



MAC CLINICAL RESEARCH

# Laboratory Services



# A Truly Integrated, End-to-End Laboratory Partner

At MAC Clinical Research, our in-house laboratories uniquely position us as a true end-to-end partner.

Our one stop shop model goes far beyond convenience - it delivers real, measurable benefits for clients.



We operate to GLP, GCP, ISO/IEC 17025, and ISO 14001 & 45001-accredited standards. In addition, we are the only ISO/IEC 17025-accredited PK laboratory in the northern hemisphere. This rare combination of accreditations provides clients with confidence that the data generated is robust, reliable, and fully aligned with regulatory expectations.

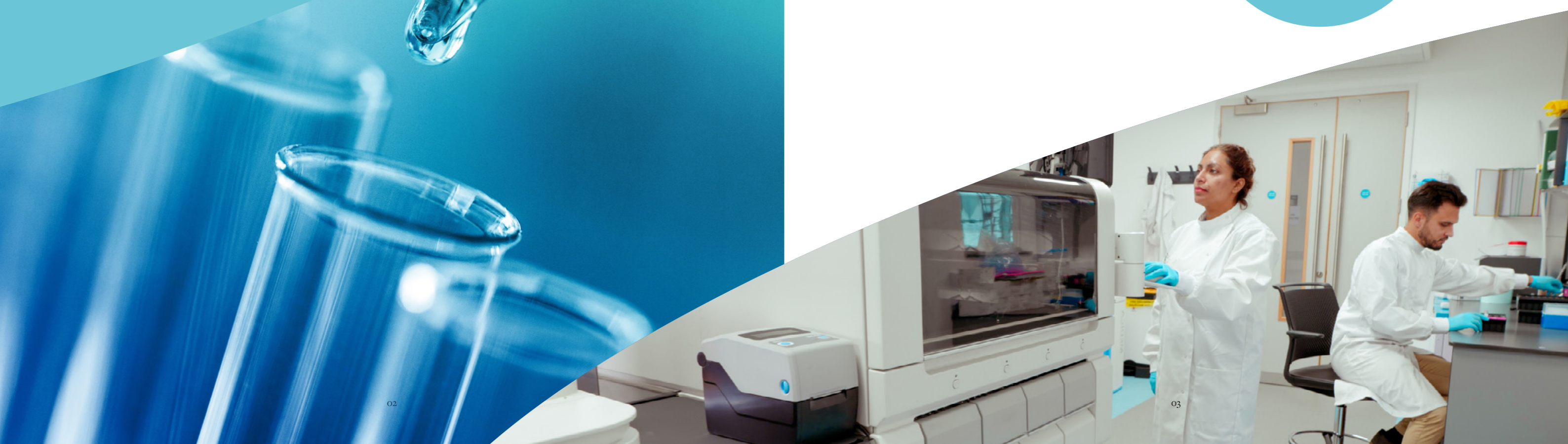
Operating to internationally recognised GLP, GCP, and ISO standards means we can support your analytical strategy from discovery through to registration, generating high-quality data that underpins key decisions across the drug development lifecycle. Our integrated capabilities enable us to deliver everything from standalone support services, such as Preclinical Analysis, Pharmacokinetics, Biomarkers, and Clinical Pathology, to the full delivery of a clinical trial, including first-in-human (FIH) studies..

By bringing all laboratory services under one roof, we simplify contracting, remove the burden of managing multiple vendors, and eliminate unnecessary handovers. Integrated workflows and single site coordination accelerate timelines without compromising quality, enabling faster, more efficient study delivery.

Our teams, systems, and expertise are aligned to reduce friction at every stage, creating a seamless client experience from start to finish. We provide a flexible, fully integrated solution, tailored to the specific needs of each project and adaptable as programmes evolve.

## The result:

Faster delivery, fewer interfaces, trusted data, and complete confidence in regulatory readiness.



# Laboratory Services

The laboratories are a core function at the heart of MAC's offering.

