# LIVERFASt™

## Fibrosis • Activity • Steatosis

## 1 Blood Draw ▶ 3 Scores ▶ complete evaluation of the liver

**AGE**

**GENDER**

**BMI**

**SERUM BIOMARKERS**

ADVANCED ANALYTICS

SCORING SYSTEM

STAGING
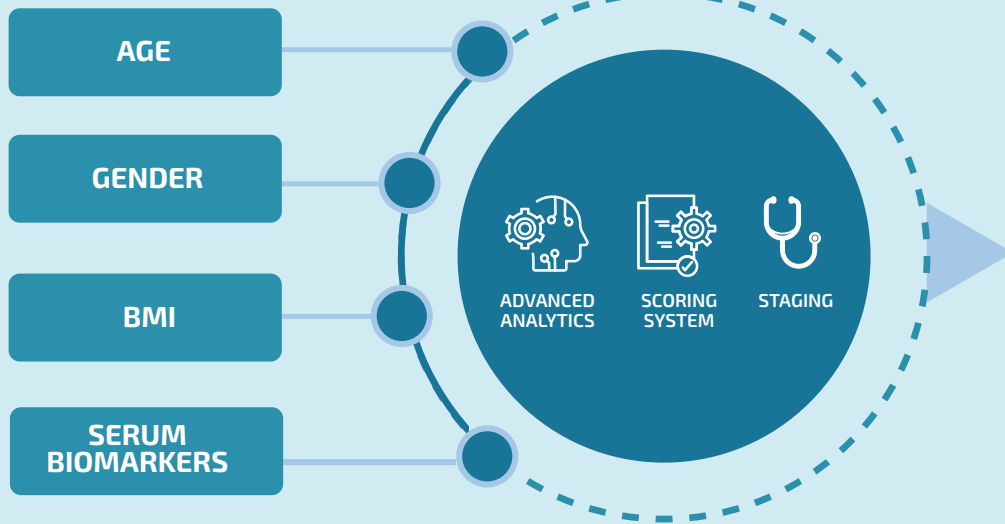
- Alpha-2-Macroglobulin
- Haptoglobin
- Apolipoprotein A1
- Total Bilirubin
- GGT
- ALT
- AST
- Fasting Glucose
- Tryglycerides
- Total Cholesterol

### Sample Result Sheet

**FIBRONOSTICS** | **LIVERFASt™** | SAMPLE RESULT SHEET

Test Id: 45843
Reference no: GLJ021031108907

PATIENT NAME:

Physician Name: **JOHN DOE M.D., P.A.**

| Patient ID | Gender | Date of Birth | Test Date | Blood Sample Date |
|---|---|---|---|---|
| B24678654 | Female | 1964-06-15 | 2024-07-17 | 2024-07-10 |

**TEST SCORES**

| Fibrosis | Activity | Steatosis |
|---|---|---|
| 0.41 | 0.43 | 0.63 |
| F0 F1 F2 F3 F4 | A0 A1 A2 A3 A4 | S0 S1 S2 S3 |
| 0.41 F2 advanced fibrosis | 0.43 A3 marked activity | 0.63 S3 marked steatosis (≥67%) |

**INTERPRETATION**

S3-A3-F2
Your result for the SAF score is S3-A3-F2. This score indicates that you have marked steatosis (≥67%), marked activity and advanced fibrosis. Consult your physician for further evaluation.

**BIOMARKER VALUES**

Age: 60 years | Height: 5 ft, 5 in | Weight: 182 lbs | BMI: *30.29

| Biomarker | Result | Unit | Biomarker | Result | Unit |
|---|---|---|---|---|---|
| Alpha-2-Macroglobulin | 130 | mg/dL | ALT | 36 | IU/L |
| Haptoglobin | 187 | mg/dL | AST | 49 | IU/L |
| Apolipoprotein A1 | 119 | mg/dL | Fasting Glucose | 97 | mg/dL |
| Total Bilirubin | 0.4 | mg/dL | Total Cholesterol | 161 | mg/dL |
| GGT | 42 | IU/L | Triglycerides | 198 | mg/dL |

\* NOTE: The highlighted value is at the extremes of the acceptable range of biomarker values.

