CHRONIC HEPATITIS

BioReference LABORATORIES
an OPKO Health Company

THE PATH TO **MEASURING LIVER FIBROSIS AND ACTIVITY**

For some people, Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) can be acute, or short-term, illnesses. But for others, HBV and HCV can become long-term, chronic infections.

The CDC estimates that there are 850,000–2.2 million people living with chronic HBV in the United States. If left unmanaged, the infection can lead to serious health issues like cirrhosis or liver cancer. An estimated 2.7–3.9 million people in the United States have chronic HCV, and most people do not know they are infected because they are not clinically ill. HCV can result in long-term health problems, such as chronic liver disease, cirrhosis or, liver cancer and even death.

What is Liver Fibrosis and Activity?

The progression of chronic HBV and HCV infections can be measured through the prognosis of the liver's fibrosis (scarring) and activity (inflammation).

- Liver fibrosis is the process of scarring through fibrous tissue deposit, which results in the destruction of the parenchyma. The ultimate progressive stage of fibrosis is cirrhosis.
- Liver activity estimates the amount of portal inflammation and hepatocellular necrosis provoked by HBV and HCV infections.

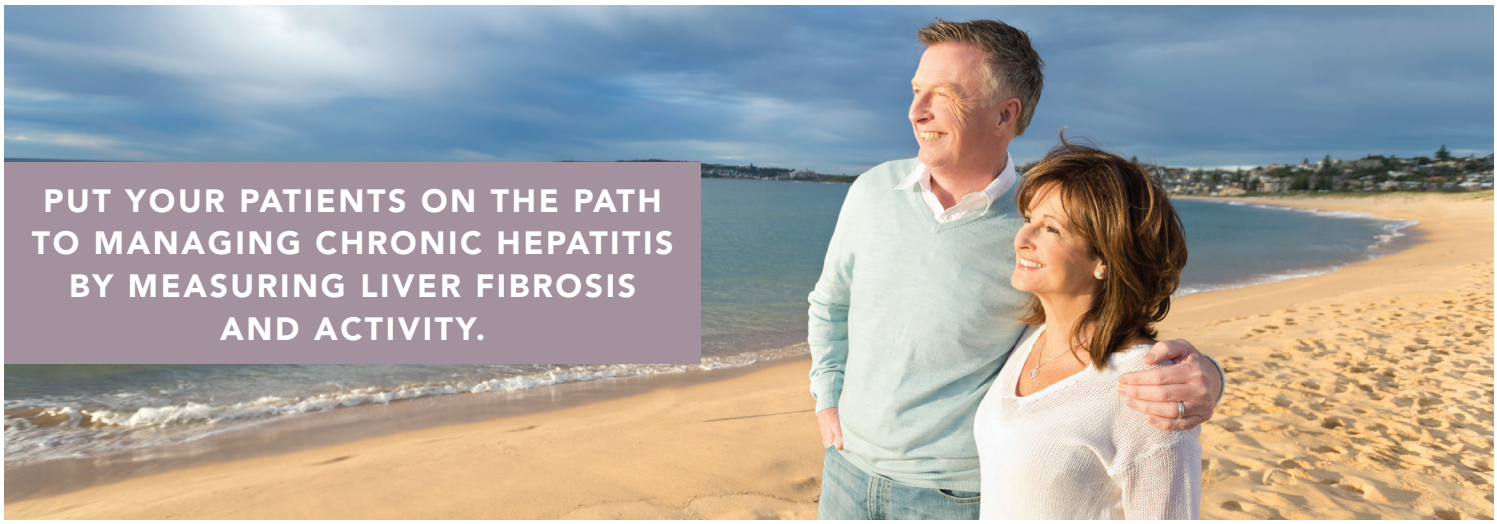
What is FibroTest-ActiTest®?

FibroTest-ActiTest is a non-invasive blood test that can predict the amount of fibrosis and activity of the liver in chronic HBV and HCV infections.

- FibroTest measures liver fibrosis with an algorithm that consists of five biomarkers (alpha-2-macroglobulin, apolipoproteinA1, total bilirubin, haptoglobin and Gamma GT), and provides result scores on a scale of 0 to 1.
- ActiTest measures liver activity by combining the FibroTest markers with the marker for inflammatory activity, Alanine aminotransferase (ALT), and provides result scores on a scale of 0 to 1.

