

1. Fibronostics

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Code : 0166U; LIVERFAST™



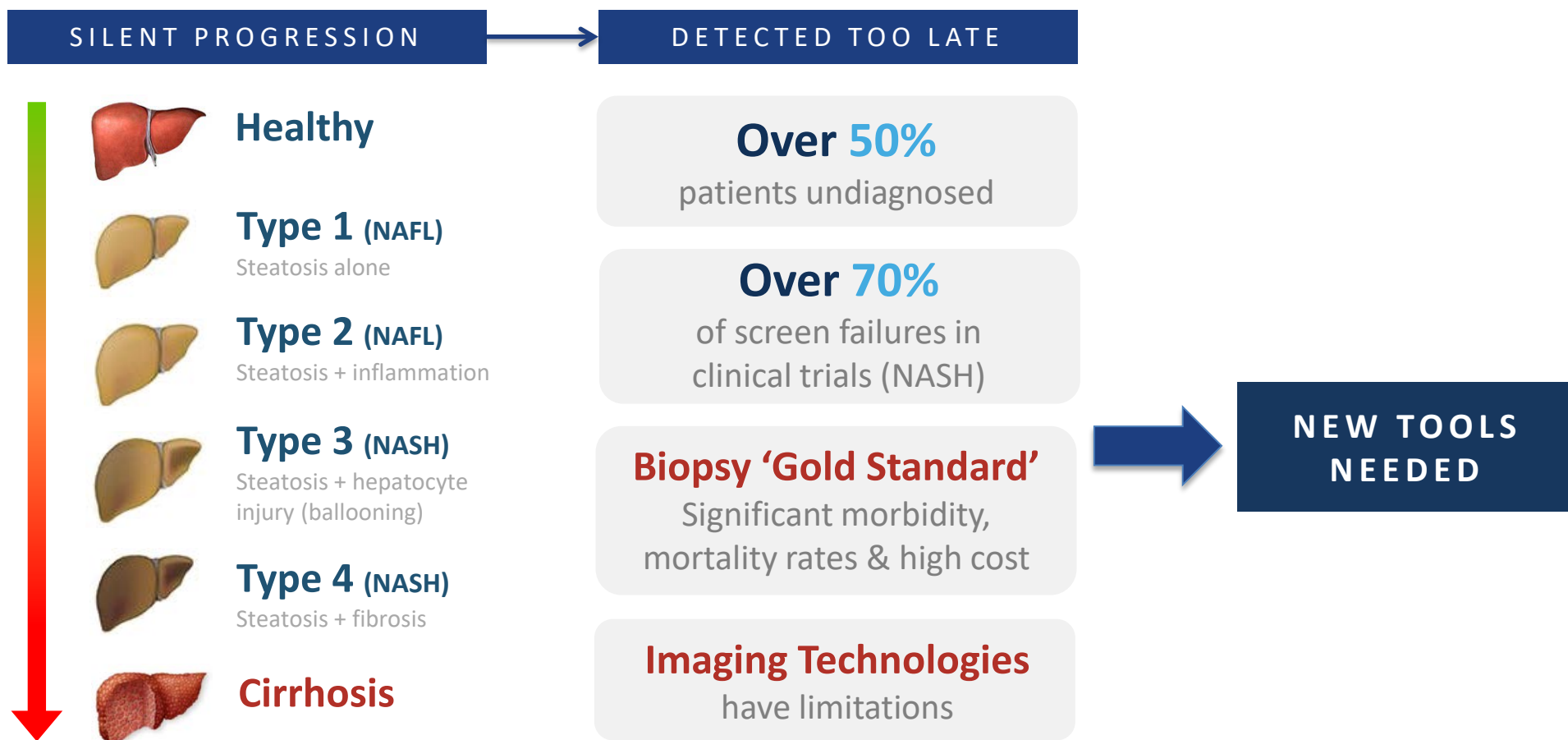
PLA CPT Code:

0166U LIVERFAST™

Long Descriptor:

Liver disease, 10 biochemical assays (α 2- macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation

New Detection Tools Needed



US: Lazo 2013, Younossi 2015, EU: France (Poynard 2010, Ratziu 2012, Blachier 2013), Germany (Haring 2009), Italy (Bedogni 2005), Spain (Caballeria 2010), UK (Armstrong 2012), China: Fan 2009, Fan 2013, Nathan et al, 2016, Younossi et al., 2018, * NAFLD – Non Alcoholic Fatty Liver Disease; NASH – Non Alcoholic Steato Hepatitis, ** Non Alcoholic Steato-Hepatitis