The performance characteristics of this test were determined by Stone Diagnostics. This test is not FDA approved/cleared. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. Results are not for use as the sole means for clinical diagnosis or patient management. M. CarmenFries Klatecka, MD - Lab Director | Stone Diagnostics | 315 Serenoa Road, Ste A, Santa RosaBeach, FL, 32459, USA | Tel: 844-786-6325 | Fax: 850-635-0638 | CLIA # 10D2161865
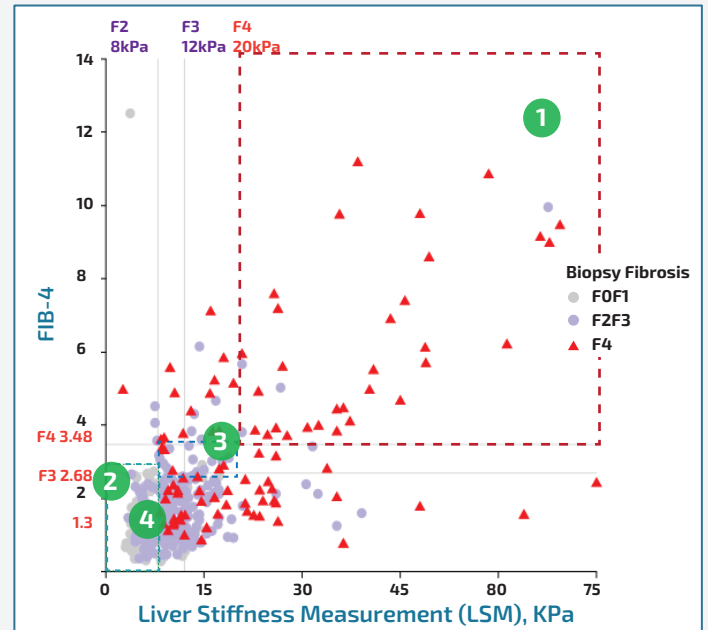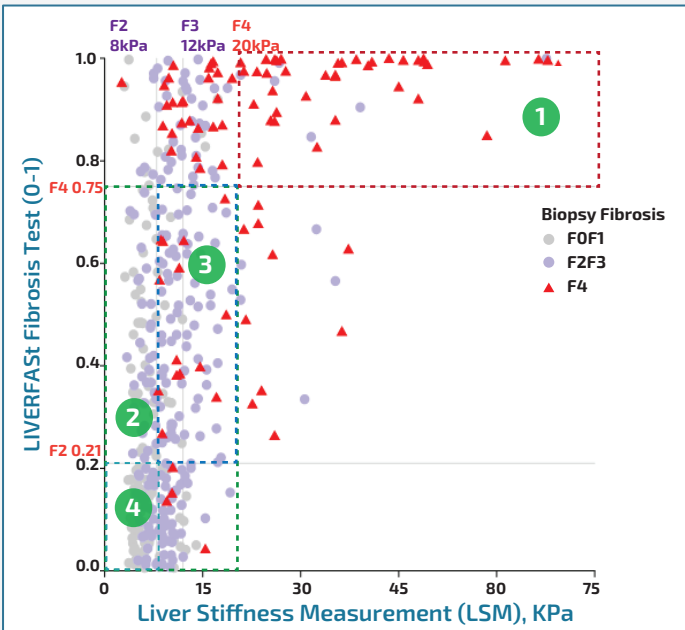This report is computer generated. No signature required. LIVERFASt 1.3.0(240711_EN)

## LIVERFASt™ outperforms ELF, FIB-4 and Fibrotest as a MASH patient screening NIT

| | LIVER**FASt**™ | ELF | FIB-4 | Fibrotest |
|---|---|---|---|---|
| Fibrosis Yes/No | YES | YES | YES | YES |
| Fibrosis Staging | YES | NO | NO | YES |
| Activity Staging | YES | NO | NO | NO |
| Steatosis Staging | YES | NO | NO | NO |
| Grey-zone | NO | YES | YES | NO |
| Easy to do | YES | NO | YES | YES |
| Works in ≥65yrs & T2D | YES | YES | NO | NO |

