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, 127 and 149 patient head-to-head clinical studies**
- **$10MM Series A financing closed Q1 2019**
  - *HCC Panel Launching in Q3 2020*
  - *Profitable in Q4 2021—expected 2022 revenue $69MM*

Series A Financing Closed

- **Fosun Pharma and NetScientific plc investors**
- **$10MM equity investment**
  - *$3MM on close*
  - *$7MM on completion of certain milestones*
- **Fosun receives:**
  - *40% equity stake in Glycotest*
  - *Exclusive license for China to:*
    - *HCC Panel early-stage liver cancer test—China commercialization targeted for 2021*
    - *Fibrosis Test for liver fibrosis–cirrhosis—China commercialization targeted for 2022*
    - *CCA Panel for cholangiocarcinoma*
    - *Glycotest earns royalty on sales in China*
  - *First right of negotiation to follow-on Glycotest liver disease tests*
- **Glycotest will use proceeds to:**
  - *Launch the HCC Panel in the US in Q3 2020*
  - *Transfer licensed products to Fosun*
  - *Further develop pipeline tests*

Fosun Pharma

- **Shanghai Fosun Pharmaceutical (Group) Co., Ltd. (Fosun Pharma)**
  - *Leading healthcare group in the PRC—$2.7B 2017 revenue (18B RMB)*
  - *Fully integrated healthcare company—pharmaceutical, diagnostic and healthcare service products and innovative R&D*
- **Equity investor in Glycotest**
- **Commercializing Glycotest liver disease tests in China through Fosun Pharma Diagnostics**
- **First product—Glycotest HCC Panel for curable early-stage liver cancer (HCC)**
  - *> 350,000 people in China die of liver cancer each year*
  - *> 350MM people in China at risk for liver cancer due to serious liver disease—viral hepatitis, fatty liver disease and NASH, alcoholic liver disease and ASH*

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*
  - *Five US and eight ex-US patents issued; additional patents pending*

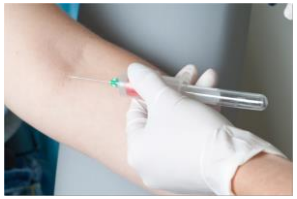
- **Focused on liver cancer surveillance**
  - *Large at-risk population— >100 MM US and >2 B global*
  - *3.1 MM patients in the US are currently candidates for liver cancer surveillance*
  - *Lead product—biomarker panel for hepatocellular carcinoma (HCC Panel) to score likelihood of disease*

Definition of HCC Panel

- **HCC Panel Test**
  - *3 Novel serum protein biomarkers—Glycotest's proprietary serum protein biomarkers assayed for extent of core fucosylation using proprietary sandwich immunoassay methodology*
  - *3 Standard serum protein biomarkers—commonly found on established immunoassay platforms*
  - *Proprietary algorithm—calculates HCC likelihood score from above 6 serum protein biomarkers plus patient age and sex*
- **Intended for regular surveillance testing of patients at high risk for HCC**
- **Clinical guidelines (AASLD) define target population and testing frequency**
  - *Target patient population—cirrhosis (any underlying cause) and non-cirrhotic chronic hepatitis B patients (at least 3.1 MM in the US)*
  - *Testing frequency—at least every 6 months*

Glycotest Process for Surveillance and Early Diagnosis of Liver Cancer

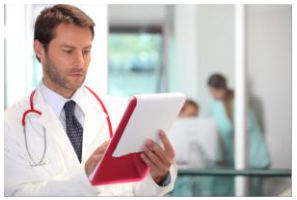
Physician orders HCC Panel.



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.

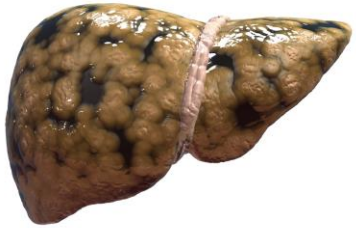


HCC Panel score considered in patient's care.

