

# Press

Malvern, PA

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## Siemens Healthineers Proud to be Recognized in a Study Conducted by the Foundation for the National Institutes of Health

- **Data from the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) study indicates Siemens Healthineers' ELF Test as the top-performing biomarker**

Siemens Healthineers is proud to be recognized in Stage I of the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) study. The data from “LO1: Primary Results of the NIMBLE Stage 1-NASH CRN Study of Circulating Biomarkers for Nonalcoholic Steatohepatitis and its Activity and Fibrosis Stage,” presented in a late-breaking oral presentation at The Liver Meeting 2021 on Sunday, November 14, show that Siemens Healthineer’s ELF™ Test performed the best of the five blood biomarkers selected for the study. The ELF Test was one of three biomarkers in the study that met the criteria for the successful identification of fibrosis stage  $\geq 2$ . The performance of the ELF Test further improved for fibrosis stage  $\geq 3$  and stage 4.

“Siemens Healthineers is proud the ELF Test was recognized as a top-performing biomarker, with potential to reshape the way NASH clinical trials are performed. We know that liver biopsies remain a major barrier for clinical trial enrollment. The study results are encouraging and demonstrate that non-invasive biomarkers provide the potential to improve the way in which we identify NASH, and evaluate treatment efficacy,” said Deepak Nath Ph.D., President, Laboratory Diagnostics, Siemens Healthineers, a member of NIMBLE. “We are at the first step to revolutionizing clinical trials in NASH, and look forward to our continued collaboration with NIMBLE in the pursuit of regulatory qualification.”

NIMBLE, the largest biomarker consortium from the FNIH, aims to revolutionize the ability to qualify non-invasive biomarkers to easily identify NASH, a serious condition associated

with obesity and diabetes, affecting about 15 million people in the United States. If successfully qualified by regulatory authorities, the selected NASH biomarkers will be used in clinical trials to develop therapies to treat NASH, as well as to identify NASH and assess patients' responses to treatment. The FDA accepted NIMBLE's Biomarker Qualification Letter of Intent in May 2020.

Tania Kamphaus, Director of Metabolic Disorders, Foundation for the NIH commented, "The results of this Stage 1 study represent a significant milestone for the NIMBLE initiative getting us closer to a better, less invasive way to conduct clinical research by reducing the need for biopsy."

Siemens Healthineers will continue to collaborate with FNIH and NIMBLE on the next stage of studies as the organizations work to pioneer new tools to evaluate NASH.

#### **About NASH**

Non-alcoholic steatohepatitis (NASH), is a serious condition associated with obesity and diabetes, affecting about 15 million people in the United States. NASH causes fat to accumulate in the liver, which leads to inflammation and cell damage. It does not present symptoms until later stages, when serious complications like cirrhosis leave few treatment options for patients. Patients with NASH typically remain undiagnosed because early-stage diagnosis is difficult and expensive. Currently, a visual imaging analysis of a liver biopsy is the only way to diagnose NASH. Surgical biopsy is also an option but is invasive, expensive, painful and may cause serious complications. It also may not provide an accurate picture of the patient's disease since it only captures a small part of the liver.

#### **About NIMBLE**

The Biomarkers Consortium Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) project is the Foundation for the National Institute of Health's (FNIH) largest biomarker consortium. NIMBLE is a five-year collaborative effort to standardize, compare and appropriately validate imaging and circulate biomarkers to diagnose NASH and assess patients' stage of disease, and measure responses to therapeutic interventions. The NIMBLE trial tests selected biomarkers, (i.e., serum/plasma-based, imaging-based, or a combination) to compare performances against liver biopsy and the ability to measure treatment responses.

For further information, please visit: <https://www.siemens-healthineers.com/en-us/laboratory-diagnostics/assays-by-diseases-conditions/liver-disease/elf-test>

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The products/features (mentioned herein) are not commercially available in all countries. Their future availability cannot be guaranteed.

The above-described study results outline a potential application of the ELF Test for clinical trial use. For routine clinical management of patients, liver biopsy is currently the gold standard for diagnosing NASH and assessing fibrosis. The ELF Test provides prognostic information supplemental to biopsy.

In the U.S., the ELF Test is indicated as a prognostic marker in conjunction with other laboratory findings and clinical assessments in patients with advanced fibrosis (F3 or F4) due to non-alcoholic steatohepatitis (NASH) to assess the likelihood of progression to cirrhosis and liver-related clinical events. The test is not for use in the diagnosis of NASH or for the staging of fibrosis.

**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 diagnostics, 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 2021, which ended on September 30, 2021, Siemens Healthineers, which has approximately 66,000 employees worldwide, generated revenue of €18.0 billion and adjusted EBIT of €3.1 billion. Further information is available at [www.siemens-healthineers.com](http://www.siemens-healthineers.com).