- **LIVERFASt™ stages** fibrosis from F0 to F4
- Gives **complete liver staging** for fibrosis, steatosis & activity in one test
- **Does not miss** F2 or F3 patients because of a "grey zone"
- **Identifies twice as many** F2 or F3 patients than FIB-4
- **Works better** in elderly & T2D
- **Clinical Path Ready** - LIVERFASt™ is ideal first step with Fibroscan
- **Great for Screening** - Identifies more target patients more easily in any setting than other NITs

## FIBRONOSTICS

# LIVERFASt + Fibroscan outperformed FIB-4 + Fibroscan strategy for identifying more at-risk MASH patients

## Overall MASLD population (n=452) with LB ≥2cm



Left scatter plot: LIVERFASt Fibrosis Test (0-1) vs Liver Stiffness Measurement (LSM), KPa. Thresholds F2 8kPa, F3 12kPa, F4 20kPa; F4 0.75, F2 0.21. Biopsy Fibrosis: F0F1, F2F3, F4.

Right scatter plot: FIB-4 vs Liver Stiffness Measurement (LSM), KPa. Thresholds F2 8kPa, F3 12kPa, F4 20kPa; F4 3.48, F3 2.68, 1.3. Biopsy Fibrosis: F0F1, F2F3, F4.

### STEP ONE – Identify & exclude cirrhosis

| N=452 | LIVERFASt & LSM agree | Liver Biopsy confirms agreement of NITs (n%) |
|---|---|---|
| (1) LIVERFASt & LSM agree on cirrhosis F4 | 47 | 41 (87%) |
| (2) LIVERFASt & LSM agree on NO cirrhosis F4 | 313 | 295 (94%) Not F4 |

### STEP ONE – Identify & exclude cirrhosis

| N=452 | FIB-4 & LSM agree | Liver Biopsy confirms agreement of NITs (n%) |
|---|---|---|
| (1) FIB-4 & LSM agree on cirrhosis F4 | 35 | 31 (89%) |
| (2) FIB-4 & LSM agree on NO cirrhosis F4 | 367 (199 with FIB-4 <1.3 or 2.68-3.48 +168 Grey Zone) | 337 (92%) Not F4 |

### STEP TWO – Identify F2 & F3

| N=295 without presumed cirrhosis | LIVERFASt & LSM agree | Liver Biopsy confirms agreement of NITs (n%) |
|---|---|---|
| (3) LIVERFASt & LSM agree on F2F3 | 107 | 74 (69%) |
| (4) LIVERFASt & LSM agree on NO F2F3 | 85 | 55 (65%) F0F1 |

