Helio GENOMICS

AI-based Multi-omics Tests for Early-stage Cancer Detection

Forward-Looking Statements

This presentation (together with the oral statements made in connection herewith, the "Presentation") contains "forward-looking statements" that involve risks and uncertainties. All statements contained in this Presentation other than statements of historical facts, including statements regarding our future financial performance, our business prospects and strategy, our market opportunity and the potential growth of that market, our anticipated financial position, our liquidity and capital needs, our expectations for HelioLiver and our product pipeline, including anticipated regulatory submissions, data read-outs, approvals, clinical trial results and other similar matters are forward-looking statements. Forward-looking statements may generally be identified by the use of words such as "anticipate," "believe," "can," "contemplate," "continue," "could," "design," "estimate," "expect," "intend," "may," "might," "objective," "plan," "potential," "predict," "project," "shall," "should," "target," "will," or "would," or the negative of these words or other similar terms or expressions. These statements are based on various assumptions, whether or not identified in this Presentation, and on the current expectations and assumptions of our management, which are inherently subject to uncertainties, risks and changes in circumstances that are difficult to predict. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, many of which are outside our control, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those discussed in the forward-looking statements. In light of these risks, uncertainties and assumptions, the future events and trends discussed in this Presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements and we cannot guarantee any future performance, conditions or results. The forward-looking statements in this Presentation speak only as of the original date of this Presentation and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. Given these risks and uncertainties, readers are cautioned not to place undue reliance on such forward-looking statements.

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Market data and industry information used throughout this Presentation are based on information management has obtained from independent industry surveys and publications conducted by third parties and other publicly available information in addition to data based on management's internal estimates, which are derived from publicly available information released by industry analysts and third-party sources and internal estimates and assumptions based on management's knowledge of the industry and market, which it believes to be reasonable. Industry surveys and publications generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of such information. All of the market data and industry information used in this Presentation involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. While we believe the estimated market position, market opportunity and market size information included in this Presentation are generally reliable, such information, which is derived in part from management's estimates and beliefs, is inherently uncertain and imprecise. No representations or warranties are made by us or any of our affiliates as to the accuracy of any such statements or projections. Projections, assumptions and estimates of the future performance of the industry in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors. These and other factors could cause results to differ materially from those expressed in our estimates and beliefs and in the estimates prepared by independent parties.

NASDAQ MarketSite Investor Day

In-Person

Justin C Li, CFA, MBA
CEO

Venture Partner, SC Masterfund
Berkeley MBA

Gary Frazier, MBA
Chief Growth Officer

Founder & CEO Worksite Labs
Hospital Executive

Alex Brenner, MBA
Chief Financial Officer

Public Co Finance

On Zoom

Shivani Mahajan, PhD
Head of Computational Science

Former Freenome Early Employee
Berkeley PhD

David Taggart, PhD
Chief Scientific Officer

Laboratory Director NRCC

Rick Van Etten, MD PhD
Chief Medical Advisor

UC Irvine Cancer Director
MD PhD Stanford

Mindie Nguyen, MD, MS, AGAF, FAASLD
Lead Principal Investigator

Stanford Medicine
AASLD Steering Committee

Genesis and History of Company

Helio GENOMICS

Foundational technology invented at UC San Diego. First product, HelioLiver developed

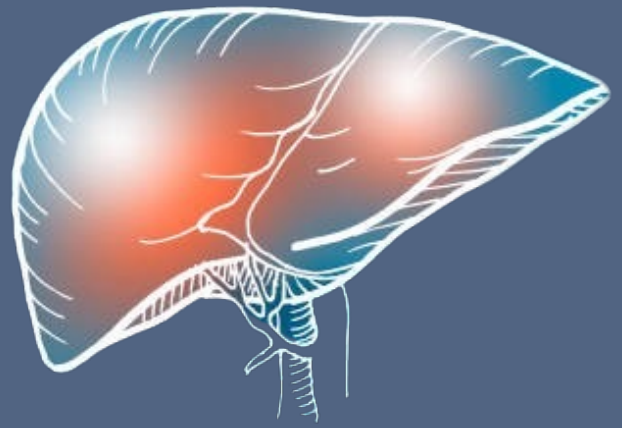
HelioLiver receives CPT PLA code “0333U” 2021 and Medicare pricing $662.32 in 2022

Completed data readout from large-scale pivotal clinical trial CLiMB with presentation at EASL in 2024

Submitted PMA Application to the FDA in May 2024 for authorization as Class III medical device

Initial Market Focus: Liver Cancer

- Existing technologies are inadequate
- Blood test can address issues of convenience, price, and accuracy
- High incidence rate in at-risk population
- At-risk population needs to be tested frequently
- Life-saving therapies exist for early-stage liver cancer
- Minimal competition



The HelioLiver Test

- Blood-based (easy to use)
- Superior sensitivity compared to Ultrasound
- Measures multi-omics signals
- Driven by ML / generative AI
- Improved Detection of Early-stage Liver Cancer
- Validated in large-scale prospective FDA clinical trials

HelioLiver Addresses Key Ultrasound Weaknesses

Accessibility	Any Clinic with Blood-Draw.	Requires imaging center and specialized equipment.
Skill and Training of the Operator	Easy to Draw Blood. Any healthcare provider.	Specialized Training Required and Results Vary Based on Technician and Radiologist.
Size and Location of the Lesion	Can detect tumor fragments from very small lesion sizes (~2cm).	Difficult to determine lesion until it is very large and late stage.
BMI of the Patient	No effect on performance of test.	Less effective in patients with high BMI.

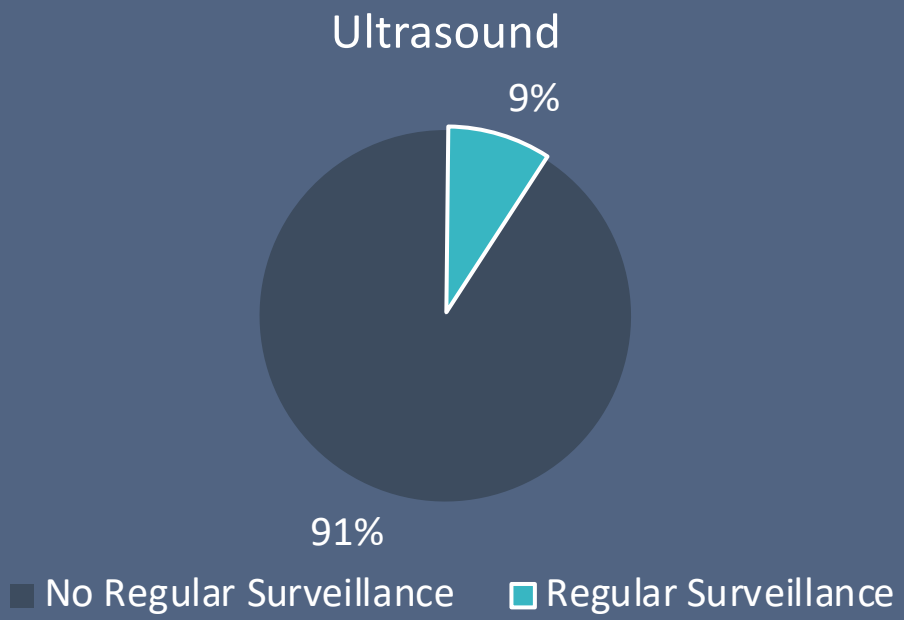
Scientific Advisory Board Highlight

"Helio is addressing the right problem in cancer – detecting it early when it may still be reversible, and their data shows that this can potentially be a game changer."

