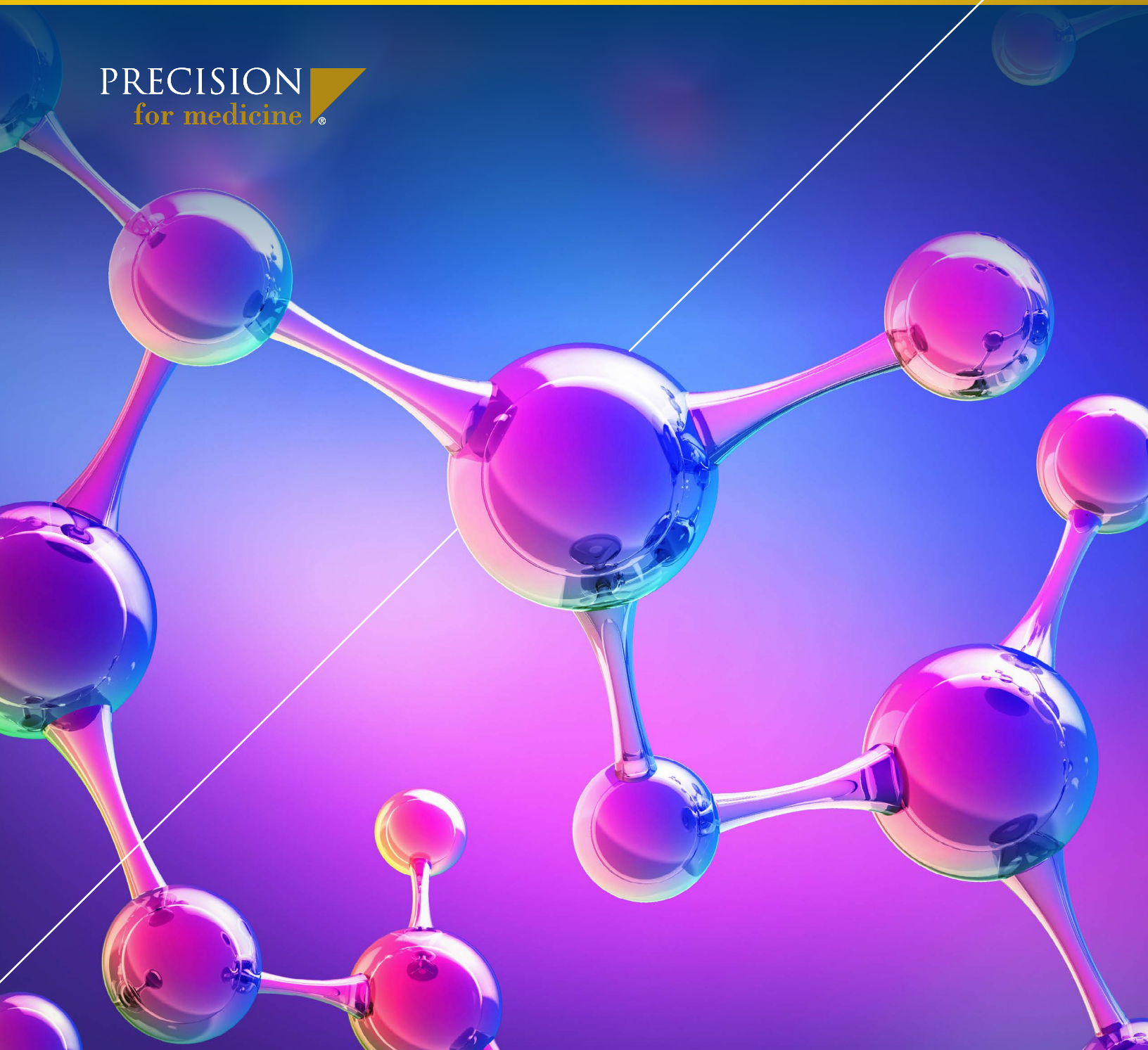
Bioanalysis
Experience Overview

PRECISION for medicine®



Precision for Medicine can evaluate pharmacokinetic and pharmacodynamic characteristics of potential biotherapeutics and their immunogenicity to support IND-enabling nonclinical studies and all phases of clinical trials.

We can recommend and deliver the optimal assays based on the appropriate stage of development and risk profile, under a robust quality system to successfully meet regulatory requirements. Notably, for AAV-based gene therapy development, we have supported co-development of neutralizing antibody assays as companion diagnostics to support commercial testing.

In tandem, Precision can perform full bioanalytical validation to ensure that the optimized method is acceptable for the analysis of biological study samples. Method validation conforms to relevant regulatory guidance. Bioanalytical method development and validation are part of the comprehensive bioanalytical services offered at Precision. Explore the therapeutic types and assays that we have helped sponsors advance.

