

LIVERFAST™

Fibrosis • Activity • Steatosis

Up to **2.2 million** people are
chronically infected with **Hepatitis B**
in the United States

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™** fibrosis and activity scores discriminate between chronic hepatitis and chronic HBV infection in both HBeAg positive and negative.
- **LIVERFAST™** has superior performance compared to ARFI* and FIB-4* to discriminate between chronic hepatitis and chronic HBV infections in both HBeAg positive and negative.
- **LIVERFAST™** helps to identify patients at risk to develop more severe disease.
- **LIVERFAST™** fibrosis and activity scores have higher NPV* than APRI*, FIB-4* and ARFI*.

* **ARFI** - Acoustic Radiation Force Impulse; **NPV** - Negative Predictive Value; **APRI** - Aspartate Aminotransferase to Platelet Ratio Index; **FIB-4** - Fibrosis-4 (Age, ALT, AST and Platelet)

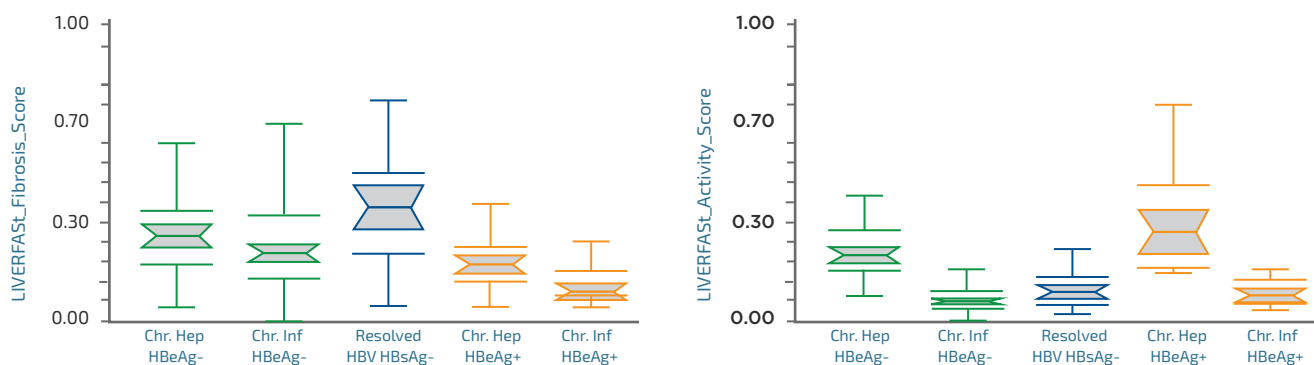
References

Lim SG, Tay A, Wai Khine HHT, Marcos Dangbis J, Gonzalo T, Quiambao R. 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. Hepatology 2020;72:1(Suppl):937A

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

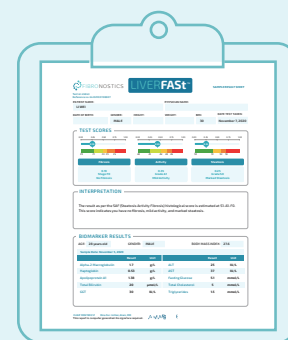
Why LIVERFAST™?

1. Detect fibrosis in the early stages to cirrhosis concomitantly with necroinflammatory activity.^{3,4}
2. Follow up: Reliable and easily repeatable fibrosis assessment for progression or regression, without any impact by flares in activity.⁴
3. Prognosis: Provides long term prognosis value by stratifying fibrosis.^{3,4}
4. Chronic HBV: No activity or fibrosis defines the patient as low risk (inactive carrier HBeAg negative).⁴



Li Wei
28 | Male

- Diagnosed with chronic hepatitis B at age of 6 years
- Asymptomatic
- No other medical conditions



Before LIVERFAST™

Laboratory Results

- Fasting blood glucose 95 mg/dL
- AST 25 IU/L
- ALT 37 IU/L
- AFP 2 IU/mL
- Hepatitis B surface antigen positive
- Hepatitis Be Antigen positive
- HBV DNA PCR quantitative 15,200,000 IU/mL

Radiology Results

Abdominal ultrasound – normal

Clinical Assessment

Immune-Active vs. Immune-Tolerant chronic hepatitis B

What to do next?

Order LIVERFAST™

Need to determine the stage of hepatic fibrosis and grade of inflammation.

LIVERFAST™ Result

Fibrosis

0.19 – F0 – No fibrosis

Activity

0.35 – A1 – Mild activity

Steatosis

0.25 – S0 – No steatosis

After LIVERFAST™

Chronic HBV infection with HBeAg positive - Requires regular monitoring to assess the need for future therapy. Prescribe LiverFAST™ to monitor patient progression as needed.

Reference – Hepatitis B AASLD Practice Guidelines – Hepatology, vol.67, number 4, 2018 – “Immune-tolerant chronic hepatitis B patients should be monitored at 3 to 6 month intervals. Patients with moderate to severe inflammation [A3 or higher] and/or fibrosis [F2 or higher] can be considered for antiviral therapy. Noninvasive methods may be used in lieu of liver biopsies to assess for severity of fibrosis and/or inflammation”.

LIVERFAST Proprietary CPT Code 0166U

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. Lim SG, et al. Hepatology 2020;72:(Suppl):937A