

# Specialty Lab Services

Deep science at scale



Advancing biomarker research

Our broad expertise and global laboratory footprint deliver deep science at scale

Specialty assays drive insight into preclinical and clinical development. Precision for Medicine understands—we’re innovators in delivering specialty assay solutions. We offer expertise in immunophenotyping, immune response, ligand binding, and cell-based assays, in addition to protein and gene expression assays, global specimen logistics, and biomarker data management. Across every area, Precision works collaboratively with clients to develop custom solutions. We extend those solutions into a variety of appropriate quality systems, supporting global needs and delivering on our promise of “deep science at scale.”

We aspire to be your scientific partner

Precision partners closely with our clients to support assay development and execution from initial research through global biomarker-driven pivotal trials. We start with

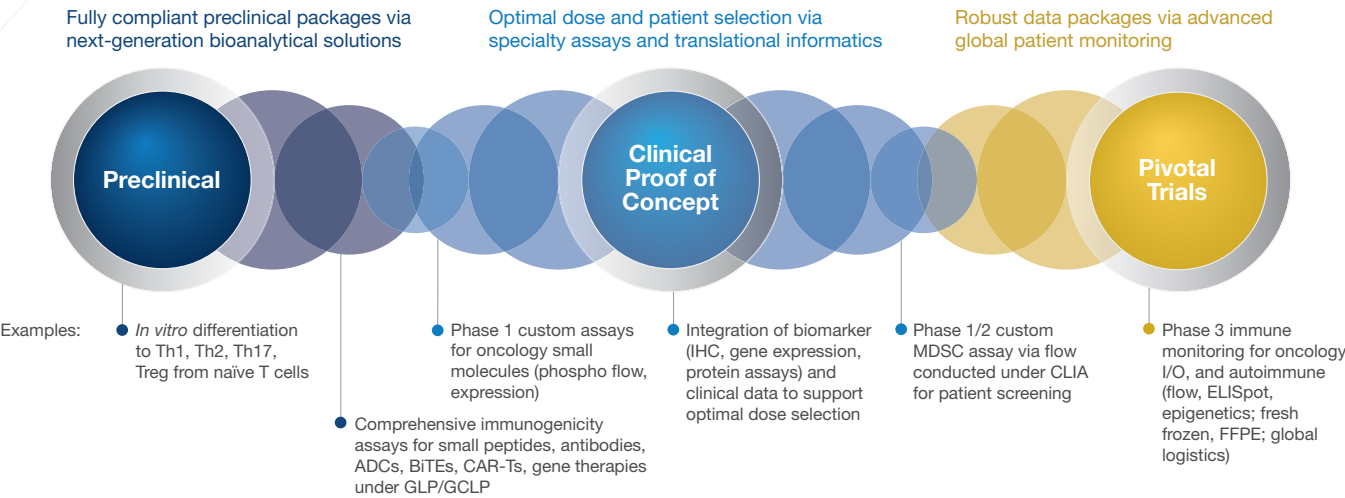
understanding your needs—efficacy, safety, mechanism of action, biomarker discovery and implementation, patient stratification, immune monitoring—and then deliver a solution, whether custom assay or standard panel, with the appropriate level of qualification/validation to meet both regulatory requirements and your budget. The solutions outlined below are representative, though not exhaustive, of the assays we routinely perform.

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We help our clients develop biomarker signatures and support their guided trials through approval.

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End-to-end experience from preclinical to postapproval



Advanced immune monitoring solutions

Precision global solutions support immune monitoring from Phase 1 to Phase 3. These assays range across multiple platforms (e.g., flow cytometry, multiplex cytokine profiling, epigenetic markers), and we process specimens in real time as required. Precision’s global labs process samples from nearly any clinical site within 24 to 30 hours of draw and utilize standardized SOPs to ensure sample integrity. Using our proprietary epigenetic panels, we can even monitor T cells from PAXgene and FFPE in most cases.

Assays include:

- Immunophenotyping via flow cytometry (up to 18 colors, research, and CLIA)
- ELISA (including time-resolved fluorescence, AlphaLISA)
- Multiplex cytokine profiling (MSD, Luminex)
- ELISpot (ImmunoSpot/FluoroSpot)
- Epigenetic markers
- T-cell activation
- Phospho flow
- Receptor occupancy
- Tetramer flow assays
- Gene expression—PCR, qPCR, RT-qPCR, NanoString
- Assays under CLIA for screening patients into trials (e.g., MDSC via flow, HAHA via ELISA)

Custom assays

Precision offers exceptional scientific depth to support the development of de novo assays, with a particular specialization in cell-based assays. We work with your scientific team to understand your needs—e.g., high content vs high throughput—and then tailor an assay to meet them.

