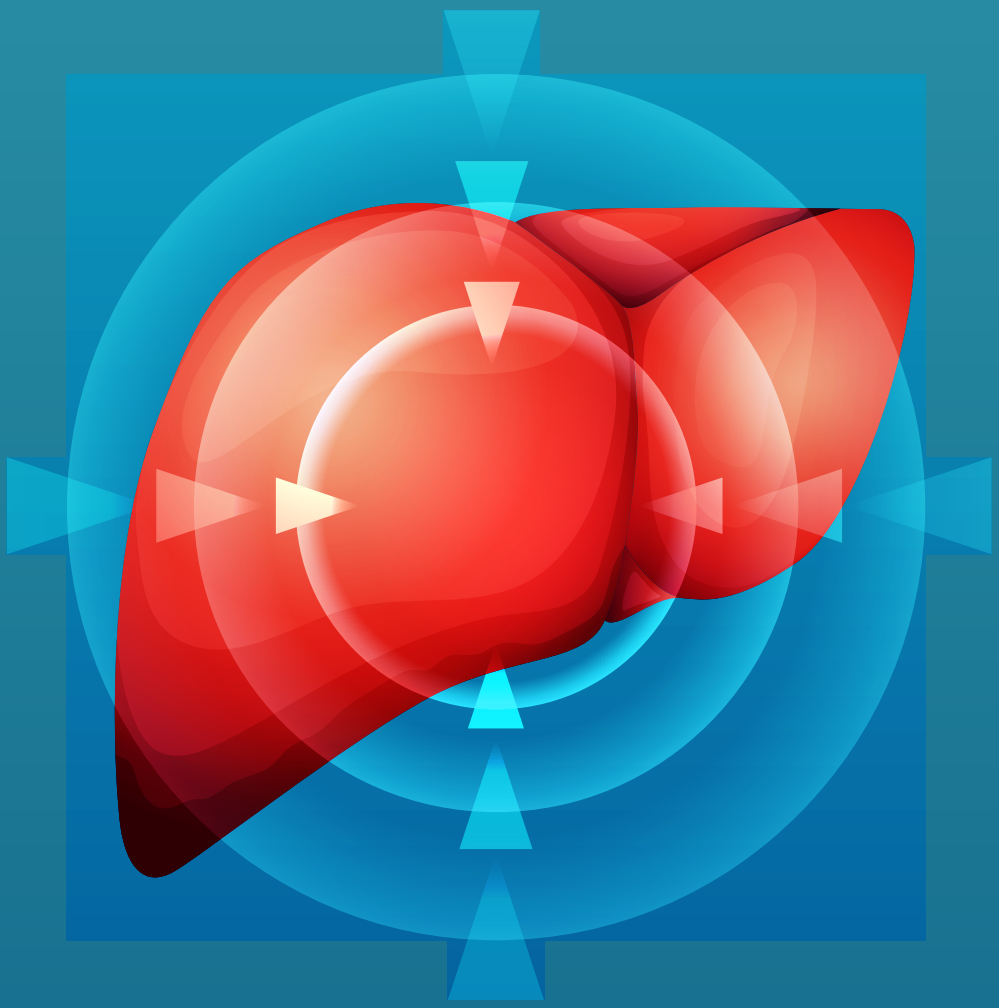
LIVERFASt™

Fibrosis • Activity • Steatosis



An innovative diagnostic and screening tool for a

COMPLETE LIVER EVALUATION

FIBRONOSTICS

LIVERFASt™ Provides a Full Liver Evaluation for Multiple Etiologies

Non-Alcoholic Fatty Liver Disease (NAFLD)

25% of the US population have NAFLD[3]

30% of NAFLD patients will develop Non-Alcoholic Steatohepatitis (NASH)

Hepatitis B (HBV)

20% -30% of patients with chronic HBV infection will develop cirrhosis or liver cancer[1]

Hepatitis C (HCV)

15% -30% of patients with chronic HCV infection will suffer from cirrhosis[2]

Alcoholic Liver Disease (ALD)

48% of all deaths from cirrhosis are caused by ALD[4]

S-A-F Score Staging[6]