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

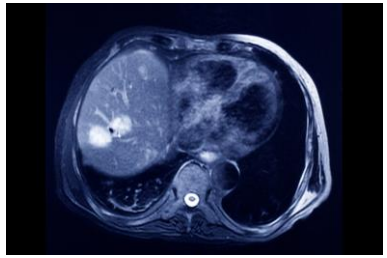
$1B Opportunity

- **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) but USA clinical guidelines recommend optional use only in combination with ultrasound—misses >50% of disease (AFP-negative disease)*
  - *Ultrasound—only HCC surveillance test definitively recommended by USA 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

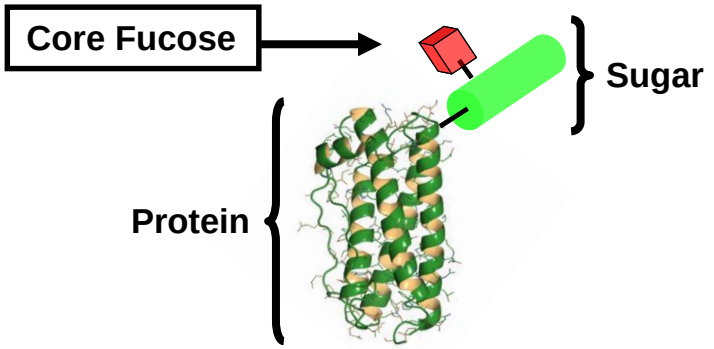
- **Glycotest is at the forefront in surveillance for early stage liver cancer**
  - *Well defined critical unmet clinical needs*
  - *Large and growing US and global markets*
  - *No currently available technology solutions*
  - *Glycotest has the proprietary biomarkers, assay technology and algorithm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

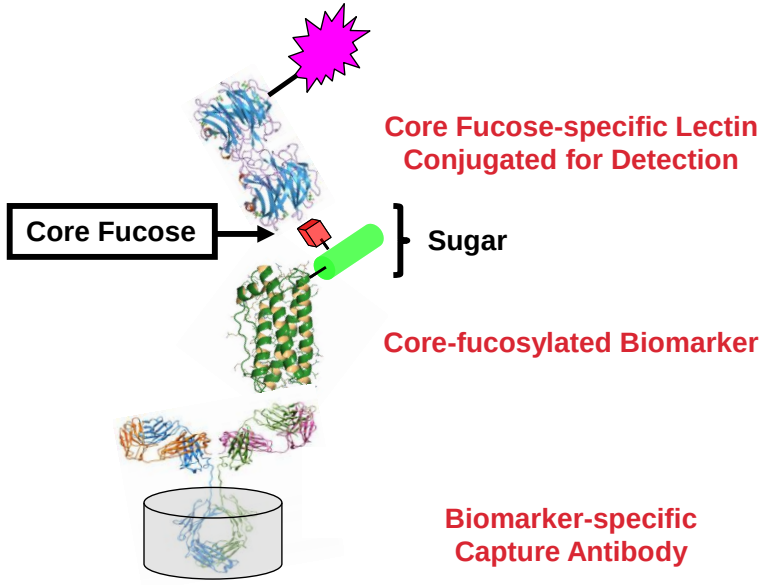
Proprietary Serum Biomarkers and Assay Technology