- Founder of Moderna
- Founder of over 40 companies
- Aggregate value of companies is over $220B at peak valuation
- >$9B capital raised for companies

Robert Langer, ScD

Outcomes are Tied to Adherence, Accessibility and Ease of Use



Study of 1,873 HCC patients diagnosed 1994-2002 identified from SEER-Medicare database

Davila JA, Morgan RO, Richardson PA, Du XL, McGlynn KA, El-Serag HB. Use of surveillance for hepatocellular carcinoma among patients with cirrhosis in the United States. Hepatology. 2010;52(1):132-141. doi:10.1002/hep.23615

J Ultrasound Med. 2024 Mar 27. doi: 10.1002/jum.16453. Online ahead of print.

Sound the Alarm: The Sonographer Shortage is Echoing Across Healthcare

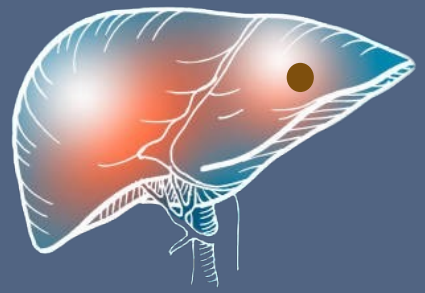
Daniel Won [1], James Walker [1], Russ Horowitz [2], Sandeep Bharadwaj [3], Edward Carlton [4], Helena Gabriel [5]

Affiliations + expand

PMID: 38534218 DOI: 10.1002/jum.16453

Early-Stage Patients Have Better Outcomes & More Treatment Options

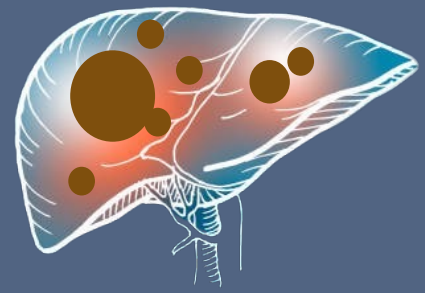
Early-stage Liver Cancer



>70% Survival at 5 Years

Resection (Partial Hepatectomy)
Microwave Ablation
Nuclear Ablation
Targeted Therapies
Radioembolization (Y90)
Transplant

Late-stage Liver Cancer



Median Survival <1.5 Years[1]

Chemotherapy
Late-stage Drugs
Palliative Therapy

1. For symptomatic advanced stage cases treated with systemic therapies. https://www.nature.com/articles/s41572-020-00240-3

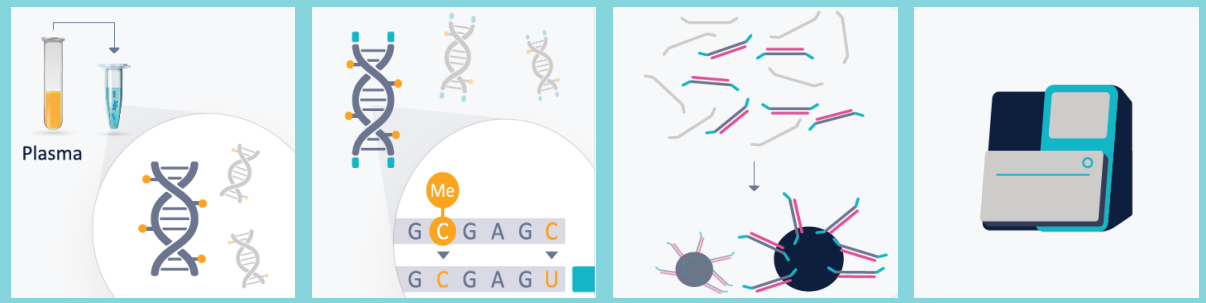
First-Mover Advantage with FDA for Early-Stage Liver Cancer Detection

	Pivotal Study	FDA Submission	CMS Submission
	100% Completed	Submitted May 2024	Planned Submission in Q3 '24
Our Competitors	Years Away from Completion	Need Pivotal Study	Need Pivotal Study

Platform Technologies

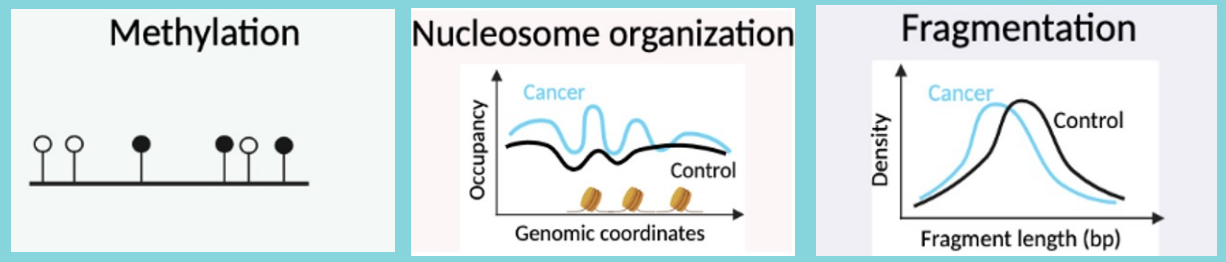
Our tests are enabled by our fully automated wet lab platform – ECLIPSE™, and our unique multimodal epigenetic sequencing assay – MESA™.

ECLIPSE™ WET-LAB PLATFORM



cfDNA extraction | Library prep and enzymatic conversion | Hybridization and capture | Pooling and sequencing

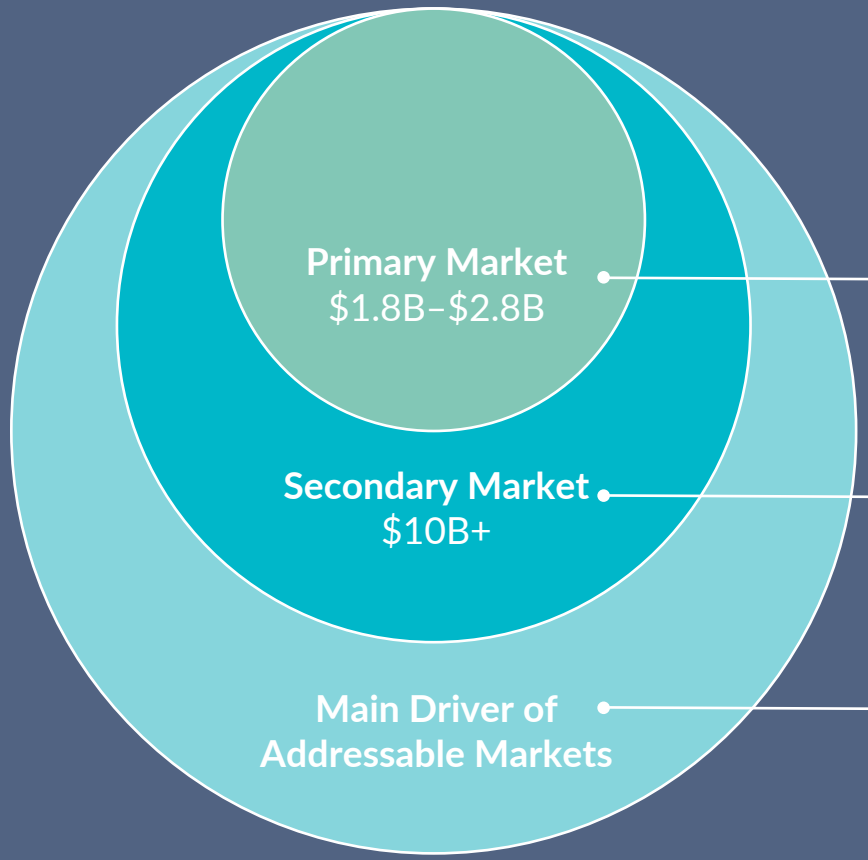
MESA™ – Multimodal Epigenetic Sequencing Assay



- Enzymatic conversion minimizes cfDNA degradation and preserves cfDNA integrity unlike traditional bisulfite conversion methods.
- A single assay can simultaneously explore methylation and fragmentomics features.

