IQVIA LABORATORIES

IQVIA Laboratories Central Labs

Comprehensive central laboratory solutions supporting clinical trials around the worlds

Our central laboratories are dedicated to clinical trial laboratory testing and associated services for clinical trials, providing a one-stop shop for all laboratory development needs. With our global delivery network, our capabilities allow rapid testing and optimized logistics costs in laboratories in North America, South America, Europe, South Africa, Singapore, India, Japan, and China.

Services and capabilities include:

- Safety testing
- Flow cytometry
- Anatomic pathology
- Companion diagnostics
- Mobile nursing services
- Local laboratory data management
- Immunoassay & biomarker testing
- Genetic/genomic testing
- Kit production
- Global logistics services
- Investigator & sponsor portal
- Biospecimen & consent management
- Biorepository & specimen management
- Laboratory data management
- Project management

>97.5% safety tests
with turnaround time within
24 hours

~99% on-time and
error-free data transfers
on average since 2017

>98% global samples
shipped and received on-time in
less than **48 hours**

Global delivery network

Central labs strategically located to offer routine safety and biomarker testing worldwide

Project management services

With the incredible complexity involved in clinical trial planning, your study's success depends on excellent central lab project management support. We have numerous study delivery and logistics processes that assure seamless study execution; such as a full governance model providing change management protocols, metrics and KPIs, trend analyses, and risk management plans. Not only do we give our customers access to one of the broadest test menus in the industry, we also provide experienced project management staff to support the highest level of delivery quality. Our seasoned project managers have experience at managing a range of small to large clinical trials, as well as high-quality project management systems and tools.

STUDY DELIVERY AND LOGISTICS

- Expedited study set-up: Rapid set-up, flexibility and commitment to support studies
- Global kit production and logistics: Navigating change through robust supply chain infrastructure, flexible kitting solutions and agile logistics support
- Near patient collection and local lab data management: Support for patients and sites with trial continuity solutions for at-home or near-patient collection

Our project services include:

- Sponsor-specific metrics and standards
- Relationship mapping
- Communication pathway
- Relationship health best practices
- Flexible operating models
- Customer feedback program
- Investigator support model

Leading with science

At the forefront of genomics, flow cytometry, anatomic pathology, and other laboratory techniques, we've been delivering cutting-edge solutions since our inception, with a continuous investment in extensive testing capabilities. Our scientific advisors are available, even before you have a protocol, to consult on protocol design, assay development, and companion diagnostic development, helping to assure no delay in your decision making:

- Early engagement with scientific advisors
- Global translational science labs performing de novo assay development and validation
- Fully harmonized testing capabilities from routine safety testing to highly complex cutting edge biomarker testing

These cutting-edge platforms are supported globally, including China, with harmonized workflows and SOPs. We also have dedicated immunoassay validation groups in the US, Europe and China to support the implementation of novel assays in clinical trials. Validation standards cover the use of these assays as exploratory, secondary or primary endpoints, inclusion/exclusion criteria or reporting to clinical trial sites for patient management as a CAP/CLIA assay.

Flow cytometry services

Flow cytometry is widely used within clinical trials and is particularly important for immune modulating therapies and biological pharmaceuticals. We have invested heavily over the past decade to provide a broad global footprint encompassing North America, Europe, Asia Pacific and China, and we continue to provide access to new state-of-the-art technologies worldwide. We have deployed next-generation spectral flow cytometry across our global laboratory network and have a breadth of experience in designing, validating and delivering flow cytometry panels perfectly designed to fit a specific clinical indication and drug mode of action.

As an established leader in global scale flow cytometry, we are able to support 30+ color flow cytometry panels and are deploying a variety of data analysis tools to support large scale data interpretation and reporting. The Cytek 5 Laser Aurora instrument was selected to greatly enhance our flow cytometry services across the globe. We use a proprietary standardization protocol across our entire fleet to ensure generation of a single, seamless data set and focus deeply on all aspects of global harmonization, including equipment, reagents, quality control, training and analysis tools, to provide flow cytometry data of the highest quality. Our test catalog encompasses a wide range of surface and intracellular immunophenotyping panels, receptor occupancy/competition assays, minimal residual disease (MRD) across a range of leukemias and lymphomas, chimeric antigen receptor T (CAR-T) cells and intracellular cytokines. More than 400 custom flow cytometry panels have been launched in the past few years.

