**Laboratory User Manual**

**Introduction**

The Precision Medicine Centre of Excellence (PMC) at Queen’s University Belfast, 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 is expertly overseen by the academic leads, Professor Manuel Salto-Tellez and Dr Jackie James for tissue hybridization and digital pathology, and Professor David Gonzalez de Castro for genomics.

The PMC truly offers clients an integrated approach that allows clients to tailor their requirements specific to their individual projects.

Further details of the service can be found at <http://www.qub.ac.uk/research-centres/PMC/>

**Contact details**

The full postal address of the centre is:

Precision Medicine Centre of Excellence

Queen’s University Belfast

Health Sciences Building

97 Lisburn Road

Belfast

BT9 7AE

Northern Ireland

Telephone for General Enquiries: +44(0)28 9097 2293

Email address: PMC@qub.ac.uk

The PMC’s application for UKAS ISO15189:2012 accreditation has been submitted, is currently being processed at UKAS (United Kingdom Accreditation Services) (customer number 20634) and we are waiting for confirmation of an assessment date.

**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.

**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/>

For enquiries on specific tests or analyses please phone/email the following staff:

Genomics: Drs Manisha Maurya/Louise Harewood

 +44(0)28 9097 2708/2889

M.Maurya@qub.ac.uk L.Harewood@qub.ac.uk

Tissue Hybridization and Digital Pathology: Drs Perry Maxwell/Matt Humphries

 +44(0)28 9097 2616/2090

 P.Maxwell@qub.ac.uk

 M.Humphries@qub.ac.uk

Bioinformatics: Dr Shambhavi Srivastava

 +44(0)28 9097 2890

S.Srivastava@qub.ac.uk

**Sample requirements and 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. 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’. Please refer to the following sample requirements:

|  |  |  |
| --- | --- | --- |
| **Specimen** | **Genomics** | **Tissue Hybridisation & Digital Pathology** |
| Peripheral blood | EDTA tube, 10 ml |  |
| DNA (from a variety of sources e.g PB, BM, FFPE) | 500ng minimum\* |  |
| FFPE scrolls | 2 x 10µm in clean Eppendorf, (plus 1x H&E slide) |  |
| FFPE sections | 2 x 10µm, for macrodissection(plus 1x H&E slide) | 3-5µm\*\* |
| FFPE blocks |  | FFPE tissue block |

*\* Please discuss with the laboratory for guidance on other amounts of DNA required*

*\*\* Please discuss with the laboratory for guidance on the number of slides required (project dependent)*

**Sample transport**

***Liquid specimens***

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

***FFPE blocks/slides***

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

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.

Samples should be sent direct 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.

Samples should be stored as detailed below, if there will be a delay before transportation:

***DNA/ Peripheral Blood***

Keep refrigerated between 2-8°C.

***Fixed Tissue Block/sections***

Keep at room temperature.

**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.

**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.

**External Quality Assurance**

The department participates in the following EQA schemes:

|  |  |
| --- | --- |
| **EQA Provider** | **Activity registered** |
| GenQA – collaboration between CEQAS and UK NEQAS Molecular Genetics | DNA extraction from FFPEDNA extraction from BloodDNA quantificationMolecular Analysis of MelanomaMolecular Analysis of Colorectal CancerMolecular Analysis of Microsatellite Instability (MSI)Molecular Analysis of Lung CancerMolecular Analysis of Additional Lung BiomarkersMolecular Analysis of SarcomaMolecular Analysis of Lymphoma (FFPE)Somatic BRCA testing in Ovarian CancercfDNA testing in lung cancer (Pilot)Tissue-iPathogenicity of Somatic Sequence Variants |
| UK NEQAS for Leucocyte Immunophenotyping LI | Molecular diagnosis of haematological malignancies:-Chronic Lymphocytic Leukaemia Gene Panels (Not Accredited) |
| UK NEQAS Immunochemistry & In-Situ Hybridization | PD-L1 |
| College of American Pathologist (CAP) | PD-L1 |

**Turnaround times for projects**

The turnaround time is dependent on the individual contract signed and will be specific to each project. For enquiries about project management, please contact the Business Manager.

**Reporting results**

Validated results will be issued electronically via email 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.

**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.

**Dealing with complaints**

All complaints received from any client by the PMC, will be thoroughly investigated and actioned to resolve any issues, according to our managing complaints policy and within a timely manner. The complaint will be triaged via the Head of Laboratory Operations to the appropriate area, depending on the nature of the complaint.

**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.

**General Enquiries**

Head of Laboratory: Dr Liz Hodges, PhD, FRCPath

 +44(0)28 9097 2611

 l.hodges@qub.ac.uk

Business/Project Manager: Beryl Graham

 +44(0)28 9097 2028

 bp.graham@qub.ac.uk

Quality Manager: Cathal McNally

 +44(0)28 9097 2956

 c.mcnally@qub.ac.uk