



RENOWN INSTITUTE FOR HEALTH INNOVATION EXPANDS PARTNERSHIP WITH GILEAD SCIENCES AND SIEMENS HEALTHINEERS TO OFFER ELF- ENHANCED LIVER FIBROSIS TESTING FOR NEVADA NASH STUDY PARTICIPANTS

Together, will test over 30,000 qualifying study participants by 2023 for risk of cirrhosis and liver-related illnesses

RENO, Nev. (Dec. 15, 2020) – Renown Institute for Health Innovation (IHI) announced today that the organization and Gilead Sciences, Inc. will be joining forces with Siemens Healthineers to offer the Enhanced Liver Fibrosis (ELF™) Test to people with risks for nonalcoholic steatohepatitis (NASH) enrolled in the Healthy Nevada Project (HNP).

The ELF Test will help identify people most at risk for progressing to cirrhosis and liver-related outcomes and allow healthcare providers to intervene before irreparable damage occurs. This noninvasive blood test uses three serum biomarkers to create an ELF score from a predefined algorithm, which can be used by doctors to help evaluate if a patient requires increased medical care and monitoring for their condition.

Nonalcoholic fatty liver disease (NAFLD), which includes NASH, is prevalent in Nevada and under-diagnosed, likely affecting more than 500,000 adult Nevadans. If undetected and untreated, NASH can result in liver cirrhosis and may require liver transplantation or lead to death. There are more than 12,000 people on a waitlist for liver transplantation in the U.S. and this number continues to rise due to the increasing prevalence of NAFLD.

“Thanks to important data collected through our Nonalcoholic Steatohepatitis Liver Disease Genome Atlas study, we now know that NASH is prevalent in the state of Nevada,” said [Tony Slonim](#), M.D., DrPH, FACHE, president and CEO of Renown Health. “We are proud to expand our partnership with Gilead and begin working with Siemens Healthineers to improve health of those with liver disease and to take early detection one step further by offering Enhanced Liver Fibrosis, ELF testing for patients of Renown Health. This test provides our team of highly-skilled physicians an advanced, noninvasive method to actively assess dynamic liver fibrosis in study participants and intervene whenever necessary, contributing to a healthier Nevada.”

“Gilead believes that noninvasive tests, including the ELF Test, will help improve the experience of people living with NASH. These tests may help to diagnose liver disease, monitor disease progression and evaluate responses to treatment without the requirement for liver biopsy,” said Rob Myers, MD, Vice President, Liver Fibrosis Clinical Research at Gilead Sciences. “The ELF Test has proven itself to be a valuable tool in NASH management and we hope this partnership will further support its use in routine care.”

“We are very pleased that NASH patients in the Healthy Nevada Project now have access to the ELF Test which offers clinically useful prognostic information for their condition with the convenience of a simple blood test. Using our advanced laboratory expertise together with Renown IHI and Gilead, we can work towards better understanding of NASH and liver disease in



a representative patient population,” said Sebastian Kronmueller, Head of Molecular Diagnostics at Siemens Healthineers.

“We launched the Healthy Nevada Project to help people understand more about their health, to identify serious health risks, and to give people access to innovations like the ELF Test, so they can live their best lives,” said Renown’s chief scientific officer, [Dr. Joseph Grzymalski](#), who is also a research professor at the Desert Research Institute and principal investigator of the Healthy Nevada Project. It’s incredibly rewarding to be able to report clinical findings to help our 50,000 volunteer study participants, and to assist healthcare providers in helping their patients.”

The provision of the ELF Test builds on a previously announced strategic collaboration between the Renown IHI and Gilead in July 2019. This ongoing partnership aims to collect and analyze de-identified genetic and electronic health data from 60,000 qualifying study participants to enhance the understanding of NAFLD and NASH and to potentially inform development of treatment options for these diseases.

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About NAFLD and NASH

NAFLD is a build-up of fat in the liver of people who do not have a history of alcohol misuse. It is normal for the liver to contain some fat, but if more than 5 percent of the liver content is fat, it’s considered a fatty liver (steatosis). NASH is the most severe form of NAFLD in which a person has liver cell damage and inflammation of the liver. Inflammation and liver cell damage can cause fibrosis, or scarring of the liver, and can cause decreased liver function (1). The symptoms of NASH are often silent or non-specific, making it difficult to diagnose. About one-third of people with NASH develop cirrhosis or irreversible liver damage (2).

About the ELF™ Test

The ELF Test is a noninvasive blood test that can quickly identify which patients are at an elevated risk for developing cirrhosis and other liver-related clinical events (LREs). In contrast to standard liver enzyme tests that reflect liver damage that has already occurred, the ELF Test combines three serum direct biomarkers of active fibrosis.