- Multidimensional view of the epigenetic landscape of cancer.
- Different feature modalities may capture complementary signal.

Market Size



Liver cirrhosis and hepatitis B virus (HBV)

1.5M–2.4M patients

800,000 –1.7M liver cirrhosis patients

700,000 HBV patients (excluding patients with liver cirrhosis)

Nonalcoholic steatohepatitis (NASH)

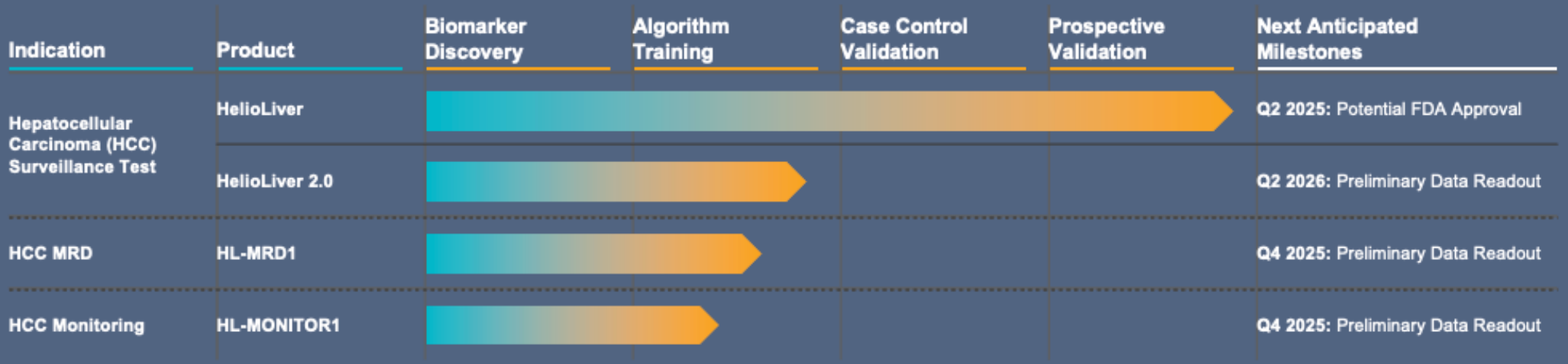
16M patients, or approximately 20% of NAFLD patients

Nonalcoholic fatty liver disease (NAFLD)

80M patients, or approximately 25% of adults in U.S.

NAFLD is the most common cause of liver cirrhosis

Current Pipeline



Low adherence, high-risk population facing ineffective SoC

Helio GENOMICS

Seamless integration into existing clinical workflow

Pipeline Expansion

Multi-Modal Multi-Omics Computational Platform

Biomarker discovery

- Automated platform leveraging external and internal datasets to identify biomarkers for multiple cancer types
- Targeted cfDNA methylation sequencing panel design

Cancer Diagnostics

- Custom automated Bioinformatics platform for data processing
- Feature engineering
- Algorithm/Model development and validation on real world sample

Treatment Response Prediction

- Leveraging advances in AI to solve complex problems beyond cancer diagnostics to ensure best treatment outcomes and patient care

MRD and Disease Monitoring

The Helio Genomics Team

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David Taggart, PhD
Chief Scientific Officer

Laboratory Director NRCC

Wei Li, PhD
Chief Bioinformatics Advisor

UCI Endowed Chair of Bioinformatics
Baylor University

Joyce Cheung, MBA
VP, Strategy and Operations

10 Years Exp with ZS Associates

Anupam Bedi, MBA
VP of Quality and Regulatory Affairs

Led Successful FDA PMA Approval Medical Devices
Kellogg MBA

Selected Board / Advisors

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Hepatology Medical Advisor

UT Southwestern and Liver KOL

Terry Belmont, MPH
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Former CEO of Hospitals
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President of Cigna

Shu Li, PhD
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Founder, 4 Successful Exits
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Peony Yu, MD
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CMO, Apollomics

Mindie Nguyen, MD, MS, AGAF, FAASLD
Lead Principal Investigator in CLiMB

Stanford Medicine
AASLD Steering Committee

Robert Langer, ScD
Scientific Advisor

Founder of Moderna
Public Co Boards

Aarif Nakhooda, MBA
Director

Former CFO, Amazon

Switching gears

CLiMB Clinical Trial Results

CLiMB Clinical Trial Results

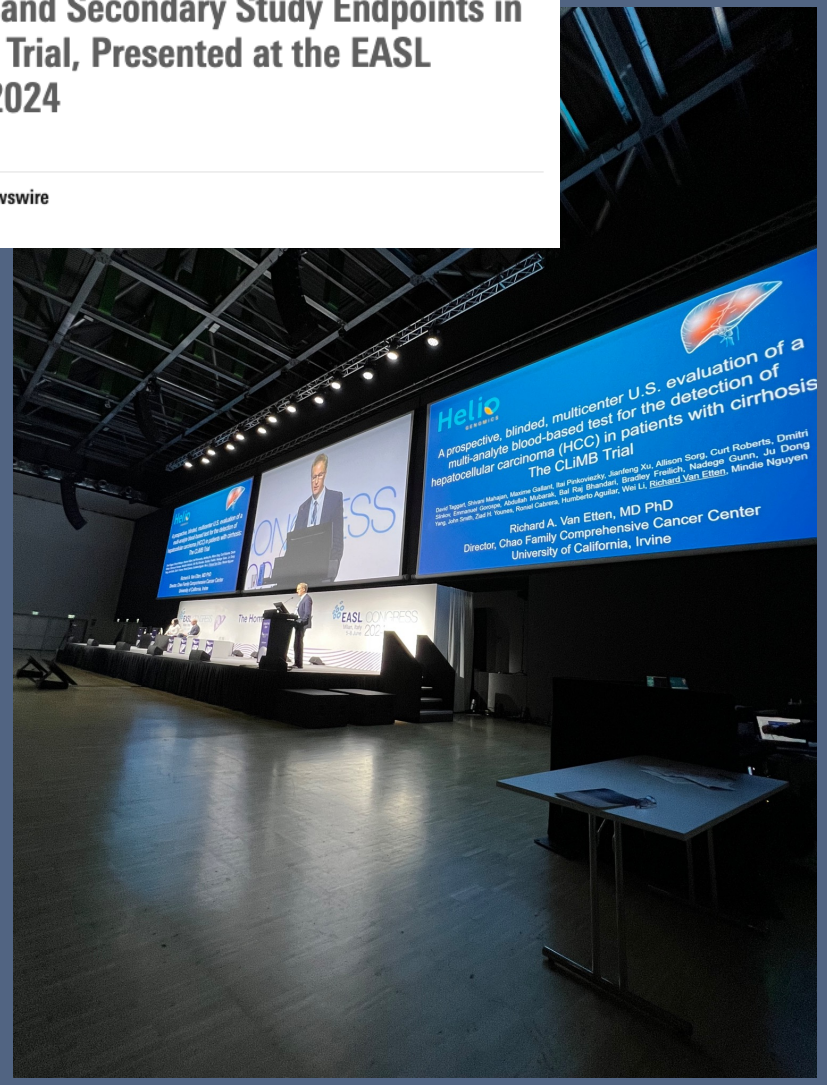
- 1,968 subjects enrolled over 3.5 years
- Fully Prospective and Blinded
- ~50 major hospitals and clinical sites
- Submitted to FDA (PMA Class III Medical Device)
- Planned MolDX application for Medicare coverage

