



Division of Laboratory Medicine

Directorate of Cellular Pathology

GREATER MANCHESTER CELLULAR PATHOLOGY GENOMICS CENTRE External Trusts - USER GUIDE

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1 Introduction

This user guide details information for the requesting of investigations, specimen requirements and communication of results for the department of **Greater Manchester Cellular Pathology Genomics Centre (GM CPGC) - Oxford Road**. Relevant ISO 15189: 2022 standards/clauses are referenced in brackets in section headers

The GM CPGC under the Division of Laboratory Medicine (DLM) at Manchester University NHS Foundation Trust (MFT) currently provides scientific services to Pathology Departments in Greater Manchester.

Hospital
Royal Oldham
Royal Manchester Children's Hospital (MFT)
Wythenshawe (MFT)
Oxford Road (MFT)

The GM CPGC is situated on the ground floor in the CADET building, room G07.

The department expects to deal with approximately 6000 cases a year and is staffed by 7 technical and support staff. Cellular Pathology has IBMS training status and support local universities in the training of Biomedical Science students.

We are committed to providing a high quality and timely regional Cellular Pathology Genomics preparation service.

Services Offered

The laboratory offers molecular sample preparation for solid tumours (excluding Haematological cancers), with an expected turnaround time of less than 48 hours from receipt in the GM CPGC to dispatch to North West Genomics Laboratory (NW GLH).

Turnaround times are monitored in accordance with NHS England. We encourage any issues to be directed to the CPGC Laboratory Manager.

2 Contact Us

2.1 Opening Hours (5.4.2c)

The laboratory is open:

Monday to Friday: 08:00 – 17:00

Saturday: Closed

Sunday: Closed

Bank Holidays: Closed

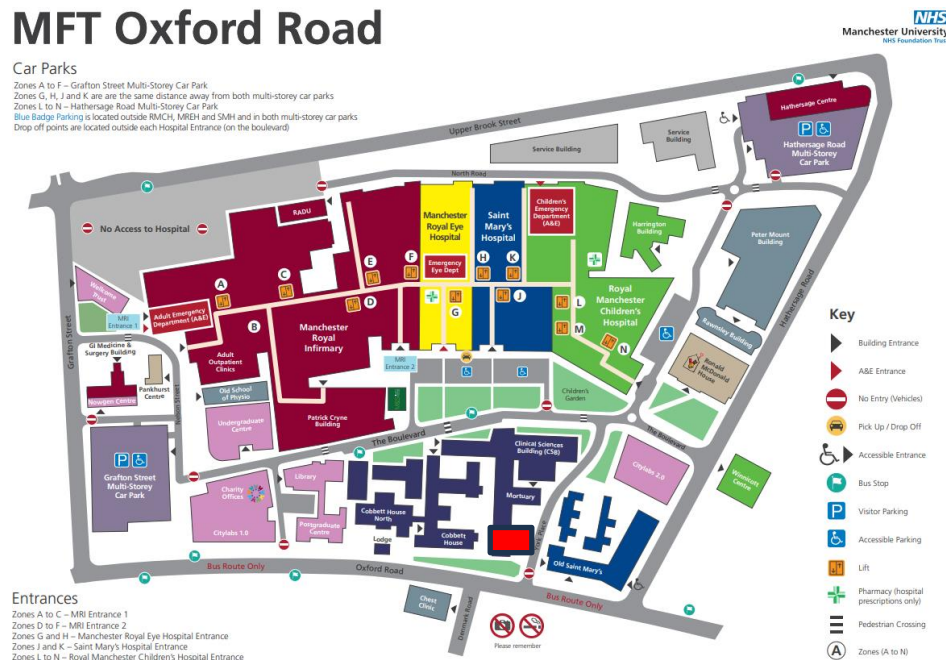
The department does not provide an out of hours testing service.

2.2 Location (5.4.2 a)

MFT Oxford Road

Car Parks

Zones A to F – Grafton Street Multi-Storey Car Park
Zones G, H, J and K are the same distance away from both multi-storey car parks
Zones L to N – Hathersage Road Multi-Storey Car Park
Blue Badge Parking is located outside RMCH, MREH and SMH and in both multi-storey car parks
Drop off points are located outside each Hospital Entrance (on the boulevard)



Address: Greater Manchester Cellular Pathology Genomics Centre
CADET Building (ground floor, room G07)
Manchester University NHS Foundation Trust
Oxford road
M13 9WL

2.3 Contact Information (5.4.2 I)

Queries	GMCPGC@mft.nhs.uk
Laboratory Enquiries	0161 701 1633

All enquiries regarding specimen requesting, labelling, transport and requirements should be directed to the laboratory.