- **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

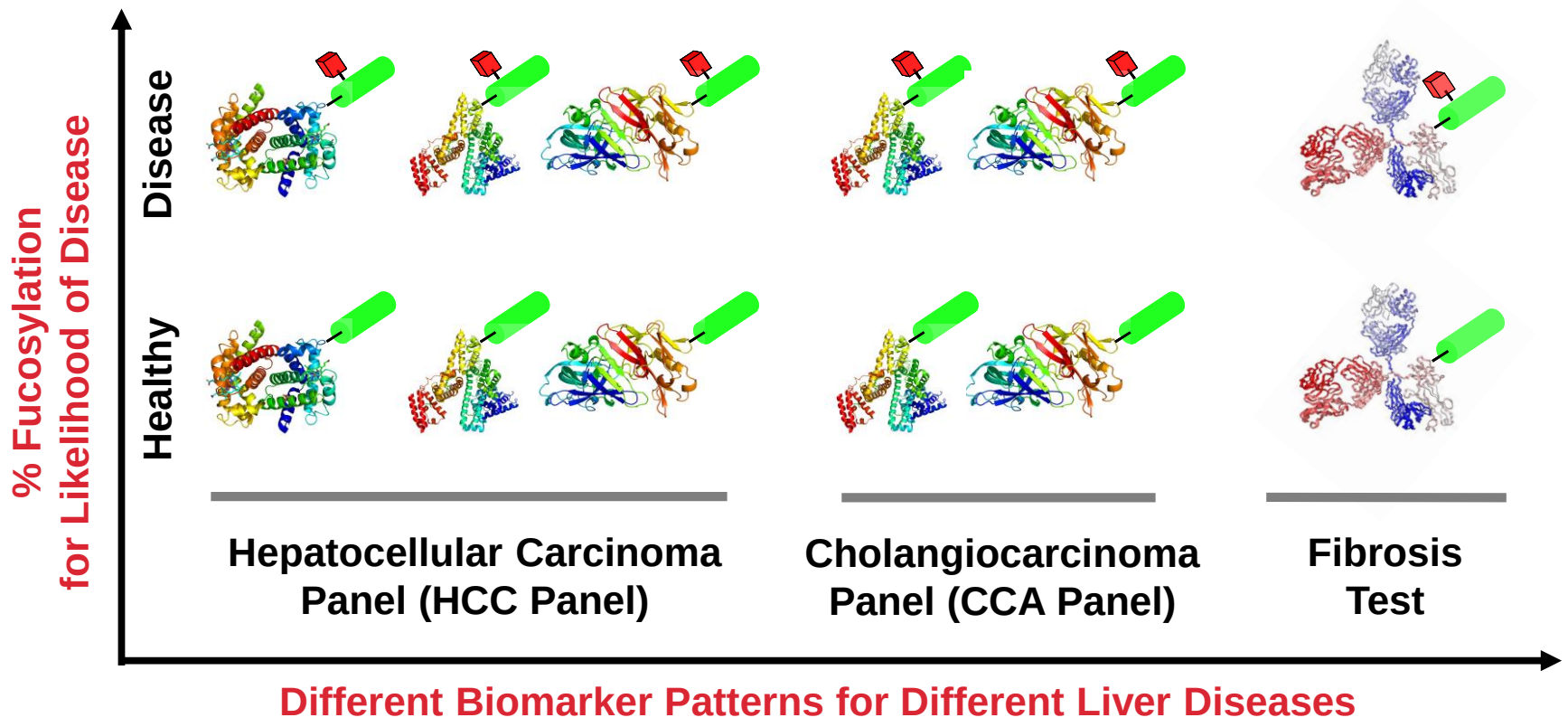
- **Proprietary assay technology optimized for core fucose quantification**
  - *Based on convenient immunoassay methodology*
  - *Exploits recombinant lectins engineered for core fucose specificity*



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—14 Issued Patents

- **HCC Panel patent application (PCT/US2017/018040 and Taiwan 106106107)**
  - *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 (2462240) and Chinese (ZL201080044720.8) patents*
  - *Protection to 2030, including in China*
- **PCT/US2006/017478**
  - *Methods for diagnosing liver disease using fucosylated biomarkers*
  - *Issued US (7,776,550; 8,183,000; 10,082,512), Australian (2006244398; 2012247075; 2015275300), Japanese (5964769; 6184935) and Canadian (2607285) patents and allowed European patent*
  - *Protection to 2026*
- **US2009/0253180**
  - *Methods for diagnosing liver disease using fucosylated LRAGG*
  - *Issued US patents (9,110,078; 10,180,436)*
  - *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, 127 patient and 149 patient head-to-head clinical studies**

