

## PROMETHEUS<sup>®</sup> FIBRO<sup>®</sup>Spect<sup>®</sup> II Cat. # 4000

### Product Description

PROMETHEUS<sup>®</sup> FIBRO<sup>®</sup>Spect<sup>®</sup> II testing can aid physicians in differentiating no/mild liver fibrosis from moderate-to-severe liver fibrosis in patients with hepatitis C, and may help reduce the number of liver biopsies required. Due to sampling error and the relative risk of biopsy, PROMETHEUS FIBRO<sup>®</sup>Spect<sup>®</sup> II testing is useful for initial patient evaluation and when biopsy is contraindicated or refused.

- 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 FIBRO<sup>®</sup>Spect<sup>®</sup> II is only offered at Prometheus Laboratories Inc.
- Patent protected.
- **Specimen Requirements** - Serum, 2.0 mL: SST or Red Top Tube.
- **Shipping and Handling** - Ambient or refrigerated.
- **Storage Conditions/Stability** - 7 days.
- **Turn Around Time** - 4 business days from date of receipt.
- **Index Reference Range** - 0-41 Consistent with METAVIR F0-F1; 42-100 Consistent with METAVIR F2-F4.

### Facilities Description

- Prometheus is located in San Diego, CA. **Tax ID#** 33-0685754 **NPI#** 1073642641.
- Licensed in several states including New York and California.
- Prometheus Laboratories Inc. is CLIA certified and accredited by the College of American Pathologists. 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.

### CPT Codes (as applied by Prometheus)

- **83883**, AMG, by Nephelometry
- **83520(X2)**, HA & TIMP-1), ELISA, quantitative

### Literature References

- Jeffers LJ, Cortes RA, Bejarano PA, et al. Prospective evaluation of FIBRO<sup>®</sup>Spect<sup>®</sup> II for fibrosis detection in hepatitis C and B patients undergoing laparoscopic biopsy. *Gastro Hepatol.* 2007;3(5):367-376.
- Patel K, 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.
- Regev A, et al. Sampling error and intraobserver variation in liver biopsy in patients with chronic HCV infection. *Am J Gastroenterol.* 2002;97(10):2614-2618.