Q² Solutions®

Turning Hope
Into Help™

Q² Solutions Biomarker Services

Providing deep scientific expertise, tools and extensive development experience to maximize your biomarker strategy

Biomarker strategy is critical to success

The use of biomarkers in clinical drug development programs is a growing requirement for many disease areas that have shifted from the one-drug-for-all to mechanism-matched clinical trial design. Clinical research relies on diverse techniques, methodologies and matrices to test for markers that are key to identifying the right patient for the right drug, as well as demonstrating drug biological safety and efficacy. Having a comprehensive biomarker strategy can be crucial to ensuring clinical and commercial success of your product.

Q² Solutions helps biopharma and diagnostics customers improve human health through innovation that turns hope into help. Q² Solutions delivers on this promise by offering tailored biomarker solutions, delivery excellence and by shaping outcomes.

Tailored biomarker solutions

Having helped develop some of the industry's most well-known biomarkers for personalized medicine, we have the expertise to develop a fit-for-purpose biomarker discovery and development strategy based on scientific knowledge and development experience, mitigating risks for improved clinical outcomes.

Utilize our early engagement scientific specialists for feasibility and methods review, assessment of regulatory requirements (e.g. IVD vs CLIA validation), and application of best practices for global scale-up and deployment.

With Q² Solutions' comprehensive solution for companion diagnostic development, we can take your therapeutic in tandem with the companion diagnostic to market faster. Our integrated solution provides flexible support across the development spectrum, from biomarker R&D services, assay development and optimization to global execution, regulatory support, and commercial, diagnostics and late-phase expertise.

>100 companion diagnostics studies supported to date across multiple methodologies

We have experience incorporating biomarkers across the development process:

Early clinical development – Our scientific experts can help you develop translational design strategies to identify biomarkers, develop assays and screen multiple biomarkers in parallel. Identifying the most relevant biomarkers sooner gets you to proof-of-concept as early as possible. Our solutions include:

- Biomarker R&D
- De novo assay development
- Companion diagnostic development
- Technology transfers
- Novel biomarkers
- Assay customization
- Low-volume batch testing

Clinical development – With clinical and scientific experts spanning nearly every major disease area, we can help optimize clinical trials by using biomarkers to improve selection or exclusion of patients for therapy or dose adjustment – and increasingly to demonstrate efficacy or detect toxicity. Finding the right patients faster can reduce trial costs and help get products to market faster. Our global teams include assay development experts working in the largest system of CAP-accredited central laboratories. Employing a comprehensive suite of genomic, molecular and protein-based platforms, we can rapidly and seamlessly develop, test, transfer and integrate biomarkers into your clinical development program to aid decision making and mitigate risks to improve outcomes.

Q² Solutions has helped developed a number of biomarkers commonly used today including **BCR-Abl, ALK, BRAF, C-KIT, EGFR, KRAS** and **HER2.**

Q² Solutions is one of the few bioanalytical laboratories successfully employing immunoprecipitation techniques and multidimensional (up to 3-D) liquid chromatography (LC) for biomarker quantitation. Our team has the experience and knowledge in development and validation of definitive quantitation addressing endogenous analytes including proteins, peptides, lipids, neurotransmitters, steroids, amino acids and other biomarker analytes. The development of these assays is followed by method validation or qualification, and sample analysis consistent with global regulatory requirements and SOPs.

- Method development
- Method qualification
- SOP training and implementation
- Laboratory correlations
- Sample analysis supporting clinical and non-clinical studies
- Inter-laboratory proficiency
- High-volume real-time testing

>45 custom genomics assays
on multiple sequencing and other genomic platforms

Pre-launch and commercialization – With access to IQVIA's global experts in market access for drug/diagnostic combinations, we can develop robust launch plans and commercial strategies to help ensure in-sync regulatory and payer submissions and launches, improving market adoption and patient access.

Delivery excellence

We offer an extensive biomarker menu, as well as a world-renowned scientific staff ready to help you develop custom tissue or fluid biomarker assays specifically for your study. Our biomarker team has more than 20 years of experience in biomarker development, validation and deployment, enabling our customers to select markers to enhance "go/no go" decisions, assess target modulation, stratify potential responders from non-responders and evaluate therapeutic benefits.