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

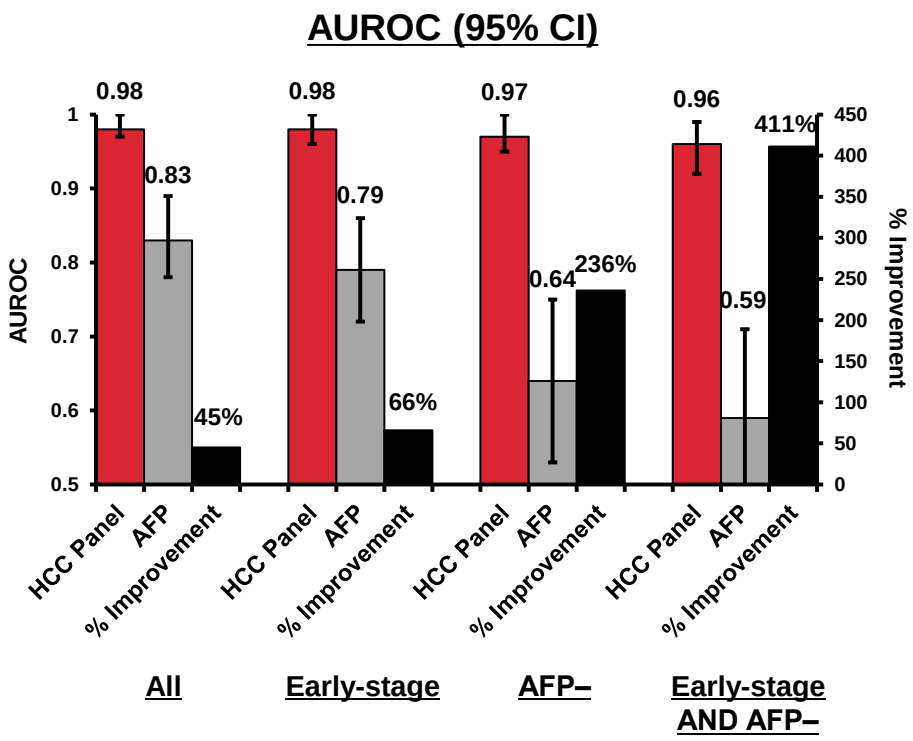
- **Three independent clinical feasibility studies (case–control studies)**
- **Collaborations between Glycotest innovator (Anand Mehta; patient sample assays and data analysis) and clinical collaborators (patient samples)**
- **Patient samples collected under IRB-approved protocols**
- **Patient cohorts 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)**
- **Study 3 stratified by curable early stage HCC (T1 + T2) and AFP-negative disease (< 20 ng/mL)**
- **Chronic hepatitis B patients (76% of Study 2 control patients) predominantly Asian**
  - *No evidence of Western–Asian difference in these studies or published clinical data on individual biomarkers*
- **Additional information available in supplementary document**

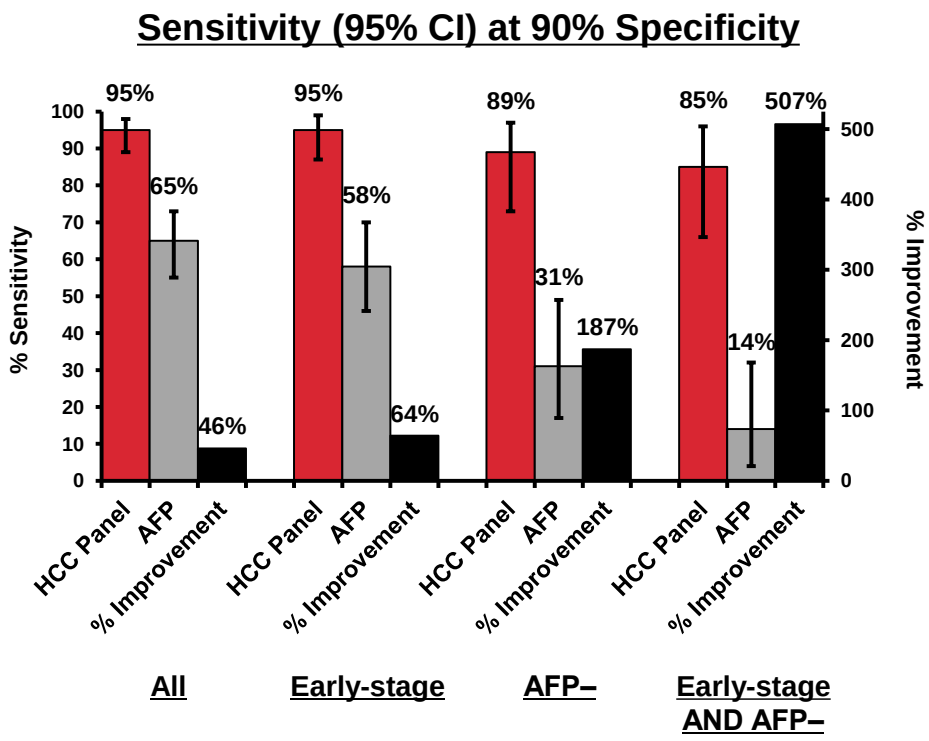
T1: 1 lesion < 2 cm
T2: 1 lesion 2–5 cm or ≤ 3 lesions < 3 cm