Representative assays include:

- T-cell activation and proliferation
- T-cell polarization of naive T cells (Th1, Th2, Th17, Treg)
- MLR
- ADCC/CDC, NK cell killing
- Dendritic cell—generation, isolation, characterization
- Macrophage differentiation
- Neutrophil migration

Bioanalytical solutions

Precision’s scientific leadership includes world-renowned experts. We are authorities in immunogenicity, having led industry groups and supported the FDA/EMA in developing guidelines currently in use by the entire industry. Precision heads the effort to develop standards for immunogenicity assessments of novel therapeutics, such as gene therapies and CAR-Ts. Additionally, Precision works with many biosimilar developers in preparing the full package of analytical characterization to support registration.

Our assays include:

- PK
- Anti-drug antibody assays (screening, confirmation, titer)
- Neutralizing antibody assays (cell based and non-cell based)
- Binding assays via Biacore
- Drug-specific IgE and complement testing
- Specialty assays to support complex molecules, such as antibody-drug conjugates, PEGylated products, and gene therapies



Supporting broader biomarker solutions

Precision delivers all critical assay needs to support biomarker drug trials. All data are delivered from within our biomarker data management platform.

Representative assays include:

- Whole genome sequencing
- Immune repertoire sequencing
- Circulating tumor cell profiling
- Cell-free DNA
- Immunohistochemistry
- FISH

Substantial specialty labs, expansive global reach

Precision pairs laboratory locations on both coasts of the United States with a worldwide footprint of specialty labs. Our facilities can provide rapid, standardized specialty tissue processing—wherever in the world your clinical site is.

- Our facilities provide extensive sample management and storage services, along with state-of-the-art cell-based and molecular assay development and execution, to clients with preclinical and clinical trial needs.
- Our 65,000-square-foot East Coast facility is ISO 9001 and ISO 13485 certified, accredited under the CAP Biorepository Accreditation Program (BAP), and CLIA registered. Our labs are also GLP and GCLP compliant.
- We have labs located in strategic biotech hubs, such as the San Francisco Bay Area, to support the local needs of emerging companies.
- Regular quality assurance, competency assessment, and monitoring ensure we are meeting ongoing optimal standards.

Processing that’s as specialized as your samples

Precision places an unwavering focus on ensuring the highest sample quality and viability—characteristics critical for use in specialty assays. Leading biopharmaceutical companies, major academic institutions, and governments trust us and rely on our global lab infrastructure for real-time processing, delivering uniform quality for any tissue type in more than 50 countries around the world.

Precision’s sample processing capabilities include:





- Custom kit development and collection
- PBMC isolations, cryopreservation, characterization, and same-day or next-day processing worldwide
- Blood fractionation for isolation of serum, plasma, and multiple cell types
- DNA/RNA extraction and quantity, quality, and purity assessment of cell subsets
- Cell-line immortalization and expansion with >97% expansion rate
- Custom processing and characterization studies
- Standardized SOPs for laboratory services, customizable on demand

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We deliver a solution, whether custom assay or standard panel, with the appropriate level of qualification/validation for its intended use.

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Delivering specialty lab biomarker solutions at scale through every stage of development

			
Sample Protection	Assay Design and Execution	Translational Informatics and Biometrics	DX Development
Samples	Assays	Informatics	Companion Diagnostics
<ul style="list-style-type: none"><li>■ Ensuring integrity and traceability of sample from draw to lab</li><li>■ Globally scalable sample management solutions</li></ul>	<ul style="list-style-type: none"><li>■ Protein, molecular biology, and imaging assays</li><li>■ Custom assays, renowned technical team, and compliant scale-up</li><li>■ Healthy and disease state specimens for research</li></ul>	<ul style="list-style-type: none"><li>■ Novel biomarker data management platform to manage complex data, conduct translational analyses, and simplify regulatory submissions</li></ul>	<ul style="list-style-type: none"><li>■ Quality and regulatory infrastructure to take biomarkers through diagnostic development and global filing</li></ul>

Global specimen logistics that minimize your risk

- Sample logistics from global sites to Precision’s local labs for processing and further testing
- Ongoing quality assurance of lab footprint from trial through commercialization
- Global PBMC processing in 24 hours or less
- Competency assessment and monitoring regularly to ensure consistency across all labs
- Real-time inventory tracking through our proprietary dashboard system to monitor sample locations
- Long- or short-term storage at optimal temperatures



Precision’s lab footprint covers the world. We are currently collecting samples in over 50 countries on 5 continents.

