A New Paradigm for Early Diagnosis and Surveillance For Liver Cancer

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A New Paradigm for Early Diagnosis and Surveillance For Liver Cancer

- **Commercial clinical laboratory services for patients at risk for liver cancer with issued patents to >50 glycoprotein biomarkers**
- **$1B opportunity—huge and growing populations with viral and non-viral hepatitis driving progressive fibrosis, liver cancer risk and need for effective disease surveillance**
- **Current blood tests and imaging modalities have low sensitivity and/or specificity—curable early-stage disease is being missed**
- **Glycotest's lead product—HCC Panel—significantly outperforms currently dominant blood test (AFP) in independent 208 and 127 patient head-to-head clinical studies**
- **Seeking $10MM Series A financing to advance towards commercialization of the HCC Panel**
  - *Launching in H2 2018*
  - *Profitable in Q4 2019—expected 2020 revenue $52MM*

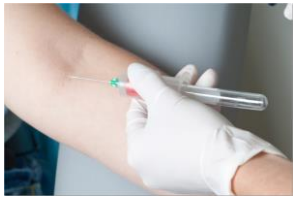
Overview

- **Glycotest, Inc.**
  - *Founded 2012 on technology innovated at the Baruch S. Blumberg Institute and Drexel University College of Medicine (Philadelphia)*
  - *Glycotest technology has benefitted from $8.9MM in grants to the innovators over past years*
  - *Proprietary blood-based biomarkers, panels and algorithms*
  - *Four US and six ex-US patents issued or allowed; additional patents pending*

- **Focused on liver cancer surveillance**
  - *Large at-risk population— >100 MM US and >2 B global*
  - *3.1 MM patients in the US are currently candidates for liver cancer surveillance*
  - *Lead product—biomarker panel for hepatocellular carcinoma (HCC Panel) to score likelihood of disease*

Glycotest Process for Surveillance and Early Diagnosis of Liver Cancer

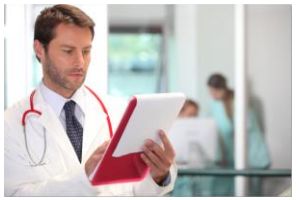
Physician orders HCC Panel.



Serum sample taken for delivery to Glycotest.

Glycotest receives serum sample for analysis in Glycotest's CLIA laboratory.

Analysis leads to HCC Panel disease likelihood score sent to physician.

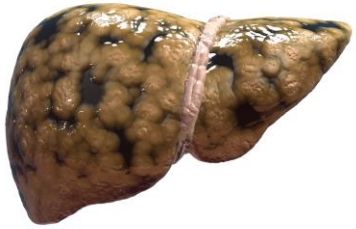


HCC Panel score considered in patient's care.

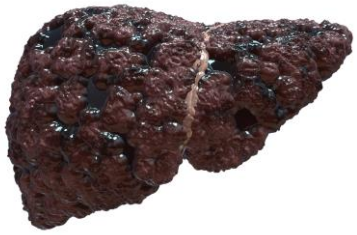
HCC Panel score informs clinical decisions like confirmatory diagnosis by CT or MRI.

$1B Opportunity

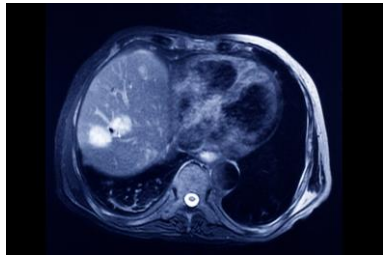
- **Huge and growing populations with viral and non-viral hepatitis—driving progressive fibrosis, liver cancer risk and need for effective disease surveillance**
  - *Chronic hepatitis B: 2.2 MM US; 360 MM WW; incurable*
  - *Chronic hepatitis C: 3.2 MM US; 170 MM WW; liver cancer risk persists despite cure*
  - *Fatty liver disease and NASH / ASH: >100 MM US; >1.5 B WW; rapidly growing populations due to obesity and metabolic disease*
  - *Cirrhosis: 3.2 MM US; 73 MM WW; secondary to hepatitis; proximate cause of most liver cancer*