Laboratory Services is housed in a modern facility and is comprised of three laboratories:

- › Sample Reception
- › Clinical Pathology
- › Bioanalytical



## Dedication to Quality:

Our laboratories are accredited to GLP, GCP, ISO/IEC 17025, and ISO 14001 & 45001 standards with ICH M10 forming the foundation of our method development and validation activities.

Our laboratories work collaboratively to deliver seamless support for clients seeking standalone services or a fully integrated, end-to-end solution.

**Designed from scratch, the laboratories' equipment and working practices were purpose-built to ensure:**

- ✓ Highest Quality
- ✓ Traceability
- ✓ Compliance to international standards
- ✓ Timely delivery
- ✓ Flexibility to meet customer needs

Having adopted a quality by design approach to the creation of Laboratory Services, it has been built from the ground up with quality management at the core. A bespoke Laboratory Information Management System (LIMS) ensures that all activities are tracked and traceable.

The LIMS provides secure data management which complies to international regulatory standards and enables the remote monitoring of key infrastructure.

## Sample Reception and processing

Sample Reception is the foundation of Laboratory Services, ensuring that your samples are stored under the correct conditions and their integrity is maintained throughout the lifecycle. Sample storage conditions available on site range from ambient to -80°C.

All of our storage areas are monitored continuously using a Hanwell® environmental monitoring system. This allows 24/7 monitoring of all storage conditions; deviations are detected immediately and real time alarms will alert our team to any temperature excursions, ensuring problems are resolved quickly.

**The Sample Reception Laboratory has responsibility for:**

- Sample lifecycle management
- Initial sample reception and quality checks
- Sample maintenance, storage and monitoring
- Inventory control
- Bespoke sample processing when required

The sample reception team ensure a smooth and efficient transition of samples from both external and internal sources into the analytical laboratories ensuring sample integrity.

## Clinical Pathology Laboratory

Clinical Pathology is a key part of Laboratory Services, working to the highest internationally recognised standards.

Investments have been made in state-of-the-art technology to achieve the highest quality results whilst still being able to meet the required turnaround times. Supporting clinical trials with a broad range of assays in several key areas. This is a major part of ensuring the safety and wellbeing of clinical trial participants.

### Haematology

**Full Blood Count measuring:**

- ✓ Haemoglobin
- ✓ Erythrocytes
- ✓ Mean Corpuscular Volume
- ✓ Platelets
- ✓ Reticulocytes
- ✓ Leukocytes
- ✓ Differential:
  - › Eosinophils
  - › Basophils
  - › Neutrophils
  - › Lymphocytes
  - › Monocytes

### Digital Morphology

Morphological analysis allows the identification of haematological diseases.

### Haemostasis analysis

A broad clotting screen is offered including clotting, chromogenic, immunologic and aggregation.

### Clinical Chemistry

**Offering an extensive chemistry profile including:**

- ✓ General Chemistry
- ✓ Hepatic Profile
- ✓ Bone Profile
- ✓ Cardiac Profile
- ✓ Lipid Profile
- ✓ Renal Function
- ✓ Cancer Markers
- ✓ HIV
- ✓ Hepatitis Testing
- ✓ Fertility Hormones
- ✓ Drugs of Abuse

### Urinalysis with a combined analyser

Allowing the early detection of kidney damage/disease.

**Measuring the following factors in urine:**

- ✓ Leukocyte Esterase
- ✓ Nitrite
- ✓ Urobilinogen
- ✓ Protein
- ✓ pH
- ✓ Blood
- ✓ Specific Gravity
- ✓ Ketones
- ✓ Bilirubin
- ✓ Glucose



## Bioanalytical Services

A core component of MAC's Laboratory Services is our state-of-the-art bioanalytical laboratory.

We provide high-quality bioanalysis of complex biological samples to support drug development at every stage. From non-regulatory early pre-clinical studies to fully validated, ICH M10-compliant GLP and GCP clinical programmes. Our advanced instrumentation also delivers the sensitivity required for low concentration samples.

