

UNILABS SERVING PHARMA



MOLECULAR DIAGNOSTICS

BIOANALYSIS, IN-VITRO ADME AND METABOLISM

FLOW CYTOMETRY





EUROPEAN LEADER

Broadest European Access

- 250+ laboratories in 16 countries
- 90+ medical imaging sites

Highly skilled workforce

- >11,900 employees
- >1500 doctors



For patient & sponsor

- 700+ collection centres
- 200+ outsourcing contracts

Providing answers

- >195 million diagnostic tests
- >3.4 million medical imaging exams per year

WE DELIVER HIGH QUALITY RESULTS

- Optimized Experienced scientists at our centers of excellence ready to setup and optimize methods and work with you to ensure timely delivery of your project
- Customized Tailoring of every project no matter the number of patient samples. Our process ensures you get exactly what is required for the project without unnecessary expenses
- Compliant GCP, GLP, CLIA & ISO accredited sites, FDA inspected, ensuring your study data is ready for regulatory submissions. Rapid implementation of guidelines
- **Relevant** Access to hospital network, clinical samples and specialist medical professionals
- Simplified Easy transfer of projects between different Centers of Excellence via our individually assigned project managers.
- Efficient Quick turnaround time. Supportive logistic ensuring safe sample shipments and short response times.



PHARMA SERVICES

MOLECULAR DIAGNOSTICS



- Expertise with liquid biopsy, cytology and FFPE samples
- Expertise with constitutional cytogeneetics, somatic cytogenetics, pharmacogenetics and esoteric analysis
- CGH, Fragment analysis, QPCR, Sanger Sequencing, Pyrosequencing, NGS (Illumina/ QIAGEN)
- Customized gene panel analysis and Whole exome sequencing by NGS
- Support for disease specific medical interpretation through medical geneticist and oncohematologist

HISTOPATHOLOGY



- State of the art laboratory setup (Agilent/Roche IHC/ISH staining instruments)
- Capabilities across all routine pathology testing, primary staining, special stains and advanced staining (immunohistochemistry and ISH)
- Specialized services include expertise in breast, dermato, gastrointestinal, uro and endocrine pathology
- Integrated workflow with molecular diagnostic laboratory for PCR/sequencing/NGS profiling of cytology/FFPE tissue specimen
- Clinical cytology expertise used in screening programs for prevention of both breast and cervical cancers

BIOANALYSIS, IN-VITRO ADME AND METABOLISM

Bioanalysis

- Cutting edge methodology and instrumentation: LC-MS/MS, ELISA, MSD, UPLC, HPLC and FSC systems
- Full method development, transfers and fit for purpose validations for small and large molecule candidates
- High-quality bioanalytical data and scientific guidance
 - Immunoassay
 - PK/PD Assays
 - Immunogenicity Assessment
 - Biomarkers

Mass Spectrometry

- PK/PD Assays
- Small molecule, Protein and Peptide Analysis
- Biomarkers

Bioanalytical experience

- More than 20 years and >3,500 bioanalytical studies conducted on small and large molecules
- Developing, validating and implementing sub pg/ mL assays
- Experience with immunogenicity towards viral vectors
- Experience with LPL deficiency testing, coagulation factors, FIX activity, FIX protein, FIX Inhibitors,
- Experience with multiple sample types including blood, urine, faeces, tissue and CSF

In-Vitro ADME and Metabolism

- Bioanalytical and ADME support for complex analytes and atypical drug modalities including In Vitro ADME screening
- Full metabolite characterisation service from early discovery in vitro experiments to late development radiolabelled studies
- Discovery Bioanalysis Rapid fit-for-purpose service for in vitro and in vivo discovery studies

FLOW CYTOMETRY



- Method development, transfers and validations
- Diagnosis of hematopoietic disorders, CD34 counting for ASCT
- Broncheo alveolar lavage, Duodenal tissue and Minimal Residual Disease measurement for AML/ Multiple myeloma
- Thrombocyte activation studies for Thrombocytopenia
- Clinical studies (central lab): AML, MDS, Rheumatology
- Minimal Residual Disease measurement

SAFETY



- European Network of safety laboratories
- Fast turnaround time
- Flexible menu of safety parameters
- Clinical chemistry using state of the art equipment and automation
- ISO15189 certified laboratories
- GCP compliant Central Laboratory

MEDICAL IMAGING

- Unilabs have broad expertise in medical imaging with more than 300 radiologist, and we provide central interpretation of radiology exams for several hundred European hospitals and manage more than 92 imaging centres across Europe.
- Most Unilabs centres have ultrasound, CT, CR, MR and/or mammography.
- Unilabs are now implementing a group wide subspecialist reporting model where incoming cases are matched with the most relevant experts for each narrow diagnostic areas. This matching is done via our proprietary technology platform Optemis and enables a world-class subspecialist reporting service.
- Experience with Image-guided injections and tissue sampling
- Medical imaging supplier for clinical trials of Alzheimer's disease, prostate cancer, lung cancer and HCC
- Multiple clinical trials of arthrosis applying CR

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OTHER

- Peripheral Blood Mononuclear Cell isolation from blood, CSF and bone marrow
- Nucleic acid extraction services, high quality extraction of RNA and DNA for downstream applications
- Sample storage at ambient, refrigerated-20°C, -80°C freezers; electronically monitored and alarmed to ensure temperature control

CHALLENGE

SOLUTION



My project costs are not transparent

You will only be charged for executed activities and detailed cost estimates ensures full transparency of costs



Will you be ready in time for study start?

You will always be prioritized and we will do our best to make sure to deliver high quality solutions aligned with your timelines



How do I ensure my data is meeting regulatory requirements?

Unilabs' experts will guide you to ensure the data package generated meets regulatory requirements



Communication with my CRO is a challenge.

You will have direct access to dedicated project manager and have regular touch points during project. In addition, we enable efficient communication directly with responsible scientist when needed.



TAILOR-MADE SOLUTIONS

UNILABS SERVING PHARMA



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