Fatty Liver



Cirrhosis



Hepatocellular Carcinoma

Current Disease Surveillance Tests Don't Work

- **Current blood tests and imaging modalities have low sensitivity and/or specificity**
  - *AFP—best current blood test for hepatocellular carcinoma (HCC; major form of liver cancer)—misses >50% of disease (AFP-negative disease)*
  - *Ultrasound—only HCC surveillance test recommended by clinical guidelines—highly operator dependent; low sensitivity*
- **Curable early-stage disease is being missed**
  - *HCC is the fastest growing cause of cancer mortality in the US—will surpass breast cancer within 8 years*
- **Effective disease surveillance tests are critical unmet clinical needs**
  - *Liver cancer tests to identify curable early-stage disease*
  - *Liver fibrosis test to stage disease and determine when to treat hepatitis*

KOL Perspectives

- **Critical unmet clinical need for an effective HCC surveillance test**
- **Chronic HBV, HCV and huge NAFLD / NASH population are key at-risk groups**
- **HCC risk persists after chronic HCV cure by antiviral therapy or transplant**
- **Recognition of HCC risk from NAFLD / NASH increasing**
- **Early-stage and AFP-negative disease detection are key**
- **Long-term disease-free survival possible for treatable early-stage HCC**

Nathan Bass, MD, PhD. Gastroenterology. Professor; Site Director, NASH Clinical Research Network; University of California, San Francisco Medical Center.

Douglass Dietrich, MD. Gastroenterology. Professor, Division of Liver Diseases; Icahn School of Medicine at Mount Sinai.

Scott Friedman, MD. Gastroenterology. Dean for Therapeutic Discovery; Fishberg Professor of Medicine; Professor of Pharmacology and Systems Therapeutics; Chief, Division of Liver Diseases; Icahn School of Medicine at Mount Sinai.

John Lake, MD. Hepatology/Gastroenterology. Director, Division of Gastroenterology, Hepatology and Nutrition; Director, Liver Transplant Program; University of Minnesota Medical Center.

Alan Venook, MD. Oncology (liver and colorectal cancers). Madden Family Distinguished Professorship in Medical Oncology and Translational Research; University of California, San Francisco Medical Center.

Value Proposition

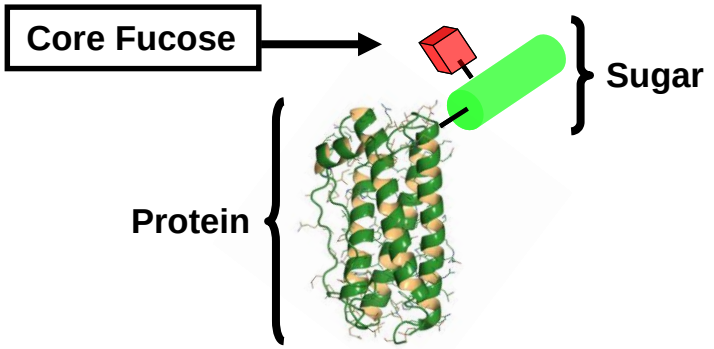
- **Glycotest is at the forefront in surveillance for early stage liver cancer**
  - *Well defined critical unmet clinical needs*
  - *Large and growing US and global markets*
  - *No currently available technology solutions*
  - *Glycotest has the proprietary biomarkers, assay technology and algorithm to provide physicians with actionable information*

- **Liver cancer surveillance drives lower healthcare costs**
  - *Early detection of HCC enables lower cost curative therapy—resection or ablation*
  - *Later stage HCC is only eligible for higher cost palliative therapy—TACE or chemotherapy*
  - *Cost effective HCC panel will enable early-stage HCC detection, lower cost treatment options, and better patient outcomes that will drive market adoption*

- **Estimated market value for the HCC Panel is $818 MM in the US alone**
  - *Assumes only 620,000 US patients under surveillance—20% of 3.1 MM eligible patients*

