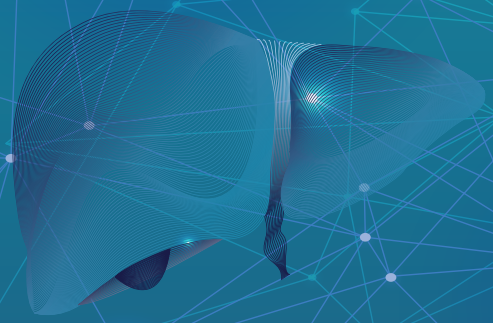
LIVERFASt™

Fibrosis • Activity • Steatosis

Non-invasive prognostic enrichment biomarker



Non-Alcoholic Fatty Liver Disease (NAFLD) is the most common cause of liver disorders worldwide.

LIVERFASt™ is an AI-based prognostic enrichment biomarker derived from a blood draw to identify and stage the main features of NAFLD: **liver fibrosis, steatosis and activity.**

Type 2 Diabetes is more than 2-fold higher in individuals with NAFLD and often evolves with normal liver enzymes.

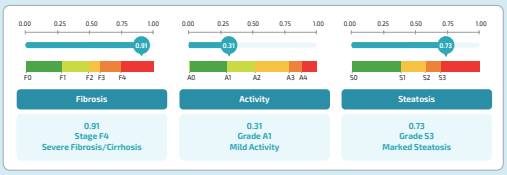
LIVERFASt™ accurately identifies severe **fibrosis and cirrhosis** in both patients with or without type 2 diabetes and irrespective to liver enzymes levels.

NASH related cirrhosis is disproportionately high in those with type 2 diabetes and is now on a trajectory to become the most common indication for liver transplantation in the U.S.

LIVERFASt™ accurately identifies **cirrhosis** in subjects with all biochemistry inside the **normal laboratory range.**

LIVERFASt™ is a complete and robust algorithm – easy to use and to interpret.

LIVERFASt™



LIVERFASt™ is a blood-based AI test validated to determine the liver fibrosis stage, activity, and steatosis grades in patients with NAFLD features intended to liver biopsy.

LIVERFASt™ utilizes the following biomarkers:

- **Liver specific proteins:** Apolipoprotein A1, Alpha-2-Macroglobulin, Haptoglobin
- **Liver enzymes:** ALT, AST, GGT
- **Metabolic panels**: Fasting Glucose, Total Bilirubin
- **Lipid profiles:** Total Cholesterol, Triglyceride
- **Anthropometrics:** Age, Gender, Weight, Height

Multiple clinical validations with consistent results in patients with NAFLD, including patients with type 2 diabetes and obesity shows:

- **LIVERFASt™** significantly outperforms FIB-4 and ELF
- **LIVERFASt™** is equivalent to transient elastography for fibrosis and cirrhosis detection

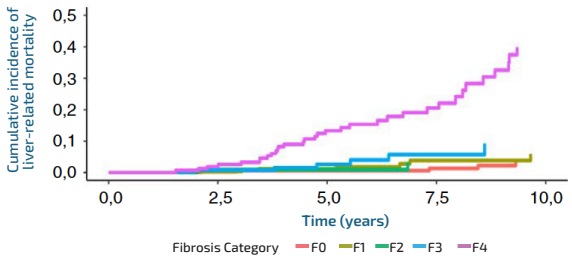
- Consistent high performance (AUROC) for staging and prognostication
  - 0.86 for predicting long-term liver-related mortality
  - 0.82 for screening either NASH with F1 fibrosis stage or NASH cirrhosis (F4 stage)
  - 0.87 for screening NAFL (steatosis S1 by 1H-MRS)

Why use LIVERFASt™?

Provides a tool for NAFLD features and for cirrhosis identification
Outperforms standards of care based on liver enzymes
More adapted to overweight patients than ultrasound-based on staging methods
Easily repeatable for monitoring of NASH patients

LIVERFASt™ predicts liver-related mortality with the highest risk per additional point compared to other SOC (FIB-4 and VCTE)

	Time (years)		
Number at risk			
437	266	75	0
336	150	41	0
125	57	14	0
166	83	18	0
175	93	23	0



Decraecker M. et alo.Aliment Pharmacol Ther. 2022;55:580-592.

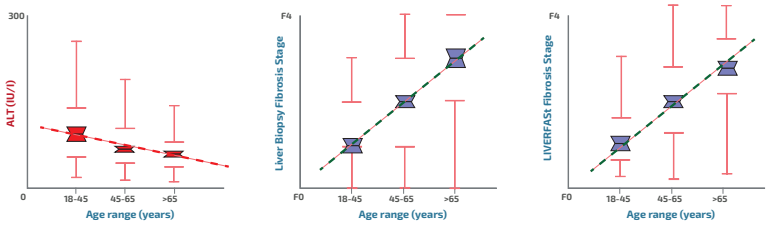
LIVERFASt™ Fibrosis test accurately detects **cirrhosis**, in NAFLD patients, with or without **type 2 diabetes** mellitus (T2DM)

LIVERFASt AUROC (95% CI) for **cirrhosis**

Patients without T2DM	0.82 (.73 - .88), p=NS versus VCTE
Patients with T2DM	0.77 (.72 - .83), p = NS versus VCTE

> **Patients with type 2 diabetes or prediabetes and elevated liver enzymes (ALT) or fatty liver on ultrasound, should be evaluated for presence of nonalcoholic steatohepatitis and liver fibrosis. […] Noninvasive tests, such as fibrosis biomarkers, may be used to assess risk of fibrosis »**
>
> American Diabetes Association, 2021

LIVERFASt™ fibrosis-specific panel overcomes limitations of NASH screenings based on ALT



ALT levels decrease with age range in NAFLD patients while liver fibrosis progress

De Ledinghen V, et al. Hepatology 2020

LIVERFASt™ improves the identification of NASH and demonstrates superior performance to FIB-4.

AUROC (95% CI) for all stages of **NASH**

LIVERFASt	0.88 (0.75 - 0.94)
FIB-4	0.68 (0.54 - 0.77), p<0.001

LIVERFASt™

- Provides reliable **fibrosis and cirrhosis** assessment even in subjects with normal liver enzymes
- **Outperforms FIB-4** for cirrhosis and bridging fibrosis staging in patients with type 2 diabetes
- More adapted to **overweight** patients than ultrasound-based technologies
- Intended for **early to late stage NAFLD** patients
- Easily **repeatable for monitoring** of disease progression or regression

How LIVERFASt™ works

Diabetic Patient → Physician Consult → Blood draw to generate 10 serum biomarkers in local lab → Result Sheet

To learn more, visit www.fibronostics.com or email service@fibronostics.com

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ABBREVIATIONS

AI Artificial Inteligence
ALT Alanine aminotransferase
AST Aspartate aminotransferase
AUROC Area Under the ROC curve
CI Confidence Interval
GGT Gamma-glutamyl Transferase
ELF Enhanced Liver Fibrosis score
NAFL Non-Alcoholic Fatty Liver
NAFLD Non-Alcoholic Fatty Liver Disease
NASH Non-Alcoholic Steatohepatitis
SOC Standard of Care
VCTE Vibration-Controlled Transient Elastography
T2DM Type 2 diabetes mellitus
1H-MRS Proton magnetic resonance spectroscopy

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