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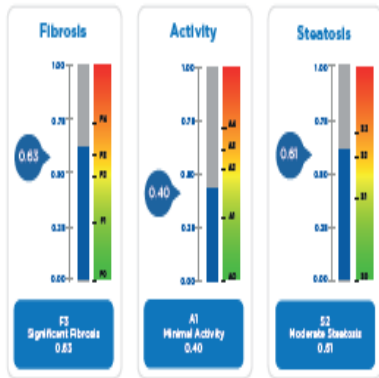
LIVERFAST™: Test Purpose


A platform technology of non-invasive, algorithmic diagnostics detecting organ lesions caused by metabolic diseases

LIVERFAST™ is a blood based diagnostic test that combines 10 biomarkers and algorithm technology to determine the fibrosis, activity and steatosis stages of the liver.

LIVERFAST™ utilizes the following biomarkers:

- alpha-2-Macroglobulin
- Haptoglobin
- Apolipoprotein A1
- Total Bilirubin
- GGT
- ALT (P5P)
- AST (P5P)
- Fasting Glucose
- Triglyceride
- Total Cholesterol





LIVERFAST™

SAMPLE RESULT SHEET

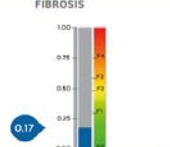
PATIENT NAME: _____ DATE OF BIRTH: _____ GENDER: _____ HEIGHT: _____ WEIGHT: _____ BMI: _____

NAME OF PHYSICIAN: _____ DATE OF TEST TAKEN: _____

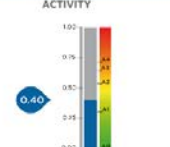
BIOMARKER RESULTS

Sample Date	08-06-2019	ALT	76 IU/L
alpha-2-Macroglobulin	1.63 g/L	AST	57 IU/L
Haptoglobin	1.44 g/L	Fasting Glucose	7.4 mmol/L
Apolipoprotein A1	1.57 g/L	Total Cholesterol	4.24 mmol/L
Total Bilirubin	16.25 µmol/L	Triglycerides	1.47 mmol/L
GGT	37 IU/L		

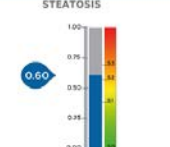
SCORES



F0
No Fibrosis
0.17



A1
Minimal Activity
0.4



S2
Moderate Steatosis
0.6

FIBROSIS: Liver fibrosis represents scarring of the liver. Scarring of the liver is due to reaction from viral infections, fat and/or alcohol.

ACTIVITY: Liver activity represents inflammation of the liver. Inflammation of the liver is due to reaction from viral infections, fat and/or alcohol.

STEATOSIS: Liver steatosis is the accumulation of fat in the liver. Liver steatosis is commonly due to metabolic anomalies (e.g. Dyslipidemia, diabetes, overweight/obesity) and/or alcohol.