Clinical Trial Multi-Analyte Blood Test (CLiMB)
NCT03694600
Registered October 3, 2018

GLOBENEWSWIRE

Helio Genomics' HelioLiver Dx Test Meets Coprimary and Secondary Study Endpoints in the CLiMB Trial, Presented at the EASL Congress 2024

Provided by GlobeNewswire
Jun 10, 2024 5:00am



Key Opinion Leader

“Helio’s liver cancer test significantly outperforms Ultrasound in Stage I and, as a blood test, will improve adherence and add value to the care of patients with liver cirrhosis.”

Mindie Nguyen,
MD, MAS, AGAF, FAASLD

- Stanford Professor of Medicine (Gastroenterology, Hepatology, and Liver Transplant) and, by courtesy, of Epidemiology and Population Health
- Steering Committee for HCC SIG for AASLD
- Active clinician, researcher on viral hepatitis, NAFLD, cirrhosis and liver cancer with over 600 publications

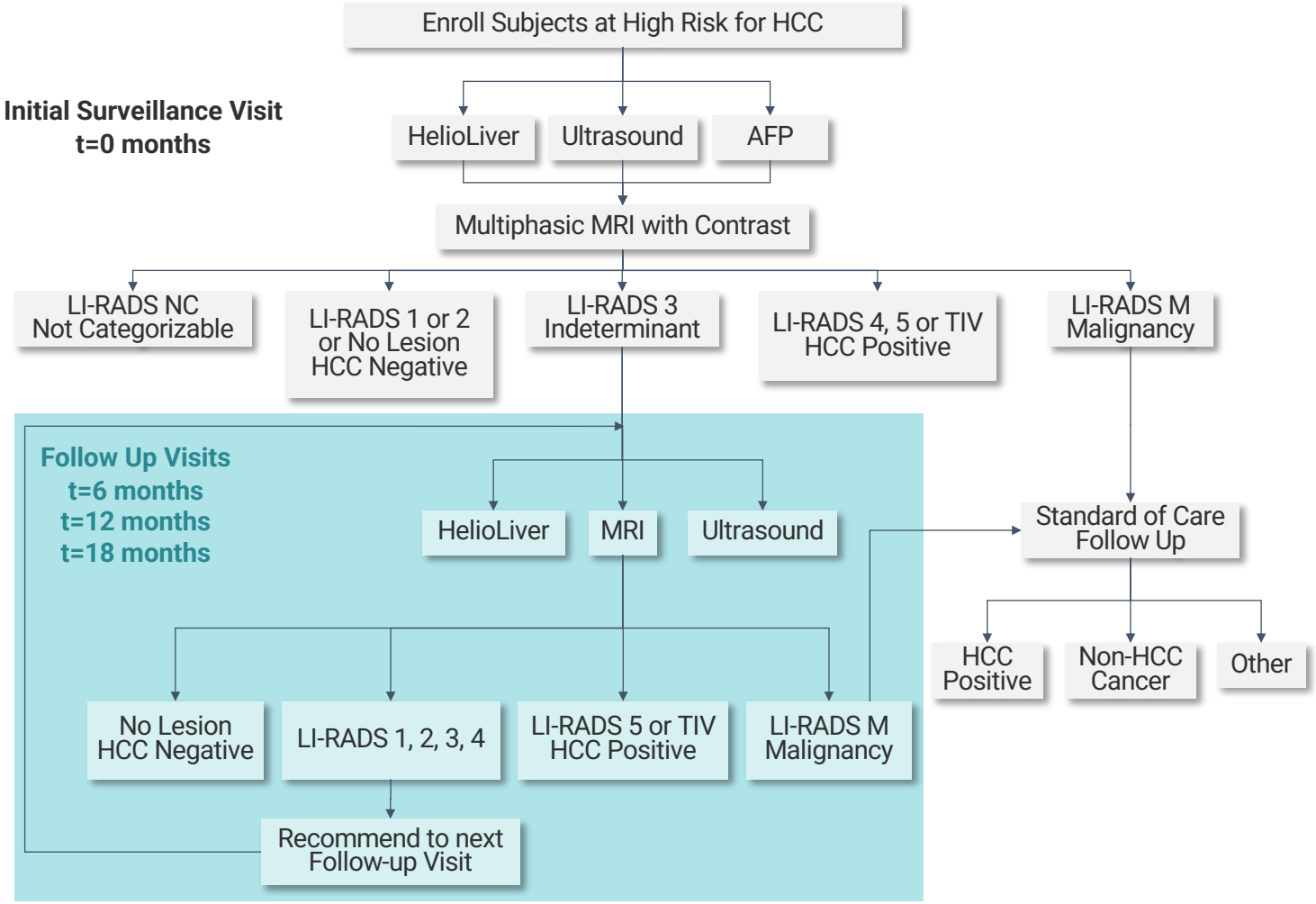
CLiMB (NCT03694600): A prospective, multi-center blinded trial

TITLE

Prospective **C**linical Trial to Detect **Li**ver Cancer through Quantification of cfDNA **M**ethylation in **B**lood (**CLiMB**)

PURPOSE

Directly compare the performance characteristics of a multianalyte blood test to ultrasound for the detection of HCC

