



Test Description

The PROMETHEUS[®] FIBRO*Spect*[®] NASH test helps detect, stage, and monitor liver fibrosis in nonalcoholic steatohepatitis (NASH) 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 the likelihood of liver fibrosis in nonalcoholic steatohepatitis (NASH) patients.
- **PROMETHEUS FIBRO*Spect* NASH is only offered by Prometheus**
- **Specimen Requirements** - 2.0 mL Serum, SST or Red Top Tube
- **Shipping Requirements** - Ambient or cold pack acceptable
- **Storage / Stability** - 7 days ambient, 30 days refrigerated
- **Turn Around Time** - 4 business days from date of receipt

Test Information

Catalog Number	Test Name	Assay	Reference Value	Result Identifier*
4100	FIBRO <i>Spect</i> NASH	Alpha-2 macroglobulin	0 – 16 Consistent with fibrosis score F0-F2 17-100 Consistent with fibrosis score F3-F4	A00054
		Hyaluronic Acid		A00055
		Tissue Inhibitor Metaloproteinase Type 1		A00056
		FIBRO <i>Spect</i> NASH Index		A00114

*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.
- Abdelmalek MF, Diehl AM, Guy CD, et al. Serum-based biomarker test accurately stratifies hepatic fibrosis in patients with Nonalcoholic Steatohepatitis. American Association for the Study of Liver Diseases; October 2017; Washington, DC.
- Angulo P, Kleiner DE, Dam-Larsen S, et al. Liver fibrosis, but No Other Histological Features, Is Associated With Long-Term Outcomes of Patients With Nonalcoholic Fatty Liver Disease. *Gastroenterology*. 2015;149(2):389-397.
- Jayakumar S, Harrison SA, Loomba R. Noninvasive Markers of Fibrosis and Inflammation in Nonalcoholic Fatty Liver Disease. *Curr Hepatol Rep*. 2016 June;15(2):86-95.
- Elizabeth M. Brunt, Nonalcoholic Fatty Liver Disease: Pros and Cons of Histologic Systems of Evaluation. *International Journal of Molecular Sciences*. 2016;17(97):1-10.

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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