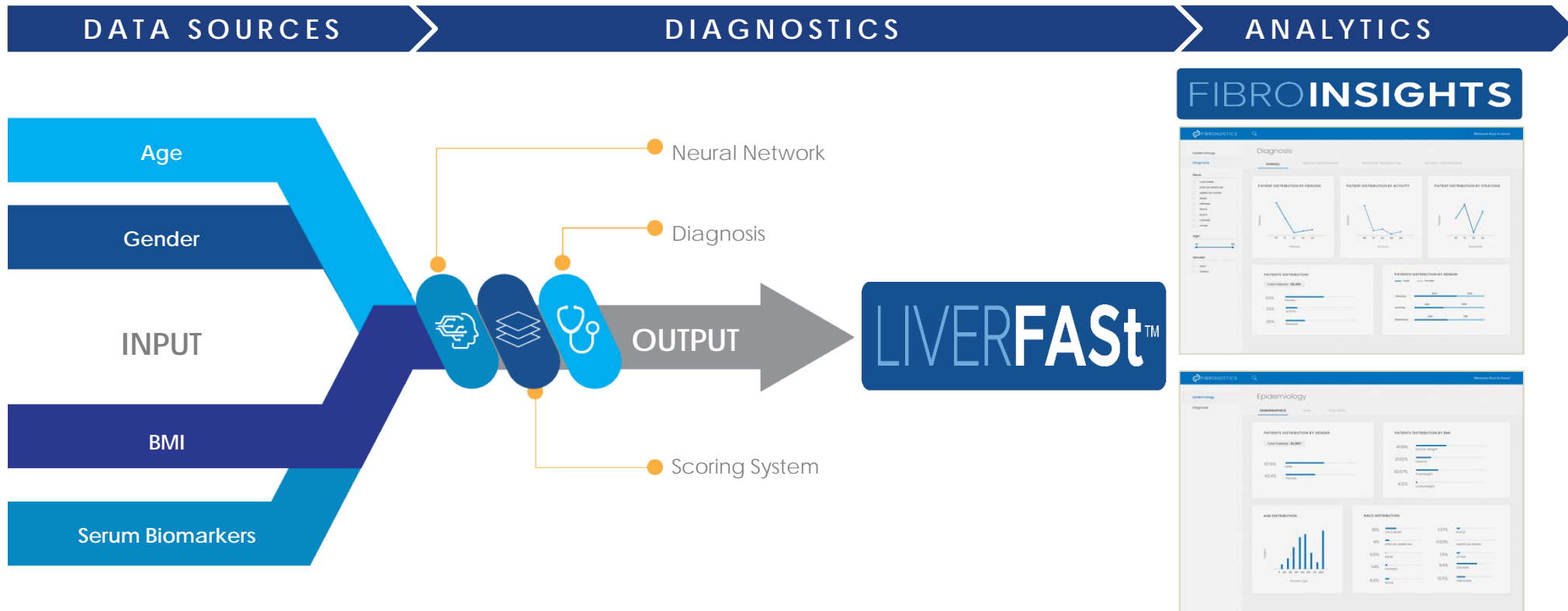
INTERPRETATION

- Your result for the SAF score is S2-A1-F0.
- This score indicates that you have moderate steatosis, minimal inflammatory activity and no fibrosis.
- Consult your physician for further evaluation.

PRECAUTIONS:

- The reliability of results is dependent on compliance with the preanalytical and analytical conditions recommended by Fibronostics.
- The test must be deferred for acute hemolysis, acute hepatitis, acute inflammation, extra hepatic cholestasis.
- The advice of a specialist must be sought for interpretation in chronic hemolysis and Gilbert's syndrome.
- The test interpretation is not validated for liver transplant patients.
- Isolated extreme values of any of the biomarker results should lead to caution in interpreting the results.
- In the case of discordance between a biopsy result and a test, it is recommended to seek the advice of a specialist.
- The causes of these discordances could be due to a flaw of the test or to a flaw in the biopsy, i.e. a liver biopsy has a 32% variability rate for one fibrosis stage.
- The fibrosis score is interpretable for chronic hepatitis B, chronic hepatitis C, alcoholic steatosis and non-alcoholic steatosis.
- The activity score is interpretable for chronic hepatitis B and chronic hepatitis C.

LIVERFAST™ Technology – From Diagnostics to Decision Making



- NAFLD/NASH stratification for patients with liver function and lipid panels

- Tailored analytics and insights
- Identify trends and leverage multiple data models to support better patient care