Fibrosis

SCORE	STAGE	INTERPRETATION
0.00 - 0.27	F0	No fibrosis
0.28 - 0.48	F1	Mild fibrosis
0.49 - 0.58	F2	Advanced fibrosis
0.59 - 0.74	F3	Significant fibrosis
0.75 - 1.00	F4	Severe fibrosis (cirrhosis)

Activity

SCORE	GRADE	INTERPRETATION
0.00 - 0.29	A0	No activity
0.30 - 0.52	A1	Mild activity
0.53 - 0.622	A2	Moderate activity
0.63 - 0.72	A3	Marked activity
0.73 - 1.00	A4	Severe activity

Steatosis

SCORE	STAGE	INTERPRETATION
0.00 - 0.37	S0	No steatosis (<5%)
0.38 - 0.56	S1	Mild steatosis (5-33%)
0.57 - 0.68	S2	Moderate steatosis (34-66%)
0.69 - 1.00	S3	Marked steatosis (>67%)

Distinctive Staging of Three Lesions

LIVERFASt™ provides a complete liver evaluation with the staging of fibrosis, activity, and steatosis.

	LIVERFASt™	APRI	FIB-4	ELF	NIS4	ProC3	Fibrosure	Fibroscan
Specific for **Fibrosis (F)**	✓	✓	✓	✓	✗ (MIX F.A.S)	✗ (MIX F.S)	✓	✓ (BMI-impacted cutoffs)
Specific for **Activity (A)**	✓	✗	✗	✗	✗	✗	✗ (MIX A.S)	✗
Specific for **Steatosis (S)**	✓	✗	✗	✗	✗	✗	✓	✓
NASH Staging	✓	✗	✗	✗	✓ Only severe NASH	✓ Only NASH Cirrhosis	✓	✓ Only severe NASH
No. of **Biomarkers**	10	2	3	3	4	1	10	US
Assessment **Unbiased towards fibrosis**	✓	✗ (AST)	✗ (AST/ALT)	✗ (non-fasting, circadian rythm)	✗ (A,S)	✗ (S)	✓	✗ (A,S)

(TE = Transient Elastography, MRI = Magnetic Resonance Imaging, APRI = AST-to-Platelet Ratio Index, ELF = Enhanced Liver Fibrosis, FIB-4 = Fibrosis-4 index)

Simple and Convenient with Immediate Results

Physician prescribes **LIVERFASt™** for the patient

Lab analyses 10 biomarkers from **1 blood sample**

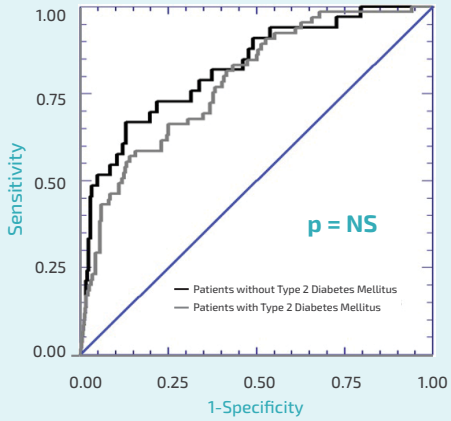
Biomarker results and **patient specific characteristics** input into Fibronostics' proprietary Artificial Intelligence (AI) platform

LIVERFASt™ results are **available immediately**

LIVERFASt™ in non-alcoholic fatty liver (NAFLD) patients[6,8-9,14]

LIVERFASt™ Fibrosis score accurately detects cirrhosis, AUROC (95%), in NAFLD patients, with or without type 2 diabetes mellitus (T2DM) and provides results similar to transient elastography (TE), P=NS.[9]

Patients without T2DM	0.824 (.737 - .888), p=NS versus TE
Patients with T2DM	0.774 (.722 - .839), p = NS versus TE



LIVERFASt™ identifies NASH even in subjects with normal liver enzymes.

