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.

Atellica, ELF, and all associated marks are trademarks of Siemens Healthcare Diagnostics Inc., or its affiliates. All other trademarks and brands are the property of their respective owners.

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

Siemens Healthcare Laboratory, LLC is an affiliate of Siemens Healthcare Diagnostics Inc.
Atellica® Solutions with Chemistry and Immunoassay testing capabilities shown.

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.

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

**Biomarker discovery research**

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

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**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.

For patient access, SHL offers development of IVD assays and digital imaging solutions for global 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 advise you on the best path forward for your blood test or imaging biomarker commercialization channel.

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

**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.

**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.

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

Gene therapy (GTx) development services

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.

Neurological biomarkers

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.

Oncology

SHL has expertise in retrovirus (hepatitis C and HIV) sequencing using Sanger and NGS technologies for comprehensive results.

Siemens Healthineers is a leading supplier of retroviral molecular and antibody tests for HIV and hepatitis C and B viruses.

Viral 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.

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.

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

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.

*Research use only.

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.

Take the Next Step

Contact your local Siemens Healthcare Laboratory representative to learn more.