



 **Q<sup>2</sup> Solutions<sup>®</sup>**



*Turning Hope  
Into Help™*

As a wholly owned subsidiary of IQVIA, our work at Q<sup>2</sup> Solutions is rooted in research, grounded in collaboration, and guided by our passion to turn the hope of patients and caregivers around the world into the help they need.

Q<sup>2</sup> Solutions is a leading drug discovery and development laboratory services organization.

Our innovative solutions encompass broad central laboratory and specialty biomarker services, including genomics, immunoassays, flow cytometry, anatomic pathology, precision medicine assays, vaccine assays, ADME and bioanalytical along with extensive offerings in antibody drug discovery, biomarker discovery, and decentralized clinical trial lab solutions.





# The right people. The right solutions.

Though the size, cost, and complexity of trials may vary, our commitment to our partners does not. Our experienced team blends seamlessly into your organization, providing the solutions and support needed to realize the full value of your project.



*Tapping into our integrated resources gives sponsors the confidence to meet all the requirements they'll encounter. And that gives them more freedom to focus on the projects they are devoted to.*



Our scientific experts will consult with you on assay development and validation across a range of therapeutic areas and technologies, supporting harmonized testing capabilities for highly complex situations. Whether you are developing a new companion diagnostic or validating an assay to support vaccine research, we will work with you to develop an end-to-end solution so that, together, we can turn hope into help for those who need it most.

### Central Laboratory Services

- Labmatrix® Clinical Trial Sample and Consent Tracking
- Biorepository and Specimen Management
- Project and Data Management
- Sponsor and Investigator Support
- Kitting and Logistics

### Precision Medicine / Biomarkers

- Assay Development
- Companion Diagnostics
- Cell and Gene Therapies
- Enterprise Biomarker Services

### Biomarker Testing

- Anatomic Pathology
- Flow Cytometry
- Immunoassay

### Specialty Laboratory Testing

- Genomics Services
- Bioanalytical Services
- ADME/DMPK
- Rules-Based Medicine Biomarker Testing Services
- Translational Science and Innovation Laboratory (TSAIL)
- Vaccines

### Therapeutic Expertise

### Innovation





## Central Laboratory Services

Through the world's largest network of CAP-accredited laboratories, Q<sup>2</sup> Solutions develops tailored lab testing solutions for global clinical trials. Our project managers and scientists can meet your development needs across a suite of central laboratory services, including flow cytometry, anatomic pathology, companion diagnostics, laboratory network solutions, pediatric drug development solutions, point-of-care testing, cell and gene therapy solutions, immunoassay development, and safety testing. All data are subject to Q<sup>2</sup> Solutions' Quality Management System, which incorporates regulatory requirements, industry standards, and best practices.

### **Clinical Trial Sample and Consent Tracking**

Our unique software solution, Labmatrix®, tracks samples through their lifecycle across the ecosystem of sites, labs, and biorepositories.

### **Biorepository and Specimen Management**

We preserve the integrity of millions of biospecimens each year, meeting clients' needs for short- and long-term storage and logistics based on study requirements.

### **Project and Data Management**

Q<sup>2</sup> Solutions' full governance model provides change management protocols, metrics, trend analyses, and risk management plans to assure seamless study execution across a range of clinical trial designs.

### **Sponsor and Investigator Support**

Our investigator website portal and telephone support team provide central laboratory guidance to keep your project running on-time and on-budget.

### **Kitting and Logistics**

With more than 25 years of experience, our network has applied globally harmonized systems and processes to service more than 180,000 investigator sites spanning 90 countries.

## Precision Medicine

Q<sup>2</sup> Solutions brings extensive expertise to precision-medicine projects that require biomarker identification, assay development, qualification and analysis. Having developed many well-known biologic markers for personalized medicine, including BCR-Abl, ALK, BRAF, C-KIT, EGFR, KRAS, HER2, MET, and PD-L1, Q<sup>2</sup> Solutions has the experience to incorporate these tools across the drug development process, including early clinical development (design and screening), clinical biomarker services and development, and pre-launch and commercialization. Whether you are developing a companion diagnostic or investigating a new cell/gene therapy, Q<sup>2</sup> Solutions offers enterprise biomarker services that can meet your project's needs.

### **Assay Development**

Q<sup>2</sup> Solutions' global network, which includes three satellite translational science laboratories, has developed and validated more than 450 routine and specialty assays (including more than 250 biomarker assays) per year since 2015.

### **Companion Diagnostics**

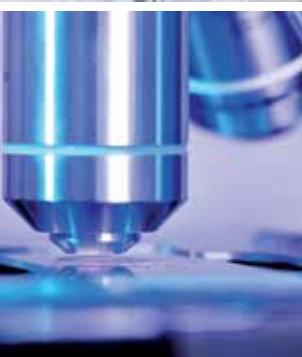
Through global coordination and expertise in IHC, next-generation sequencing, and quantitative PCR methods, we routinely develop harmonized companion diagnostics assays for protein/gene expression, mutation detection, copy number, and translocations.

### **Cell and Gene Therapies**

We provide testing solutions for cell and gene therapy-based development programs, including CAR-T cell therapies, across multiple clinical trial centers.