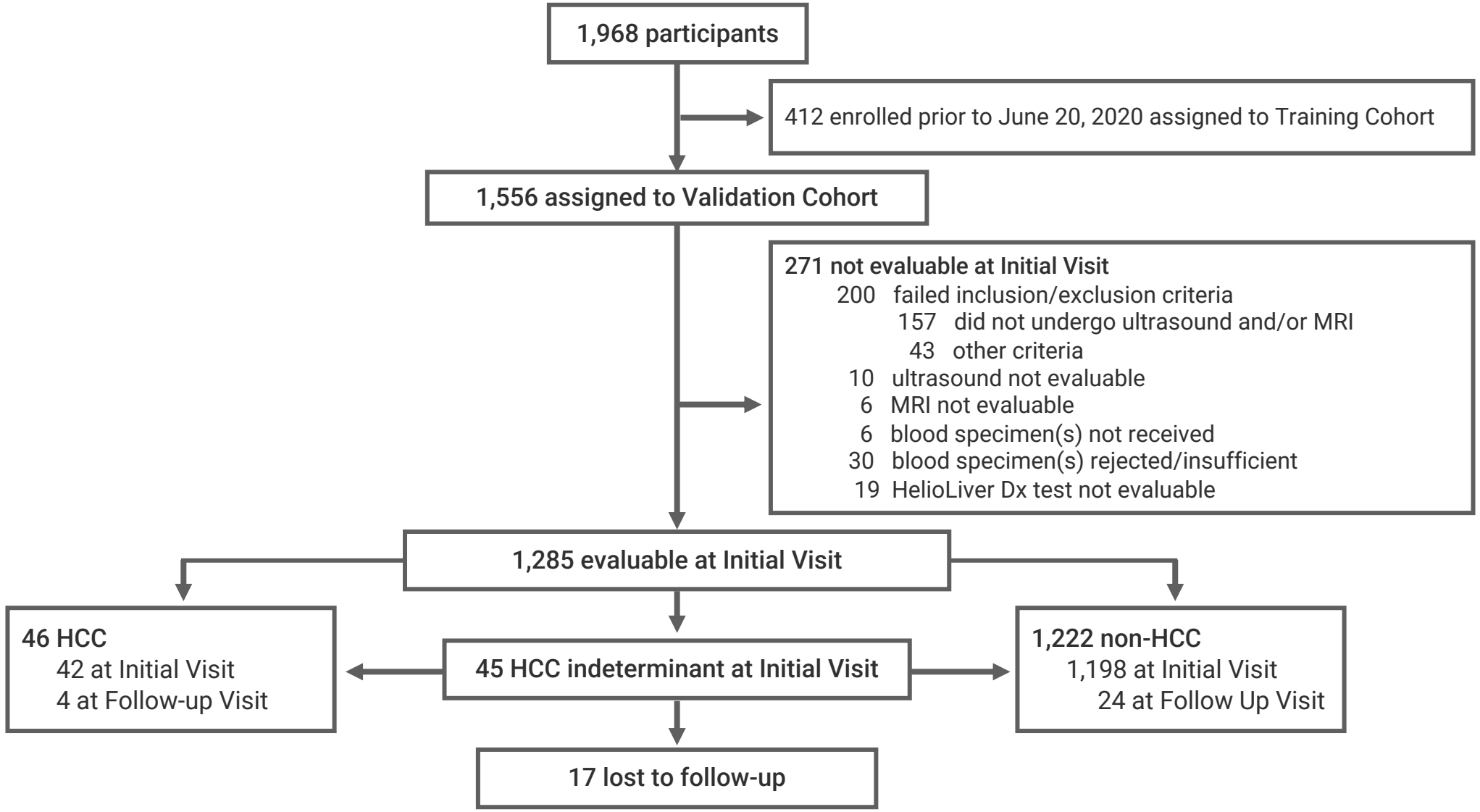


Subject Demographic Characteristics

	HCC Positive (n = 46)	HCC Negative (n = 1222)
Age, y, mean (SD)	64.6 (7.4)	59.4 (10.9)
Sex, n (%)		
Male	30 (65.2)	596 (48.8)
Female	16 (34.8)	626 (51.2)
Ethnicity, n (%)		
Hispanic	20 (43.5)	405 (33.1)
Non-Hispanic	26 (56.5)	814 (66.6)
Race, n (%)		
White	40 (87.0)	1039 (85.0)
Non-white	6 (13.0)	182 (15.0)
Obesity, n (%)	26 (56.5)	676 (55.2)
Diabetes mellitus, n (%)	21 (45.7)	503 (41.1)
Study Setting, n (%)		
Academic Center (%)	8 (17.4)	243 (19.9)
Community Based Center (%)	38 (82.6)	979 (80.1)
Liver Disease Etiology, n (%)		
NAFLD	23 (50.0)	626 (51.2)
ALD	10 (21.7)	262 (21.4)
Viral (HBV and/or HCV)	16 (34.8)	205 (16.8)
Other	3 (6.5)	204 (16.7)

Disposition of Subjects in the CLiMB Trial

Participants enrolled on or after June 20, 2020 were included in the Validation Cohort

