

A photograph of two female scientists in a laboratory setting. They are both wearing white lab coats, blue gloves, and safety glasses. The scientist on the left is also wearing a blue surgical mask. They are looking at a monitor that displays a colorful, abstract image. The monitor has the 'Quanterix' logo on its bezel. In the background, there are shelves with various laboratory equipment and supplies. A yellow circular graphic is in the top right corner.

Quanterix®

Discovery Fueled by Ultra-Sensitivity

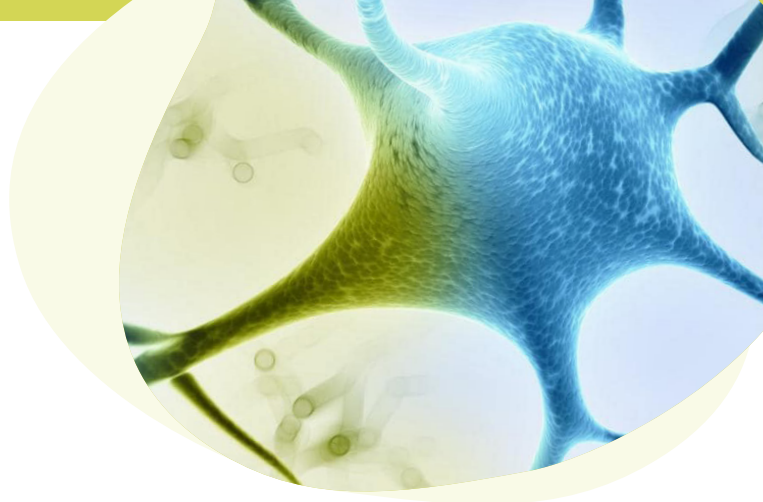
Quanterix® Accelerator Laboratory

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

Reagent Identification

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.

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.

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
TESTING**



Immunoassay Evolution

Accelerating your research through deeper detection than ever before

1970-2000	2000-2014	2014+
(ng/mL)	(pg/mL)	(fg/mL)



Assay Research Milestones

Assay Feasibility Testing and Prototype Development

- Reagent screening
- Identify and screen antibody to select the best antibody pair for prototype development
- Prototype assay development
- Assay analytical optimization
- Preliminary 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:

- Reagent optimization
- Assay design and protocol optimization including titration of reagent and optimization of diluent formulation
- Matrix evaluation and optimization
- Evaluation of assay robustness and precision

Assay Validation

Following optimization, assays are validated according to sponsor-defined requirements. The categories of validation provided include:

- Fit for purpose validation
- Full validation
- Clinical/LDT validation

Examples of validation components:

- Determine analytical and functional sensitivity and dynamic range
- Precision and accuracy (intra- and inter-assay)
- Dilutional linearity and parallelism
- Verify LOQ in matrix

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
Will test results be analyzed / correlated with results from future studies?	Premium/LDT
Will test results be included in a validation or regulatory submission?	Premium/LDT
Do you want access to product experts to support validations, regulatory submissions, or audits?	Premium/LDT
Is test being ordered by a physician to aid in diagnostic assessment and/or treatment decisions?	LDT
Are test results being used to determine inclusion/exclusion from a Clinical Trial?	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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