### This ensures:

- > **Rapid sample turnaround times**
- > **High-quality data**
- > **Robust quality control**

The laboratory is equipped with the latest Ultra High-Pressure Liquid Chromatography (UHPLC) systems, coupled with Triple Quadrupole (QqQ) Mass Spectrometers (shown, right). Using UHPLC enables rapid, reliable separation of the molecules from complex mixtures that are present in biological samples, such as urine, plasma, CSF, or faeces. Using UHPLC and QqQ together ensures that we can selectively, specifically, and quantitatively detect drug molecules and their metabolites.

### Additional bioanalytical laboratory features include:

- Secure data storage and transfer
- Pharmacokinetic (PK) analysis
- Metabolite identification
- Bespoke Laboratory Information Management System (LIMS)

Experienced staff enable the undertaking of projects at all readiness levels (concept to mature).

### The Bioanalytical Laboratory team can offer:

- ✓ Method Development
- ✓ Technology Transfer
- ✓ Method Verification
- ✓ Method Validation
- ✓ Analytical Service

All carried out in compliance to the highest international standards.

## Pharmacokinetic (PK) and Pharmacodynamic (PD) Analysis

Use of liquid chromatography/mass spectrometry (LC-MS/MS) enables rapid drug level monitoring in the bloodstream following administration.

This data is used to create a pharmacokinetic (PK) profile, allowing our team to determine the appropriate dosing regimen. During a clinical trial, the amount of drug detected in the patient's blood is used to ensure compliance or check for accumulation.

To inform optimal dose determination, adjustment, and monitoring, MAC provides PK/PD analyses, support services, and in-house statistics and programming as stand-alone or integrated services.

Working with internal and/or external stakeholders and processes to meet high standards, our specialists obtain relevant PK parameters from industry-standard software (Phoenix WinNonlin) to develop individual/stand-alone outputs and analyses.



### Our PK/PD services include:

- End-to-end PK input from protocol development to final report
- Non-compartmental and statistical data analyses, including:
  - > PK/PD relationship analysis with linear and nonlinear mixed modelling approaches and simulation techniques
  - > Bioequivalence, bioavailability, dose-proportionality, and food effect
- Blinded/unblinded interim PK reports to support early phase research
- Measurement of plasma drug level using triple quadrupole mass spectrometers

## Bespoke Analytics

To meet the specific analytical requirements of clients, our Bespoke Analytics team offers tailored analyses. This empowers clients to incorporate the monitoring of novel biomarkers and companion diagnostics, helping to streamline clinical trials.

### Our expert team use their experience to:

- › Transfer existing methods from clients
- › Modify methods as needed
- › Create bespoke methods when required
- › Perform device validation and cross validation
- › Support and perform "Fit for Purpose" validations
- › Support the use of bespoke analytics in sample analysis

Our highly experienced team work collaboratively with clients to meet all of their analytical needs.



## MAC Clinical Research

Your dedicated laboratory partner

### › Comprehensive laboratory solution

From pre-clinical analysis, pharmacokinetics, biomarkers, and clinical pathology through to full clinical trial delivery, including first-in-human (FIH) studies.

### › Highly accredited

Operating to GLP, GCP, ISO/IEC 17025, and ISO 14001 & ISO 45001 standards.

### › State-of-the-art instrumentation

Enabling precision, sensitivity, and reliability.

### › Fast results, quality data

Delivering timely insights without compromising data integrity.

MAC Clinical Research is one of Europe's largest contract research organisations (CRO), taking a science-based approach to clinical research.

Our experienced clinical and medical teams are capable of managing even the most complex studies, with Early Phase and Late Phase capabilities, and providing the best quality data for your research.

Headquartered in the UK with offices globally, we conduct studies both through our fully-owned network of dedicated research sites in the UK and through contracting with sites across the globe. We offer the global clinical study management you need to meet your clinical outcome goals.

**Science at  
the heart  
of everything  
we do**



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