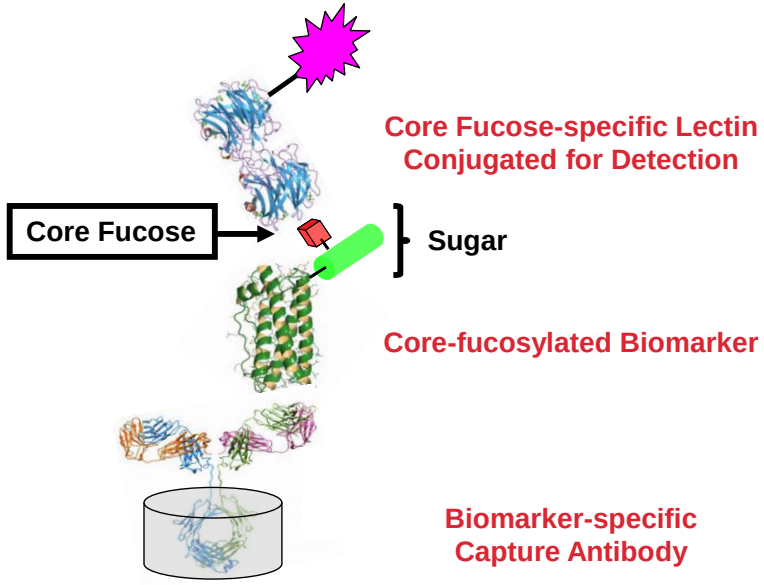
Proprietary Serum Biomarkers and Assay Technology

- **Proprietary serum biomarkers with unique core fucose chemistry**
  - *Issued patents to >50 glycoprotein biomarkers—*
    liver-secreted acute phase proteins associated with inflammation and stress
  - *Unique abnormal change in sugar structure in liver disease—*
    core fucose disease signal



A Glycotest Glycoprotein Biomarker

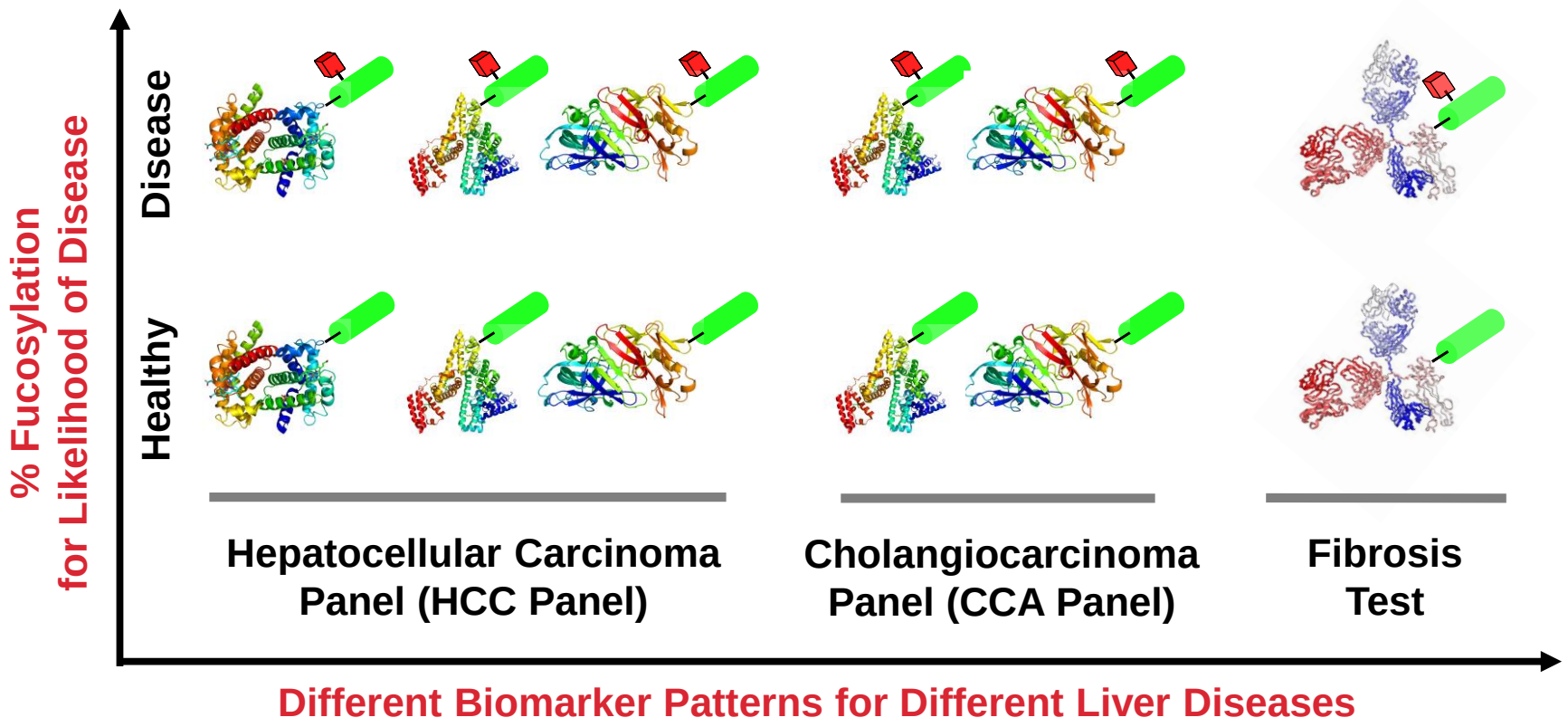
- **Proprietary assay technology optimized for core fucose quantification**
  - *Based on convenient immunoassay methodology*
  - *Exploits recombinant lectins engineered for core fucose specificity*