HCC Panel—First Clinical Study

Glycotest

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





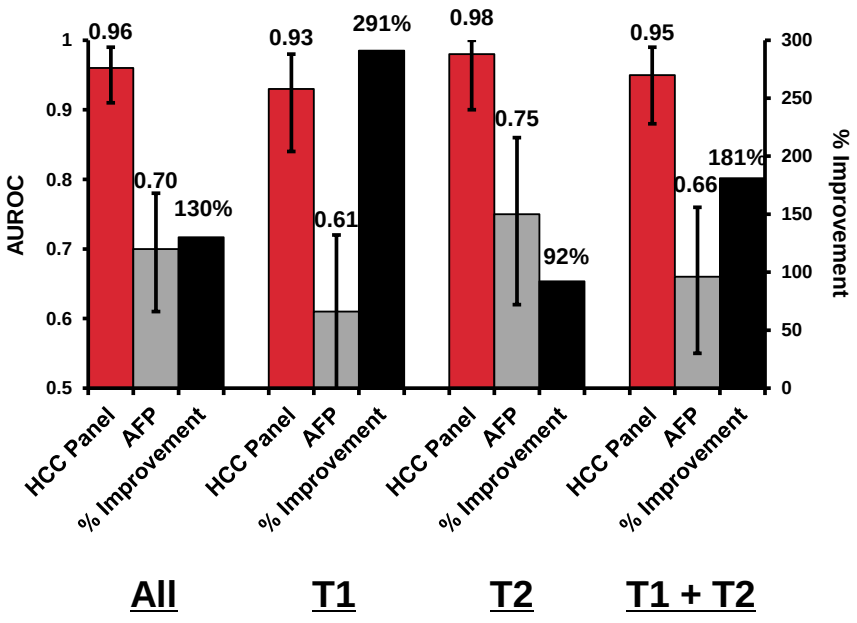
All: HCC (N=115) vs. cirrhosis (N=93)
Early-stage: HCC UNOS stage T1/T2 (N=69) vs. cirrhosis (N=93)
AFP ¯ (< 20 ng/mL): HCC (N=39) vs. cirrhosis (N=84)
Early-stage AND AFP ¯: HCC (N=29) vs. cirrhosis (N=84)
HCC Etiology (%): HCV (61); HBV (6); Other (33)
Cirrhosis Etiology (%): HCV (48); HBV (10); Other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