Bioanalysis Scientific and Technical Expertise

>50
Bioanalytical Assays Supporting Gene and Cell Therapies

Broad Range of Indications, Including Oncology, Rare Disease, Gastroenterology

Our bioanalytical capabilities span a wide variety of services:

- PK assays
- Immunogenicity
- Assay development, GLP/GxP/CLIA validation, and implementation
- Regulated clinical trial assays and companion diagnostics

Our experience includes a range of molecule types including:

- Antibody-drug conjugates (ADCs)
- Biosimilars
- Gene therapies
  — Multiple AAV serotypes
- Cell therapies
- Antibodies (including ADC and bispecific)
- Oligonucleotides
- PEGylated products
- Proteins and peptides
- Vaccines

Underlying technologies and complementary lab services:

- Meso Scale Discovery
- ELISA
- Quanterix™
- Flow cytometry
- ELISpot, FluoroSpot
- Olink® proteomics platforms

Accompanied by Comprehensive Regulatory Consulting

Precision for Medicine is a regulatory leader in industry with expertise in emerging fields, including gene therapy CDx, with extensive knowledge in NAb and TAb assay development, supporting 14 different rare disease pipelines. Globally situated, Precision can conduct testing in laboratories in both US and Germany.

With 125+ years of cumulative IVD regulatory experience, our team provides end-to-end regulatory solutions and support with industry knowledge developing global regulatory strategies, CLIA- and CLSI-compliant analytical validation study designs, and clinical trials enabling regulatory submissions, in addition to marketing authorization regulatory filings globally. In the field of immunogenicity assay for Gene therapy alone, Precision has completed:

20+
Q-submissions (SRDs, pre-IDEs, and presubmissions) for gene therapy CDx

6
approved IDE applications

2 NAb assays
registered in the EU

1 IVDR
registered sample collection kit

Regulatory Solutions at Every Phase

Preclinical Development

- Global IVD regulatory strategy for clinical trial testing and commercialization
- Product design considerations
- Clinical trial assay analytical validation study designs
- Risk assessment and Study Risk Determination Q-submission
- QMS development

Product Development and Evidence Collection

- Cutoff selection and assay use considerations
- Pre-IDE Q-submissions to support IDE approvals
- Development of Annex XIV, ITA, and IDE applications
- IRB and local ethics committee submissions
- Breakthrough Device designation

Pivotal Clinical Trials

- Presubmissions and meetings
- CLSI-compliant performance validation studies
- Regulatory agency and notified body communications
- BIMO audit preparation

Global Registrations

- Long-term safety
- Labeling/advertising promotion
- QMS mock audits
- Registration and listing
- PMA submissions, technical file dossiers, and other global registration filings

In-Market Support

- Post-market surveillance
- QMS certification
- Product life cycle management
- Product updates and supplementary filings

Gene Therapy

Our team has accumulated a wealth of experience in immunogenicity and molecular genomics, backed by extensive capabilities and strong regulatory experience. At Precision for Medicine, we support customers' therapies through every stage of the drug development life cycle.

Wild-Type AAV Vectors

Serotypes	Assay Type	Species	Indication	Regulatory Level
AAV2i8	ELISpot	Human	Cardiology	GxP
AAV5	NAb	Human	Rare Disease	CLIA/CE Mark, GxP
AAV5	ELISpot	Human	Rare Disease	GxP
AAV6	TAb	NHP	Oncology	GLP
AAV8	TAb	NHP	Gastroenterology, Neurology, Ophthalmology, Rare Disease	GLP
AAV9	ADA, TAb	NHP	Gastroenterology	GLP

Capsid Variants

Serotypes	Assay Type	Species	Indication	Regulatory Level
AAV2 Variant	FluoroSpot, NAb, TAb	Human	Oncology	GxP
AAV2.7m8 Variant	ELISpot, NAb, PK, TAb	Human	Rare Disease	Non-GLP
AAV5 Variant	ELISpot, TAb	Human	Rare Disease	GxP
AAV6 Variant	TAb	NHP	Oncology	GLP
AAV8 Variant	NAb, TAb	Human, NHP	Gastroenterology, Neurology, Ophthalmology, Rare Disease	GxP
AAV9 Variant	NAb, TAb	Human, NHP	Gastroenterology, Muscular	GxP
Engineered Capsid	NAb	Human	Rare Disease	CLIA/IDEA
MyoAAV Variant	ELISpot, NAb, TAb	Canine	Muscle Disease	GLP

Non-AAV Gene Therapy – Antibodies and Miscellaneous

Therapeutic Type	Assay Type	Species	Matrix	Indication	Regulatory Level
HSV-1 IgG	ADA	Human	Serum	Oncology	GxP
HSV-1 IgM	ADA	Human	Serum	Oncology	GxP

Gene Therapy – Transgene Proteins

Therapeutic Type	Assay Type	Species	Indication	Regulatory Level
Gene Therapy (Transgene Protein)	ADA, ELISpot, FluoroSpot, NAb, TAb, PK	Human, NHP	Ocular, Rare Disease, Oncology, Muscle Disease	GxP
PCSK9	ELISpot	Human	Oncology	GxP

Cell Therapy

Therapeutic Type	Assay Type	Species	Matrix	Indication	Validation Level
Cell Therapy (CD7 CAR)	ELISpot	Human	PBMCs	Oncology	GxP
Cell Therapy (iNKT)	ELISpot	Human	PBMCs	Oncology	GxP
Cas9 Antigen	ADA	Human, NHP	Serum	Oncology	GxP

Therapeutic Antibodies

Therapeutic monoclonal antibodies are one of the largest and fastest-growing classes of large-molecule biotherapeutics. Accurate and reliable quantification of these biotherapeutics in biological matrix is mandatory for their pharmacokinetic and pharmacodynamic assessments. Precision has developed 25 assays of these for multiple programs summarized below.

