax or e-mail. All reports are handled and transmitted confidentially. Laboratory procedures listed separately (G1) detail factors that need to be considered and included in the written report if appropriate.

G3 The telephoned report
Telephoned reports are managed by the following procedure which meets the requirements of the CPA (UK) standard G3.1:
- DOC2065 - RGLS Telephoning, Faxing and E-mailing Results

G4 The amended report
Amended reports are issued when necessary and conform to the CPA (UK) standard G4.1. The procedures for the issue of amended authorised reports are:
- DOC2048 - Issuing Amended Reports

G5 Clinical advice and interpretation
The laboratory procedures for reporting results (see 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 only given by appropriately trained staff.

Clinical advice and interpretation is available from scientific staff during routine working hours, Monday – Friday (with the exception of Bank Holidays, Christmas Day and Boxing Day).

12. EVALUATION AND QUALITY ASSURANCE
H1 Evaluation and improvement processes
There is ongoing evaluation and quality improvement to ensure we deliver a high quality service [DOC1017 - Monitoring quality indicators]. Procedures for evaluation and quality improvement processes are detailed in this section of this quality manual (H1.1). These procedures include those relating to:

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, UKNEQAS ,EMQN, ECFN, ERNDIM and CDC.
f) quality improvement, including corrective and preventive action and the monitoring of quality indicators (H6)
g) Identification and control of non-conformities (H7)

The results of these evaluation and quality improvement processes are available to all staff via the Laboratory Quality Management system (see 4.2) and are also 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 GDL has a system by which complaints are recorded on Q-Pulse, processed and monitored until resolved. User satisfaction questionnaires are issued on a regular basis to monitor laboratory performance. The protocol DOC1187 (Assessment of user satisfaction and complaints) meets this standard.

The laboratories assess the clinical relevance of all genetic investigations performed within the GDL and the reliability of interpretive reports in conjunction with users. All the laboratories participate in the evaluation of clinical effectiveness, audit and risk management activities within CMFT (H2.1) via the Directorate Clinical Effectiveness Group.

The laboratory seeks to meet performance targets in all areas.

H3 Internal audit of quality management system
The GDL has established a procedure for internal audit of the quality management system [DOC1288]. The internal audit process is planned and scheduled on a yearly basis. Audits are conducted against agreed criteria including the relevant CPA (UK) standards. A significant number of staff are appropriately trained in the procedure of internal audit.

The record of internal audit includes the activities, areas or items audited, nonconformities or deficiencies found and the recommendations and time scales for corrective and preventative action. Full details of the Audit schedule and completed audits are recorded in the Q-Pulse database Audit Module. 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. This standard is fulfilled by procedures: general/generic.
The Audit Lead is Nicola Wolstenholme.

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 the laboratory procedures available on the Q-Pulse database (H4.2). The results of all internal audits are evaluated by the Audit Lead and/or Quality Manager who ensure that corrective and preventative actions are undertaken in a timely fashion and communicated to all members of staff via Laboratory meetings and e-mail (H4.4). All details of the audit, an audit check list (if appropriate), non-conformances, and the corrective and preventative actions are recorded on Q-Pulse.

H5 External Quality Assessment
The GDL participates in External Quality Assessment Schemes organised by the UKNEQAS, EMQN, ECFN, ERNDIM and CDC (H5.1). A record of performance is kept in several locations (Electronically stored on Q-Pulse, on the Genetics server and within the labs secure account area on the EMQN, UKNEQAS and ERNDIM websites). EQA activity is communicated to all staff at laboratory meetings (H5.2 & H5.3) and via the Quality Notice board in Room L6.CV.107 and L6.CV.033. Hard copies are available from the Quality Manager (UKNEQAS and EMQN reports are all available on the respective website report archives). The following policies relates to this standard:

- DOC1564 - Policy for internal quality control (IQA) and participation in external quality assessment (EQA)
- DOC697 - External Quality Assessment Procedures (Willink)
- DOC2062 - EQA Documentation (Biochemical Genetics)
- DOC1325 - EQA Documentation (Cytogenetics)
- DOC2036 - EQA Documentation (Molecular Genetics)

H6 Quality improvement
Quality improvement is an essential role for all staff at all levels of the service and improvement suggestions and ideas are welcomed and encouraged from all. Quality improvement can be proactive – new ideas about different ways of working, achieving increased efficiency for example. The laboratory is seeking to introduce LEAN practice and has recently assigned Mike Bulman and Sancha Bunstone to the roles for the newly merged services of Cytogenetics and Molecular Genetics. Claire Hart takes the lead for the Willink Biochemistry laboratory.

Quality improvement is also sometimes reactive and follows the results of scheduled audits, review of adverse incidents (reported to the Trust) and incident reports (reported on Q-Pulse) as well as user feedback. These improvement suggestions are discussed and developed in team meetings (including the quality team) and include discussion of remedial action, corrective action, preventative action, root cause analyses and improvement processes. The continued quality improvement monitoring following preventative actions is in the form of scheduled audit.
Suggestions for improvement can be recorded via the Q-Pulse database. 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 Team Meetings are documented, circulated to participating staff and available to all staff via Q-Pulse.

**H7 Identification and control of nonconformities**

Procedures are in place to ensure that non-conformances are managed effectively. The Quality Management team via the quality leads are responsible for managing non-conformances and ensure that actions are appropriately assigned, and completed within an established timeframe. The procedure DOC1189 (Identification and control of Non Conformities) describes how the GDL meets this standard.

### 13. Appendix

A summary of CPA standards and the related GDL documents on Q-Pulse can be found by clicking on the link below.

S:\all.users\Lab objectives\List of doc