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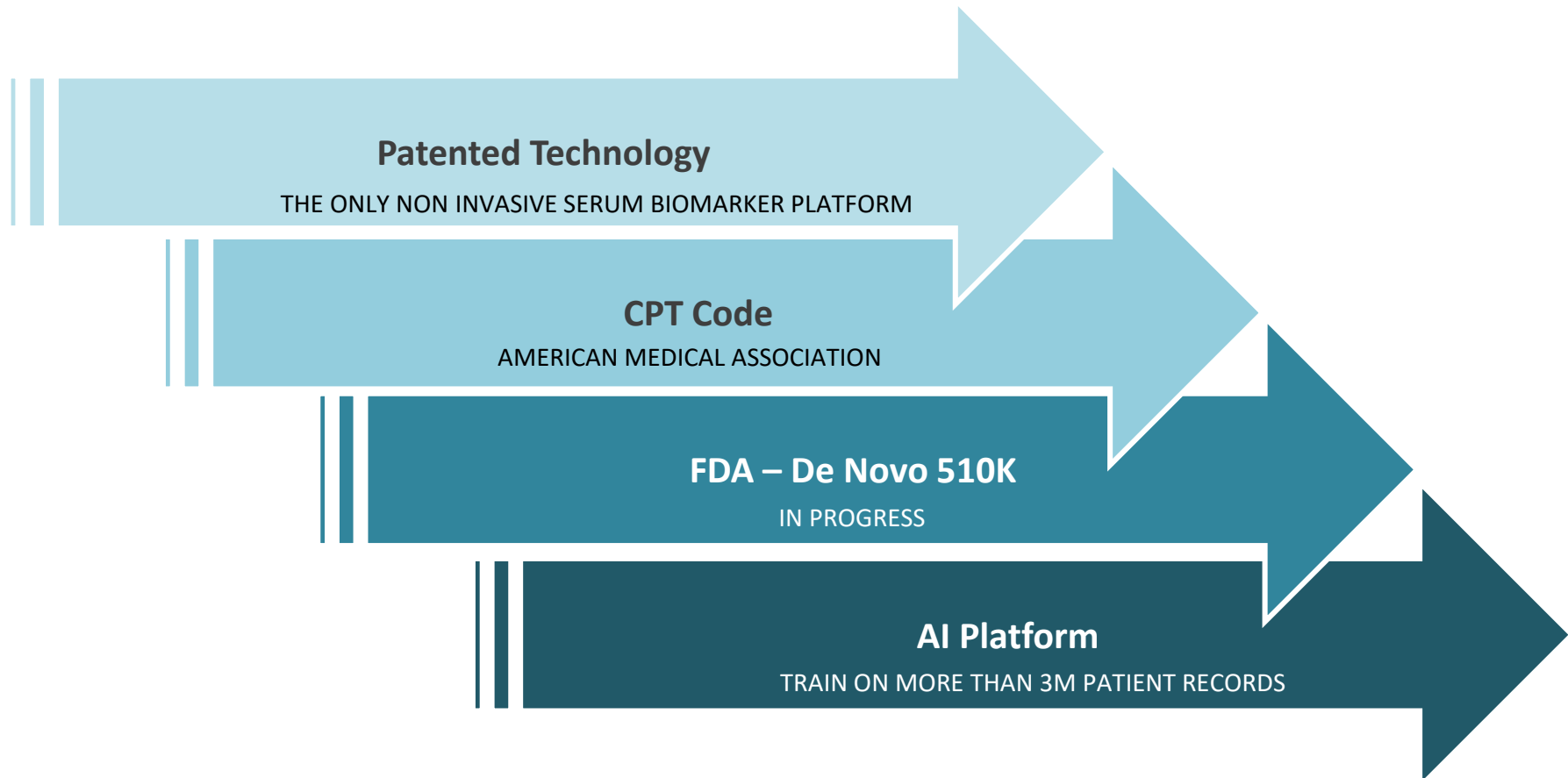
Differences from other Analyte on the CLFS

Staging\Grading of three lesions – Fibrosis Activity & Steatosis

	LIVERFAST™	TE*	MRI	Ultrasound	APRI*	ELF	FIB-4*
Fibrosis	YES	YES	YES	NO	YES	YES	YES
Activity	YES	NO	NO	NO	NO	NO	NO
Steatosis	YES	YES	YES	YES	NO	NO	NO
# Biomarkers	10	NA	NA	NA	2	3	4

LIVERFAST is the only test able to discriminate fibrosis from steatosis and activity without bias in fibrosis estimation related to the presence of activity or steatosis.

LIVERFAST™ Uniquely Positioned Among Non-Invasive Technologies



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Public Comment and Rationale

Public Comment	Rationale
0003M- \$503.40	<p>Consistent with code descriptor:</p> <p>0003M- Ten biochemical assays (ALT, A2-macroglobulin, Apolipoprotein A-1, Total Bilirubin, GGT, Haptoglobin, AST, Glucose, Total cholesterol and Triglycerides) utilizing serum, prognostic algorithm reported as quantitative scores for fibrosis, steatosis, and nonalcoholic steatohepatitis</p> <p>0166U- 10 biochemical assays (α2- macroglobulin, haptoglobin, apolipoprotein A1, bilirubin, GGT, ALT, AST, triglycerides, cholesterol, fasting glucose) and biometric and demographic data, utilizing serum, algorithm reported as scores for fibrosis, necroinflammatory activity, and steatosis with a summary interpretation</p>