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in healthcare.**

**For everyone.  
Everywhere.**

Siemens Healthcare  
Laboratory, Berkeley, CA

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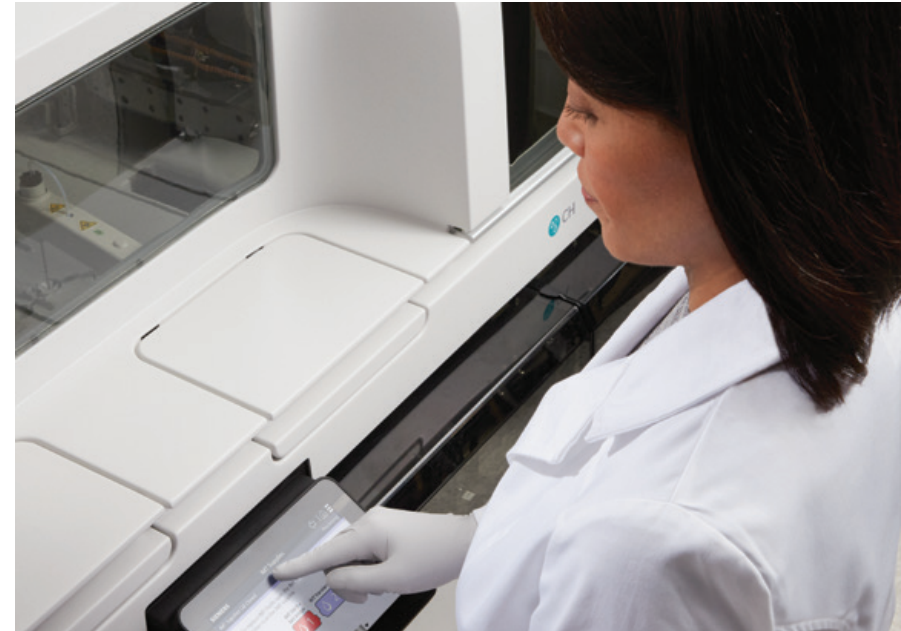


**SIEMENS**  
**Healthineers** 

# End-to-end Diagnostic Services for Biopharmaceutical Development

Siemens Healthcare Laboratory (SHL), LLC offers end-to-end diagnostic solutions for our biopharma partner therapy development programs. Our services may begin with biomarker discovery, leading to prototype development, use in clinical trials, followed by optional development and commercialization of In Vitro Diagnostic (IVD) assays.

- Our rigorous, stepwise biomarker-development process supports development of high-quality biomarker assays for early- to late-stage clinical trials testing.
- Assay prototypes of these biomarkers can be developed on our proprietary technology clinical laboratory platforms and validated for fit for purpose uses.
- Our CAP-accredited, CLIA-licensed laboratory offers high-quality testing services to support your clinical trial needs and beyond.



## We offer end-to-end diagnostic solutions...



### Biomarker Discovery Next Gen Proteomics

Our discovery team has expertise in working independently or jointly through a partner to discover the best biomarkers for specific intended uses.

Our strategic partner's proprietary mass spectrometry technology, enables depths of proteome coverage with reproducible and precise quantification to identify the most promising, actionable biomarkers to support clinical decision making.



### Identification of Biomarker Candidates

Derive more value from diagnostic data obtained from your clinical trials and discover biomarkers for next-generation systems.

SHL can optimize existing organ-specific models to build new multi-analyte/modality algorithms for specific therapies and new disease states.



### Assay Prototype Development

Our rigorous, stepwise biomarker assay development process offered through our CLIA laboratory in Berkeley, CA, enables you to deploy qualified tests for your most demanding early- or late-phase clinical trials.

If your biomarkers are developed on our proprietary technology platforms, they may also serve as prototypes for future IVD kit development projects, reducing technology compatibility risks and costs.



