



## Helio Health and Fulgent Genetics Announce Late-Breaking Positive Performance Data of HelioLiver™ for Early Liver Cancer Detection

November 8, 2021

**Data from the ENCORE study to be presented at The Liver Meeting® 2021, hosted by the American Association for the Study of Liver Diseases (AASLD)**

IRVINE, Calif. and TEMPLE CITY, Calif., Nov. 8, 2021 /PRNewswire/ -- [Helio Health](#) ("Helio") and its commercial partner, [Fulgent Genetics, Inc.](#) (NASDAQ: FLGT) ("Fulgent") today announced new data at AASLD demonstrating the performance of [HelioLiver](#) in detecting early hepatocellular carcinoma (HCC). At 91% specificity, the sensitivity of HelioLiver was 76% in early-stage HCC and 85% in overall HCC<sup>1</sup>, demonstrating superior performance over alpha fetoprotein (AFP) alone and the GALAD model.



	Early Stage (I + II) Sensitivity	Overall Sensitivity
HelioLiver <sup>1</sup>	76%	85%
AFP (≥ 20 ng/mL) <sup>1</sup>	57%	62%
GALAD Score (≥ -0.63) <sup>1</sup>	65%	75%
Ultrasound <sup>2</sup>	47%	84%

*Note: Table denotes HelioLiver sensitivities at 91% specificity<sup>1</sup>*

HelioLiver is a multi-analyte blood test that utilizes both cell-free DNA (cfDNA) methylation patterns and protein tumor markers to detect early-stage HCC with high accuracy. HelioLiver has the potential to reduce morbidity and mortality in HCC patients as there are more curative treatment options when the cancer is found at earlier stages. A highly sensitive blood test can drive patient adherence to surveillance guidelines and provide a more convenient and cost-effective way to detect HCC.

"As one of the fastest growing and deadliest cancers worldwide, it is essential to detect liver cancer as early as possible to initiate treatment intervention to optimize successful patient outcomes," said Dr. Richard A. Van Etten, Director of the NCI-designated Chao Family Comprehensive Cancer Center and member of the Division of Hematology/Oncology at the University of California, Irvine. "These results indicate HelioLiver has significant promise to redefine the standard of care in terms of providing a highly sensitive, easy-to-use blood test for patients and healthcare providers alike."

"As a result of rigorous scientific evaluations, these new findings underscore HelioLiver's potential to detect liver cancer early and ultimately save lives," said Justin Chen Li, U.S. Chief Executive Officer, Helio Health. "Through our partnership with Fulgent Genetics, we look forward to delivering new early cancer diagnostic technologies beginning with HelioLiver in the U.S. in the near future."

The ENCORE study was a blinded, multicenter validation study using blood specimens drawn from 303 subjects. The study included 122 subjects diagnosed with HCC, 125 control subjects diagnosed with a benign liver disease, and 56 subjects diagnosed with other cancer types.

The poster presentation, titled "A Multi-Analyte Blood Test for Accurate and Early Detection of Hepatocellular Carcinoma," will be available for viewing by the attendees of The Liver Meeting® beginning November 8, 2021.

The HelioLiver test continues to be evaluated in Helio's pivotal prospective study, CLiMB ([NCT: 03694600](#))

For more information about HelioLiver, please visit [www.helioliver.com](http://www.helioliver.com).

## About Helio Health

Helio Health is an AI-driven healthcare company focused on commercializing early cancer detection tests from a simple blood draw. The company's mission is to simplify cancer screening so lives can be saved by detecting cancer earlier. With Helio's AI-driven technology, both physicians and their patients gain powerful insights from accurate, accessible, and convenient blood tests.

Building on a robust research and development program, and with access to thousands of patient samples, the company is currently in clinical trials in the US and China with its lead liver cancer detection test. Helio's development program is focused on liver, colon, breast and lung cancer.

Helio Health is headquartered in Irvine, CA, with R&D, GMP and CLIA facilities in Irvine, CA and West Lafayette, IN, Guangzhou and Beijing.

## About Fulgent Genetics

Fulgent Genetics is a technology-based genetic testing company focused on transforming patient care in oncology, infectious and rare diseases, and reproductive health. Fulgent's proprietary technology platform has created a broad, flexible test menu and the ability to continually expand and improve its proprietary genetic reference library while maintaining accessible pricing, high accuracy, and competitive turnaround times. Combining next generation sequencing with its technology platform, Fulgent performs full-gene sequencing with deletion/duplication analysis in an array of panels that can be tailored to meet specific customer needs. A cornerstone of our business is our ability to provide expansive options and flexibility for all clients' unique testing needs through a comprehensive technology offering including cloud computing, pipeline services, record management, web portal services, clinical workflow, sequencing as a service and automated lab services.

## About Helio Health and Fulgent Genetics Partnership

In a strategic partnership announced in August of 2021, Helio Health and Fulgent Genetics plan to commercialize and co-brand HelioLiver, a cell-free DNA (cfDNA) methylation blood test that incorporates protein markers and demographics for the detection of hepatocellular carcinoma (HCC) – or liver cancer. HelioLiver is currently undergoing clinical trials in the U.S. and China. Fulgent will be responsible for laboratory operations, supply chain operations, and marketing and sales leveraging its operational excellence and significant market reach, initially focused in the U.S. and Canada. Helio will provide intellectual property and continued support across research and development, publication development, market access and sales, as well as reimbursement operations. Fulgent and Helio will also collaborate on the development of additional liquid biopsy tests for different types of cancer in the future.

<sup>1</sup> Lin N, Lin Y, Xu J, et al. A multi-analyte blood test for accurate and early detection of hepatocellular carcinoma. Poster presented at: *American Association for the Study of Liver Diseases – The Liver Meeting*; November 12-15, 2021; Virtual.

<sup>2</sup> Tzartzeva K, Obi J, Rich NE, et al. Surveillance Imaging and Alpha Fetoprotein for Early Detection of Hepatocellular Carcinoma in Patients With Cirrhosis: A Meta-analysis. *Gastroenterology*. 2018;154(6):1706-1718.e1. doi:10.1053/j.gastro.2018.01.064



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