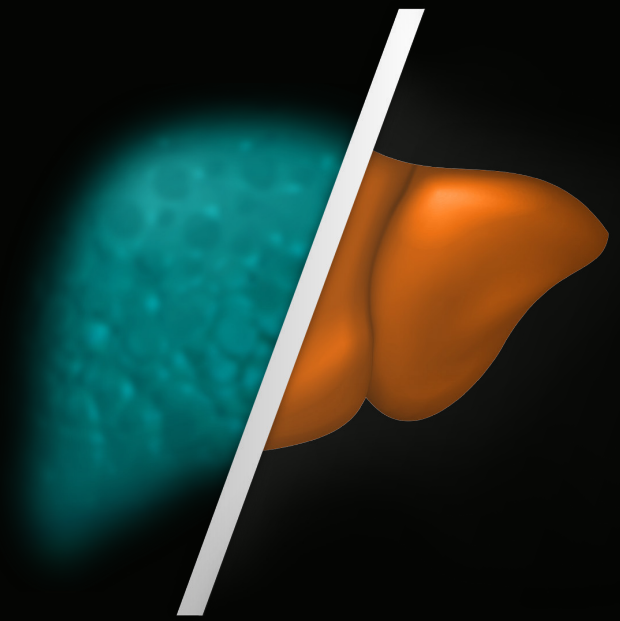
The Enhanced Liver Fibrosis (ELF®) Test

The simple blood test that can assess prognosis of patients with advanced fibrosis due to MASH*.



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*Formerly known as non-alcoholic steatohepatitis (NASH).

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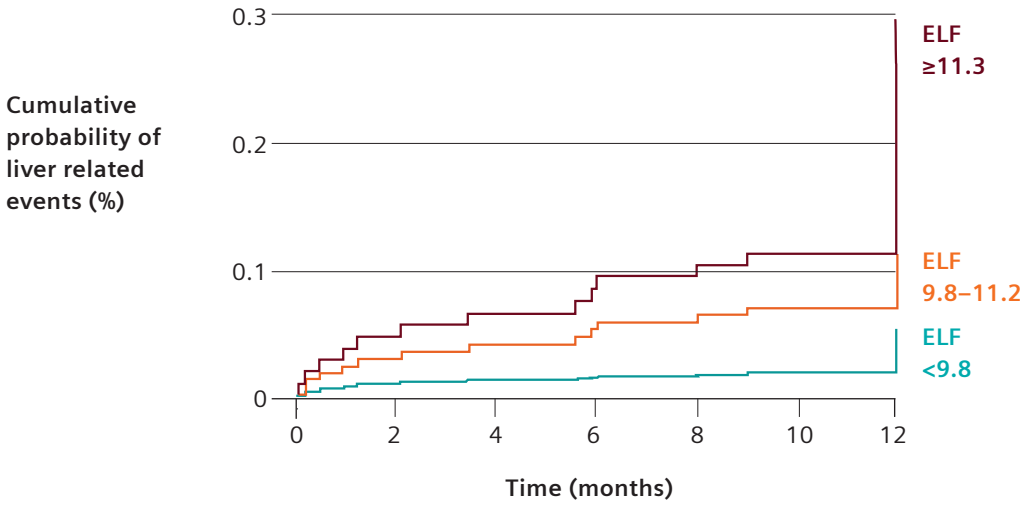
The ELF Test can help determine risk of liver-related events in patients with MASH and compensated cirrhosis

ELF score at baseline[1]



ELF score†	Absolute risk	Likelihood ratio	Hazard ratio
≥11.3	32.7	1.88	4.81
9.8–11.2	16.9	0.79	1.46
<9.8	10.5	0.46	1.00

The results indicated that ELF ≥11.3 is associated with **5x greater risk** of experiencing a liver related event* within a year.

* Liver related events can include:
  - Development or progression of gastroesophageal varices
  - New-onset ascites
  - Variceal hemorrhage
  - Hepatic encephalopathy

1. Are VS, Vuppalanchi R, Vilar-Gomez E, Chalasani N. Enhanced Liver Fibrosis Score Can be Used to Predict Liver-related Events, Clin Gastroenterol Hepatol. 2021;19(6):1292-1293.e3

How does the ELF test work?

The ELF Test measures three serum biomarkers:

1. Hyaluronic acid **(HA)**
2. Amino-terminal propeptide of type III procollagen **(PIIINP)**
3. Tissue inhibitor of matrix metalloproteinase 1 **(TIMP-1)**

The three direct markers are combined into an ELF score

This ELF score indicates the risk of a patient's progression to cirrhosis or liver-related events in the future.