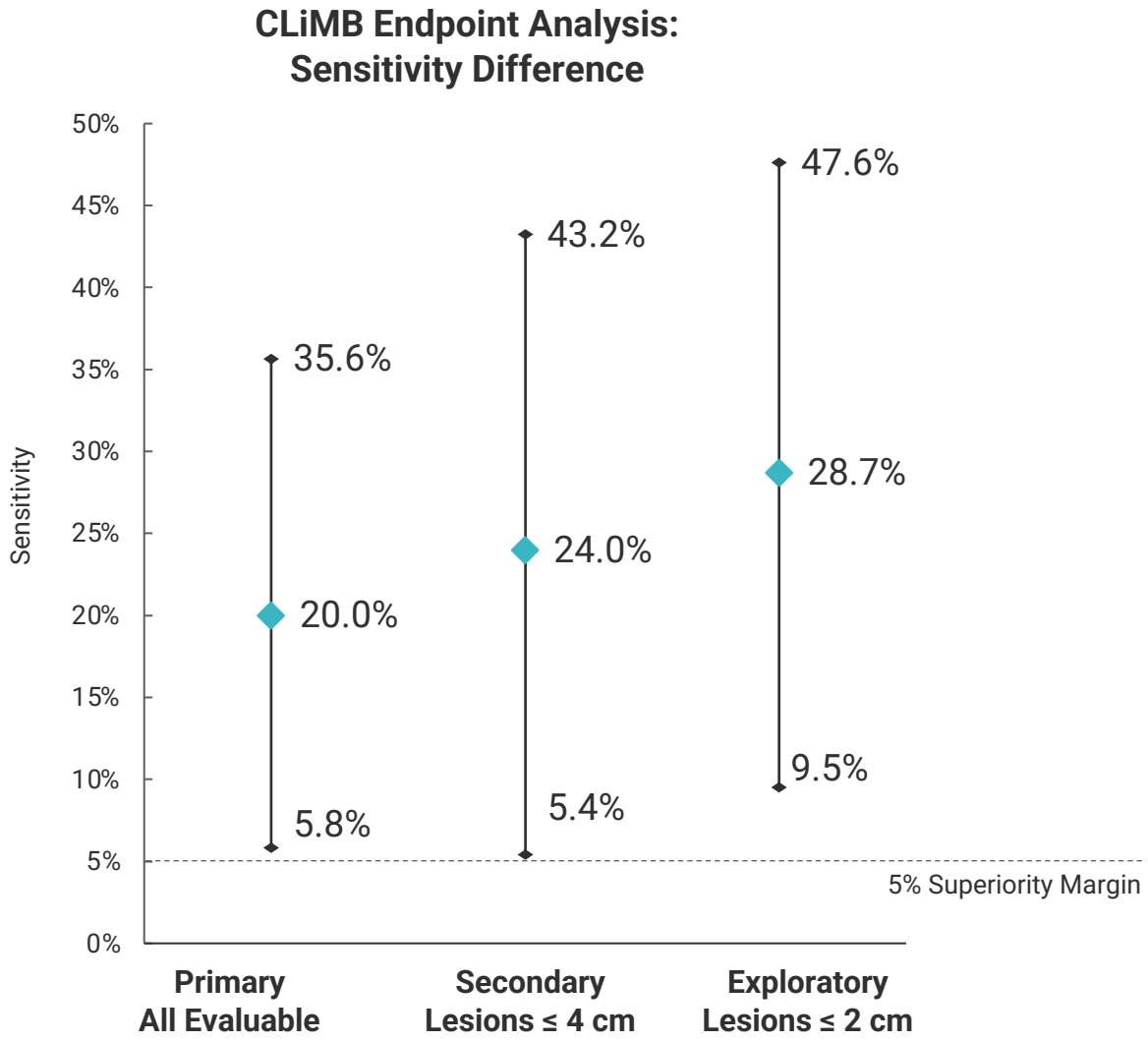


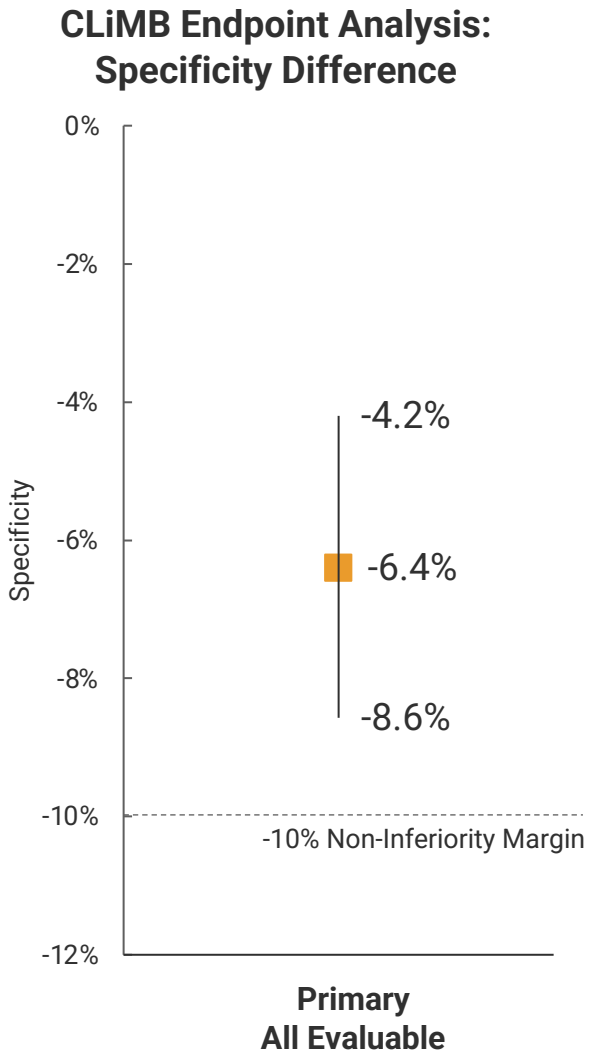
HCC Tumor Characteristics

The majority of participants with HCC (74%) had small lesions of ≤ 3 cm

	HCC Positive (n = 46)
Total HCC Lesions, n (%)	
1	30 (65.2)
2	8 (17.4)
>2	8 (17.4)
HCC Lesion Size, n (%)	
≤ 1 cm	4 (8.7)
> 1 to ≤ 2 cm	17 (37.0)
> 2 to ≤ 3 cm	13 (28.3)
> 3 to ≤ 4 cm	3 (6.5)
> 4	9 (20.0)
HCC Lesion T Stage, n (%)	
T1	27 (58.7)
T2	5 (10.9)
T3	3 (6.5)
T4	3 (6.5)
Unstaged or Unknown	8 (17.4)

HelioLiver Dx met the Primary and Secondary Endpoints



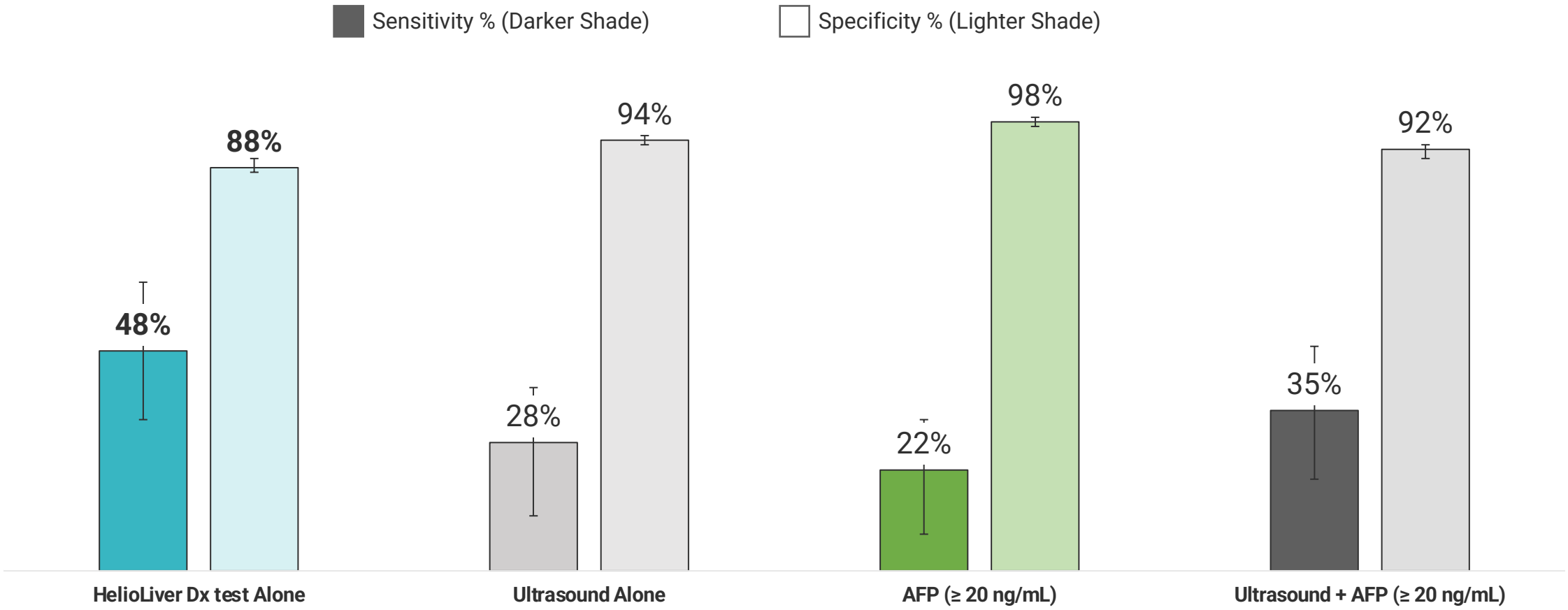


Test Performance Characteristics

HelioLiver Dx test was 20% more sensitive and 6% less specific than ultrasound alone.

HelioLiver Dx had a higher sensitivity and specificity than the combination of ultrasound + AFP (10 ng/mL).

