



Division of Laboratory Medicine

Directorate of Cellular Pathology

GREATER MANCHESTER CELLULAR PATHOLOGY GENOMICS CENTRE USER GUIDE FOR MFT



Table of Contents	
1 Introduction	3
2 Contact Us	3
2.1 Opening Hours	3
2.1 Opening Hours	4
2.3 Contact Information	4
3 Quality	5
3.1 External Quality Assurance (EQA)	5
3.2 Data Protection	5
3.3 Uncertainty of Measurement	5
3.4 Patient Consent	6
4 Requesting of Investigations	
4.1 Specimen Acceptance Policy	
4.5 Transport of Specimens	
5 Research	Error! Bookmark not defined.
6 Communication of Results	
6.1 Reports	10
7 Enquiries and Complaints	



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) provides scientific services to Pathology Departments in Greater Manchester.

Hospital		
The Christie		
Northern Care Alliance		
Stepping Hill		
Bolton		
Wythenshawe (MFT)		
Oxford Road (MFT)		

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

The department deals 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 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)



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 (5.4.2.1)

2.5 Contact information (5.4.2 I)	
Queries	GMCPGC@mft.nhs.uk mft.GMCPGC@nhs.net
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	emma.jacobs@mft.nhs.uk Ext 10603
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Megos Tesfamichael	os Tesfamichael <u>megos.tesfamichael@mft.nhs.uk</u>	
Specialist Biomedical scientist	11633	
Elizabeth Beckett	elizabeth.beckett@mft.nhs.uk	
Specialist Biomedical scientist	11633	

3 Quality

The Greater Manchester Cellular Pathology Genomics 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 CPGC must comply with our specimen acceptance requirements.

The following mandatory information <u>must</u> be provided for us to accept the specimen:



MFT Requests

Instructions for Pathologists ordering genetics

 Pathologist orders Genetic request electronically in HIVE using the I-Gene form. Please refer to Instructions For Pathologists: Ordering Genetic Testing via Hive [GCSRINS1]

The following fields MUST be completed as a minimum (mandatory selections are in BOLD):

- 1) Class: Select option applicable to the request. Sensitive orders will not be visible to Clinicians
- 2) Status: Future
- 3) What Type of Referral Do You Require? Standard
- 4) Specimen Type: FFPE-Shavings / Slides
- 5) Specimen Source: Select applicable option
- 6) Please Select Clinical Indication(s)
- 7) Please Select Test(s)
- 8) Test Type: Diagnostic / Prognostic / Therapeutic
- 9) Neoplastic Cell Content Level
- 10)Specimen Description(s)/Sample Identifier(s) for DNA or Pathology Material (e.g. Block No)

The above field MUST contain CASE AND BLOCK NUMBER to avoid delays

- 11)Date of Specimen Collection: the date of surgery
- 12) Acknowledge that DNA sample will be stored upon completion of testing
- 13)Email Addresses: GMCPGC@mft.nhs.uk + requesting pathologist's email address
- 14) Confirmation of Consent for Testing
- 15) Name of Supervising Clinician.
- 2. Pathologist orders tasks in case builder, two options for requesting genetics
 - CPGC on this block
 - Send to CPGC Minimal tissue cut with IHC (also order the desired IHC and select in the order to be cut).
- 3. The laboratory will follow their local SOP's for retrieving the material to be sent. There is no requirement for sending pathology reports to the CPGC for MFT patients. The CPGC will print these documents to send to the NW GLH on a packing list



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

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

- Unique pathology lab number, block suffix
- Patient surname

Specimens that do not contain the required information or have discrepancies between the request and block/slides <u>will not be processed</u> in the laboratory, until the necessary information has been obtained. The sender will be contacted to amend the error electronically were 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 CPGC should be sent using a transport 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 transport / mail bags. Mail bags are provided by the CPGC and must be clearly addressed to the CPGC address. The mail window has a card with the 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

General Guidance for MFT

 Use 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.
- 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 an envelope and then place it the PINK transport bag.

Transport arrangements

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

Oxford Road transport arrangements

Creating a packing list for sending material to the CPGC [GCSRINS2]

- Specifically designed for purpose, specimen transport bags are used to transport samples within the Trust, by local pathology departments directly to the CPGC.
- The CPGC will return blocks and slides by hand with a printed packing list for traceability, using the mail bags.

Wythenshawe transport arrangements

Creating a packing list for sending material to the CPGC [GCSRINS2]

The transfer of blocks between the CPGC and Wythenshawe Histopathology is facilitated by an external courier service, CitySprint, which operates three scheduled collections per day. All materials are to be transported inside a pink mailer bag along with a **printed packing list**.

- On return to Wythenshawe, Blocks are placed and sealed in their brown, labelled envelopes.
- On return to Wythenshawe, Slides are to be packaged inside a *clean*, *correctly labelled* slide mailer.
- Each bag must also contain an Apple AirTag for real-time tracking and a printed packing list to ensure traceability.

It is essential that packages are handed directly to the courier.

CitySprint collections **from** the CPGC are currently scheduled for Mon-Fri at the following times, arriving at Wythenshawe approximately 2-2.5 hours after collection:

- 10:00
- 11:00
- 14:00



The CPGC will update Wythenshawe and inform them that the Packing List is in transit. This is done through the Secure Chat function in Hive.

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.

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.