

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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# Shaping the Future of Healthcare

Siemens Healthcare Laboratory, Berkeley, CA

[siemens-healthineers.com/shl](https://www.siemens-healthineers.com/shl)



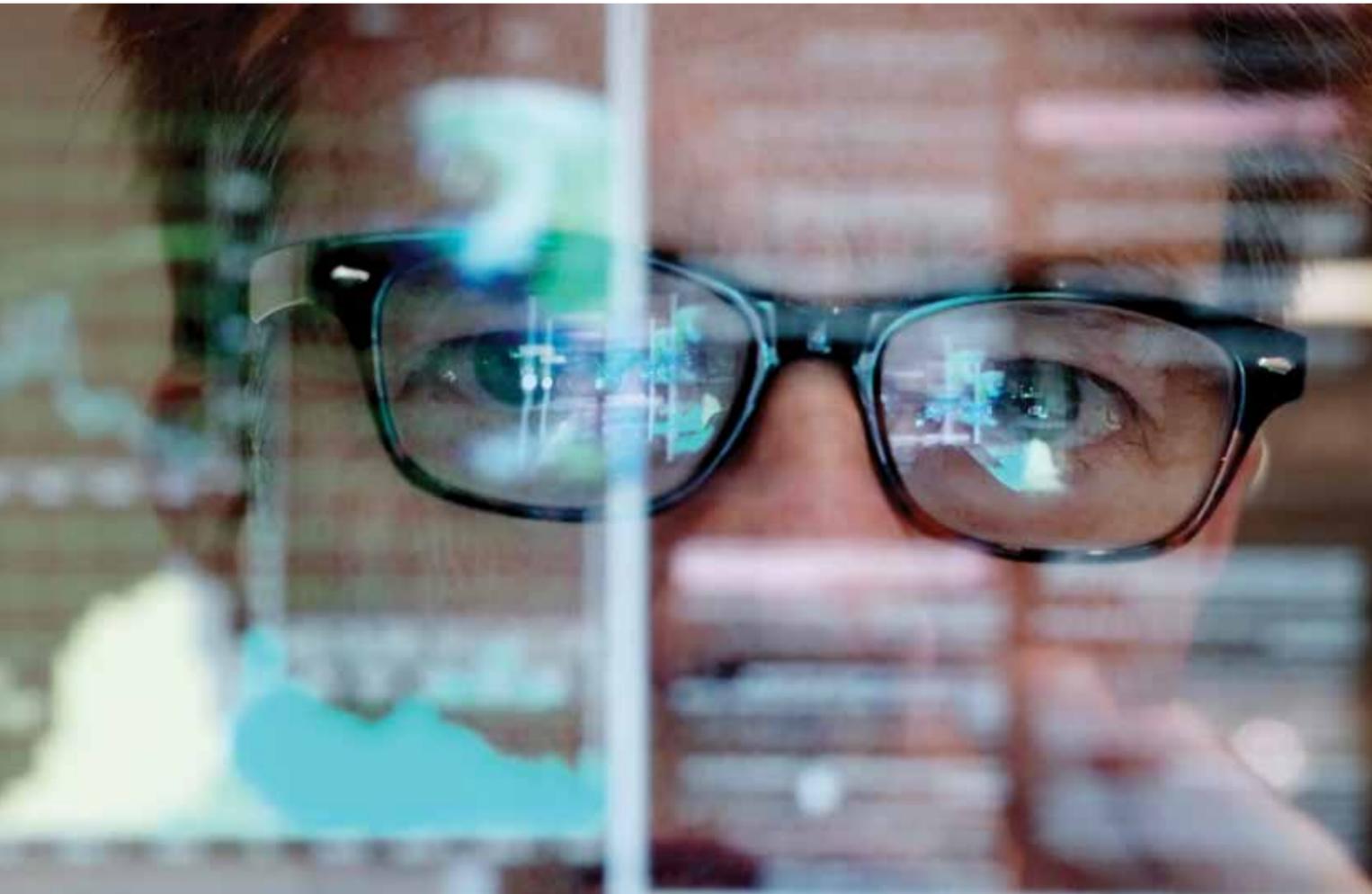
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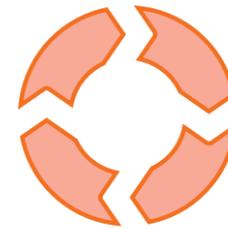
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## End-to-end Diagnostic Services for Biopharmaceutical Development

The Siemens Healthcare Laboratory (SHL), LLC offers state-of-the-art biomarker diagnostic test development and testing services for therapy development programs, from biomarker discovery to global commercialization of diagnostic tests for patient access.