Glycotest Core Fucose-specific Assay Technology

Proprietary Biomarker Panels, Algorithms and Single Biomarker Tests

- **New tests to address serious unmet clinical needs**
  - *Refer asymptomatic patients with worsening liver disease for additional care*
  - *Detect curable early-stage disease*



Intellectual Property

- **HCC Panel patent application (PCT and Taiwan)**
  - *One of two most important Glycotest patent families—protects Glycotest HCC Panel test*
  - *Fresh application providing protection to 2037, including in China*
- **PCT/US2010/044307**
  - *Second of two most important Glycotest patent families—protects engineered lectins for fucosylated biomarker assays*
  - *Issued European patent (2462240)*
  - *Protection to 2030, including in China*
  - *Prosecution of Chinese application 201080044720.8 claiming priority to PCT/US2010/044307 underway*
- **PCT/US2006/017478**
  - *Methods for diagnosing liver disease using fucosylated biomarkers*
  - *Issued US (7,776,550; 8,183,000), Australian (2006244398; 2012247075) and Japanese (5964769) patents; additional Australian and Japanese patents allowed*
  - *Protection to 2026*
- **US2009/0253180**
  - *Methods for diagnosing liver disease using fucosylated LRAGG*
  - *Issued US patent (9,110,078) and additional US patent allowed*
  - *Protection to 2028*
- **Trade Secrets**
  - *Fucosylated biomarker assay manufacturing technology*
  - *Fucosylated biomarker assay methods*

Lead Product—HCC Panel

- **Algorithm-driven panel—surveillance for curable HCC**
  - *To detect curable early-stage disease*
  - *To provide a convenient blood test that guides CT / MRI confirmation*
  - *For patients at risk due to both viral and non-viral hepatitis*
- **Early-stage HCC is curable**
  - *Resection and ablation lead to long-term disease free survival*
  - *Curative treatment is less costly than palliative care for later stage disease*
- **Large and expanding population needs an effective HCC surveillance solution**
  - *Cirrhosis + chronic hepatitis B w/o cirrhosis—3.1 MM US; 323 MM WW*
  - *NASH pandemic expanding market*
  - *Chronic testing opportunity—repeat testing every 3-6 months*
- **Glycotest's HCC Panel significantly outperforms currently dominant blood test (AFP) in independent 208 patient and 127 patient head-to-head clinical studies**

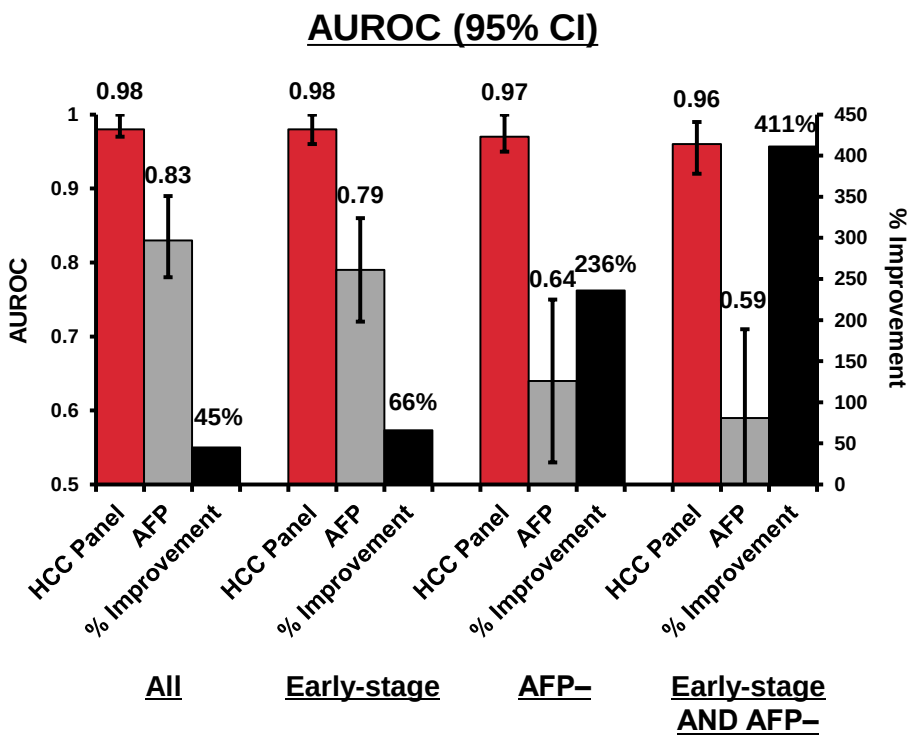
Clinical Feasibility Studies—Head-to-head Comparison of the Glycotest HCC Panel to AFP

