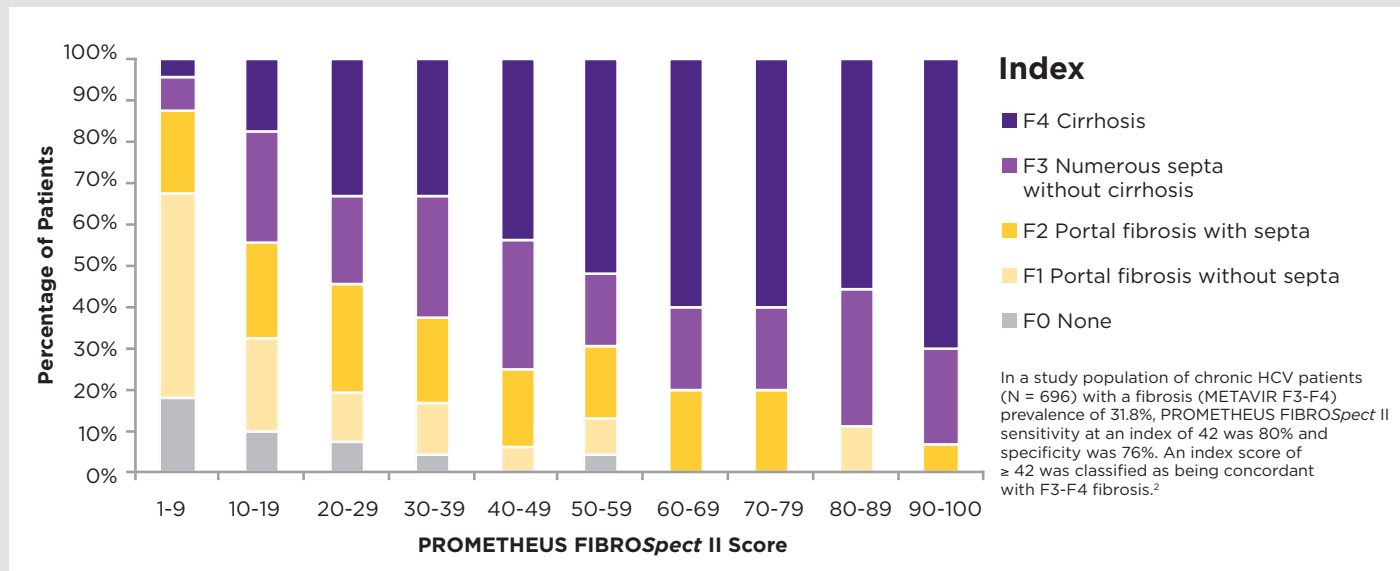


# Added clarity in detecting liver fibrosis

**PROMETHEUS® FIBROSpect® II is now designed to differentiate lower-stage (METAVIR F0-F2) from advanced liver fibrosis/cirrhosis (METAVIR F3-F4), which may help with hepatitis C virus treatment authorization and reimbursement.**

Provides the determinant test results you need

Unique set of extracellular matrix biomarkers combined with a proprietary algorithm helps diagnose liver fibrosis using a novel index for individualized patient results<sup>1</sup>



F0-F2  
F3-F4

PROMETHEUS®  
**FIBROSpect® II**

# Noninvasive.

# Nonfasting.

# Always provides determinant test results.

PROMETHEUS®  
**FIBROSpect® II**

- May reduce the need for liver biopsy, be used as an adjunct to biopsy, or used when biopsy is contraindicated
- Many advantages over liver biopsy:
  - No risk of indeterminate test results
  - Validated predictive algorithm is objective
  - Can be repeated frequently, easily, and safely
  - No surgical costs

“An accurate assessment of fibrosis is vital in assessing the urgency for treatment...”

— AASLD-IDSAs  
Recommendations<sup>3</sup>

| Patient & Order Information                    |                                 | Report Recipient   |
|--|---------------------------------|--|
| Order ID<br><b>3256116</b>                     | Patient<br><b>Patient, Test</b> | Example Medcenter<br>AAA Medical Laboratory<br>5678 South Main Street<br>Suite 150, MailDrop SM80<br>San Diego, CA 92121 |
| DOB<br><b>05/05/1955</b>                       | SSN<br><b>XXX-XX-0000</b>       | Sex<br><b>M</b>  |
| Institution ID<br><b>Prometheus ID 2057095</b> | Ordered<br><b>01/26/2016</b>    | Completed<br><b>01/26/2016</b>   |
| Ordered By<br><b>Ordering Physician M.D.</b>   | Sample ID: <b>ST12345678</b>    | Collection Date: <b>01/26/2016 5:40AM (Serum)</b>  |
| Institution Sample ID:                         |                                 | 555/555-3456 Phone 555/555-6789 Fax  |

| Test Result | Clinical Interpretation              | FIBROSpect II Index Reference Range  |
|-------------|--------------------------------------|--|
| <b>81</b>   | <b>Consistent with METAVIR F3-F4</b> | <b>0 - 41 Consistent with METAVIR F0-F2<br/>42 - 100 Consistent with METAVIR F3-F4</b> |

**FIBROSpect II Index Interpretation**  
In a study population of chronic HCV patients (n=402) with a fibrosis (METAVIR F3-F4) prevalence of 31.8%, FIBROSpect II sensitivity at an index of 42 was 80% and the specificity was 70%. Tests performed to determine FIBROSpect II result: alpha-2-macroglobulin (AMG) by nephelometry, Tissue inhibitor of metalloproteinases-1 (TIMP-1) by electrochemoluminescence, Hyaluronic acid (HA) by ELISA.

**METAVIR Description**  
F0 - No fibrosis  
F1 - Portal tract fibrosis  
F2 - Septal fibrosis  
F3 - Bridging fibrosis  
F4 - Cirrhosis

**Reference Range Studies**  
In a study population of chronic HCV patients (n=402) with a fibrosis (METAVIR F3-F4) prevalence of 31.8%, FIBROSpect II sensitivity at an index of 42 was 80% and the specificity was 70%. Tests performed to determine FIBROSpect II result: alpha-2-macroglobulin (AMG) by nephelometry, Tissue inhibitor of metalloproteinases-1 (TIMP-1) by electrochemoluminescence, Hyaluronic acid (HA) by ELISA.

- 1) 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;41:305-312.
- 2) A. Zaman et al., Assessment of FIBROSpect II to Detect Hepatic Fibrosis in Chronic Hepatitis C Patients. *Am J Med* 2007;120(3):280-284.
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- 5) K. Patel et al., An independent and prospective comparison of two commercial fibrosis marker panels (HCV FibroSURE and FIBROSpect II) during interferon alpha-2b combination therapy for chronic hepatitis C. *J Viral Hepatitis* 2009;16:175-185.
- 6) Data on file, Prometheus Laboratories Inc. DOP16-001, 01/2016.

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 108.11

**References:** 1. The French METAVIR Cooperative Study Group. Intraobserver and interobserver variations in liver biopsy interpretation in patients with chronic hepatitis C. *Hepatology*. 1994;20(1 pt 1):15-20. 2. Data on file. Prometheus Laboratories Inc. 3. AASLD/IDSAs HCV Guidance Panel. Hepatitis C guidance: AASLD-IDSAs recommendations for testing, managing, and treating adults infected with hepatitis C virus. *Hepatology*. 2015;62(3):932-954.

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