HCC Panel—Second Clinical Study

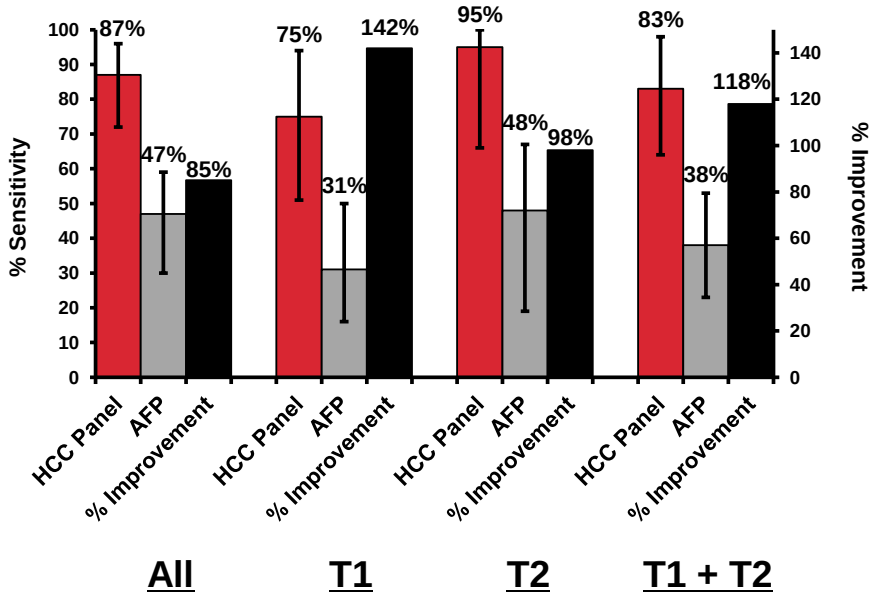
Glycotest

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

HCC Panel—Third Clinical Study

Glycotest

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

- **Entire Cohort**
  - *HCC cases N = 75; non-HCC controls N = 74*
  - *HCC Panel AUROC = 0.97 (95% CI 0.94 – 1.00); 93% sensitivity @ 92% specificity*
  - *AFP AUROC = 0.88 (95% CI 0.83 – 0.94); 71% sensitivity @ 92% specificity*
- **Early-stage Cohort (T1 + T2)**
  - *HCC cases N = 24; non-HCC controls N = 74*
  - *HCC Panel AUROC = 0.96 (95% CI 0.91 – 1.00); 88% sensitivity @ 91% specificity*
  - *AFP Panel AUROC = 0.87 (95% CI 0.77 – 0.97); 75% sensitivity @ 91% specificity*
  - *The HCC Panel identified 78% of the HCC patients missed by AFP*
- **AFP-negative Cohort (AFP < 20 ng/mL)**
  - *HCC cases N = 29; non-HCC controls N = 72*
  - *HCC Panel AUROC = 0.93 (95% CI 0.85 – 1.00); 86% sensitivity @ 90% specificity*
  - *AFP AUROC = 0.73 (95% CI 0.62 – 0.83); 34% sensitivity @ 90% specificity*
  - *The HCC Panel identified 86% of the HCC patients missed by AFP*

KOLs Regard HCC Panel Clinical Data to be Highly Promising

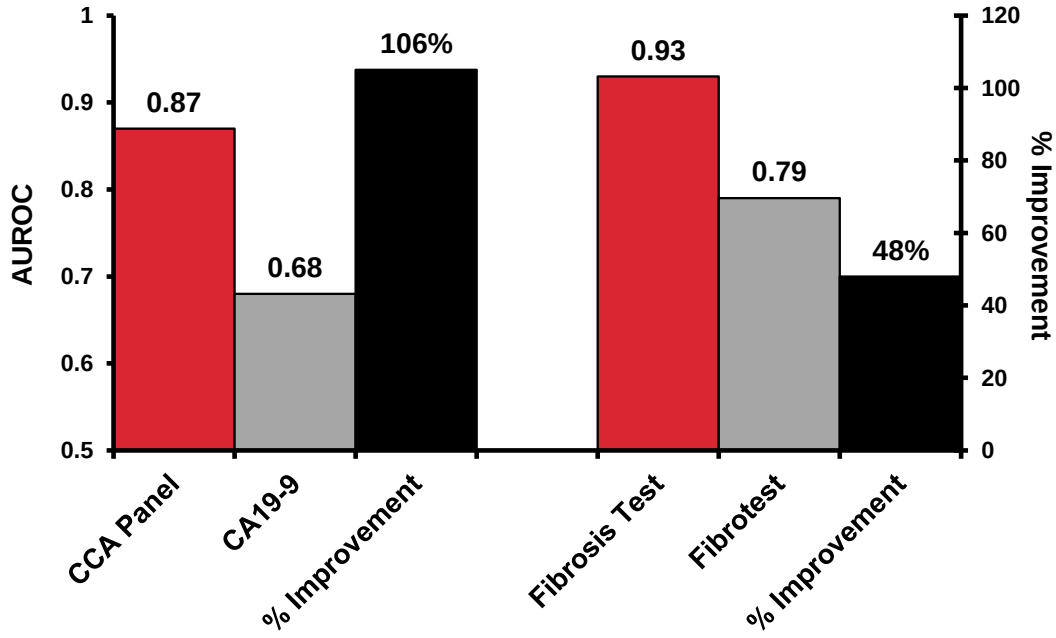
- **Glycotest engaged a market research firm (Defined Health) to determine how experts assessed Glycotest's HCC Panel**
- **Defined Health conducted telephone interviews with 5 US hepatologists**

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 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*
  - *Enable HCC Panel in CLIA lab—complete analytical validation, pre-analytical effects, algorithm training*
  - *Complete 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*

Current Liver Cancer Surveillance Test Competition

Glycotest

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 USA Clinical Guidelines for Surveillance	Optional	No	No	Yes (marginal sensitivity)	No	No	Not Yet!