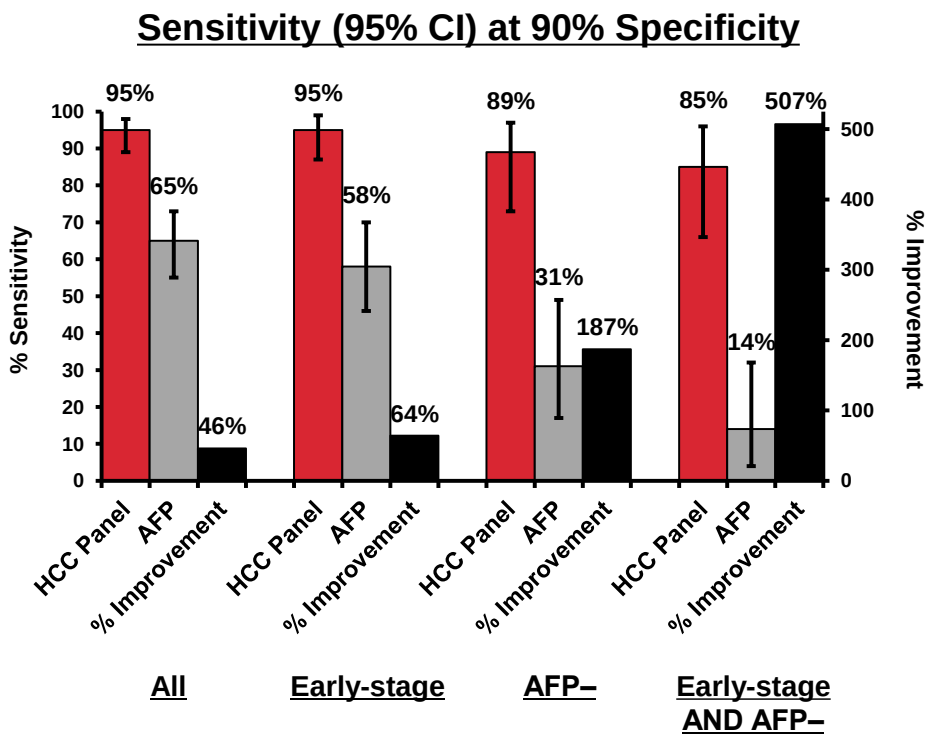
- **Two independent clinical feasibility studies (case–control studies)**
- **Collaborations between Glycotest innovator (Anand Mehta; patient sample assays and data analysis) and clinical collaborators (patient samples)**
- **Patient samples collected under IRB-approved protocols**
- **Patient cohorts assembled by clinical collaborators**
- **Glycotest innovator blinded to clinical data until after samples were assayed**
- **Study 1 stratified by curable early stage HCC (T1 + T2) and AFP-negative disease (< 20 ng/mL)**
- **Study 2 stratified by HCC disease stage (curable HCC: T1; T2; T1 + T2)**
- **Chronic hepatitis B patients (8% of Study 1 patients; 76% of Study 2 control patients) are predominantly Asian**
  - *No evidence of Western–Asian difference in these studies or published clinical data on individual biomarkers*
- **Additional information available in supplementary document**

T1: 1 lesion < 2 cm
T2: 1 lesion 2–5 cm or ≤ 3 lesions < 3 cm

Lead Product—HCC Panel

Performance Superior to AFP for the Discrimination Of Early-stage and AFP-negative HCC from Cirrhosis



