

HEPATITIS C VIRUS (HCV) FIBROSURE®



Noninvasive assessment of liver fibrosis and necroinflammatory activity for patients with HCV

HCV FibroSure® is a noninvasive blood test of 6 biochemical markers that provides METAVIR fibrosis staging and necroinflammatory grading. HCV FibroSure has been validated against liver biopsy in multiple studies,¹⁻³ and has demonstrated diagnostic value comparable to liver biopsy in assessing fibrosis.²

Clinical Application

- HCV FibroSure is a quantitative assessment of liver fibrosis ranging from 0.00 to 1.00. This range corresponds to the established METAVIR scoring stages F0–F4.
- FibroSure additionally provides a measure of necroinflammatory activity, corresponding to METAVIR activity grades A0–A3.^{1,2}
- A FibroSure result may be used, in combination with other noninvasive markers, to support or rule out the need for a liver biopsy.^{4,5}
- While liver biopsy is considered the gold standard, FibroSure may help in assessing liver status in individuals who are at risk for biopsy complications.
- FibroSure may supplement biopsy in cases of equivocal results or concern of biopsy sampling error.
- HCV FibroSure may be used in the following circumstances:
 - Assessment of liver status following a diagnosis of HCV
 - Pretreatment baseline and/or posttreatment assessment during HCV therapy
 - Liver status of patients with HIV/HCV coinfection¹
 - Monitoring and treatment of patients with HBV¹

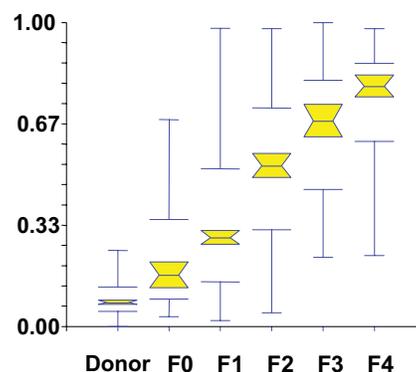
Scientific Expertise

- FibroSure has been tested and validated in numerous study populations over the last 8 years.
- Six biochemical markers are combined with age and gender to provide both fibrosis staging and necroinflammatory grading.

Superior Service

- Comprehensive testing services for the management of HCV and HBV patients
- Broad network of managed care health plans
- Connectivity with more than 350 practice management and EMR systems
- Patient service centers available nationwide

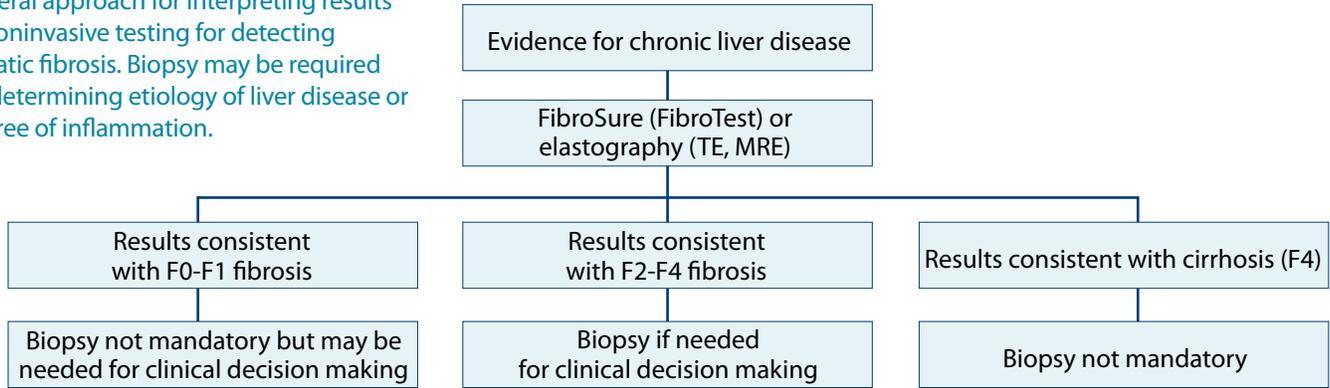
Conversion between HCV FibroSure and Fibrosis Stage



Adapted from *Comparative Hepatology*, 2004, 3:8.

Notched box plots reflect the median distribution of data and show a linear relationship between FibroSure results and progressive liver fibrosis as measured by METAVIR scoring F0–F4.

General approach for interpreting results of noninvasive testing for detecting hepatic fibrosis. Biopsy may be required for determining etiology of liver disease or degree of inflammation.



Hepatology. 2011;53(6):2107-2110.

FibroSure Components

- Alanine aminotransferase (ALT)
- α2-macroglobulin
- Apolipoprotein A1
- Bilirubin, total
- γ-glutamyl transferase (GGT)
- Haptoglobin
- Patient's age and sex

For more information, please contact your local account representative.

Test Name	Hepatitis C Virus (HCV) FibroSure®
Test Number	550123

METAVIR Group Scoring System

Fibrosis Stage (FibroTest)	Range
F0 – No fibrosis	0.00-0.21
F0-F1	> 0.21-0.27
F1 – Portal fibrosis	> 0.27-0.31
F1-F2	> 0.31-0.48
F2 – Bridging fibrosis with few septa	> 0.48-0.58
F3 – Bridging fibrosis with many septa	> 0.58-0.72
F3-F4	> 0.72-0.74
F4 – Cirrhosis	> 0.74-1.00
Activity Stage (ActiTest)	Range
A0 – No activity	0.00-0.17
A0-A1	> 0.17-0.29
A1 – Minimal activity	> 0.29-0.36
A1-A2	> 0.36-0.52
A2 – Moderate activity	> 0.52-0.60
A2-A3	> 0.60-0.63
A3 – Severe activity	> 0.63-1.00

For the most current information regarding test options, including specimen requirements and CPT codes, please consult the online Test Menu at www.LabCorp.com.

References

1. Poynard T, Imbert-Bismut F, Munteanu M, et al. Overview of the diagnostic value of biochemical markers of liver fibrosis (FibroTest, HCV FibroSure) and necrosis (ActiTest) in patients with chronic hepatitis C. *Comp Hepatol*. 2004 Sept 23;3:8.
2. Poynard T, Morra R, Halfon P, et al. Meta-analyses of FibroTest diagnostic value in chronic liver disease. *BMC Gastroenterology*. 2007 Oct 15;7:40.
3. Crockett SD, Kaltenbach T, Keefe EB. Do we still need a liver biopsy? Are the serum fibrosis tests ready for prime time? *Clin Liver Dis*. 2006;10:513-534.
4. Sebastiani G, Vario A, Guido M, et al. Stepwise combination algorithms of non-invasive markers to diagnose significant fibrosis in chronic hepatitis C. *J Hepatol*. 2006;44:686-693.
5. Sebastiani G, Vario A, Guido M, Alberti A. Sequential algorithms combining non-invasive markers and biopsy for the assessment of liver fibrosis in chronic hepatitis B. *World J Gastroenterol*. 2007;13:525-531.

