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 α2-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

<table>
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<tr>
<th>Catalog Number</th>
<th>Test Name</th>
<th>Assay</th>
<th>Reference Value</th>
<th>Result Identifier*</th>
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<td>FIBROspect II</td>
<td>Alpha-2 macroglobulin</td>
<td>0 – 41 Consistent with METAVIR F0-F2</td>
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<td>Hyaluronic Acid</td>
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<td>Tissue Inhibitor Metaloproteinase Type 1</td>
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<td>FIBROspect II Index</td>
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*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

- 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.
- 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

FIB16005 04/16