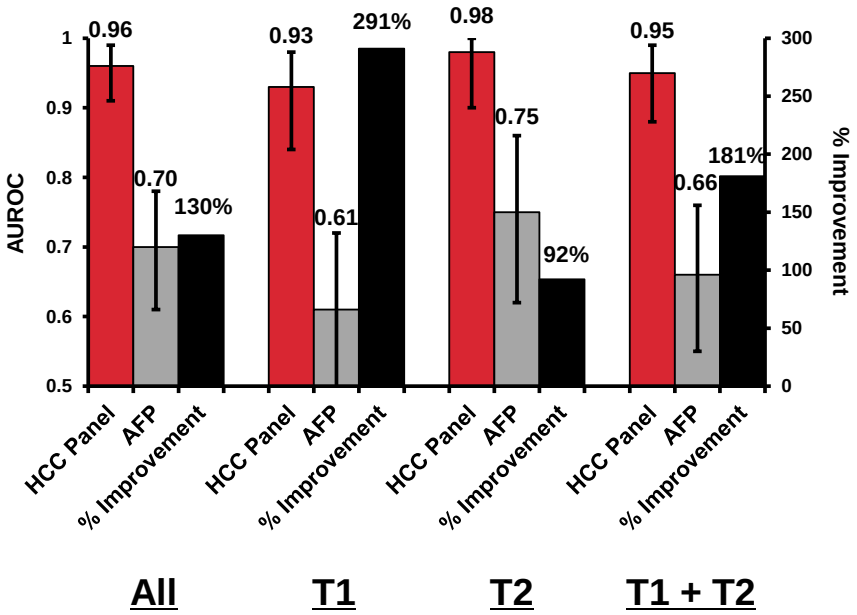


All: HCC (N=115) vs. cirrhosis (N=93)
Early-stage: HCC UNOS stage T1/T2 (N=69) vs. cirrhosis (N=93)
AFP⁻ (< 20 ng/mL): HCC (N=39) vs. cirrhosis (N=84)
Early-stage AND AFP⁻: HCC (N=29) vs. cirrhosis (N=84)
HCC Etiology (%): HCV (61); HBV (6); Other (33)
Cirrhosis Etiology (%): HCV (48); HBV (10); Other (42)

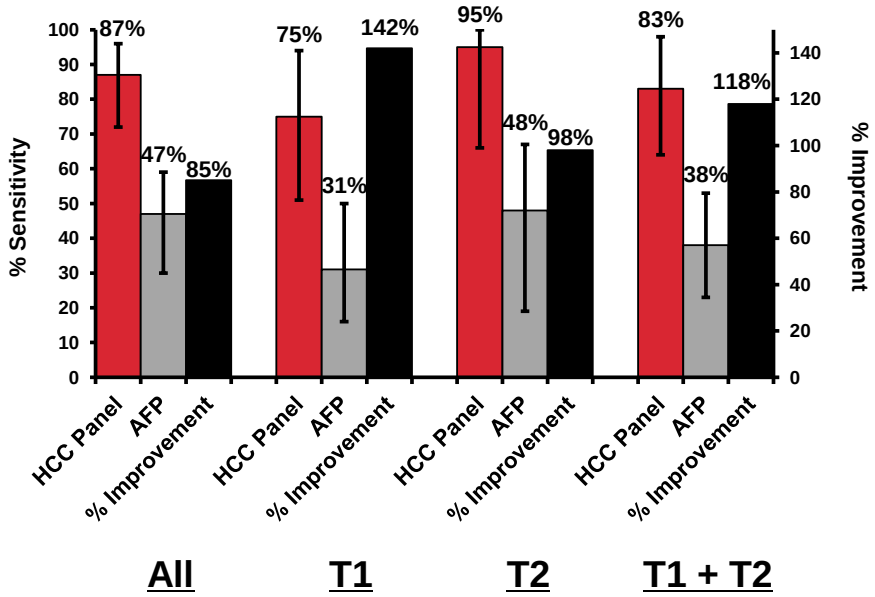
HCC Panel—Second Clinical Study

Independent Confirmation of Performance Superior to AFP for Detecting Early-stage HCC

AUROC (95% CI)



Sensitivity (95% CI) at 90% Specificity



All: HCC (N=93) vs. chronic liver disease (N=34)
HCC stage: T1 N=32; T2 N=21; T3-4 N=20; unknown stage N=20
Chronic liver disease: cirrhosis N=9; HBV N=22; HCV N=2; ALD N=1

