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

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Test Name</th>
<th>Assay</th>
<th>Reference Value</th>
<th>Result Identifier*</th>
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<tr>
<td>4000</td>
<td>FIBROspectrum HCV</td>
<td>Alpha-2 macroglobulin</td>
<td>0 – 41 Consistent with fibrosis score F0-F1</td>
<td>A00054</td>
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<td>Hyaluronic Acid</td>
<td>42-100 Consistent with fibrosis score F2-F4</td>
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<td>Tissue Inhibitor Metaloproteinase Type 1</td>
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<td>FIBROspectrum HCV Index</td>
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</table>

*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.
- C. Christensen et al., Diagnostic accuracy of a fibrosis serum panel (FIBROspectrum II) compared with Knodell and Ishak liver biopsy scores in chronic hepatitis C patients. J Viral Hepatitis. 2006;13:652-658.

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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