### STEP TWO – Identify F2 & F3

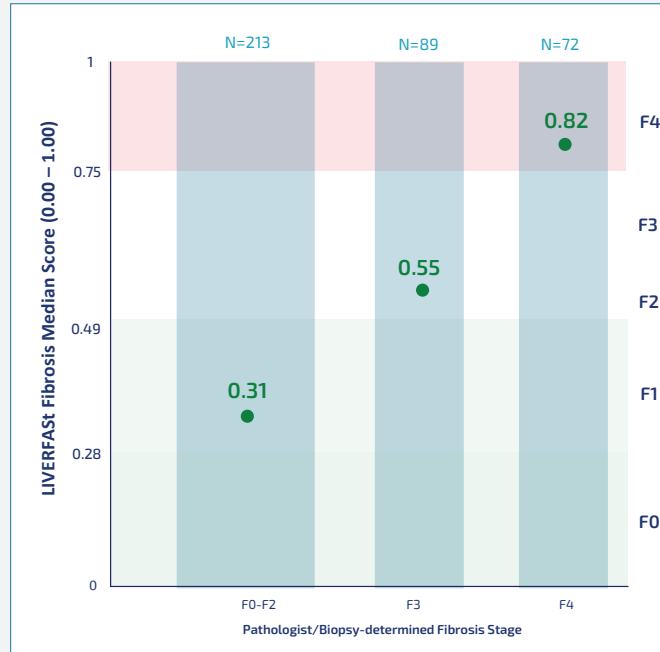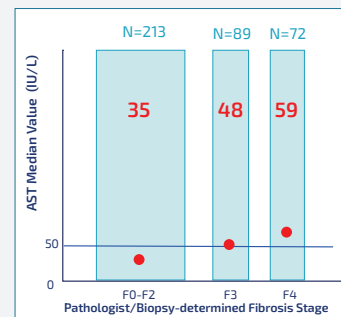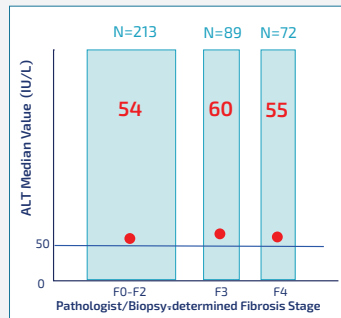| N=337 without presumed cirrhosis with both NITs | FIB-4 & LSM agree | Liver Biopsy confirms agreement of NITs (n%) |
|---|---|---|
| (3) FIB-4 & LSM agree on F2F3 | 19 presumed F3 (+106 Grey Zone, presumed F2) | 10 (53%) F3 23(22%) F2 Grey Zone* |
| (4) FIB-4 & LSM agree on NO F2F3 | 99 | 60 (61%) F0F1 |

*If 1 stage discordance between FIB-4 and LSM is accepted, the 86 (69%) (13 between 2.68-3.48 and 73 GZ) are confirmed F2 or F3

- LIVERFASt + LSM identifies more F4 livers correctly than FIB-4 + LSM, 41 vs 31

- LIVERFASt provides a continuous score from 0 to 1, differentiating between each different stage of fibrosis

- LIVERFASt + LSM identifies 74 out of 107 F2F3 fibrosis patients correctly (69%)

- The use of rule-in/rule-out cut-offs results in a grey zone, making it difficult to specify F2 stage of fibrosis

- FIB-4 + LSM identifies only 33 out of 125 F2F3 livers correctly (26%)

- FIB-4 + LSM is in practice not as efficient as a 2 sequenstial NIT strategy for F2F3F4 stages

# LIVERFASt™ predicts biopsy results, ALT and AST do not

## Overall MASLD population (n=374)



*ALT Median Value (IU/L) chart — Pathologist/Biopsy-determined Fibrosis Stage:*
- N=213, F0-F2: 54
- N=89, F3: 60
- N=72, F4: 55

*AST Median Value (IU/L) chart — Pathologist/Biopsy-determined Fibrosis Stage:*
- N=213, F0-F2: 35
- N=89, F3: 48
- N=72, F4: 59

*LIVERFASt Fibrosis Median Score (0.00 – 1.00) — Pathologist/Biopsy-determined Fibrosis Stage:*
- N=213, F0-F2: 0.31
- N=89, F3: 0.55
- N=72, F4: 0.82

*deLedinghen V. et al. Hepatology Suppl 2020

- LIVERFASt scores correlate with biopsy stage of fibrosis as determined by a pathologist
- ALT and AST values are random, do not correlate with biopsy determined staging
- ALT and AST values go down naturally with increasing age
- Since FIB-4 depends on both ALT and AST, it does not and cannot work well as a screening and identification tool for fibrosis
- LIVERFASt is a useful tool to screen at-risk patients for advanced liver disease
- LIVERFASt is easy to do, using standard blood biomarkers