LIVERFASt™ Steatosis score outperforms ultrasound in the detection of moderate steatosis (Grades S2S3, >33% of hepatocytes) in obese patients and CAP for obese patients with BMI>35Kg/m2 and T2Diabetes.[9]

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[9]

> Look for NAFLD in patients with Type 2 Diabetes Mellitus, irrespective of liver enzyme levels, due to high risk of disease progression.[14]
>
> EASL, 2016

> **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 »** [15]
>
> American Diabetes Association, 2021

25%

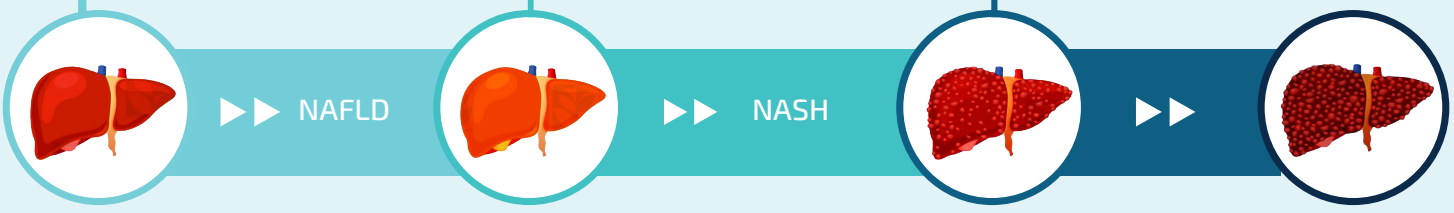
of people with Metabolic Syndrome risk factors* have non-alcoholic fatty liver disease (NAFLD).
Prevalence of NAFLD in patients with Type 2 Diabetes is two times higher than in the general population.

30%

of people with fat droplets in their liver cells develop non-alcoholic steatohepatitis (NASH), where the liver becomes inflamed and the hepatocytes suffer from ballooning.[3,13]

20%

of people with NASH will develop scarring (fibrosis) of the liver and the hepatocytes suffer from ballooning.[3,14]



Healthy Liver — **Simple Fatty Liver** — **Fatty Liver with Inflammation /Scarring** — **Liver Cirrhosis**

FIBRONOSTICS **LIVERFASt™**

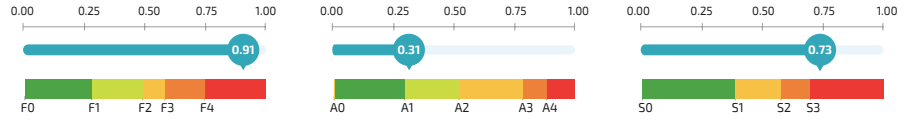
SAMPLE RESULT SHEET

Test id: 45326
Reference no: US20210311000754

PATIENT NAME:	PHYSICIAN NAME:
	JOHN SMITH M.D., P.A.

DATE OF BIRTH:	GENDER:	HEIGHT:	WEIGHT:	BMI:	DATE TEST TAKEN:
January 30, 1961	Male	6 ft 0 inch	287lb	38.9	March 15,2021

TEST SCORES



Fibrosis	Activity	Steatosis
0.91 Stage F4 Severe Fibrosis	0.31 Grade A1 Mild Activity	0.73 Grade S3 Marked Steatosis

INTERPRETATION

The result as per the SAF (Steatosis Activity Fibrosis) histological score is estimated at S3-A1-F4. This score indicates severe fibrosis, mild activity, and marked steatosis.

BIOMARKER RESULTS

AGE: 60 years old GENDER: Male BODY MASS INDEX: 38.9*

Sample Date: March 12,2021

	Result	Unit		Result	Unit
alpha-2-Macroglobulin	391	mg/dL	ALT	30	IU/L
Haptoglobin	57	mg/dL	AST	29	mg/dL
Apolipoprotein A1	112	mg/dL	Fasting Glucose	99	mg/dL
Total Bilirubin	0.7	mg/dL	Total Cholesterol	214	mg/dL
GGT	147	IU/L	Triglycerides	204	mg/dL

*Warning: This value is out of the 98% range. Check this value.

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FIBRONOSTICS

Fibronostics specializes in algorithm-based non-invasive diagnostic solutions.

For more information, please visit
www.fibronostics.com

LIVERFASt Proprietary CPT Code 0166U

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