



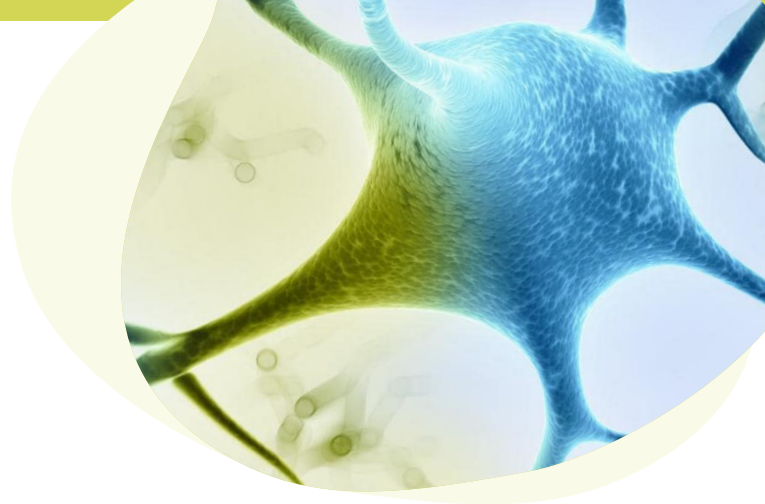
Quanterix® Accelerator Laboratory

Custom assays research and biomarker testing services

Empowering Discovery, Driving Scientific Breakthroughs.

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Quanterix's Accelerator Lab is where expertise drives innovation in research, drug discovery, biomarker testing, and pathology studies. We specialize in Custom Assays Research (CARE) and Biomarker Testing, providing tailored solutions to support a wide range of research needs. **Whether you're in academia, biotech, pharma, or a CRO, our end-to-end services are designed to meet your goals with precision and expertise.**



Our Mission

At Quanterix, we believe in empowering the future of drug discovery and deepening the understanding of pathology. Our mission is to deliver ultra-sensitive assay development, precise sample pre-analytics, and innovative process workflow optimization services. We aim to simplify early discovery, preclinical, and clinical trial workflows, enabling scientists and researchers to focus on what they do best—advancing scientific knowledge and improving health outcomes.

Our Commitment to Excellence and Collaboration

Quanterix's Accelerator Lab is driven by a commitment to excellence. Our team comprises experienced scientists and technicians dedicated to providing unparalleled expertise and personalized support throughout your research journey. We believe in collaboration, working closely with you to understand your objectives and overcome any challenges you face.

About the Laboratory

The Simoa® Accelerator Laboratory is your premier, CLIA-licensed resource for custom biomarker and biopharmaceutical research, assay development, clinical sample testing, and precision data delivery. Access Quanterix's full suite of advanced instruments and assays, and propel your research beyond the capabilities of any other contract research company by detecting proteins and nucleic acids at the lowest possible levels with Simoa® technology.

- 1000x higher assay sensitivity compared to standard ELISA

- Quantify proteins that are BLOQ in typical immunoassay platforms and access baseline analytes in healthy subjects and disease indicators
- Use your proprietary antibodies/reagents or commercially available reagents for custom assay development
- Flexible scale to handle studies of one plate up to thousands of samples
- Singleplex and multiplex detection of proteins

A Customized Approach

Work with an experienced team of Quanterix scientists dedicated to sponsored research using Simoa® technologies. Working individually with the project sponsor, we create a custom scope of work to help you achieve your research objectives efficiently, cost-effectively, and faster than ever before.

Quanterix Accelerator Laboratory: Custom Assays Research

Comprehensive Research Support: From discovery to drug development, across all fields of research

Custom Assay Development with Optimization & Validation

Collaborative expertise for ultra-sensitive assay solutions

Quanterix scientists partner with you to develop your project requirements and assay criteria to transform commercially available or proprietary reagents into a fully validated, ultra-sensitive Simoa® assay that delivers the highest level of performance.

Best Antibody Pairs

Accelerate homebrew Simoa® assays in your lab with Accelerator Antibody Screening.

Creating the best assay often necessitates screening large numbers of antibody pairs. Let Accelerator help select the best antibody pairs for a Simoa® homebrew singleplex or multiplex assay. We utilize a network of antibody suppliers and will screen different antibody clones to help develop the most suitable assay for the customer.

Custom On-Demand Assay Kit Production

Get access to assay kits not commercially available on the Simoa® platform.

The Accelerator Lab builds custom assay kits or specific kit components with commercial available reagents or sponsor's proprietary reagents for use in the sponsor's own facility or in the Accelerator lab according to sponsor defined protocols.



FEASIBILITY/
PROTOTYPE
ASSAY
DEVELOPMENT

ASSAY
OPTIMIZATION/
MATRIX
EVALUATION

ASSAY
VALIDATION

KIT BUILD
& SAMPLE
ANALYSIS

Quanterix Accelerator Laboratory: Custom Assays Research

Comprehensive Research Support: From discovery to drug development, across all fields of research

Assay Development Milestones

Assay Feasibility Testing and Prototype Development

- Reagent screening
- Identify antibody sources and reference materials
- Antibody screening (includes antibody-flip to evaluate all possible combinations)
- Select the best antibody pair for prototype development
- Matrix evaluation

Assay Optimization

Following development of a prototype assay, Quanterix scientists optimize assays to further improve assay performance prior to sample testing. The project scope is to define expected outcomes and timelines. Specific project activities may include:

- Further DOE to optimize bead coating, detector labeling, detector antibody and substrate concentrations
- Optimize calibrator/control, bead, detector and sample diluent formulations (salt, detergent, blockers, protein concentration, buffers, pH)
- Optimize spike recovery and serial dilution in final matrix
- Verify LOD in matrix

- Assess analyte levels with research level reagents
- Document assay protocol

Assay Qualification/Validation

Following optimization, assays are validated according to sponsored defined requirements.

