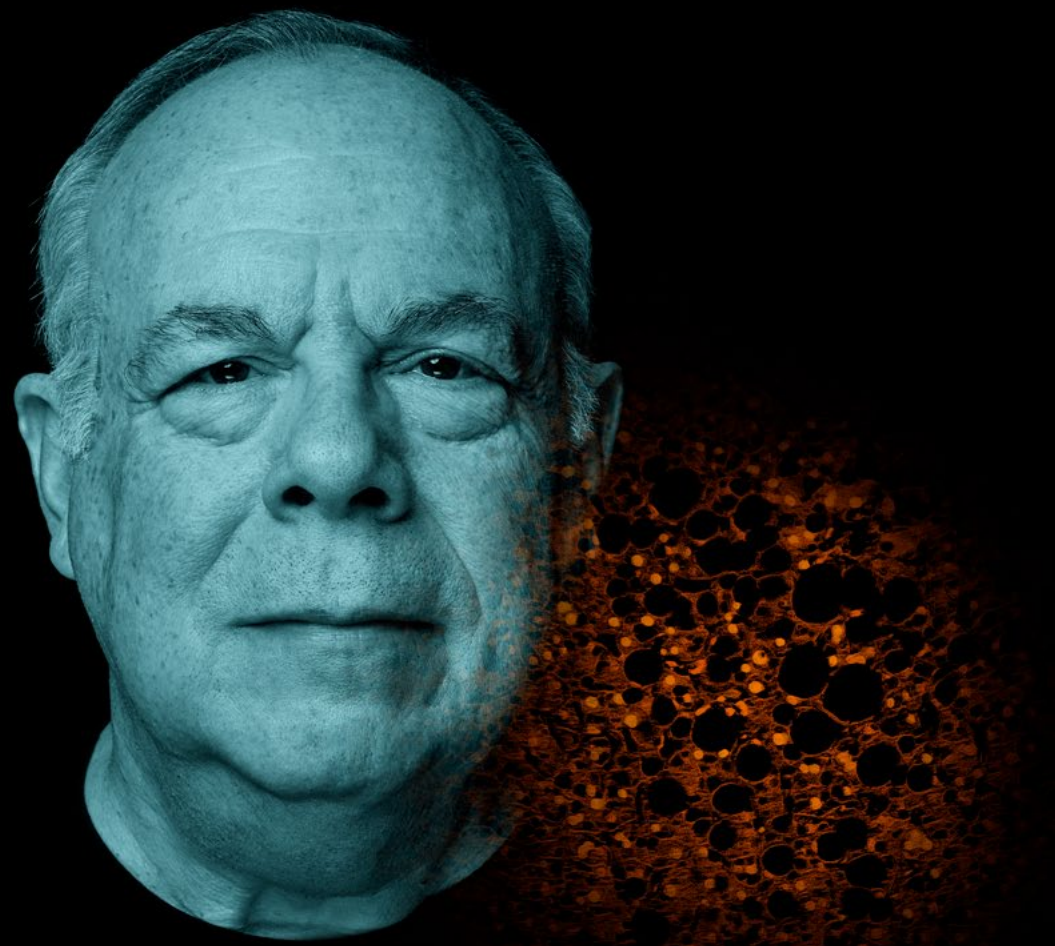
The Enhanced Liver Fibrosis (ELF) Test

Assess the risk of disease progression in patients with advanced fibrosis due to nonalcoholic steatohepatitis (NASH) with a simple blood test

siemens-healthineers.us/elf



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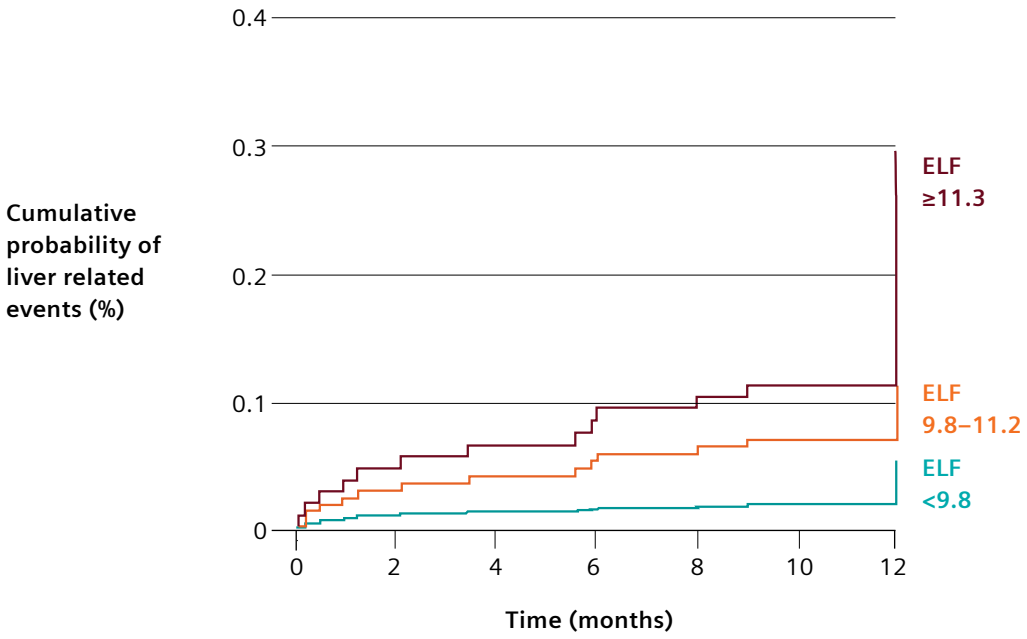
ELF can help determine risk of liver-related events in patients with NASH and compensated cirrhosis

ELF at baseline



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

How does the ELF test work?

The ELF™ Test measures three serum biomarkers:

1. Hyaluronic acid (HA)
2. Procollagen III N-terminal peptide (PIIINP)
3. Tissue inhibitors of 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, and their likelihood of having a liver-related event in the future

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

The ELF test assesses 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 NASH or fibrosis.

Each ELF Test biomarker composing the ELF score is:

- Standardized to ensure reproducible analytical and clinical quality.
- Designed and validated for prognostic risk assessment.

ELF is Clinically Valuable in NASH Prognostic Care

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

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	0-1.3	0-2.5	MONITOR
MEDIUM TO HIGH RISK	≥ 1.3[1]	≥ 2.5[1]	Confirmation of advanced fibrosis due to NASH

***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

Start* therapy

Intensive Lifestyle Intervention

Change Therapy *(if applicable)*

Refer to Clinical Trial *(liver biopsy as appropriate)*

Further assessment (may conduct additional tests)

**Once therapies are available*

Individuals with metabolic diseases are at a higher risk of developing or having NAFLD

Comorbidities

BMI ≥30
60-95%
also have NAFLD

Type 2 Diabetes
50-74%
also have NAFLD

2 or more features of metabolic syndrome

90%
also have NAFLD

Cardiovascular Disease
69%
also have NAFLD

Hypertension
50-74%
also have NAFLD

~12% have lean NAFLD

NAFLD 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 identifying patients with NASH with advanced fibrosis (F3 or F4) at risk of progressing to cirrhosis and/or LREs.

The widely studied ELF Test can assess 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 advanced NASH patients most at risk of progressing to cirrhosis and LREs.[11]
- Enhance patient management with a blood test that facilitates more frequent prognostic assessments to optimize patient management.

Reimbursement

MAAA CPT Code	0014M	$176.19 ✓

First blood test granted De Novo marketing authorization by the FDA for prognosis in advanced fibrosis due to NASH

Characteristics of an ideal non-invasive NASH 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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