### **Enterprise Biomarker Services**

Q<sup>2</sup> Solutions can help you integrate biomarkers into your clinical development program with our expertise in biomarker development, assay testing, and strategies for co-developing a drug with a companion diagnostic.



## Biomarker Testing

Our biomarker testing services to support identification and analysis include immunoassays, flow cytometry, genomic panel-based and targeted sequencing, liquid chromatography–mass spectrometry (LC/MS), and anatomic pathology and molecular pathology solutions. Biomarker testing services are performed by Rules-Based Medicine (RBM), a Q<sup>2</sup> Solutions owned and CLIA-certified biomarker and multiplexed immunoassay testing laboratory. We can help you develop a rigorous, comprehensive, and innovative strategy to test analytes across a wide range of applications.

### Anatomic Pathology

Q<sup>2</sup> Solutions employs more than 25 expert pathologists who carry out histology, tissue embedding and sectioning, H&E staining for FISH and IHC analyses, and digital pathology services using globally harmonized SOPs.

### Flow Cytometry

Our integrated flow cytometry team joins translational science with clinical laboratory and global cytometry support to provide unique high-parameter flow cytometry services, including next-generation flow cytometry, custom panel design services, and automated results reporting.

### Immunoassay

By applying standard-plate ELISA and ultra-high sensitivity platforms, multiplexing capabilities (e.g., bead-based detection, biochips, immunoblotting), and automated immunoassay platforms, Q<sup>2</sup> Solutions brings extensive testing capabilities to enable comprehensive, global immunoassay solutions.

### Translational Science and Innovation Laboratory (TSAIL)

TSAIL melds industry-leading expertise with numerous cutting-edge technologies to support all aspects of biomarker development and delivery, including tailored biomarker assay development, bioinformatics, data analytics, digital innovations, and the capability to evaluate novel technologies.

## Specialty Laboratory Testing

Q<sup>2</sup> Solutions is focused on helping clients develop assays that are tailored to meet their needs. As such, we incorporate specialty tests as needed to design and validate fit-for-purpose assays. Our areas of analytical expertise include genomics, small and large-molecule analyses, ADME/DMPK support, immunoassays, and vaccines.

### Genomics Services

Across four global genomics laboratories, Q<sup>2</sup> Solutions processes more than 100,000 samples annually. We offer a range of services to support drug discovery, precision medicine and clinical development.

### Bioanalytical Services

We offer bioanalytical services to support every phase of drug discovery and development, from high-throughput screening and human clearance predictions to drug-drug interaction risk assessments and metabolite profiling. Specific services, including small- and large-molecule/peptide LC-MS, LC/MS/MS analysis, immunoassays, and ADME screening assays, can be bundled into custom integrated drug metabolism solutions.

### ADME/DMPK

From *in vitro* ADME screening assays and drug-drug interaction risk assessment to metabolite identification *in vitro* and *in vivo*, Q<sup>2</sup> Solutions facilitates rapid drug discovery ADME property optimization and enables accelerated regulatory filings.

### Rules-Based Medicine Biomarker Testing Services

With more than 20 years of experience developing and manufacturing and validating multiplex immunoassays, RBM applies innovative microsphere-based technology with rigorous QC measures to support mechanistic, pharmacodynamic, prognostic, and predictive clinical studies across all stages of drug discovery and development.

### Vaccines

Drawing on more than 35 years of experience in clinical vaccine development, Q<sup>2</sup> Solutions operates an ISO 9001-certified vaccine laboratory that has tested more than 900,000 samples from more than 175 Phase I to IV studies during the previous decade.

### Specific Antibody Libraries and Technologies

The construction and delivery of *in vitro* antibody libraries and the ability to create custom libraries from specific patient or donor populations.

### Protein Sciences

Reagents tailored to your specifications in scale, purity, and other analytical characteristics.

### ImmunXperts (Immunogenicity, Immuno-Oncology, and Cell & Gene Therapy)

Fit-for-purpose bioassays utilizing high-quality human primary immune cells to assess wanted and unwanted immunogenicity.



## Therapeutic Expertise

Q<sup>2</sup> Solutions brings therapeutic expertise in assay development for oncology, infectious diseases, and rare diseases. We have extensive experience in oncology clinical research and can help design genomics-based assays that account for the complex biology of solid and hematologic tumors. Our global vaccine laboratory network brings over three decades of experience with infectious disease testing for bacterial pathogens and viruses, including vaccine immunogenicity and efficacy studies, vector-specific detection, and viral and bacterial neutralization assays. Our focus on precision medicine also uniquely positions us to meet the complex needs of orphan drug development through optimal study design and accelerated regulatory approval.



## Innovation

Through our dedicated Digital innovation department, Q<sup>2</sup> Solutions focuses on driving operational improvements and quality of services. Our LabMatrix<sup>®</sup> Clinical Trial and Sample Consent Tracking system provides comprehensive lifecycle support for in-study samples, next-generation biobanking, and data mining, have been utilized in more than 1,000 trials to date. In 2021, Q<sup>2</sup> Solutions opened our state-of-the-art custom-designed Innovation Laboratories facility, a scientific community that incorporates a broad array of services and capabilities to support drug discovery and development. This facility includes the Vaccines Center of Excellence, Genomics Center of Excellence, TSAIL, and other large-molecule bioanalytical services.



[www.Q2LabSolutions.com](http://www.Q2LabSolutions.com)

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