KOLs Regard HCC Panel Clinical Data to be Highly Promising

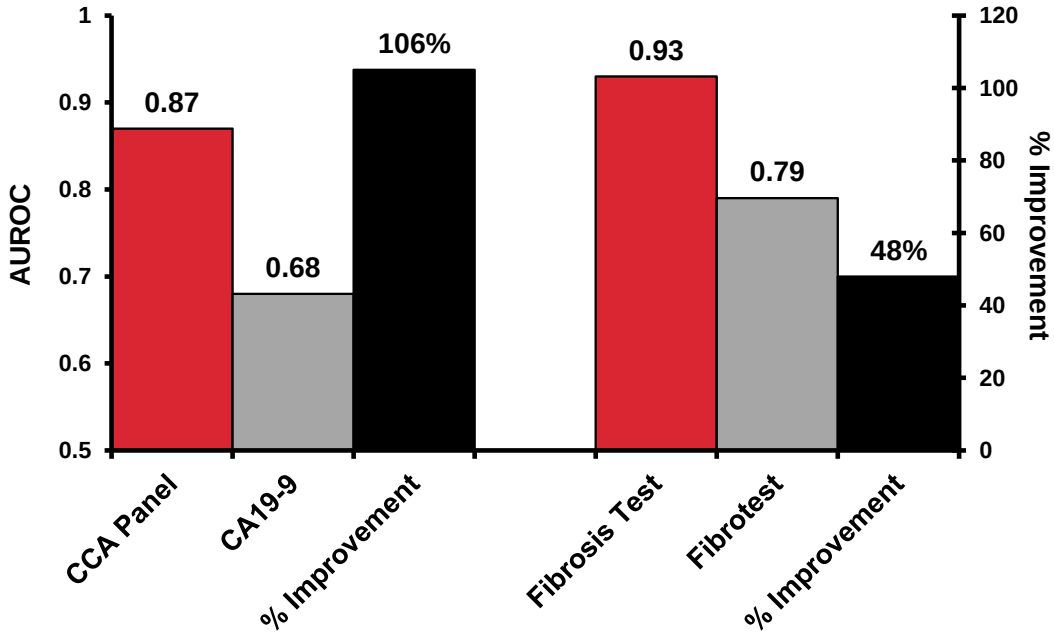
- **Glycotest engaged a market research firm (Defined Health) to determine how experts assessed Glycotest's HCC Panel**
- **Defined Health conducted telephone interviews with 5 US hepatologists**

Title	Affiliation
• Professor of Medicine • Medical Director of Liver Tumor Program • Director of Hepatology • Chief of Hepatology • Professor of Medicine	• Harvard Medical School • East Carolina University • UT Southwestern Medical Center • Stanford University • UT Southwestern Medical Center

- **Comments from the experts interviewed:**
  - *"If you can have 95% sensitivity at a 90% specificity, that's wonderful."*
  - *"Surely as I look at these AUROCs they look mighty good. It's pretty hard to do better than 97-98% AUROCs. It's pretty good numbers here."*
  - *"With these numbers, this test could replace the need for US."*
  - *"This is better [than US+AFP]. No question about it."*
  - *"Specifically the ability to detect early and AFP negative tumors, I think is attractive."*

Pipeline—CCA Panel; Fibrosis Test

- **CCA Panel for cholangiocarcinoma surveillance**
- **Fibrosis Test for staging intermediate fibrosis**



AUROCs >0.9 and/or >20% higher (0.5–1 AUROC range) than comparators are clinically meaningful improvements.

CCA (cholangiocarcinoma) Panel: CCA (N=39) vs. primary sclerosing cholangitis (N=31)

Fibrosis Test: discrimination of intermediate stage fibrosis; Ishak Stage F1-2 (N=24) vs. F3-6 (N=178; Glycotest; Mehta, AS, et al. J Virol. 2008; 82:1259-1270.); Ishak Stage F0-2 vs. F3-6 (HCV FibroSURE; historical data: Halfon, P, et al., Am J Gastroenterol. 2006; 101:547-555.)