IMPORTANCE OF BIOMARKERS FOR IMMUNO-ONCOLOGY

- Gain insight in disease and mechanism of action
- Predict drug responders
- Evaluate drug efficacy (Pharmacodynamics)
- Predict immune related Adverse Events (irAE)
- Predict drug resistance and hyper-progressornear-patient collection

Anatomic pathology

Anatomic Pathology (AP) is an essential part of many clinical trial protocols and is particularly important within the oncology field. Our extensive Anatomic Pathology footprint is strategically located in North America, Europe, Asia-Pacific and China, and includes both validation and assay transfer capabilities. We provide a fully harmonized in-house Anatomic Pathology service, with co-localized AP, IHC/ISH, tissue molecular testing capabilities, and an experienced team of more than 25 qualified Pathologists in-house. We continue to provide new innovative technologies and solutions for complex clinical trials and are implementing a program of digital innovation, including deploying a custom-designed electronic pathology report form (ePRF) system, allowing us to meet tight turnaround times and achieve the very highest quality standards. We report more than 200,000 cases yearly.

Immunohistochemistry (IHC) and immunofluorescence assays (ISH) biomarker assays, often utilizing special stains and procedures, are conducted in our lab facilities for drug development to evaluate a range of biomarkers, assess immunotherapy success, identify toxicity and support companion diagnostics (CDx) clinical trials. Multiplexing technology is employed where necessary and reduces the need to run numerous assays.

Companion diagnostics

Companion Diagnostics (CDx) are assays that are required to be used before a specific therapy can be initiated, often co-developed alongside a therapeutic during its clinical development journey. Extensive testing in clinical trials is required, often in multiple sites across the globe, with challenging regulatory conditions.
We have a history in supporting CDx co-development projects, including producing lab testing data to support the successful approval of several CDx assays. From that depth of experience, our organization has the appropriate operational structure and attributes to help deliver successful CDx programs:

- **CDx Track Record** – We have extensive CDx experience across the world, including Asia-Pacific, China, EMEA and US, with generated lab data supporting >150 CDx clinical trials engagements. Our experience covers multiple testing areas including anatomic pathology, molecular pathology and genomics, immunology and biochemistry
- **Technology Breadth** – With experience in state-of-the-art techniques as well as extensive instrument footprint in laboratories across the world, we can service CDx requests for protein expression, gene expression, mutation detection, copy number and translocations
- **Globally Harmonized Footprint** – Most clinical development programs require testing to occur in sites across the globe, and we have a detailed training program along with harmonized CDx SOPs which allows for the highest quality of data. Coupled with CDx global oversight, we have site Principal Investigators, Pathologists, CDx study coordinators, and both regional and local project managers at every testing site
- **Alternative CDx Models and the Path to Approval** – CDx projects are often complicated and not without significant cost and risk in their development. To help meet the needs of our sponsors, we support different CDx paths including traditional programs with in vitro diagnostic device (IVD) companies as well as single-site premarket approval (ssPMA)

Immunoassay analysis and technologies

The detection of soluble biomarkers by immunoassay is fundamental to many clinical trials with these assays being used as predictive or indicative of response to drug, informative of biological mechanism and safety profiling. We have a broad soluble biomarker portfolio covering single analyte, multiplex, high sensitivity and fully automated assays using the following platforms:

- SpectraMax® Plate Reader
- Aushon CiraScan™
- Luminex
- Meso Scale Discovery
- Quanterix SiMoA®
- ProteinSimple Ella

BIOTECH LABORATORY SOLUTIONS

Biotech companies are powering the pharmaceutical pipeline by driving innovation to address unmet medical needs. Navigating a rapidly changing and increasingly complex landscape takes expertise and experience, and we can help you find your path to success. Biotech customers seek a partner who can provide operational knowledge, best practices, and strategic insights. As a leading global laboratory services provider, we have a team of experts offering a comprehensive and proven set of flexible solutions that can be customized to your specific needs, enabling you to utilize expansive institutional knowledge while keeping your organization lean and focused. With experience in more than 1,300 biotech studies, we deliver the optimal operational knowledge, scientific expertise, best practices, and strategic insights to suit programs.

