ecmc
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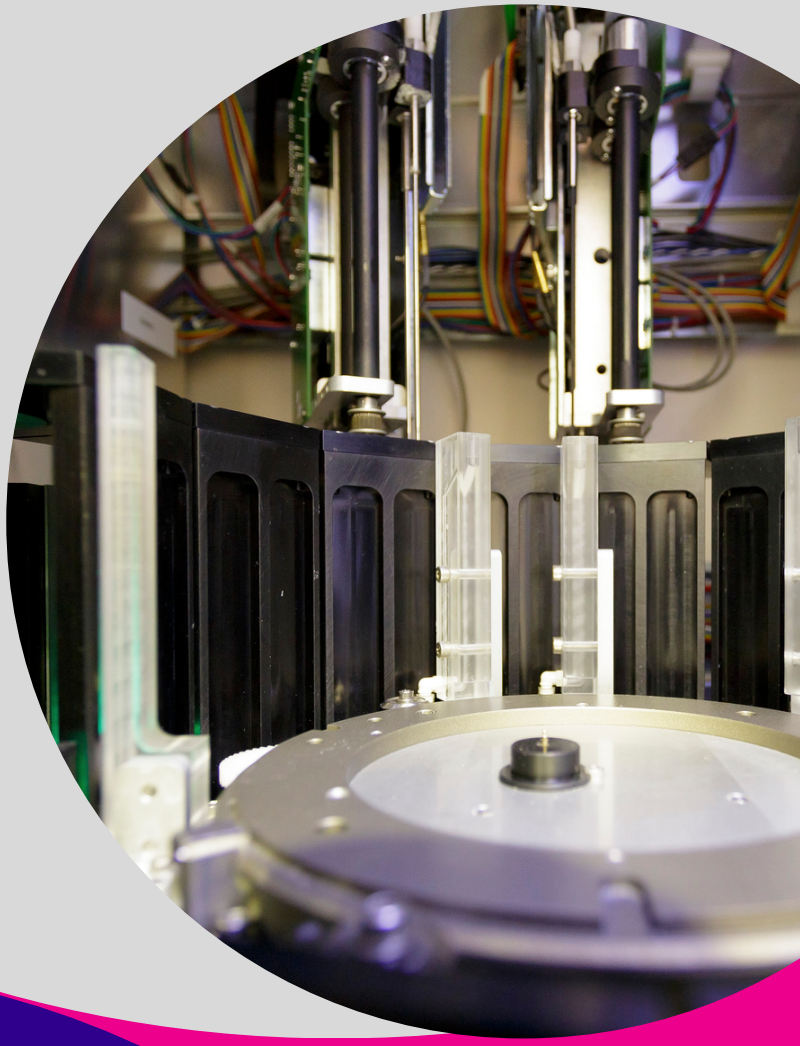
UCL ECMC GCLP Facility



Processing, storage and analysis of samples from Clinical Trials in accordance with Good Clinical Practice (GCP) regulations.

The UCL ECMC GCLP Facility is a standalone Facility located on the ground floor of the UCL Cancer Institute, specifically designed for the purpose of clinical trial sample handling, analysis, and storage.

The Facility operates to the principles of Good Clinical Laboratory Practice (GCLP) in order to ensure all work for clinical trials is carried out in accordance with current Clinical Trial regulations.

GCLP is a quality system for laboratories that process, store and analyse samples from Clinical Trials in accordance with Good Clinical Practice (GCP) regulations

GCP is a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and data reporting of clinical trials that provides assurance that the data and the reported results are credible and accurate, and that the rights, integrity, and confidentiality of the trial subjects are protected.

The Facility has full accreditation in GCLP (Accreditation number 06519, Qualogy 2002 Ltd).

Facility

The Facility is organised into a human Sample Handling Laboratory, G05, and a main Assay Laboratory, G03. Newly acquired space has greatly increased the capacity for clinical trial sample handling prior to analysis.

All trial implementation, assay validation, sample processing & storage, sample and data analysis, and all equipment in the Facility are run to GCLP standards, and compliance is maintained for active clinical trial analysis.

The Facility can be contracted to perform any of the above aspects as part of a clinical trial. The Facility can also provide support and knowledge transfer for research laboratories and staff wishing to perform clinical trial analysis. There are currently several affiliated staff from Cancer Institute research groups, trained to perform clinical trial sample processing and analysis to GCLP standards in the Facility.

Equipment

Immunotherapy

Flow Cytometry

- BD Biosciences FACSVerse™ 3 lasers/8 colours
- BD Biosciences FACSLyric™ 3 lasers/10 colours
- BD Biosciences FACSLyric™ 3 lasers/12 colours

RT-qPCR

- Thermo Fisher Scientific™ Quantstudio™ 5 Real-time PCR

Circulating Tumour Cell Analysis

Isolation, enumeration & phenotypic markers

- Menarini Silicon Biosystems CellSearch®

Isolation

- Angle PLC Parsortix

Biomarker Assessment

ELISpot

- Bioreader® 6000 Bio-Sys GmbH

Multiplex Biomarker Quantification

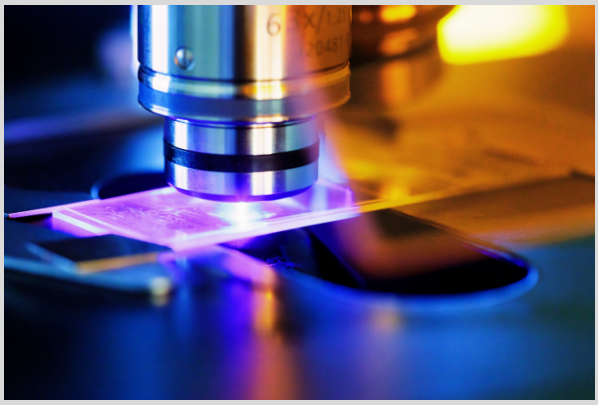
- Luminex® 200

Immunofluoresence Microscopy

- Zeiss AxioImager M1

Multi-mode plate reader

- Molecular devices Spectramax® i3



DNA/RNA Quantification & Sequencing

Fluorometric Quantification
- Thermo Fisher Scientific™ Qubit 4

Quality & Quantification
- Agilent Technologies 4200 Tapestation System

NGS Libraries
- Hamilton NGS Star Liquid Handling system

Nucleic acid purification
- Qiagen QIA Symphony

Sequencing
- Ilumina MiSeq™
- Illumina NextSeq™

Sample Management & Integrity

Temperature Monitoring
- T-Scan Ltd.

Freezerworks Sample Tracking
- Dataworks Development Inc.

How can we help.....

• Facility: Provide a controlled space with validated equipment & a fully implemented Quality Management System

• Guidance: Implementation of quality systems for research laboratories

• Advice: GCLP guidelines & regulatory requirements

• Assistance: GCLP in practice, training, standard operating procedures, analytical plans

• Support Translational research, method development and validation, clinical trial sample processing & analysis

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