Specific validation components may include:

- Establish calibration curves with final diluent formulations
- Determine analytical and functional sensitivity and dynamic range
- Precision (intra- and inter-assay)
- Dilutional linearity and parallelism
- Verify LOQ in matrix
- Reagent scale-up for sample testing
- Create protocols for method transfer
- Verification report that captures assay design, specifications and performance data
- Ability to perform different levels of validation - Fit-for-purpose, Clinical validation, LDT validation



Quanterix Accelerator Lab offers comprehensive end-to-end research solutions as the world's leading CRO for Simoa® development and testing, with unmatched expertise in developing challenging assays.

Quanterix Accelerator Laboratory: Your Biomarker Testing Solution

Accelerate Your Drug Development Journey
with Tailored Biomarker Testing Services

Biomarkers can make or break clinical trials, providing critical insights into the safety, efficacy, and progression of new drugs. Quanterix Accelerator Laboratory offers a range of service tiers tailored to the specific needs of your research and clinical programs. Our tiered approach guarantees the level of validation and data integrity required for each stage of your drug development process, ensuring robust and reliable results.

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The Accelerator Lab, and Quanterix in particular, are the pioneers in this ultra-sensitive technology to measure not only neurofilament but other biomarkers.

- Disarm Therapeutics,
A subsidiary of Eli Lilly and Company



Quanterix Accelerator Laboratory: Your Biomarker Testing Solution

Tailored Solutions for Your Research and Clinical Needs

Explore Quanterix's service tiers tailored to meet the diverse needs of your research and clinical programs. Whether you're conducting exploratory studies or advancing therapeutic trials, our structured approach ensures the optimal level of validation and data integrity at every stage. From early-stage research with RUO options to precise clinical diagnostics with LDT offerings, discover tailored solutions to support your goals effectively.

Explore Our Service Tiers

RUO (Research Use Only)

Ideal for exploratory research, including preclinical and Phase 1 studies, where identifying the right biomarkers is crucial. This service level is perfect for early-stage studies where biomarker test results are not intended for regulatory applications or patient enrollment decisions, offering flexibility and efficiency without the constraints of higher validation requirements.

Premium

This service tier is designed for clinical research and therapeutic trials requiring high data integrity. It supports program scalability across different disease indications and concurrent trials. RUO Premium offers rigorous validation and audit support to meet industry standards, ideal for studies aiming for regulatory submissions or requiring stringent validation processes.

Laboratory Developed Tests (LDT)

Our LDT service sets the gold standard in clinical diagnostics, ideal for researchers aiming to efficiently screen clinical trial candidates with personalized reporting. It offers faster and more cost-effective screening than imaging methods. Whether used for biomarker testing in patient care or regulatory-approved diagnostics, LDT ensures unmatched reliability and precision. CLIA-certified in 49 states, with ability to obtain a waiver for NY.



Quanterix Accelerator Laboratory: Your Biomarker Testing Solution

Tailored Solutions for Your Research and Clinical Needs

Features of Accelerator Laboratory Service Tiers

The tables below describe the features and typical applications for each service tier.

Class of Service	RUO	Premium	LDT
Analytical Characterization	✓	✓	✓
Analytical Validation		✓	✓
Clinical Validation		✓	✓
Quality Compliance		CLIA	CLIA
Endogenous Quality Controls		✓	✓
Audit Support		✓	✓
Established Reference Ranges / Cutoffs			✓
Sample collection supplies provided			✓
Individual Subject Reports			✓
Priority Turnaround Time (TAT)			✓

Applications for Accelerator Laboratory Service Tiers

The service levels offered are intended to satisfy the requirements of different study types.

Study Type	RUO	Premium	LDT
General	R&D	Clinical Trials	Trial Eligibility / Patient Care
Proof of principle	✓		
Exploratory use	✓		
Preliminary study design	✓		
Grant applications	✓		
Longitudinal studies		✓	
Data for regulatory submissions		✓	✓
Diagnostic use or clinical trial inclusion			✓

Quanterix Accelerator Laboratory: Your Biomarker Testing Solution

Tailored Solutions for Your Research and Clinical Needs

Qualifying Questions

Questions to help you identify which service level is appropriate for your study.

Qualifying Questions	Recommended Service Tier	
	No	Yes
Will test results be analyzed / correlated with results from future studies?	RUO	Premium/LDT
Will test results be included in a validation or regulatory submission?	RUO	Premium/LDT
Do you want access to product experts to support validations, regulatory submissions, or audits?	RUO	Premium/LDT
Is test being ordered by a physician to aid in diagnostic assessment and/or treatment decisions?	RUO	LDT
Are test results being used to determine inclusion/exclusion from a Clinical Trial?	RUO	LDT

Still have questions about which level of service is right for you?

**Ask your Quanterix Account Executive
to schedule a project review.**

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Quanterix®
Discovery Fueled by Ultra-Sensitivity

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