Alpha Labs

Enhanced Liver Fibrosis (ELF™) Score

An easy, non-invasive way to assess risk of NASH disease progression

20% of patients with non-alcoholic fatty liver disease (NAFLD) progress to non-alcoholic steatohepatitis (NASH), which is strongly linked to liver fibrosis and can lead to cirrhosis, liver transplantation, or even death.[1]

1 in 5

Patients with advanced fibrosis **progress to cirrhosis** in 2.5 years.[2]

#1

It is estimated that by 2030, NASH will be the **#1 most frequent reason for liver transplants** in the U.S.[4]

Who is at risk of NAFLD with significant liver fibrosis and cirrhosis?[3]

People with the following conditions are likely to have NAFLD and **should be considered at high risk** and assessed for liver fibrosis:

- Obesity and/or features of metabolic syndrome
- Prediabetes or type 2 diabetes
- Hepatic steatosis on any imaging study and/or persistently elevated plasma aminotransferase levels (over 6 months)

A non-invasive blood test requiring a single non-fasting tube of serum, the **ELF Score is based on 3 direct markers of fibrosis:**

Hyaluronic acid (HA)
+ Extracellular matrix (ECM) component

Procollagen III N-terminal peptide (PIIINP)
+ ECM component

Tissue inhibitor of metalloproteinase 1 (TIMP-1)
+ Inhibits breakdown of collagen III

2022 NAFLD guideline recommendations for blood testing and referral[3]

According to recommendations for blood testing and referral developed by **AACE** and cosponsored by **AASLD**, patients in the high-risk groups with an **indeterminate or high FIB-4 index** should be considered for further testing with the ELF score.

The ELF Score can be used as a prognostic marker for patients who need urgent specialized intervention.

ELF Score Ranges based on FDA Indication	Risk of Disease Progression (Development of Cirrhosis or Liver-Related Events)
<9.80	Lower
≥9.80 – <11.30	Mid[a]
≥11.30	Higher

[a]In the Mid group, the risk of disease progression is similar to the pre-test risk. Pre-test risk refers to the likelihood of disease progression in the overall intended use population without considering the ELF Score. Results should always be interpreted in conjunction with the patient's medical history, clinical presentation, and other findings.

Test Type	Test Name	Reported Components
ELF	Enhanced Liver Fibrosis (ELF) Score	ELF Score and Interpretation

References

1. Younossi ZM, Koenig A, Abdelatif, D, et al. Global epidemiology of nonalcoholic fatty liver disease-Meta-analytic assessment of prevalence, incidence, and outcomes. *Hepatology.* 2016;64(1):73-84. doi:10.1002/hep.28431.
2. Sanyal AJ, Harrison SA, Ratziu V, et al. The Natural History of Advanced Fibrosis Due to Nonalcoholic Steatohepatitis: Data From the Simtuzumab Trials. *Hepatology.* 2019;70(6):1913-1927. doi:10.1002/hep.30664.
3. Cusi K, Isaacs S, Barb D, et al. American Association of Clinical Endocrinology Clinical Practice Guideline for the Diagnosis and Management of Nonalcoholic Fatty Liver Disease in Primary Care and Endocrinology Clinical Settings: Co-Sponsored by the American Association for the Study of Liver Diseases (AASLD). *Endocr Pract.* 2022 May;28(5):528-562. doi:10.1016/j.eprac.2022.03.010.
4. Charlton MR, Burns JM, Pedersen RA, Watt KD, Heimbach JK, Dierkhising RA. Frequency and Outcomes of Liver Transplantation for Nonalcoholic Steatohepatitis in the United States. *Gastroenterology.* 2011;141(4):1249-1253. doi:10.1053/j.gastro.2011.06.061.

Alpha Labs

Assess liver disease and improve outcomes

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