Key Contact Details

Dr. Noreen Akhtar Clinical Lead GMCPGC Consultant Histopathologist	Noreen.akhtar@mft.nhs.uk
John Hayes Cellular Pathology Directorate Manager	John.hayes@mft.nhs.uk 0161 276 6138
Emma Jacobs Operational Lead BMS CPGC	emma.jacobs@mft.nhs.uk Ext 10603
Patrick Townsend Senior Biomedical scientist	patrick.townsend2@mft.nhs.uk 11633

Megos Tesfamichael Specialist Biomedical scientist	megos.tesfamichael@mft.nhs.uk 11633
Elizabeth Beckett Specialist Biomedical scientist	elizabeth.beckett@mft.nhs.uk 11633

3 Quality

The Greater Manchester Cellular Pathology Centre is fully accredited by the ISO15189:2012 accreditation standards. Our UKAS Medical Laboratory Reference Number is 8648. The department participates in regular exhaustive assessments to maintain its accreditation status.

The department is committed to deliver a quality service to our users and continual improvement. A quality management system is utilised to ensure all documents, processes, quality records and clinical material are controlled to DLM (Division of Laboratory Medicine) policy. Processes and systems are regularly audited to identify non-conformities and quality improvements.

3.1 External Quality Assurance (EQA) (5.6.3.1)

The department participates in the **Tissue-I EQA** external quality assurance scheme for tumour assessment.

3.2 Data Protection (5.4.2m)

The department complies with trust, DLM and departmental policies relating to the handling, use and protection of personal information (DLM-QUAL-PRO-022 Management of Data and Information).

- We only ask for information that we need to allow interpretation of results
- We protect the information and ensure only those staff who need to see the information can access it
- We share the information only when we need to for patient care, for example sending the information to another laboratory for testing
- We don't store information for any longer than is absolutely necessary

For more information please visit: <http://mft.nhs.uk/laboratorymedicine>

3.3 Uncertainty of Measurement (5.5.1.4)

In clinical laboratory testing there are potential uncertainties that can affect test results, such as poor specimen collection or transport, patient related factors or other interfering factors. The laboratory examination process itself is subject to some degree of variability and our department regularly monitors this by the use of internal quality control, audit and participation in external quality assurance schemes.

In accordance with the RCPATH guidance, an assessment of the uncertainty of measurement will be carried out for any measurement that is included in the diagnostic report if it is deemed to have actual or potential “direct clinical impact.”

Where weights and measurements are part of an overall description and do not impart prognostic or predictive value, an assessment will not be carried out.

3.4 Patient Consent (5.4.2.i)

Consent to a specimen being taken and analysed is implied by the patient presenting at the point of specimen collection. It is the responsibility of the requesting clinician to ensure that any objections or restrictions expressed by a patient to the use of their tissue are clearly recorded on the request card.

For samples submitted from external locations, it is the responsibility of the referring Trust to ensure consent for testing is in place, please be aware that evidence of consent may be required prior to sample testing.

4 Requesting of Investigations.

DLM guidelines for specimen acceptance must be followed to ensure that all samples are correctly and unambiguously identified. The policy provides an overarching process to specimen rejection to help balance the requirement to process against the risk to patient safety. Clinical governance issues may arise from errors in specimen identification and/or insufficient clinical information being given with a specimen. To ensure that specimens are linked to the correct patient, adequate identifiers are essential.

Gene panel and direct mutation tests will be performed by NW Genomic laboratory, located on the 6th floor (address below). These tests will be performed on **FFPE** samples which the CPGC will prepare. **Please do not send fresh tissue.**

Genomic Diagnostics Laboratory
Manchester Centre for Genomic Medicine
6th Floor, St Mary's Hospital, Oxford Road, Manchester
M13 9WL

4.1 Specimen Acceptance Policy (5.4.2j)

All samples sent to GM CPGC must comply with our specimen acceptance requirements.

EXTERNAL TRUSTS

For non MFT sites, see acceptance criteria below. Complete the appropriate form which can be found on [Referral Forms - Manchester University NHS Foundation Trust](#)

The following mandatory information **must** be provided for us to accept the specimen:

Genetic Request form

1. First name
2. Surname
3. Date of birth
4. NHS or hospital number (or equivalent unique number)
5. Pathology lab number and block suffix
6. Name and contact details of the requester
7. The destination / email address for the final report which will be released by the NW GLH.
8. Testing required, include national test directory code, if known.
9. Percentage neoplastic cell content.
10. Date the genetic request is made.

