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

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.

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

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.

Artificial intelligence solutions

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

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

SHL can optimize existing organ-specific models or build new biomarker models for specific therapies and new disease states.
Domains of Service Expertise

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

**Neurological Markers**
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.

**Oncology**
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.

**Rare Diseases**
GSHL 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.

**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.

**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.

**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.

**Neurological biomarkers**
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.

**Gene therapy (GTx) development services**
As an integrated diagnostics company, we also offer access to our expertise in the use of imaging technologies for management of patients with cancer.

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

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

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

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

**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.**

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**Take the Next Step**
Contact your local Siemens Healthcare Laboratory representative to learn more.