



Test Description

PROMETHEUS[®] FIBROSpect[®] II testing can aid physicians in differentiating no/mild liver fibrosis from moderate-to-severe liver fibrosis in patients with hepatitis C. FIBROSpect[®] II is now designed to differentiate between lower-stage (METAVIR F0-F2) and advanced liver fibrosis/cirrhosis (METAVIR F3-F4). Due to sampling error and the relative risk of biopsy, PROMETHEUS FIBROSpect II testing is useful for initial patient evaluation, to reduce the need for liver biopsy, as an adjunct to biopsy and when biopsy is contraindicated or refused.

- A quantitative analysis of hyaluronic acid (HA), tissue inhibitor of metalloproteinase (TIMP-1), and α 2-macroglobulin (AMG) interpreted utilizing an algorithm to predict with no indeterminate results the likelihood of liver fibrosis in patients with hepatitis C.
- PROMETHEUS FIBROSpect II is only offered at Prometheus
- Patent protected
- **Specimen Requirements** – 2.0 ml Serum, SST or Red Top Tube
- **Shipping Requirements** – Ambient or cold pack
- **Storage Stability** – 7 days ambient, 30 days refrigerated
- **Turn Around Time** – 4 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
4000	FIBROSpect II	Alpha-2 macroglobulin	0 – 41 Consistent with METAVIR F0-F2 42-100 Consistent with METAVIR F3-F4	A00054
		Hyaluronic Acid		A00055
		Tissue Inhibitor Metalloproteinase Type 1		A00056
		FIBROSpect II Index		A00031

*Result identifier provided for use in HL7 applications.

Laboratory Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- This test was developed and its performance characteristics determined by Prometheus Laboratories Inc. It has not been cleared or approved by the U.S. Food and Drug Administration. Prometheus Laboratories Inc. is a CAP-accredited CLIA laboratory.

CPT Codes (as applied by Prometheus)

- 83883, AMG, by Nephelometry
- 83520, HA, ELISA
- 82397, TIMP-1, Chemiluminescence

Literature References

- K. Patel et al. Evaluation of a panel of non-invasive serum markers to differentiate mild from moderate –to-advanced liver fibrosis in chronic hepatitis C patients. *J Hepatol.* 2004;41:935-942.
- A. Zaman et al., Assessment of FIBROSpect II to Detect Hepatic Fibrosis in Chronic Hepatitis C Patients. *Am. J Med* 2007;120:280.e9-280.e14.
- C. Christensen et al., Diagnostic accuracy of a fibrosis serum panel (FIBROSpect II) compared with Knodell and Ishak liver biopsy scores in chronic hepatitis C patients. *J Viral Hepatitis* 2006;13:652-658.
- K. Patel et al., Correlation of FIBROSpect II With Histologic and Morphometric Evaluation of Liver Fibrosis in Chronic Hepatitis C. *Clin Gastroenterol H* 2008;6:242-247.
- K. Patel et al., An independent and prospective comparison of two commercial fibrosis marker panels (HCV FibroSURE and FIBROSpect II) during albinferon alfa-2b combination therapy for chronic hepatitis C. *J Viral Hepatitis* 2009;16:178-186.
- Data on File. Prometheus Laboratories Inc. DOF 16-001, 01/2016

Assays and methods within this test may be covered by one or more US pending or issued patents. For details, please visit www.prometheuslabs.com

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