Sensitivity and Specificity by Testing Modality from CLiMB



Test Performance Characteristics

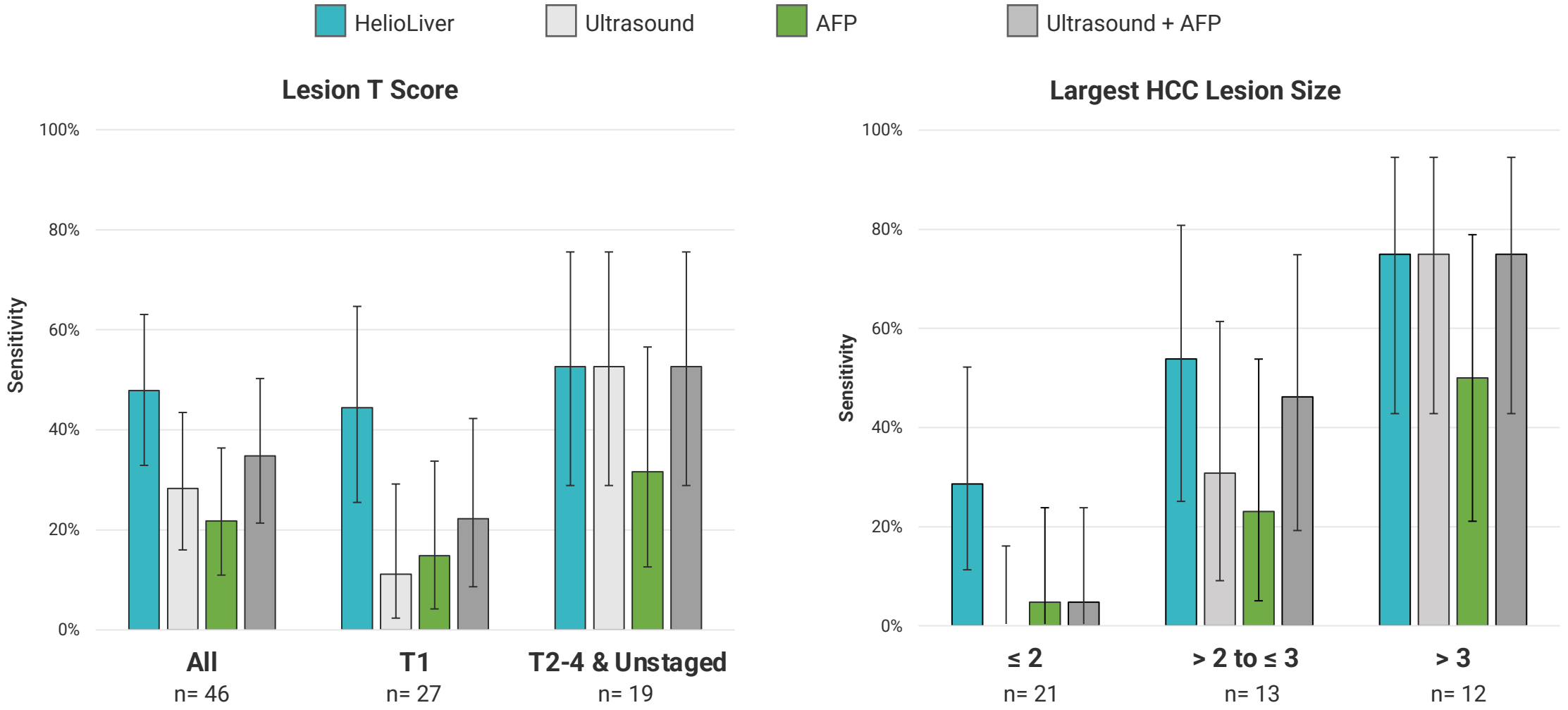
	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV (%)	NPV (%)
HelioLiver Dx test Alone	**48 (33, 63)**	**88 (86, 89)**	**12.6**	**97.8**
Ultrasound Alone	**28 (16, 44)**	**94 (93, 95)**	**15.3**	**97.2**
Ultrasound + AFP (≥ 20 ng/mL)	35 (21, 50)	92 (91, 94)	14.3	97.4
Ultrasound + AFP (≥ 10 ng/mL)	39 (25, 55)	87 (85, 89)	10.5	97.4
AFP (≥ 20 ng/mL)	22 (11, 36)	98 (97, 99)	29.4	97.1
AFP (≥ 10 ng/mL)	33 (20, 48)	93 (92, 94)	15.0	97.3
HelioLiver Dx test and Ultrasound	52 (37, 67)	83 (81, 85)	10.3	97.9

PPV, Positive Predictive Value; PLR; NPV, Negative Predictive Value

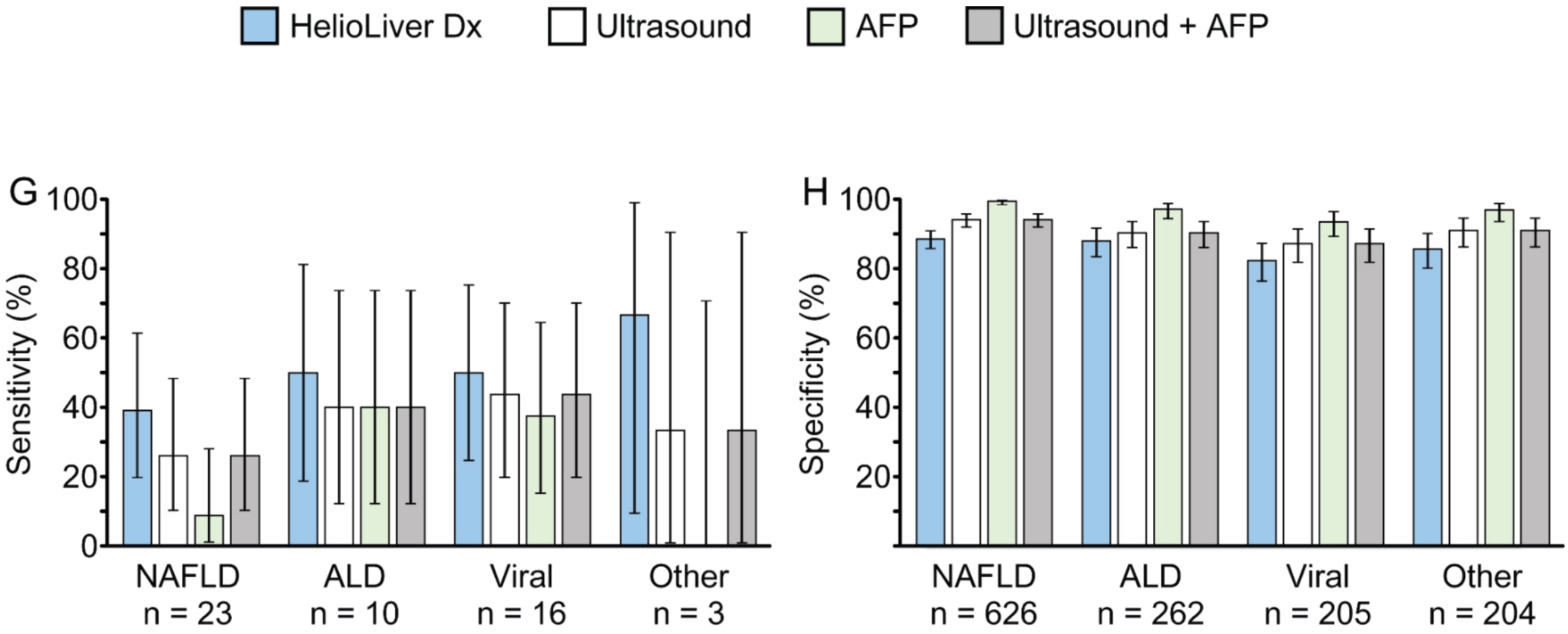
- HelioLiver Dx test was 20% more sensitive and 6% less specific than ultrasound alone
- HelioLiver Dx had a higher sensitivity and specificity than the combination of ultrasound + AFP (10 ng/mL)