Why FibroTest-ActiTest?

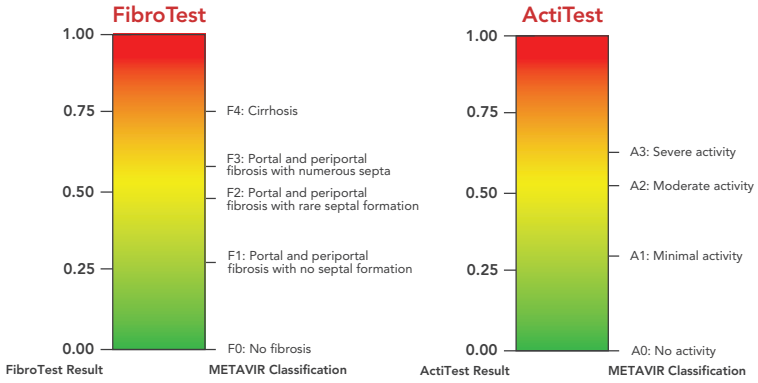
While traditional liver biopsy is the gold standard for measuring fibrosis and activity, it is an invasive test with attendant risk of morbity from bleeding, collapsed lung and peritonitis. FibroTest-ActiTest has the same diagnostic relevance as a 25mm liver biopsy, is easily reproduced and has the accuracy of a biochemical measurement (coefficient of variation < 5 percent).



Interpretation of Results

One of the most used histological classification scores for chronic HBV and HCV infections is the METAVIR system, which assesses fibrosis according to a five-stage classification and activity according to a four-grade classification. FibroTest-ActiTest proportionately measures the severity of the fibrosis and activity with a conversion to the METAVIR classification. Each report provides the FibroTest and ActiTest score, correlating METAVIR classification and results interpretation notes.

The colored charts below compare FibroTest and ActiTest scores with the METAVIR classifications, and indicate the various classes of severity:



The ranges below convert the FibroTest and ActiTest scores into the METAVIR classification:

FibroTest Score	METAVIR Fibrosis Stage	ActiTest Score	METAVIR Activity Grade
0.75-1.00	F4		
0.73-0.74	F3-F4	0.62-1.00	A3
0.59-0.72	F3	0.61-0.62	A2-A3
0.49-0.58	F2	0.53-0.60	A2
0.32-0.48	F1-F2	0.37-0.52	A1-A2
0.28-0.31	F1	0.30-0.36	A1
0.22-0.27	F0-F1	0.18-0.29	A0-A1
0.00-0.21	F0	0.00-0.17	A0

Results Precautions:

- The reliability of results is dependent on compliance with the preanalytical and analytical conditions recommended by BioPredictive.
- The tests have to be deferred for acute hemolysis, acute hepatitis, inflammation and extra hepatic cholestasis.
- The advice of a specialist should be sought for interpretation in chronic hemolysis and Gilbert's syndrome.
- The test interpretation is not validated in liver transplant patients.
- Isolated extreme values of one of the components should lead to caution in interpreting the results.
- In case of discordance between a biopsy result and FibroTest–ActiTest, it is recommended to seek the advice of a specialist. The causes of these discordances could be due to a flaw of the Test or to a flaw in the biopsy: i.e., a liver biopsy has a 33% variability rate for one fibrosis stage.
- FibroTest is interpretable for both chronic HBV and HCV and alcoholic and non-alcoholic steatosis (NASH).
- ActiTest is interpretable for chronic HBV and HCV.

HIGHLIGHTS AND REFERENCES:	
Test Code:	H510-1
Specimen Requirements:	SST
Storage Requirements:	Refrigerate
Turn-Around-Time:	4 Days
CPT Codes:	82172; 82247; 82977; 83010; 83883; 84460

Additional Resources:

http://www.biopredictive.com
http://www.cdc.gov/hepatitis

REFERENCES:

1. Salkic NN, et al. FibroTest Fibrosure for significant liver fibrosis and cirrhosis in chronic hepatitis B: A meta-analysis. Am J Gastroenterol 2014;109:796-809.
2. Sebastiani G, et al. The impact of liver disease aetiology and the stages of hepatic fibrosis on the performance of non invasive fibrosis markers: An international study of 2411 cases. Aliment Pharmacol Ther 2011;34:1202-1216.

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