PMC

Precision Medicine Centre of Excellence

LABORATORY USER GUIDE

20634

Laboratory User Guide

1.0 Introduction

The Precision Medicine Centre of Excellence (PMC) at Queen's University Belfast, was established in 2019, and provides an integrated cancer diagnostic service encompassing high-throughput genomics, digital pathology, and big data analytics in a fully integrated fashion. The PMC proposes to accelerate the translation of potentially relevant diagnostic, prognostic, and therapeutic findings into clinically actionable information by applying state-of –the-art technology in a clinical laboratory environment. By creating partnerships and collaborations with industry, academia and healthcare organisations, the PMC will maximise the potential to capitalise on the value of integrated clinical and biomarker information to improve patient's outcome. The PMC operates within a structure of two interconnected cores, Genomics and Tissue Hybridization & Digital Pathology, linked by a Bioinformatics team, and supported by a dedicated management team. Our long-term vision for Precision Cancer Medicine is to ensure that all cancer patients have access to high quality, comprehensive and timely characterisation of their tumour to inform therapeutic and clinical management.

The investment in the latest technology and automation, coupled with an experienced team in delivering clinical cancer genomics, unlocks a wide range of possibilities for innovative collaborations in large-scale genomic studies, making the translation of science into clinical applications faster than ever. The PMC is at the forefront of genomics, modern hybridization pathology, digital pathology and artificial intelligence applied to tissues and cells. The investigation and implementation of predictive biomarkers for targeted therapies can aid in the development of diagnostic and prognostic algorithms to formally classify and risk-stratify patients with early and late-stage cancers. And by integrating tissue analysis with circulating biomarkers, we can generate new algorithms to improve clinical care, develop strategies for early detection and carry out novel interventional studies with non-invasive technologies.

Our aim is to advance the clinical applications of cancer using the integration of genomics, tissue hybridization and digital pathology, and artificial intelligence to support industry, clinical trial endeavours and programmatic research.

The PMC provides the necessary infrastructure to meet the increasing demands in the changing field of healthcare and industry in terms of technologies and expertise. The PMC truly offers clients an integrated approach that allows clients to tailor their requirements specific to their individual projects. The PMC is expertly overseen by Laboratory Directors Professor Manuel Salto-Tellez for tissue hybridization and digital pathology, and Professor David Gonzalez de Castro for genomics.

2.0 PMC Information and Contact Details:

PMC INFORMATION AND CONTACT DETAILS	
PMC Website	https://www.qub.ac.uk/research-centres/PMC/
Full Postal Address	Precision Medicine Centre of Excellence Queen's University Belfast Health Sciences Building 97 Lisburn Road Belfast BT9 7AE Northern Ireland
General Enquiries	+44(0)28 9097 2293 PMC@qub.ac.uk
Tissue Hybridization and Digital Pathology	Drs Perry Maxwell/Dominique French +44(0)28 9097 2616/2709 p.maxwell@qub.ac.uk/d.french@qub.ac.uk
Genomics	Drs Manisha Maurya/Peter Stewart +44(0)28 9097 2708/2889 m.maurya@qub.ac.uk/p.stewart@qub.ac.uk
Bioinformatics	Dr Sirintra Nakjang +44(0)28 9097 2890 s.nakjang@qub.ac.uk
Quality/Training Manager	Cathal McNally +44(0)28 9097 2956 c.mcnally@qub.ac.uk

3.0 Opening Times

Monday to Friday 9:00am to 5:00pm

To ensure safe arrival of samples, please call the laboratory if the samples will arrive before 9:00am or after 5:00pm.

4.0 Requesting Information

The customer requirement form and/or sample request form can be obtained from the laboratory or downloaded from http://www.qub.ac.uk/research-centres/PMC/

5.0 Samples

5.1 Sample Requests

All samples must be accompanied by the sample request form or completed documentation identifying the project identification number, sample type, number of samples, and individual sample identification numbers.

5.2 High Risk Samples

All samples are regarded as high risk, but it is essential that appropriate labels are attached to the request form and container where a sample is known to be 'High Risk'.

5.3 Postal Regulations

When sending samples by post, all samples should be packaged according to current guidance and conform to current postal regulations (P650) applicable and UN 3373 and labelled according to the guidelines.

5.4 Sample Requirements

Sample Type	Genomics	Storage details prior to transport to PMC
Peripheral blood	EDTA tube, 10 ml	Keep refrigerated between 2-8°C.
DNA (from a variety of sources e.g PB, BM, FFPE)	500ng minimum* (and please indicate buffer type)	Keep refrigerated between 2-8°C.
FFPE scrolls	2 x 10µm in clean Eppendorf, plus 1x H&E stained slide	Keep at room temperature.