- Expertise in critical disease and therapeutic areas: neurological, liver disease, oncology, rare and viral diseases, viral vector gene therapies
- Expertise in developing and offering testing services through our CLIA laboratory for clinical trials
- Exclusive laboratory testing services for Enhanced Liver Fibrosis (ELF™) test in the U.S. for use in early- or late-stage clinical trials for metabolic-disease therapies
- Full range of immunoassay and chemistry tests offered on Siemens Healthineers routine laboratory testing platforms
- Capabilities to leverage artificial intelligence (AI) for discovery of new biomarkers using our industry-leading imaging database
- Expertise in digital imaging biomarkers

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

# End-to-end Diagnostic Services and Solutions for Biopharmaceutical Therapy Development Programs

## Pharma Services Offered

Biomarker Discovery Research	Biomarker Assay Development	CDx IVD Development and Deployment	Reference Laboratory Testing	AI for Next generation Systems Biomarkers
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### Biomarker discovery research

We help you find the right biomarkers to support your therapy development programs and establish clinical validity.

Our discovery team has expertise in working independently or jointly with pharmaceutical partner teams to discover the best biomarkers for specific intended uses. We have technology expertise in mass spectrometry, all aspects of

immunoassay development, and molecular next generation sequencing (NGS) such as exome sequencing.

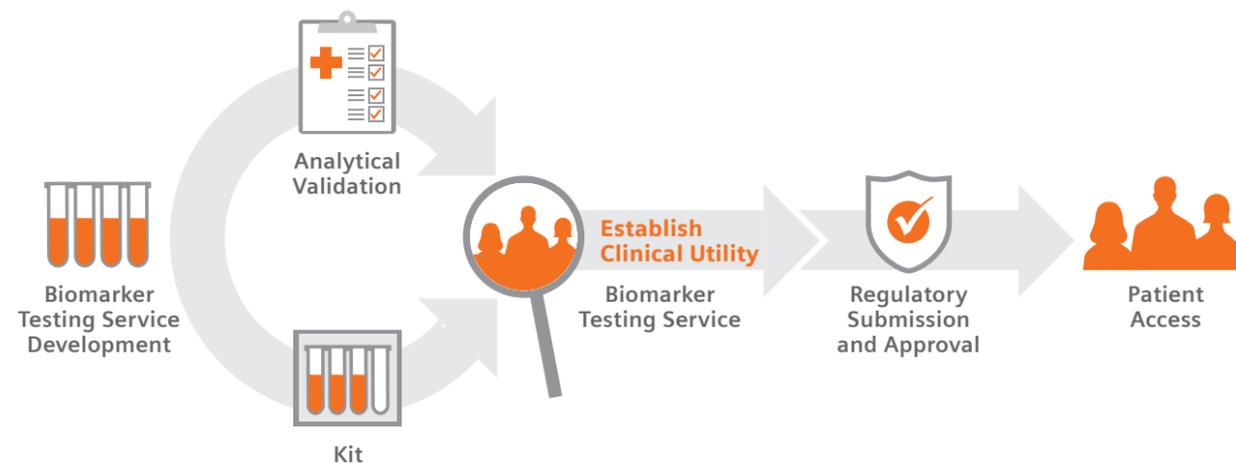
Through our digital imaging team and our world-class experts in ultrasound, MR, and PET CT, molecular imaging technologies are available to help discover potentially useful imaging biomarkers.



### Biomarker assay development for clinical trial applications

Our rigorous, stepwise biomarker development process supports development of high quality biomarker assays which may be offered through our CLIA laboratory in Berkeley, CA, enabling 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.



### IVD test development and deployment

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

We will advise you on the best path forward for your blood test or imaging biomarker commercialization channel.

We understand the stringent regulatory environments, such as the U.S. FDA, European notified bodies and others, for blood and imaging biomarker commercialization.



Atellica® Solution with Chemistry and Immunoassay testing capabilities shown.