Test Sensitivity by HCC Lesion T Score and Size

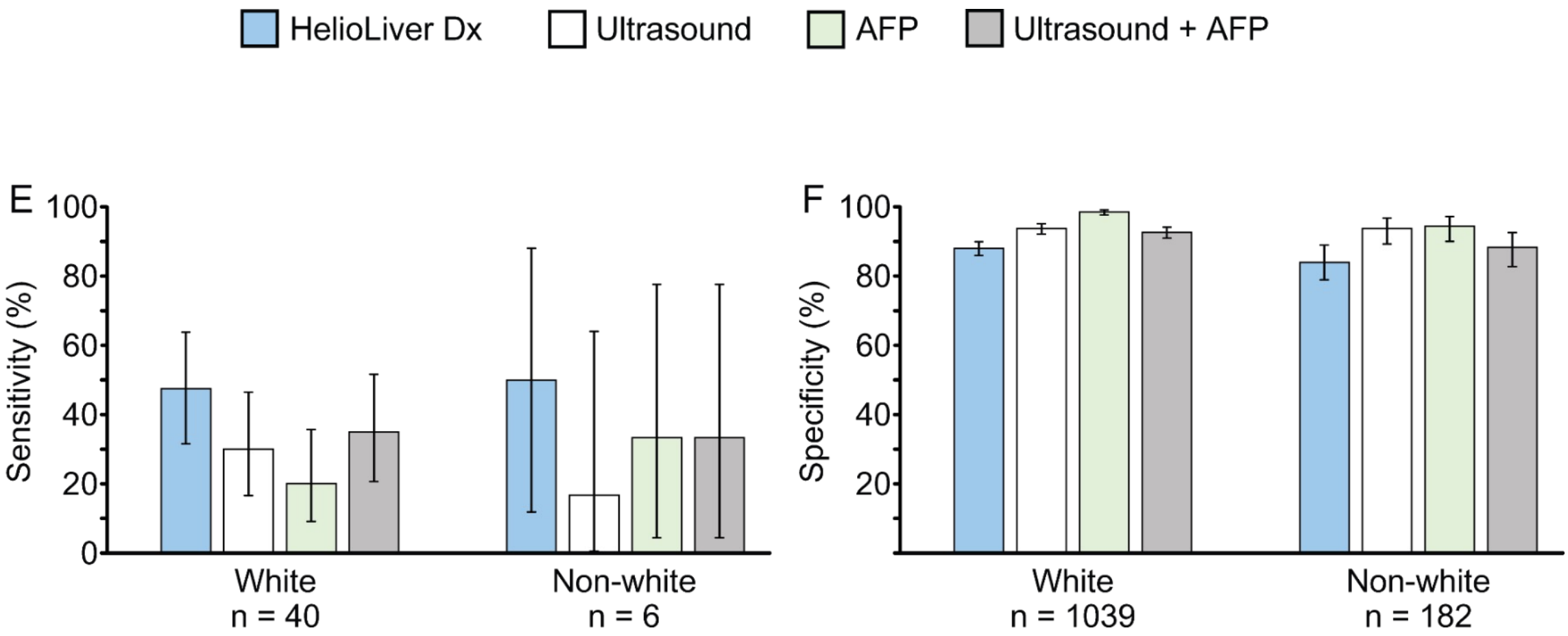
The HelioLiver Dx test (Blue) was more sensitive than other test modalities for early T1 lesion and for lesions ≤ 3 cm



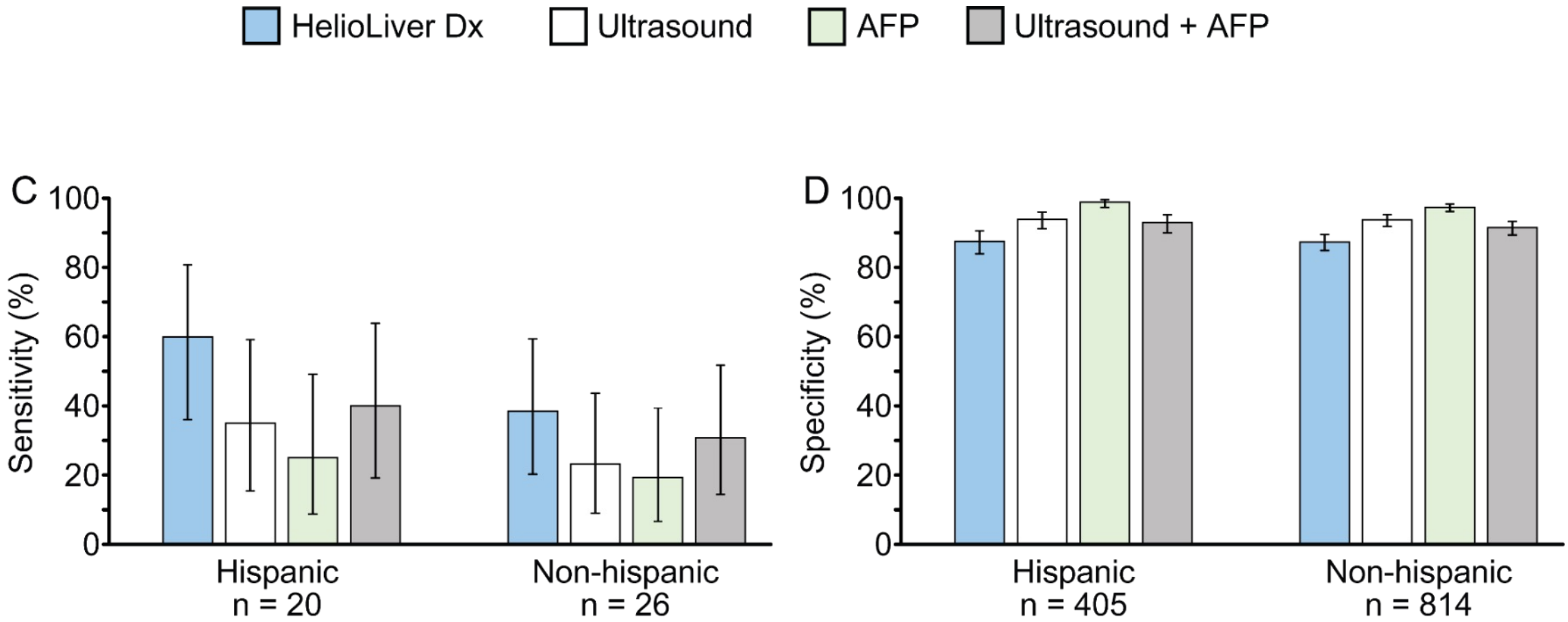
Subgroup Analysis – Etiology of Liver Cirrhosis



Subgroup Analysis - Race



Subgroup Analysis - Ethnicity



Conclusions

- The CLiMB trial met the co-primary endpoints for superior sensitivity (5% margin) and non-inferiority for specificity (-10% margin) compared to abdominal ultrasound

- The HelioLiver Dx test was more sensitive than ultrasound for the detection of HCC in a high-risk population in very early HCC (<2cm)

- An accurate, easy to use blood test for the detection of HCC may help improve patient outcomes through improved adherence and superior early detection of HCC

Thank You

For Follow-up Questions Please Contact
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