Go-to-Market Plan—HCC Panel

- **Business model**
  - *US: Commercialize Laboratory Developed Test (LDT) service products in Glycotest CLIA lab—regulated by CMS, not FDA*
  - *Ex-US strategy: Partner for large Asian liver disease markets*

- **Commercial launch strategy**
  - *Commercial assay manufacturing development with CROs*
  - *Open Glycotest lab—complete analytical validation, pre-analytical effects, algorithm training*
  - *Establish CLIA certification / CAP accreditation for commercial operation*
  - *Complete retrospective-prospective clinical validation study for commercial launch*
  - *KOL engagement and aggressive publication program to support marketing*

- **Coverage and reimbursement strategy**
  - *Developed with QURE Healthcare and Morgan Lewis*
  - *Conduct planned clinical utility studies with QURE*
  - *Register the HCC panel and seek Medicare coverage through Palmetto MolDX program*
  - *Positive decision from Palmetto will influence private payer policies*
  - *High margin HCC Panel test projected by preliminary value-based pricing study*

Liver Cancer Test Competition

Feature	AFP	Wako Blood Tests		Imaging			Glycotest HCC Panel + Algorithm
		AFP-L3	DCP	Ultrasound	CT	MRI	
Effective for Early-stage HCC	No	No	No	No	No	No	Yes
Effective for AFP-negative HCC	No	No	No	Yes	Yes	Yes	Yes
Operator Independent	Yes	Yes	Yes	No	Yes	No	Yes
No Difficulty in Obese Patients	Yes	Yes	Yes	No	Yes	No	Yes
In Clinical Guidelines for Surveillance	No	No	No	Yes (marginal sensitivity)	No	No	Not Yet!

Team, Advisors and Key Resources

Management

Lawrence Cohen, CEO
Charles Swindell, PhD, COO
George Hu, Director, Asian BD

Innovator–Advisors
Timothy Block, PhD; Blumberg Institute, Hepatitis B Foundation
Anand Mehta, DPhil; Medical University of South Carolina

Senior Clinical Advisor; MAB Chair
David Chernoff, MD; Industry Veteran
(Crescendo; XDx; CardioDx; Tethys; Chiron; Elan)

Clinical Study Support and Management
DOCRO (oncology diagnostics CRO)

Manufacturing
Precision Antibody (reagent specialist)
Radix BioSolutions (assay specialist)

Regulatory Affairs and Compliance
Elizabeth Lison; Advocea (IVD specialist)

Quality
Michael Kochersperger; Veteran Quality Consultant

Corporate Counsel
Fahd Riaz; DLA Piper

Coverage and Reimbursement
QURE Healthcare (health economics firm)
Andrew Ruskin; Morgan Lewis

Intellectual Property Counsel
Baker & Hostetler

Finance, HR and IT
NetScientific

Initial Medical Advisory Board

- **David Chernoff, MD, Chair**
  - *Molecular Dx industry veteran*
  - *Crescendo; XDx; CardioDx; Tethys; Chiron; Elan*
- **Scott Friedman, MD**
  - *Icahn School of Medicine at Mount Sinai, New York*
  - *Dean for Therapeutic Discovery; Chief, Division of Liver Diseases; Fishberg Professor of Medicine; Professor of Pharmacology and Systems Therapeutics*
  - *Gastroenterology*
- **Douglas Dieterich, MD**
  - *Icahn School of Medicine at Mount Sinai, New York*
  - *Director, Institute for Liver Medicine, Mount Sinai Health System; Professor of Medicine*
  - *Gastroenterology*

Current Status and Timeline

- **Progress to date**
  - *Individual biomarker evaluation in >800 patients*
  - *Basic HCC algorithm development in 1000s of patients*
  - *Two HCC Panel vs. AFP clinical studies in 335 patients*
  - *HCC Panel clinical validation study plan developed; investigators and sites identified*
  - *HCC Panel coverage and reimbursement strategy developed; clinical utility and value-based pricing plans developed*
  - *Pipeline opportunities in cholangiocarcinoma and fibrosis–cirrhosis identified*

- **Current status**
  - *HCC Panel commercial biomarker assay manufacturing methods development underway*

- **Timeline to commercial launch of HCC Panel in 2018**
  - *Q3 2017: Series A funding closed*
  - *Q4 2017: Assay methods qualified*
  - *Q4 2017: Laboratory opened; team expanded; manufacturing; clinical sample collection initiated*
  - *Q1 2018: Analytical validation complete*
  - *Q2 2018: Pre-analytical effects; algorithm training; CLIA registration*
  - *Q3/4 2018: Clinical validation study complete; commercial launch*