



Test Description

The PROMETHEUS[®] FIBROSpect[®] HCV test helps detect, stage, and monitor liver fibrosis in hepatitis C (HCV) patients. The test is a non-invasive, serum diagnostic that provides a quantitative fibrosis score to help physicians risk stratify and monitor patients based on 3 clinically relevant biomarkers.

- A quantitative analysis of hyaluronic acid (HA), tissue inhibitor of metalloproteinase (TIMP-1), and alpha-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 HCV is only offered by Prometheus**
- **Specimen Requirements** - 2.0 mL Serum, SST or Red Top Tube
- **Shipping Requirements** - Ambient or cold pack is acceptable
- **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 HCV	Alpha-2 macroglobulin	0 – 41 Consistent with fibrosis score F0-F1 42-100 Consistent with fibrosis score F2-F4	A00054
		Hyaluronic Acid		A00055
		Tissue Inhibitor Metaloproteinase Type 1		A00056
		FIBROSpect HCV 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 all 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 (Alpha-2 macroglobulin), by Nephelometry
- 83520, HA (Hyaluronic Acid)
- 82397, TIMP-1, Chemiluminescent

Literature References

- Data on file, Prometheus Laboratories Inc. DOF17-003, 07/2017.
- 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(3):280.e9-280.e9-14.
- 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 albinterferon alfa-2b combination therapy for chronic hepatitis C. *J Viral Hepatitis.* 2009;16:178-186.

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

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