# LIVERFASt has high clinical performance for Fibrosis & Activity

| LIVERFASt Activity Test performance | |
|---|---|
| MASLD population (n=223) | |
| AUROC (95% CI) | 0.79 (0.71 - 0.85) |
| Specificity | 0.85 |
| Sensitivity | 0.59 |
| Negative Predictive Value | 0.65 |
| Positive Predictive Value | 0.85 |

| LIVERFASt Fibrosis Test performance | |
|---|---|
| MASLD population (n=223) | |
| AUROC (95% CI) | 0.867 (0.807 - 0.910) |
| Specificity | 0.85 |
| Sensitivity | 0.75 |
| Negative Predictive Value | 0.88 |
| Positive Predictive Value | 0.71 |

| The concordance for cirrhosis with Liver Biopsy (n=452) | | |
|---|---|---|
| LIVERFASt | LSM | FIB-4 |
| 67/95 (71%) | 51/95 (54%) | 45/95 (47%) |

Only LIVERFASt provides clinically and therapeutically relevant identification of fibrosis and activity in ONE easy-to-do blood-based test.

LIVERFASt combines well with LSM in a 2 step sequential NIT strategy from screening, identification and monitoring of at-risk MASH patients.
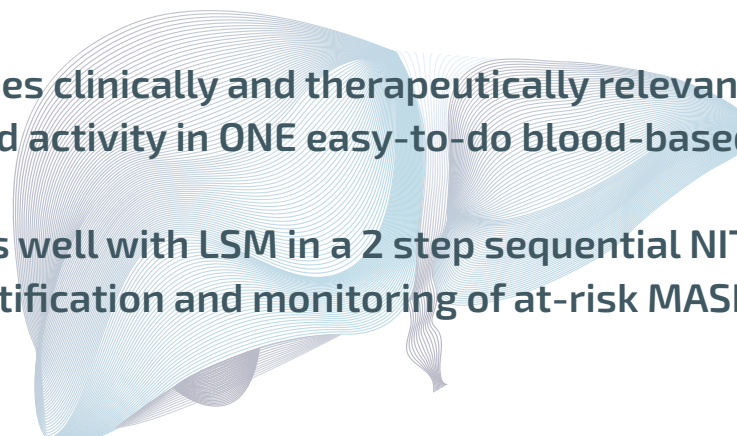
# Easy to do in multiple settings to help specialists manage MASH

**Physician prescribes LIVERFASt™**

**Lab analyzes 10 biomarkers from 1 blood draw**

**Biomarker values** plus **age, height, weight, gender**, are entered into the **LIVERFASt™ platform**

**LIVERFASt™** results are **available immediately**

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*Patients have to **wait 2 months** to get an appointment at my clinic and then **70%** of their Fibroscans come back clean...*

## Large at-risk patient populations in primary-care settings

Screening and identification with

**LIVERFASt™**

**All at-risk patients**

> 80% F0-F2 ▶ remain in primary-care

< 20% F3F4 ▶ referral to specialist

- ✓ Fast + Easy to do
- ✓ High degree of Dx certainty
- ✓ Low percentage of false positives
- ✓ Avoids need for biopsy

**Confirmation of identified F3F4 patients with LSM**

< 20% of screened patients **referred to specialist**

**MASH patients confirmed** by 2 sequential NITs strategy

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**Screening**
Liver specific

**Staging**
Early to late staging

**Monitoring**
Easily repeatable

**Prognosing**
Patient outcomes and management

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## Contact Us
service@fibronostics.com | **P**: 1-888-552-1603 | **F**: 1-321-256-6061

# FIBRONOSTICS

**FIBRONOSTICS US, INC.**
274 E. Eau Gallie Blvd., #346
Indian Harbour Beach, FL 32937

For more information, please visit
**www.fibronostics.com**

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**\* Abbreviations**
**ALT** Alanine aminotransferase
**AST** Aspartate aminotransferase
**GGT** Gamma Glutamyl Transpeptidase
**LB** Liver Biopsy
**LSM** Liver Stiffness Measurement
**PCOS** Polycystic ovary syndrome
**MASLD** Metabolic Dysfunction-Associated Steatotic Liver Disease
**MASH** Metabolic Dysfunction-Associated Steatohepatitis
**SLD** Steatotic liver disease

ISO 13485
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MD 779363
BS EN 13485

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