FFPE sections**	2 x 10µm, for macrodissection (on non-coated slides) plus 1x H&E stained slide	Keep at room temperature.
Sample Type	**Tissue Hybridisation & Digital Pathology**	**Storage details prior to transport to PMC**
FFPE blocks#	FFPE tissue block	Keep at room temperature.
FFPE sections	3-5µm** (on coated slides)	Keep at room temperature.

** Please discuss with the laboratory for guidance on other amounts of DNA required (Qubit quantification)*
*** Please discuss with the laboratory for guidance on the number of slides required (project dependent)*
*# The PD-L1 assay in NSCLC FFPE samples, has **not** been validated for use with decalcified bone samples and thus these samples will not be accepted for testing*

6.0 Sample transport

6.1 Liquid specimens

Liquid specimens must be collected into leak proof containers, which must be closed securely and not contaminated on the outside.

6.2 FFPE blocks/slides

FFPE blocks and slides should be sent securely packaged in appropriate block boxes or slide mailers, respectively.

6.3 Sending Samples

Samples should be sent directly to the PMC and all unfixed samples should be delivered to the laboratory within 24 hours. If there is any doubt about how to send a sample, please contact the PMC.

7.0 Turnaround Times and Project Management

7.1 Turnaround times

The turnaround time is dependent on the individual contract signed and will be specific to each project.

7.2 Project Management

Each project will be managed according to the specific project schedule, with regular meetings to discuss project updates. Enquiries related to project management should be directed to TH/DP or Genomics contacts listed in section 2.0.

8.0 Reports and Results

8.1 Electronic reports

Validated results will be issued securely via email or drop box, and the format will be dependent on the specification outlined in the project customer requirement form which may be in the form of a project report of the results, excel spreadsheet or pdf formats.

8.2 Telephoning of results

Results or updates on projects will be telephoned to the client, when the need arises, depending on the nature and contract of the individual project.

8.3 Clinical Advice, Interpretation and Scientific advice

PMC has experienced staff to cover all aspects of the service and has Consultant Pathologists/Consultant Clinical Scientists, Clinical Scientists as well as Scientific Leads. All Consultant Pathologists hold GMC/GDC registration and Clinical Scientists hold HCPC registration.

9.0 Governance

The PMC is an UKAS accredited Medical Laboratory, reference number 20634, click here for our UKAS scope. And as such, all policies and documentation meet the requirements of ISO 15189:2022 Medical laboratories — Requirements for quality and competence.

9.1 External Quality Assurance

The department participates in the following EQA schemes to demonstrate technical and interpretive competencies:

EQA Provider	Activity Registered
GenQA	DNA extraction from formalin-fixed paraffin-embedded (FFPE) tissue DNA extraction from venous blood* DNA quantification Melanoma Colorectal cancer – Extended MMR Lung cancer - Comprehensive Molecular Analysis of Lymphoma (FFPE)* BRCA testing for ovarian and prostate cancer - somatic HRR Testing in Prostate Cancer NTRK Fusions Thyroid Cancer (pilot)

	Breast Cancer (PIK3CA Testing) Cholangiocarcinoma Endometrial Tumours Circulating free (cf) DNA testing in lung cancer* Tissue-i (Tumour annotation and assessment) Lymphoma Technical NGS* Pathogenicity of BRCA/HRR variants Pathogenicity of somatic sequence variants Pathogenicity of haematological neoplasm variants* Pathogenicity of RNA splicing variants*
UK NEQAS for Leucocyte Immunophenotyping	Lymphoid Gene Panels (Pilot - Not Accredited)* Leukaemia Diagnostic Interpretation (Part 2)* Myeloid Gene Panels (Pilot – Not Accredited)*
Euroclonality EQA	IG/TR clonality testing in suspected lymphoproliferations*
UK NEQAS Cellular Pathology Technique (CPT)	Tissue Diagnostics
UK NEQAS Immunochemistry & In-Situ Hybridization	NSCLC PD-L1 IHC (Pilot)

** Please note these activities are currently **not** within our UKAS scope, and therefore the PMC is not UKAS accredited for these tests*

9.2 Information Governance

All staff at the PMC have a legal duty to keep information confidential and protect the privacy of projects. All staff adhere to the Queen's University data protection and confidentially policy and take part in mandatory training for Information Governance.

9.3 Dealing with complaints

All formal complaints should be sent to relevant TH/DP or Genomics Lead – contact details are captured in section 2.0 of this document. Complaints will be thoroughly investigated and actioned to resolve any issues, according to our managing complaints policy, within a timely manner.

10.0 User Satisfaction

The PMC encourages feedback on project management by clients, during the duration of the project and initiates user satisfaction surveys on a regular basis.