A **block / slide dispatch form** must accompany samples sent and must include:

1. Unique pathology lab number and block suffix
2. Patient details.
3. Originating hospital details

Or an accompanying **packing list / delivery note** must be sent, this document typically lists the items included in a shipment.

An accompanying **pathology report** must be sent, as this will go to NWGLH. The report must include

1. Patient details – Name, DOB, NHS number
2. Unique pathology lab number
3. Date of Surgery

The department receives **FFPE blocks** which must be clearly labelled with:

1. Unique pathology lab number, block suffix
2. Patient surname

Genomic Requests Requiring Predictive IHC.

The Laboratory offers a streamlined, one-stop approach to pathology departments that submit genomic requests that require predictive Immunohistochemistry staining such as ROS-1, ALK, PD-L1 and gastric HER2, performed by a third-party laboratory.

- A prior arrangement must be in place between your department and the laboratory performing the IHC staining (e.g., Birmingham, Wythenshawe).
- Only send requests if this arrangement exists.
- Use the designated external IHC request form, ensure all required patient and sample information is accurately completed
- Send the request form along with the genomic request, block and pathology report.
- Upon receipt, the CPGC will prepare the genomic request and co-ordinate the IHC staining.

Specimens that do not contain the required information or have discrepancies between the request and block/slides will not be processed in the laboratory, until the necessary information has been obtained. The sender will be contacted to amend the error electronically where possible, or the department will return material sent for correction. The person correcting the patient or specimen details should be of appropriate seniority and able to take responsibility for the error.

4.2 Transport of Specimens

Samples intended for the GM CPGC should be sent using a transport or courier service and NOT BY ROYAL MAIL. Samples should arrive in the CPGC no later than 4:30pm

Packing requirements

Samples must be packaged in a labelled padded envelope, inside the pink mail bags. Mail bags are provided by the GM CPGC and must be clearly addressed to the GM CPGC address. The mail window has a card with the GM CPGC address on one side and on the opposite side is the address of Pathology department.

The mail bags have an Apple Air Tag attached inside – this is for tracking purposes to prevent loss.



Air tags and transport bags provided by CPGC

The mailbags must be securely fastened using a security seal



General Guidance External Pathology departments

- Use pink transport bags provided by the Trust. These are designed to be robust and contain trackers to monitor the location of samples and mitigate delays / missing samples.
- Ensure that the transport bag is appropriate for the purpose and is securely closed using a security seal
- Ensure that the correct side of the address card is clearly displayed.
- Ideally, each sample should be placed in individual plastic specimen bags and sealed, not secured with clips or staples. Then place in a brown padded envelope and then place it the PINK mail bag.
- Please do not place the request form with the sample, instead separately in the side pocket (kangaroo pouch) of the specimen bag.

Transport arrangements

Samples may be sent to the Laboratory in the following ways:

External Pathology Department Arrangements	Details
Salford and Oldham	Hospital transport system linking the laboratory to other hospitals within GM. Delivers to Central Specimen Reception at Oxford Road.
Bolton	Own transport arrangements, plus Citysprint Monday only. Collect Bolton 08:30, expected delivery at CPGC by 10:30.
Stepping Hill	Established courier service.

Christie Pathology	Citysprint courier service.
Route 1	Monday to Friday excluding Bank Holidays. CPGC → Christie → Wythenshawe → CPGC. Collect from CPGC at 11:00, expected delivery by 13:30.
Route 2	Monday to Friday excluding Bank Holidays. CPGC → Christie → Wythenshawe → CPGC. Collect from CPGC at 13:45, expected delivery by 16:30.

5 Research

The CPGC supports both internal and external research projects. The department also participates in clinical trials. The department supports trials for the Cancer Vaccine Launch Pad.

6 Communication of Results

6.1 Reports

Results from genomic testing are sent by the North West Genomics Hub to the requesting Pathologist / Pathology department.

Results from third party laboratory for IHC are sent by the third party laboratory.

7 Enquiries and Complaints

To enable us to deal with enquiries efficiently, please ensure you use the correct contact information, as detailed in section 2 (Contact us). The department is committed to fully investigating all complaints regarding the standard and quality of services that we offer. We welcome any suggestions for service improvement. Please contact our laboratory manager on the contact information below.

Laboratory Manager/ Lead Biomedical Scientist		
Emma Jacobs	0161 701 0603	emma.jacobs@mft.nhs.uk

Complaints are managed through the PALs (Patient Advice and Liaison Service) and Trust Risk Management Service Ulysses. Any complaints made direct to the Department are passed to PALs for investigation.