# LIVERFASt™

## Fibrosis • Activity • Steatosis

# Nearly 2.4 million Americans are living with Hepatitis C

# 50% may NOT know they're INFECTED

## Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) are major causes of

- Chronic Liver Disease
- Cirrhosis
- Hepatocellular Carcinoma

LIVERFASt™


**LIVERFASt™** is a blood based diagnostic test that combines 10 biomarkers and algorithm technology to determine the fibrosis, activity, and steatosis stages of the liver.

**LIVERFASt™** utilizes the following biomarkers:

- Alpha-2 Macroglobulin
- Haptoglobin
- Apolipoprotein A1
- Total Bilirubin
- GGT
- ALT (P5P)
- AST (P5P)
- Fasting Glucose
- Triglycerides
- Total Cholesterol

- **LIVERFASt™** identifies advanced fibrosis and necro-inflammatory activity in patients with chronic hepatitis C.
- **LIVERFASt™** diagnostic performance for advanced clinical fibrosis was significant and similar to that of liver stiffness measurement and other NITs.

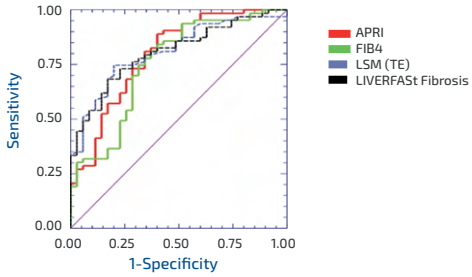

**References**

Tangvoraphonkchai K, Suttichaimongkol T, Kularbkaew C, Sangaimwibool P, Sukeepaisarnjaroen W. Comparative assessment liver lesions using non-invasive serum biomarkers LIVERFASt™ , FIB4, APRI and liver stiffness measurement (LSM, Fibroscan) in chronic hepatitis C (CHC) patients with liver biopsy. (Data under submission)

# LIVERFASt™ differentiates low risk from high risk patients and predicts the survival rate by stratifying fibrosis level.

## Why **LIVERFASt™**?

1. **Diagnose** fibrosis and cirrhosis to guide treatments with novel direct acting agents (DAA) regardless of ethnicity, gender, ALT level, HCV genotype or viral load.[5]




- **Best applicability** compared to elastographic methods (98% vs 80%).[3]
- **High AUROC for fibrosis (>=F2)**: 0.806, p=NS versus transient elastography, versus FIB4.[3,5]
- **Identifies Cirrhosis** and the risk of developing hepatocellular carcinoma (HCC)3,5arcinoma (HCC).[3,5]

2. **Estimates** the necroinflammatory activity more accurately than ALT. [3,5]

3. **Follow up**: Easily repeatable for the assessment of disease regression or the residual risk of HCC after viral cure.[3,5]

# David

## 38 | Male

- Currently taking Methadone for his substance use disorder
- Drinks alcohol regularly
- Obese
- Past medical history of diabetes mellitus
- Medicaid health insurance


## Before LIVERFASt™

### Laboratory Results

- Fasting blood glucose 175 mg/dL
- AST 45 IU/L
- ALT 30 IU/L
- Creatinine 0.7 mg/dL
- Platelet count 110,000 per mcL
- HCV Antibody positive
- HCV RNA PCR Quantitative 1,200,000 IU/L
- HCV genotype 3
- Hepatitis B surface antigen negative
- HIV antibody negative

### Radiology Results

Abdominal ultrasound – echogenic liver

### Clinical Assessment

- Newly diagnosed with hepatitis C as part of screening at his medication-assisted treatment center.
- With baseline low platelet count and AST >ALT – does patient have advanced fibrosis?
- Medicaid health insurance criteria for hepatitis C treatment must meet >F2 fibrosis.

### What to do next

Advise patient to abstain from alcohol use

Consider hepatitis B vaccination

Order LIVERFASt™

Need to determine the stage of hepatic fibrosis:

- Does David have advanced fibrosis [F3-F4]?
- Does David meet minimum fibrosis criteria to qualify for treatment as per Medicaid?

Any other coexistent liver diseases - Need to determine the degree of hepatic steatosis with history of obesity, diabetes, and alcohol use?

## LIVERFASt™ Result

### Fibrosis

**0.73 – F3 – Significant fibrosis**

### Activity

**0.52 – A2 – Moderate activity**

### Steatosis

**0.75 – S3 – Marked steatosis**

## After LIVERFASt™

**Patient approved for direct acting antiviral HCV therapy. Check abdominal ultrasound every 6 months for liver cancer surveillance. Prescribe LiverFASt™ to monitor patient progression as needed.**

Reference – www.hcvguidelines.org – update August 2020 – Recommendation for pretreatment assessment – "Evaluation for advanced fibrosis using noninvasive markers and/or elastography, and rarely liver biopsy, is recommended for all persons with HCV infection to facilitate decision making regarding HCV treatment strategy and determine the need for initiating additional measures for the management of cirrhosis [eg. hepatocellular carcinoma screening]".

LIVERFASt Proprietary CPT Code 0166U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References
1 http://www.ncbi.nlm.nih.gov/pubmed/26171595
2 http://onlinelibrary.wiley.com.ezproxyhhs.nihlibrary.nih.gov/doi/10.1002/hep.28109/epdf Roberts et al
3.Aravind A et al. Machine Learning Technology for Evaluation of Liver Fibrosis, Inflammation Activity and Steatosis (LIVERFASt™) JILSA 2020, 12, 31-49.
4. Lim SG et al. Predictive value of non-invasive methods liverfast, acoustic radiation force impulse (ARFI), FIB-4 and APRI to identify the natural phases of chronic hepatitis B (CHB) infection from the National University Hospital (NUH) CHB study cohort of Singapore. Submitted to AASLD Liver Meeting 2020
5.Tangvoraphonkchai K. et al. Comparative assessment liver lesions using non-invasive serum biomarkers Liverfast, FIB4, APRI and liver stiffness measurement (LSM, Fibroscan) in chronic hepatitis C (CHC) patients with liver biopsy.


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