MAYO CLINIC LABORATORIES

Test Definition: ELF

Enhanced Liver Fibrosis (ELF), Serum

Overview

Useful For

As a prognostic marker in conjunction with other laboratory findings and clinical assessments to assess the likelihood of progression to cirrhosis and liver-related clinical events in patients with advanced fibrosis (F3 or F4) due to metabolic dysfunction-associated steatohepatitis (MASH)

Method Name

Direct Chemiluminescent Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Serum

Specimen Required

Patient Preparation: For 12 hours before specimen collection, patient **should not** take multivitamins or dietary supplements (eg, hair, skin, and nail supplements) containing biotin (vitamin B7).
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 1 mL Serum
Collection Instructions: Within 2 hours of collection, centrifuge and aliquot serum into a plastic vial. **Specimens that have not been aliquoted will be rejected.**

Forms

If not ordering electronically, complete, print, and send Gastroenterology and Hepatology Test Request (T728) with the specimen.

Specimen Minimum Volume

Serum: 0.5 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	OK

Gross icterus	OK

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Refrigerated (preferred)	7 days	
	Ambient	48 hours	
	Frozen	365 days	

Clinical & Interpretive

Clinical Information

Chronic liver disease is a major cause of morbidity and mortality throughout the world. Typical disease etiologies that lead to chronic liver disease include metabolic dysfunction-associated steatotic liver disease (MASLD), alcoholic liver disease, primary sclerosing cholangitis, primary biliary cholangitis, and viral hepatitis due to chronic infection with hepatitis B virus and hepatitis C virus.

Metabolic dysfunction-associated steatotic liver disease is now the most common underlying cause of chronic liver disease.

Within MASLD, metabolic dysfunction-associated steatohepatitis (MASH) is the more severe form, characterized by hepatic steatosis (fatty infiltration of the liver), inflammation, and hepatocyte injury (ballooning).

The clinical course of chronic liver disease is highly variable, but the typical progression involves the advancement of fibrosis, leading to cirrhosis followed by either decompensation or hepatocellular carcinoma, and ultimately liver transplantation or death.

Reference Values

ELF score	Risk of disease progression
> or =9.20	Diagnostic cut-off for clinically significant fibrosis (fibrosis stage 2 or greater)
> or =11.30	Prognostic cut-off for higher risk of progression to liver-related clinical events

Interpretation

A prognostic risk assessment using the enhanced liver fibrosis (ELF) score, in conjunction with other laboratory findings and clinical assessments, may be useful in determining which patients could benefit from additional examinations, increased monitoring, and potential lifestyle changes and treatment interventions.

The ELF score quantifies analytes that are components of the extracellular matrix (ECM), which directly contribute to liver fibrosis. Hyaluronic acid, a glycosaminoglycan produced by hepatic stellate cells, is an essential component within the connective matrix. Amino-terminal propeptide of type III procollagen (PIIINP), produced by fibroblasts in the liver, is

a marker of fibrogenesis and inflammation. Tissue inhibitor of matrix metalloproteinase 1 is a circulating inhibitor of matrix metalloproteinase enzymes that can inhibit fibrolysis and fibrosis repair. Together, these analytes reflect qualitative and quantitative changes in the ECM associated with progression of liver disease.

The ELF score is a prognostic marker for patients with advanced fibrosis (F3 or F4) due to metabolic dysfunction-associated steatohepatitis. ELF is used to assess the risk of progression to cirrhosis and future liver-related clinical events up to 3.9 years following baseline ELF score.

Cautions

Biotin concentrations greater than 150 ng/L falsely decreases propeptide of type iii procollagen and enhanced liver fibrosis score.

In rare cases, some individuals can develop antibodies to mouse or other animal antibodies (often referred to as human anti-mouse antibodies [HAMA] or heterophile antibodies), which may cause interference in some immunoassays. Caution should be used in interpretation of results, and the laboratory should be alerted if the result does not correlate with the clinical presentation.

Clinical Reference

1. Rinella ME, Neuschwander-Tetri BA, Siddiqui MS, et al. AASLD Practice Guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023;77(5):1797-1835. doi:10.1097/HEP.0000000000000323
2. Palladino A, Gee M, Shalhoub V, Kiaei D. Analytical performance of the Enhanced Liver Fibrosis (ELF) Test on the Atellica IM Analyzer. Clin Chim Acta. 2023;548:117461. doi:10.1016/j.cca.2023.117461
3. Sanyal AJ, Shankar SS, Yates KP, et al. Diagnostic performance of circulating biomarkers for non-alcoholic steatohepatitis. Nat Med. 2023;29(10):2656-2664. doi:10.1038/s41591-023-02539-6

Performance

Method Description

The enhanced liver fibrosis (ELF) score uses the measured concentrations of hyaluronic acid (HA), amino-terminal pro-peptide of type III procollagen (PIIINP), and tissue inhibitor of matrix metalloproteinase 1 (TIMP-1), abbreviated as CHA, CPIINP, and CTIMP-1, respectively, in the equation below. Testing is performed using the fully automated ADVIA Centaur instrument with the ADVIA Centaur HA, ADVIA Centaur PIIINP, and ADVIA Centaur TIMP-1 reagents. These reagents are based on 2-site sandwich assay methodology and direct chemiluminescent technology. The concentrations of HA, PIIINP, and TIMP-1 are not reported individually.(Package insert: Advia Centaur XPT ELF. Siemens Healthcare Diagnostics Inc.; 11205858_EN Rev. 02, 10/2022)

The ELF score is calculated from the concentration of the 3 measured analytes using the following equation:
ELF (score) = 2.278 + 0.851 ln(CHA) + 0.751 ln(CPIIINP) + 0.394 ln(CTIMP-1)

PDF Report

No

Day(s) Performed
Monday through Friday

Report Available
Same day/1 to 3 days

Specimen Retention Time
7 days

Performing Laboratory Location
Mayo Clinic Laboratories - Rochester Main Campus

Fees & Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their account representative. For assistance, contact Customer Service.

Test Classification
This test has been cleared, approved, or is exempt by the US Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
81517

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
ELF	ELF (Enhanced Liver Fibrosis), S	88055-9

Result ID	Test Result Name	Result LOINC® Value
ELFSC	ELF Score	88055-9