The ELF Test algorithm measures each of these biomarkers to create an ELF score, which can be used as an aid to assess the risk for future disease progression. Doctors may use this ELF score to help evaluate if a patient requires increased medical care and monitoring for their condition. Individuals interested in determining their risk for NASH and its progression are encouraged to enroll in the Nonalcoholic Steatohepatitis Liver Disease Genome Atlas study. Those who have already consented and participated in the study will be contacted with more information on how to receive an ELF blood test. For more information or to enroll, please contact RenownIHI@renown.org or (775) 982-6914.

The Enhanced Liver Fibrosis (ELF™) Test kit is not available for sale in the U.S. Product availability may vary from country to country and is subject to varying regulatory requirements.

In the U.S., the ELF Testing Service is available from Siemens Healthcare Laboratory, LLC (SHL), a CLIA-certified laboratory located in Berkeley, Calif. The ELF Testing Service, including the establishment of performance characteristics, was developed by SHL. The ELF Test has not been cleared or approved by the U.S. Food and Drug Administration. SHL is regulated under CLIA as qualified to perform high complexity testing. The ELF Test is used for clinical purposes and should not be regarded as investigational use only or research use only.

About Renown Health

Renown Health is the region’s largest, locally owned and governed, not-for-profit integrated healthcare network serving Nevada, Lake Tahoe and northeast California. With a diverse workforce of more than 7,000 employees, Renown has fostered a longstanding culture of excellence, determination and innovation. The organization comprises a trauma center, two acute care hospitals, a children’s hospital, a rehabilitation hospital, a medical group and urgent care network, and the region’s largest, locally owned not-for-profit insurance company, Hometown Health. Renown’s institute model addresses social determinants of health and includes: Child Health, Behavioral Health & Addiction, Healthy Aging and Health Innovation. Clinical institutes include: Cancer, Heart and Vascular Health,



Neurosciences and Robotic Surgery. Renown is currently enrolling participants in the world's largest community-based genetic population health study, the Healthy Nevada Project®. For more information visit, renown.org.

About the Renown Institute for Health Innovation

Renown Institute for Health Innovation is a collaboration between Renown Health - a locally governed and locally owned, not-for-profit integrated healthcare network serving Nevada, Lake Tahoe and northeast California; and the Desert Research Institute - a recognized world leader in investigating the effects of natural and human-induced environmental change and advancing technologies aimed at assessing a changing planet. Renown IHI research teams are focused on integrating personal healthcare and environmental data with socioeconomic determinants to help Nevada address some of its most complex environmental health problems; while simultaneously expanding the state's access to leading-edge clinical trials and fostering new connections with biotechnology and pharmaceutical companies. Learn more at healthynv.org.

Renown Health is Nevada's most comprehensive and integrated healthcare network and maintains electronic health records for 1.02 million registered patients. In 2016, Renown Health and the Desert Research Institute established the Healthy Nevada Project (HNP), the nation's first community-based population health study. In 2017 HNP began a partnership with Helix to leverage its population health services, Exome+™ sequencing, and consumer engagement tools. The HNP is now an ongoing collaboration between Renown IHI, the Desert Research Institute, a global leader in environmental data and applied research, and [Helix](https://helix.com), a personal genomics company. HNP combines genetic, environmental, social and clinical data to address individual and community health needs with the goal of improving health across the state and the nation. The HNP currently has over 60,000 participants. For more information, visit healthynv.org.

About Siemens Healthineers

Siemens Healthineers AG (listed in Frankfurt, Germany: SHL) is shaping the future of Healthcare. As a leading medical technology company headquartered in Erlangen, Germany, Siemens Healthineers enables healthcare providers worldwide through its regional companies to increase value by empowering them on their journey towards expanding precision medicine, transforming care delivery, improving the patient experience, and digitalizing healthcare. Siemens Healthineers is continuously developing its product and service portfolio, with AI-supported applications and digital offerings that play an increasingly important role in the next generation of medical technology. These new applications will enhance the company's foundation in in-vitro diagnostic, image-guided therapy, and in-vivo diagnostics. Siemens Healthineers also provides a range of services and solutions to enhance healthcare providers ability to provide high-quality, efficient care to patients. In fiscal 2020, which ended on September 30, 2020, Siemens Healthineers, which has approximately 54,000 employees worldwide, generated revenue of €14.5 billion and adjusted EBIT of €2.2 billion. Further information is available at www.siemens-healthineers.com.

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