Laboratory network solutions

Through our laboratory network solutions (LNS) model, not only can we manage your central laboratory, genomics and bioanalytical/ADME services, we also coordinate additional third-party external laboratories. We manage and integrate data streams across our global labs as well as external labs through our customer-focused technology platforms. Data visualizations and on-demand reports from our technology platforms keep you in control of your study, while at the same time our governance and change management expertise means you can shift more of the day-to-day activities to us and focus on strategy.

Biorepository and specimen management

You can trust us to preserve the integrity of your biospecimens for as long as you need to store them. Over the past year we accessioned more than five million testing specimens, added more than four million specimens to our biostorage facilities and shipped more than three million specimens to third parties on behalf of our customers. We provide two main biostorage solutions. During the life of a study, our central laboratory customers rely on us to hold specimens in short-term storage, and to transport them based on study requirements via scheduled and unscheduled shipments. In addition, we provide long-term storage solutions for both our central laboratory customers and others.

Optimized network

We have the largest network of CAP-accredited central laboratories with presence in the Americas, Europe, Asia and Africa, including dedicated bioanalytical, ADME, genomics and specialty laboratories. That means our footprint is in the right geographies with the systems and technologies to deliver top-quality services and innovation.

YOU CAN EXPECT:

- **Innovation**: State-of-the-art laboratory facilities with industry leading test menu and platforms and room for expansion to meet current and expanding customer needs for end-to-end laboratory solutions
- **Data integrity**: Clean, reliable and comparable globally harmonized data
- **Superior project management**: Site support that enables optimal study performance
- **Value**: Superior technology coupled with logistical and supply chain optimization that enables on-time and cost effective delivery of lab results
- **Quality**: Six Sigma Quality Systems and integrated LIMS system coupled with our seasoned scientific and operational experts that manage >72 million lab tests each year, delivering the high quality data and informed insights needed for today's complex drug development programs
- **Specimen management**: Proactive management of global logistics and biospecimens to ward off delays
- **Local language support**: More labs in more places mean our team is able to provide follow the clock coverage and local language support in many regions

Clinical Trial Sample Tracking (CTST)

Patient samples are the lifeblood of your clinical trials. Labmatrix® is a web-accessible clinical & translational research management sample and consent tracking software system.

Labmatrix can meet the requirements for enterprise-wide in study and future use clinical trial sample and consent management, as well as next generation biobanking. Our unique software solution tracks these clinical samples through their lifecycle across the ecosystem of sites, labs, biorepositories, and other trial partners. Your study teams are empowered with up-to-date, accurate and actionable insights on biospecimen and related patient informed consent activities, boosting trial execution productivity while reducing operational and compliance risks for both ongoing trials and future translational medicine studies.

TOTAL SAMPLE LIFECYCLE MANAGEMENT SOLUTIONS

- Clinical trial sample and consent tracking
- Near real-time reconciliation of eClinical data
- In study and future use sample consent
- Virtual biorepository

Kitting and logistics excellence

>1.5M shipments per year with **98.5% on-time** logistics performance

>3.5M kits built/year with **99.962% accuracy**

We have more than 25 years of kitting and global logistics experience to support our clinical trial laboratory services offerings. Within IQVIA Laboratories, and via 3rd party partners, we utilize eight Clinical Trials Materials (CTM) facilities around the globe. This global footprint allows us to build and distribute kits and supplies within region, reducing transit time to investigator sites and transport costs. All of our kitting facilities operate under globally harmonized systems and processes and thus provide a strong business continuity structure for our clients.

We consider global logistics management a key component to successful service delivery, and we have dedicated logistics staff in key global regions (Americas, EMEA, and Asia) to ensure quality logistics service is provided.

As a large global central laboratory provider, our focus is on assuring specimen quality in transport by meeting stringent stability guidelines. These include strict temperature - refrigerated, ambient, and frozen - and transport time frame requirements in order to maintain stability for testing.

We deliver differentiated logistics analytics to enable evidence-based continual strategic improvements.

Servicing >180k investigator sites in >90 Countries

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