>110 PhDs,
>30 Medical Doctors,
>25 expert pathologists

Key disciplines and services to support your biomarker strategy

	Methodology
Immunoassays:	• Singleplex (ELISA automation) and high-sensitivity (Quanterix) • Multiplex (Luminex, MSD, Randox Biochip, Aushon Ciraplex) • Ligand binding assays • Custom Immunogenecity assays
Flow cytometry:	• Custom panel design, optimized gating strategies, QC management • Esoteric panels for cytokine/chemokine receptors, cell proliferation and apoptosis • Total and phosphorylated signal transduction markers • Receptor and drug occupancy • PBMC isolation and cell purification (magnetic bead-based) • Ex vivo stimulation, ICC, and phospho-flow • Circulating Tumor Cells (CTCs) and Circulating Endothelial Cells (CECs)
Molecular/genomics:	• Nucleic acid isolation - e.g. FFPE/frozen tissue, blood, stool, saliva, buccal swabs, etc • qPCR/RT-PCR - Oncology gene mutation analysis from FFPE tissue - Custom multiplex mRNA profiling - Quantitative gene rearrangements by PCR - Quantitative viral load assays • Single and multiplex SNP analysis • Microarrays • Next-generation sequencing including targeted exome sequencing and RNAseq • Direct DNA sequencing (microbial, viral) • Bioinformatics • HLA genotyping in an ASHI- and NMDP-certified laboratory
Mass spectrometry:	• LC/MS biomarker assays • Microarray • Focused set • FFPE services
Anatomic and molecular pathology:	• Pathology services, including confirmation of diagnosis • IHC, ISH, FISH and PCR/RT-PCR • Digital pathology (remote image access)/Whole-slide imaging • Tissue processing, including fresh/formalin-fixed tissue, bone marrow aspirates and trephine biopsies • Mutation analysis • Special stains

Spotlight on oncology

Modern clinical oncology emphasizes the value of biomarkers and their utility in diagnosing, monitoring and treating what is recognized as an increasingly complex disease. Clinical cancer research relies on diverse techniques, methodologies and matrices to test for markers that are key to identifying the right patient for the right drug, as well as demonstrating drug biological activity. Q² Solutions offers comprehensive **tissue and fluid-based testing for protein biomarkers**, as well as robust methods for **DNA/RNA analysis** to analyze tumors at the nucleic acid level. With experience in **anatomic and molecular pathology, flow cytometry, immunoassay and genomics-based assay development**, Q² Solutions can provide customized, global laboratory solutions specifically suited for the unique combinations of therapeutic indication and targeted mechanism-of-action driving modern oncology drug development.

Since 2011 provided services for
>890 oncology studies

Key areas of focus:

- Dedicated scientists for tissue and fluid biomarker assay development
- Global anatomic and molecular pathology laboratories, including wholly-owned facility in Beijing, China
- >25 expert pathologists with extensive molecular and anatomic pathology expertise
- Rapid turnaround for results required at patient screening
- Digital pathology solutions, including image analysis and remote image access
- Gene expression profiling and signatures

223 gene CLIA-validated cancer panel

Key areas of development:

- **Liquid biopsies** – Ongoing efforts in method development for plasma/circulating DNA analysis; working relationship with Cynvenio for circulating tumor cell (CTC) analysis and ability to validate stabilization methods in regional labs for analysis using other platforms
- **Hematological malignancies** – Current capabilities include cytogenetics (FISH) and flow-based analysis for MRD and immunophenotyping; expanding FISH menu and 10-color panels; flow cytometry
- **Cancer immunology** – Impact of the tumor microenvironment (TME), including tumor-infiltrating lymphocytes and expression of immunomodulators; CTLA4, PD-1/PD-L1 immunomodulator inhibitor expertise
- **Genomic profiling** – Assessing molecular signatures associated with disease subtype and mechanisms of susceptibility/drug resistance
- **Companion diagnostics** – With Q² Solutions pathologists as Principal Investigators, our laboratories have supported 30+ companion diagnostic studies to-date across multiple methodologies

>150 NEW BIOMARKER ASSAYS each year since 2012

To learn more about Q² Solutions' companion diagnostics offering, visit www.Q2LabSolutions.com/precision-medicine/companion-diagnostics

Shaping outcomes

Q² Solutions has the breadth and depth of biomarker expertise, tools and capabilities to prepare and implement strategies to help drug developers effectively gain a competitive advantage – helping ensure your success in clinical trials, regulatory approvals and new product launches.

Q² Solutions is your partner of choice for any development program which requires identifying, designing and/or validating biomarkers, because we're able to go a step further to help you understand how these biomarkers can help turn hope into help.

Q² Solutions helped develop **93%** of the **Top 30 best-selling oncology products** of 2016

Q² Solutions has helped develop **61%** of all **FDA-approved oncology pharmacogenomics products** to date

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