

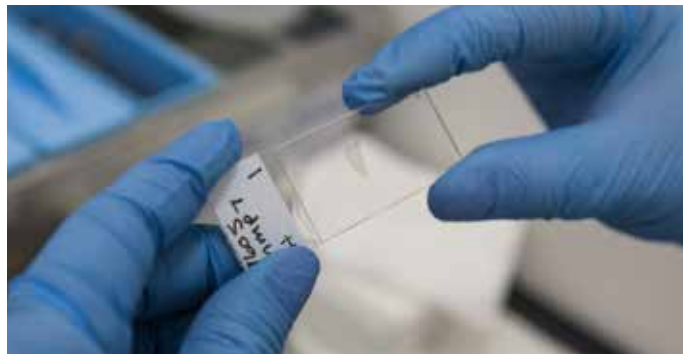
At a glance

Quintiles oncology biomarker services

Comprehensive support for fluid and tissue-based testing

Quintiles and oncology biomarkers

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 key in identifying the right patient for the right drug as well as demonstrating drug biological activity.



Quintiles Global Laboratories 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 Centers of Excellence for anatomic and molecular pathology, flow cytometry, immunoassay and genomics-based assay development (EAIQuintiles), Quintiles 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.

Key strengths and 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
- In-house pathologists
- Rapid turnaround for results required at patient screening
- Digital pathology solutions, including image analysis and remote image access
- Gene expression profiling and signatures

Areas of developmental focus

In addition to routine clinical lab capabilities, Quintiles is continuously exploring and bringing on new technologies, platforms and science to support modern oncology studies. operationalizes over 150 new biomarker assays each year.**

Liquid Biopsies

Expanding capabilities for less-invasive disease assessment

Hematological Malignancies

Validated FISH and MRD panels; expanding to 10-color flow cytometry

Immuno-Oncology

Assays to monitor status of tumor, stroma and systemic immune environment

Genomic Profiling

Genomics, bioinformatics and R&D to examine signatures of susceptibility and resistance

Companion Diagnostics

From IHC and ELISA to FISH and somatic mutation analysis, Quintiles is a trusted partner in the development of companion diagnostics

- **Liquid Biopsies** – Ongoing efforts in method development for plasma/circulating DNA analysis; working relationship with Cynvenio for 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
- **Cancer Immunology** – Impact of the tumor microenvironment (TME), including tumor-infiltrating lymphocytes and expression of immunomodulators
- **Genomic Profiling** – Assessing molecular signatures associated with disease subtype and mechanisms of susceptibility/drug resistance
- **Companion Diagnostics** – With Quintiles lab directors as Principal Investigators, our laboratories have supported 30+ companion diagnostic studies to-date across multiple methodologies

List of services

With a growing menu of tissue and fluid biomarkers, Quintiles specialises in the development of esoteric biomarker tests for clinical research applications. Our dedicated global Assay Development Laboratory designs, validates and operationalizes over 150 new biomarker assays each year.**

Discipline	Methodology	Instruments	Example Assays**
Anatomic and Molecular Pathology	- Tissue processing (FFPE, TMAs) - Immunohistochemistry - FISH/ISH - Mutation analysis - Digital pathology: (remote image access)	- Dako Autostainer 48 - Ventana Benchmark Ultra and XT - Abbott m2000, Roche cobas 4800, Qiagen RotorGene, ABI 7500, Sequenom MassARRAY analyzer - Aperio XT and BioView Duet Scanning Station	- IHC: HER2/p-HER2, ER, PgR, Ki67, p16, EGFR, PTEN, Stathmin, cMET/p-cMET, Akt/pAkt, pRSK, MMPs, HIF1α, CD8, CD4, FoxP3, CD31, CD20, Bcl-6, CD10, CD5, MUM1/IRF4, p-ERK1/2, Cleaved Caspase3, γH2AX, pPRAS40, pS6, TTF-1 - ISH: cMET, EGFR, HPV, PIK3CA, FGFR1, HER2, cMyc, CLL panel - Mutations: PIK3CA, EGFR, PTEN, KRAS, BRAF, OncoCarta v.1, MelaCarta
Immunoassay	- Manual or automated ELISA - Multiplex ELISA (bead-based detection, biochips)	- Luminex (FLEXMap 3D, 200) - Hamilton robot - Randox - MSD	- Immunogenicity assays - Soluble tumor antigens (CA-125, CA-15-3, CA-19, CEA, HE4) - Inflammatory and angiogenesis panels, e.g. TNF-α, IL1β, IFNγ, VEGFs, Ang-2, etc). - Oncoproteins/ligands: HGF, FGF, SCF, EGFR ligands, soluble receptors (VEGFR, FGFR, sHER2)
Flow Cytometry	Light scatter and cellular fluorescence	- FACS Canto II - FACS Canto Plus	- MRD panels - B lymphocyte clonality (κ/λ) - Immunophenotyping (T cell subsets-effector, memory, regulatory, Th17); B cell subsets-plasma cells, activation) - Functionality and signaling: phosphoflow and cytokine secretion
Genomics (with EAI Quintiles)	- NextGeneration Sequencing (from blood or FFPE/frozen tissue) - Bioinformatics and pipeline development - Mass-spec based sequencing - Microarrays	- Illumina HiSeq 2000, 2500, and MiSeq - PacBio RS II System - Life Technologies Ion Torrent PGM - Fluidigm BioMark - Nanostring - Affymetrix GeneChip System	- RNAseq - Whole exome sequencing - DNA methylation sequencing - miRNA sequencing - Targeted gene sequencing - e.g. AmpliSeq CancerPanel 2.0, Quintiles Comprehensive Cancer Panel (QCCP)

****From LDTs to commercial kits, Quintiles Assay Development Laboratory designs, validates and operationalizes over 150 new biomarker assays each year.**

Contact us

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