Therapeutic Type	Assay Type	Species	Matrix	Indication	Regulatory Level
Bispecific Antibodies	ADA, PK	Human	Plasma	Oncology	GxP
Monoclonal Antibodies	ADA, ELISpot, NAb, PK	Human, NHP	Serum, Serum/Plasma, PBMCs	Autoimmune, Gastroenterology, Oncology, Pulmonary	GxP
Antibody Fusion Proteins	ADA, PK	Human	Serum	Oncology	GxP

Therapeutic Proteins (Chimeric and Recombinant)

We specialize in a broad range of analytical testing techniques to measure therapeutic proteins as well as the immune response to therapeutic proteins.

Therapeutic Type	Assay Type	Species	Matrix	Indication	Regulatory Level
Chimeric protein	ADA, NAb, PK	Human	Serum	Hepatology	GxP
Recombinant Protein	ADA, ELISpot, NAb, PK	Human, NHP, Mouse	Serum, PBMCs	Gastroenterology, Oncology, Rare Disease	GxP

PEGylated Therapeutics

Attachment of polyethylene glycol (PEG) to biotherapeutics can improve pharmaceutical pharmacokinetic properties and enhance in vivo biological efficacy. Successful clinical development of PEGylated pharmaceuticals requires accurate methods for the analysis of PEG conjugates and anti-PEG antibodies in biological fluids.

Therapeutic Type	Assay Type	Species	Matrix	Indication	Regulatory Level
PEGylated Cytokine	ADA	Human	Serum	Oncology	GxP
PEGylated Protein	ADA (IgE)	Human	Serum	Rare Disease	GxP
PEGylated Protein	ADA (IgG)	Human	Serum, Plasma	Rare Disease	GxP
PEGylated Protein	ADA (IgM)	Human	Serum	Rare Disease	GxP

Other Therapeutics

Therapeutic Type	Assay Type	Species	Matrix	Indication	Regulatory Level
Multineoantigen Vaccine	ELISpot	Human	PBMCs	Oncology	GxP
pDNA Vaccine	ELISpot	Human	PBMCs	Oncology	GxP

Solving the most complex challenges in biomarker-driven and precision therapeutic development

Precision for Medicine is the first clinical research services organization engineered to support life sciences companies in the use of biomarkers essential to targeting patient treatments more precisely and effectively. Combining deep scientific expertise, clinical trial excellence, and advanced approaches for data science, Precision accelerates therapeutic development from the late preclinical phase through commercialization.

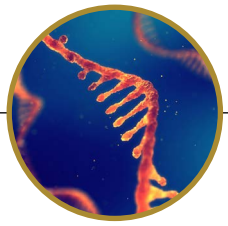
- 7 specialty labs throughout North America and Europe
- Sample processing labs on 5 continents
- Central lab services, including custom kitting, logistics, processing, and storage
- Assays available under GxP, CLIA, CLSI, CAP, ISO 9001/13485

Comprehensive suite of technologies, capabilities, and proprietary approaches to interrogate any sample type

DNA

- PCR - ddPCR, qPCR
- NGS - whole exome and targeted resequencing

RNA

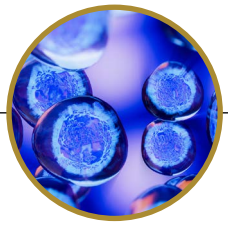


- Gene expression profiling - NanoString
- CAR T and virus (ie, gene therapy) biodistribution
- rtPCR
- MicroRNA analysis

Protein

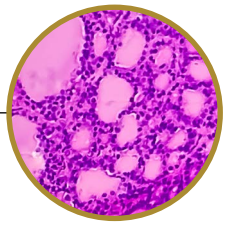
- Comprehensive large molecule bioanalysis - PK, ADA, NAb
- Multiplex cytokine profiling, receptor occupancy, tetramer staining
- Custom ligand binding assays - ELISA, MSD, Biacore
- Quantitative image analysis of protein expression (eg, phosphorylation, signaling

Cell



- Flow cytometry - up to 31 color panels, ICS, phosphoflow, receptor occupancy
- Functional assays - eg, T cell activation, ADCC, ELISpot
- Single-cell quantitative image analysis
- Proprietary cell separation technology for CTCs and cfDNA
- Immunophenotyping via proprietary epigenetic platform

Tissue



- Multiplex IHC with centralized pathology reading
- Quantitative IF - up to 9 concurrent markers
- FISH, ISH, sequencing

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Rev. 01

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