

Patient Name: Susie Q Example

Ordering Physician: Michael Hew M.D.

Birth Date: 05/05/1966	Sex: F	SSN: 555-55-5555	Order ID: 123456789	Patient ID: 0123456789	Report Recipient: Example Medcenter 5678 South Main Street San Diego, CA 92121	Contact Info: P: (858) 555-3456 F: (858) 555-3458
Ordered: 10/03/2017	Collected: 10/02/2017 8:30 AM	Type: Serum	Reported: 10/06/2017	Sample ID: ST12345686	Institution Sample ID: 1524502088	

Test Results

58
 PROMETHEUS®
 FIBROSpect® HCV
 Index

Fibrosis Score
F2-F4
 Clinical Interpretation

FIBROSpect HCV Index Reference Range
0 - 41: Consistent with fibrosis score F0-F1
42 - 100: Consistent with fibrosis score F2-F4

Fibrosis Score Description
F0: No fibrosis
F1: Portal tract fibrosis
F2: Septal fibrosis
F3: Bridging fibrosis
F4: Cirrhosis

General Test Information

- In a study population of 696 well-characterized, clinically diagnosed HCV patients with fibrosis (N=696), 348 patient samples were used for training and 348 patient samples were used for validation. In the validation samples, the prevalence of F2-F4, using the METAVIR fibrosis scoring system, was 51.7%. At a FIBROSpect HCV index of 42, the sensitivity and specificity for differentiating F0-F1 from F2-F4 were 82.2% and 70.8%, respectively.
- FIBROSpect HCV test result is analyzed using assays for alpha-2 macroglobulin (AMG) by nephelometry, tissue inhibitor of metalloproteinases (TIMP-1) by chemiluminescence, and hyaluronic acid (HA) by ELISA.

References: **1.** Data on File. Prometheus Laboratories Inc. DOF17-003, 07/2017. **2.** Patel K, Gordon SC, Jacobson I, 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. **3.** Zaman A, Rosen HR, Ingram K, et al. Assessment of FIBROSpect II to detect hepatic fibrosis in chronic hepatitis C patients. *Am J Med.* 2007;120(3):280.e9-14. **4.** Christensen C, Bruden D, Livingston S, 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 Hepat.* 2006;13:652-658. **5.** Patel K, Nelson DR, Rockey DC, et al. Correlation of FIBROSpect II with histologic and morphometric evaluation of liver fibrosis in chronic hepatitis C. *Clin Gastroenterol Hepatol.* 2008;6:242-247. **6.** Patel K, Benhamou Y, Yoshida EM, 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.

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Curtis A. McGuyer, MD, Medical Director

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