< 9.8	Lower
≥ 9.8 – < 11.3	Mid*
≥ 11.3	Higher

The ELF test measures analytes that reflect active, dynamic fibrosis rather than the damage it has caused.

These individual biomarkers reflect integral extracellular matrix (ECM) components of dynamic fibrogenesis and fibrolysis processes in real time.

In contrast, indirect-biomarker panels merely reflect a mixture of biochemical abnormalities found in chronic liver disease that are not specific to MASH or fibrosis.

Each ELF Test biomarker composing the ELF score is standardized to ensure reproducible analytical and clinical quality.

**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.*

The ELF Test is Clinically Valuable in MASH Prognostic Care

ELF can be integrated into patient management pathways once at-risk patients are identified in primary care

INITIAL VISIT

EVIDENCE OF ≥1 OF THE FOLLOWING:

- Fatty Liver on Imaging?
- BMI ≥ 30?
- Type 2 Diabetes?
- Elevated LFTs?

CALCULATE FIB-4* (standard blood work)

	Under 65	65 & Older‡	
LOW RISK	< 1.3	0-2.67	MONITOR
MEDIUM TO HIGH RISK	≥ 1.3	> 2.67	Once diagnosed with advanced fibrosis due to MASH

***FIB-4 is a simple calculation involving:**

1. Platelet count
2. Age
3. Liver Enzymes (ALT & AST)

ELF Test

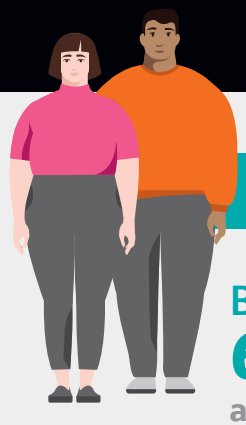
≥9.8 – <11.3	≥ 11.3
Mid risk for progression and liver-related events	Higher risk for progression and liver-related events

NEXT STEPS

- **Start therapy**
- **Intensive Lifestyle Intervention**
- **Change Therapy** *(if applicable)*
- **Refer to Clinical Trial** *(liver biopsy as appropriate)*
- **Further assessment** (may conduct additional tests)

‡ McPherson S, et. al. Age as a Confounding Factor for the Accurate Non-Invasive Diagnosis of Advanced NAFLD Fibrosis. Am J Gastroenterology. 2017 May;112(5):740-751.

Individuals with metabolic diseases are at a higher risk of developing or having metabolic dysfunction-associated steatotic liver disease (MASLD)



Comorbidities

BMI ≥30
60-95%
also have MASLD[3]

Type 2 Diabetes
50-74%
also have MASLD[2]

2 or more features of metabolic syndrome
90%
also have MASLD[5]

Cardiovascular Disease
69%
also have MASLD[6]

Hypertension
50-74%
also have MASLD[4,7]

~12% have lean MASLD[8]

MASLD is seen as the liver manifestation of metabolic syndrome

The ELF Test

The Enhanced Liver Fibrosis (ELF) Test is a noninvasive blood test that quantifies three analytes which directly contribute to liver fibrosis. ELF measurements have proven valuable for assessing the risk of progression to cirrhosis or LREs in patients with advanced fibrosis (F3 or F4) due to MASH.

The widely studied ELF Test measures analytes that reflect active, dynamic fibrosis rather than the damage it has caused. This allows the ELF Test to be used as a prognostic marker.

- Access noninvasive testing with a simple blood test available to all patients, including those with type 2 diabetes mellitus and obesity.[9,10]
- Improve patient care by stratifying the risk of progression to cirrhosis or LREs in patients with advanced fibrosis due to MASH.[11]
- Enhance patient management with a blood test that facilitates more frequent prognostic assessments to optimize patient management.

Reimbursement

CPT Code	81517	$176.19 ✓

The first and only blood test authorized for use as a prognostic marker in patients with advanced fibrosis due to MASH.

Characteristics of an ideal non-invasive MASH test

	Applicable in different patients			Economic Health Value		Access	
	Adults	Obesity	Diabetes	Add Clinical Value	Improve ease and frequency of prognostic evaluation	Simple blood test	Large installed base
The ELF Test	✓	✓	✓	✓	✓	✓	✓

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†The ELF score is derived from an algorithm that combines the quantitative measurements of HA, PIIINP, and TIMP-1 in human serum using the Atellica® IM Analyzer and other legacy instruments.

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