### Reference laboratory testing for clinical trials and beyond

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

SHL also offers services for pre-analytical molecular RNA and DNA extraction that produces high quality yields from a variety of body fluids as well as testing services for a range of routine blood tests available on the new Siemens Healthineers laboratory platforms.

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



### Artificial intelligence solutions

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 or build new biomarker models for specific therapies and new disease states.

Our unique research use only artificial intelligence (AI) modeling technologies can help characterize your patients and increase understanding of clinical trial outcomes (RUO).

# Domains of Service Expertise

## Domains of Service Expertise

Viral Vectors GTx	Neurological Markers	Oncology	Rare Diseases	Viral Diseases	Liver Disease
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### Gene therapy (GTx) development services

SHL specializes in developing molecular shedding, cell based infectivity, and detection viral antibodies using immunoassay for gene therapy development applications.

At the cutting edge of medicine, viruses have been engineered to serve as therapy delivery platforms to infect and deploy genetic material to correct deleterious genetic mutations in specific target tissues.



### Neurological biomarkers

SHL has an active program developing cerebral spinal fluid and serum biomarkers for a variety of dementia conditions.

Digital biomarkers may also revolutionize the management of dementia. Our digital imaging teams currently support several groundbreaking projects to help accurately diagnose Multiple Sclerosis and Alzheimer's for use in clinical trials and beyond.



### Oncology

SHL offers solid tumor, SM liquid biopsy, and exome next generation sequencing NGS services for comprehensive gene alteration and variant analysis for all stages of clinical trials.

As an integrated diagnostics company, we also offer access to our expertise in the use of imaging technologies for management of patients with cancer.



### Rare diseases

Diagnostics are critical in identifying patients with rare diseases. Our expertise with molecular and serological protein tests, combined with our biomarker assay development and testing services via our CLIA laboratory, can help to make diagnostic solutions affordable for your rare disease therapies.

Implementation of our AI algorithms for digital data analysis may help you gain more insight from your rare disease clinical trials data for better outcomes.



### Viral diseases (including Coronavirus SARS-CoV-2 that causes COVID-19)

SHL has extensive expertise in viral detection and antibody test development for therapy and vaccine development programs against a range of viruses including SARS-CoV-2 virus, HIV and hepatitis viruses.

Siemens Healthineers is a leading supplier of retroviral molecular and antibody tests and is expanding testing capabilities to address the COVID-19 pandemic.



### Liver diseases

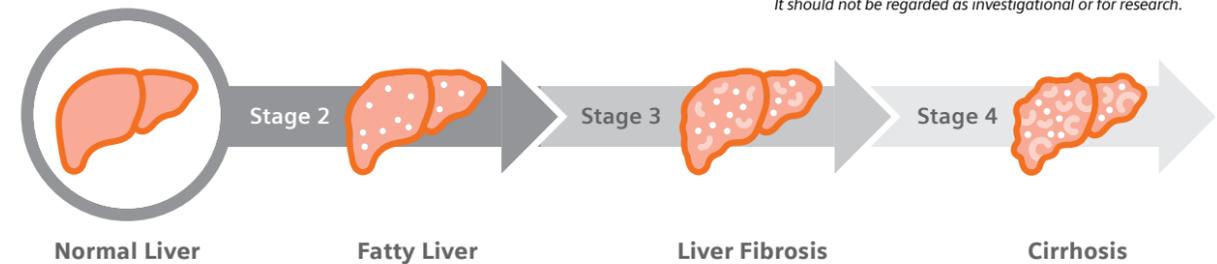
SHL is the exclusive provider of the noninvasive Enhanced Liver Fibrosis (ELF™) testing\* service for all stages of clinical trials in the United States.

In addition, a full range of routine diagnostic tests for liver-related conditions is available upon request.

The ELF test\* is a simple blood test performed in our CLIA laboratory in Berkeley, CA. It is currently used in several early- and late-stage clinical trials for metabolic disease (including primary biliary cirrhosis [PBC] and nonalcoholic steatohepatitis [NASH]), hepatitis C, and hepatitis B therapies.

As an integrated diagnostics company, we also offer access to our expertise in the use of ultrasound and magnetic resonance (MR) for noninvasive management of patients with liver fibrosis.

\*ELF testing service was developed and its performance characteristics determined by Siemens Healthcare Laboratory, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration. Our 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.



### Take the Next Step

Contact your local Siemens Healthcare Laboratory representative to learn more.