Development-stage HCC Surveillance Tests

Glycotest

No Potential HCC Tests in Development Have Been Reported to Outperform the Glycotest HCC Panel For the Detection of Early-stage HCC Patients in the Population Eligible for Surveillance

Genetic Tests			
Organization	**Test**	**Comments**	**Publications**
Exact Sciences and Mayo Clinic	Methylation of 6 genes in cfDNA	Early-stage HCC performance unclear (unclear control group, specificity)	Kisiel, JB et al. Gastroenterology. 2018; 154 (Issue 6, Supplement 1):S-1113–S-1114
Epigenomics	Methylation of single tumor suppressor gene in cfDNA	Early-stage HCC vs cirrhosis: AUROC = 0.86 Sensitivity @ 86% specificity = 73%	Oussalah, A et al. EBioMedicine. 2018; 30:138–147.
JBS Science	Methylation of 2 genes and mutation of 3 genes in urine DNA	No data reported for early-stage HCC	Song, W et al. J Clin Oncol. 2016; 34 (suppl):abstr e15640.
UCSD and other US and Chinese academic institutions	Methylation of 8 ctDNA markers	No data reported for early-stage HCC	Xu, R et al. Nat Mater. 2017; 16:1155–1161.
Cleveland Clinic, GRAIL and other US organizations	Methylation of cfDNA	No data reported for early-stage HCC	Klein, EA et al. J Clin Oncol. 2018; 36 (suppl; abstr 12021).
Blood Protein Tests			
Organization	**Test**	**Comments**	**Publications**
Wako	GALAD Panel (AFP, AFP-L3, DCP)	Early-stage HCC vs chronic liver disease: AUROC = 0.91–0.93 Sensitivity @ ≥90% specificity = ≤80%	Berhane, S et al. Clin Gastroenterol Hepatol. 2016; 14:875–886.
Chinese Academy of Medical Sciences, Peking Union Medical College and other Chinese organizations	AFP + DCP + age + gender	Early-stage HCC vs cirrhosis ± chronic HBV: AUROC = 0.81–0.87 Sensitivity @ 90% specificity = 56–63%	Chen, H et al. Cancer Manag Res. 2018; 10:1947–1958.

Team, Advisors and Key Resources

Management

Lawrence Cohen, CEO
Charles Swindell, PhD, COO, CSO
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
Marcia Zucker, PhD; ZIVD LLC (Dx clinical operations specialist)

Manufacturing
Precision Antibody (reagent specialist)

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

Quality
Claudia Campbell; 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
RSM; TriNet

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*
- **Anand Mehta, DPhil**
  - *Medical University of South Carolina, Charleston, South Carolina*
  - *SmartState Endowed Chair of Proteomic Biomarkers*
  - *Glycotest technology innovator*

Current Status and Timeline

- **Progress to date**
  - *Individual biomarker evaluation in >800 patients*
  - *Basic HCC algorithm development in 1000s of patients*
  - *Three HCC Panel vs. AFP clinical studies in >480 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*
  - *HCC panel commercial biomarker assay manufacturing methods developed*
  - *Series A financing closed*

- **Timeline to commercial launch of HCC Panel in 2020**
  - *Q1 2019: Series A financing closed*
  - *Q1 2019: Start manufacturing and clinical sample collection*
  - *Q2 2019: Initiate analytical validation*
  - *Q3 2019: Complete analytical validation; expand team*
  - *Q4 2019: Complete algorithm training*
  - *Q1 2020: Initiate clinical utility studies and internal selling and marketing capability*
  - *Q3 2020: Complete clinical validation study; commercial launch*