## Domains of Service Expertise



### Liver diseases

Noninvasive Liver Fibrosis diagnostics to **aid patient selection and monitor for liver diseases** such as NASH

- Enhanced Liver Fibrosis (ELF) Blood Test\*
- Liver modeling
- Biomarker Integration



### Neurology

Biomarkers that aid in **monitoring therapeutic effectiveness and diagnosis** of neuro-degenerative diseases, including dementia, Alzheimer's Disease (AD), and Multiple Sclerosis

- Neurofilament Light (NfL)
- AD markers: CSF AB42/Tau
- Clinical Decision Support



### Oncology

Diagnostics to aid in **stratification, therapy selection, and monitoring** in clinical research settings

- Patient immuno-status



### Infectious diseases

Diagnostic tools to support the **use of pathogen and viral detection**

- Sepsis

**Viral detection and antibody test development expertise** for therapy and vaccine development programs against a range of viruses including HCV, HIV, and SARS-CoV-2

\*Test Information: The ELF score is indicated, in conjunction with other laboratory findings and clinical assessments, as a prognostic marker in patients with chronic liver disease to assess the risk of progression to cirrhosis and liver-related clinical events. This test was developed and its performance characteristics determined by the Siemens Healthcare Laboratory. The Laboratory Developed Test has not been cleared or approved by the US Food and Drug Administration. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. This test is used for clinical purposes. It should not be regarded as investigational or for research.

## ...for our biopharma partners' therapy development programs



### Establishment of Clinical Utility via Clinical Testing

Our CAP-accredited, CLIA-licensed laboratory offers high quality, testing services to support your clinical trial needs and beyond, if required.

SHL has extensive testing and regulatory experience with early small or late-stage large clinical trials, including multinational clinical trials.



### Potential Development of IVD Assay

For global biomarker availability, Siemens Healthineers offers development of IVD assays and digital imaging solutions for deployment on our routine platforms.

We understand the stringent regulatory environments, such as the U.S. FDA, European notified bodies and others, for blood and imaging biomarker commercialization. We will recommend a path forward for your blood test or imaging biomarker commercialization channel.



### Commercialization of IVD Assay

Developed IVD is designed to run on Siemens Healthineers immunoassay platforms for use in hospitals, reference laboratories, and specialty laboratories.

With the availability of the IVD as routine tests on clinical platforms, clinical laboratories will be able to offer these biomarker tests to patients and their providers to optimize their treatment selection and outcome.

At Siemens Healthineers, our purpose is to drive innovation to help humans live healthier and longer. Through our products, services and solutions we help physicians, medical staff, and healthcare providers prevent illnesses from occurring and to correctly diagnose and determine the right treatments for people who do become ill—resulting in fewer complications, shorter hospital stays, and faster patient recovery.

Our mission is to enable healthcare providers to increase value by expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. With our comprehensive portfolio—from in-vitro diagnostics and imaging to therapy and follow-up care—we address the complete care continuum for many of the world's most threatening diseases.

Every hour, more than 240,000 patients are touched by technologies provided by Siemens Healthineers. We are at the center of clinical decision making with almost three-quarters of all critical clinical decisions influenced by our solutions. We are a leading medical technology company with over 120 years of experience and more than 65,000 highly dedicated employees around the globe who are innovating every day, truly shaping the future of healthcare.

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Siemens Healthcare Laboratory, LLC is an affiliate of Siemens Healthcare Diagnostics Inc.

## Take the Next Step

Phone: +1 800-434-2447

Email: [shl.team@siemens-healthineers.com](mailto:shl.team@siemens-healthineers.com)

Or contact your local Siemens Healthcare Laboratory representative for more details.

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### Siemens Healthineers Headquarters

Siemens Healthcare GmbH  
Henkestr. 127  
91052 Erlangen, Germany  
Phone: +49 9131 84-0  
[siemens-healthineers.com](http://siemens-healthineers.com)

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Siemens Healthcare Diagnostics Inc.  
Laboratory Diagnostics  
511 Benedict Avenue  
Tarrytown, NY 10591-5005  
USA  
Phone: +1 914-631-8000

### Local Contact Information

Siemens Healthcare Laboratory, LLC  
725 Potter Street  
Berkeley, CA 94710-2722  
USA  
Phone: +1 800-434-2447