Novel approaches to managing massive biomarker data sets

Today’s clinical trials rely on dense, complex data generated from multiple assays—often run by multiple labs. It can be challenging to efficiently manage both data and vendors to inform real-time trial decisions. Precision can help.

Our unique approach combines subject matter expertise with our proprietary biomarker data management platform to streamline your efforts.

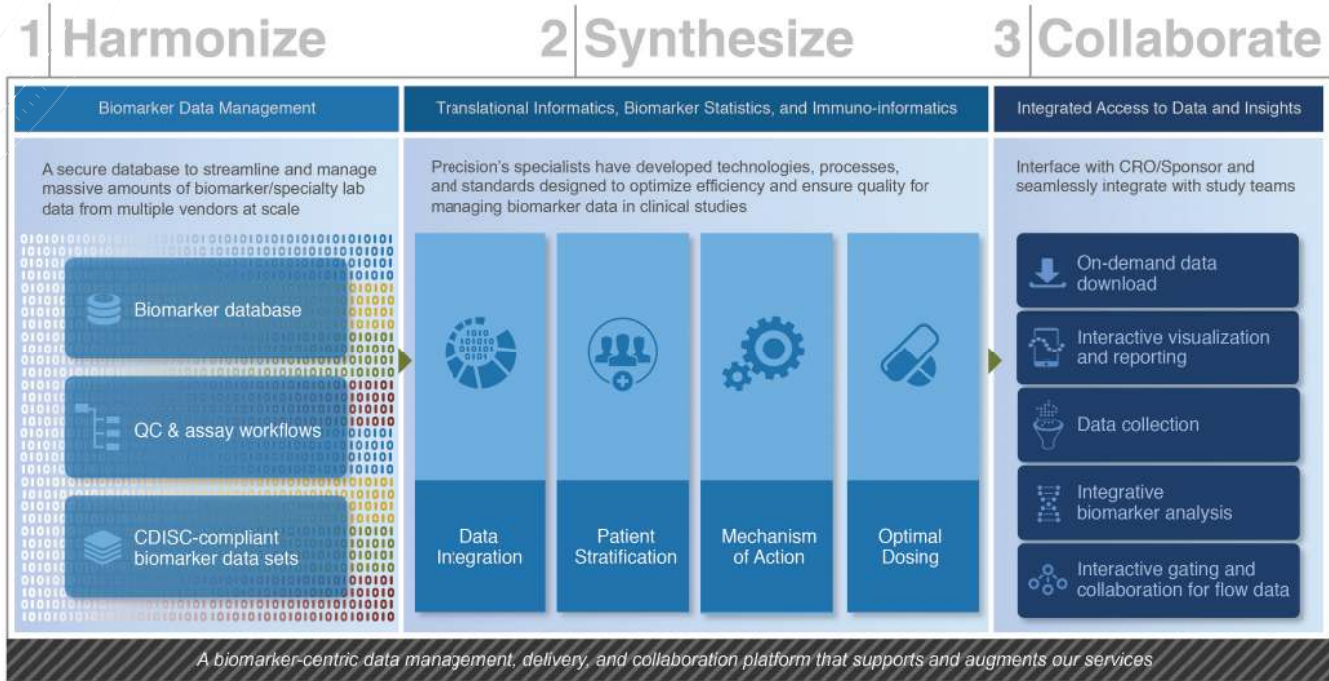
- We have a deep team whose wide-ranging expertise spans data science, programming, data management, and biomarkers.
- We are experienced in handling the full spectrum of assays in all major therapeutic areas including oncology, CNS, and auto-immune, regularly helping Sponsors address objectives such as data integration, development of biomarker signatures, patient stratification, assessment of mechanism of action, and optimal dosing.

- Our cloud-based biomarker data management platform supports all aspects of our services; you have access to the data throughout the study via customized reporting packages and interactive visualizations and analysis workflows.

**The result:** You gain an orders-of-magnitude reduction in time and cost—and a mitigation of major risk to interim and final study deliverables.

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A biomarker-centric data management, delivery, and collaboration platform that supports and augments our services





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For more information about our specialty lab services,  
please contact us at [info@precisionformedicine.com](mailto:info@precisionformedicine.com).