

LiverFASt

The innovative non-invasive test that determines the degree of liver damage in people with certain common liver diseases.

Over one million tests done in 50 countries

Strong Scientific Evidence:
A widely used, well researched, validated and patented test

285 studies

1133 authors

89 journals

Reference:

1. EASL-EASD-EASO Clinical Practice Guidelines for the Management of Non-Alcoholic Fatty Liver Disease, May 2016.
2. FLIP Consortium (Fatty Liver Inhibition Progression), June 2014



Innovative Diagnostics is a medically managed service practice led by a group of doctors and supported by a dedicated team of senior and experienced industry professionals. We achieved the industry gold standard CAP Accreditation in 2013 and are forging a new path. We aspire to set industry benchmarks in doctor and patient experiences.

innovative DIAGNOSTICS

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LiverFASt

Test for assessing liver damage in
Common Liver Diseases

HEPATITIS C, HEPATITIS B, NAFLD*, NASH*, ASH*



innovative
DIAGNOSTICS

What is the LiverFASt test?

LiverFASt test is an innovative, diagnostic test which determines the degree of liver damage in people with a variety of liver diseases.

Why is it done?

The LiverFASt is a non-invasive test. Traditionally, liver biopsy has been utilized to assess the liver and to estimate the degree of liver damage.

However, this procedure has several drawbacks:

- it is invasive
- it is subject to complications, ranging from minor (up to 30% experience pain) through to more severe complications (including death in approximately 0.03%)
- there is considerable sampling variability (up to 40% for fibrosis staging)

"...numerous studies strongly suggest that due to the limitations and risks of biopsy, as well as the improvement of the diagnostic accuracy of biochemical markers, liver biopsy should no longer be considered mandatory⁽¹⁾."

What does it test for?

LiverFASt is the combination of up to three non-invasive liver tests: FibroTest, ActiTest, SteatoTest.

The LiverFASt utilises the results of these three tests, based on the 10 biomarkers from your blood draw, to generate a score to determine the degree of liver damage based on sex, age, weight and height. LiverFASt has high prognostic value with less inconvenience to the patient.

The use of the LiverFASt

1. **FibroTest:** Assesses hepatic fibrosis
2. **SteatoTest®:** Assesses hepatic steatosis (otherwise known as 'fatty liver') – the most common cause of ALT and GGT abnormalities
3. **ActiTest®:** Assesses viral necro-inflammatory activity

How does it work?

Simple, convenient and provides results quickly

1 Your Doctor prescribes LiverFASt test for you

3 The laboratory analyses 10 biomarkers from your blood sample:

- Alpha2macroglobulin
- Haptoglobin
- Apolipoprotein A1
- Total Bilirubin
- Gamma GT
- Fasting Glucose
- Total Cholesterol
- Triglycerides
- Activated ALT
- Activated AST

2 You have a blood sample taken which is sent to Innovative Diagnostics Laboratory

4 The laboratory releases your blood test results to your doctor and Digital Diagnostics. Digital Diagnostics will input the results into a software to create the LiverFASt test report. *(See sample report)*

5 The LiverFASt test report is then sent to your doctor for review.

Turnaround time between 4-7 business days from receipt of the sample in the Laboratory.

What is it?

- A non-invasive diagnostic test for Non-Alcoholic Fatty Liver Disease (NAFLD).
- A combination of 3 tests on the same result sheet which provides physicians with simultaneous and complete estimation of the liver injury.
- Fibrosis (Fibrotest)
- Steatosis (Steatotest)
- Necroinflammatory histological Activity (Actitest).

What else is needed for this test?

- Patient's Date of Birth
- Weight (in cm)
- Height (in kg)
- Gender
- patient must be fasting (minimum 8 hours)

What biomarkers are tested?

- Fasting Glucose
- Total Cholesterol
- Triglycerides
- Activated ALT
- Activated AST
- GGT (calibrated against IFCC)
- Total Bilirubin
- Apolipoprotein A1
- Haptoglobin
- Alpha-2-macroglobulin

LiverFASt

Why is it done?

- To reduce the need for invasive testing (liver biopsy) without compromising reproducibility and accuracy.

When is it done?

- In primary care settings - to identify the risk of NAFLD among individuals with increased metabolic risk.
- in secondary and tertiary care settings - to identify those with worse prognosis, e.g. severe NASH.
- to monitor disease progression.
- to predict response to therapeutic interventions.

Sample report

LiverFASt

Sample report

A first line assessment of liver damage

PATIENT NAME: ANNIE TAN **DATE OF BIRTH:** 1961-11-01 **GENDER:** FEMALE **HEIGHT:** 1.68 m **WEIGHT:** 58 kg **BMI:** 20.5 kg/m²

Patient Information:

With auto calculation of BMI for LiverFASt

NAME OF PHYSICIAN: TEST **DATE OF TEST TAKEN:** 2016-11-30

BIOMARKER RESULTS

| Sample Date | 2016-11-30 | | |
|----------------------|------------|-------------------|------------|
| Alpha2 Macroglobulin | 10 g/l | ALT | 160 IU/l |
| Haptoglobin | 3.2 g/l | AST | 180 IU/l |
| Apolipoprotein A1 | 2 g/l | Fasting Glucose | 4.4 mmol/l |
| Bilirubin | 22 µmol/l | Total cholesterol | 3.8 mmol/l |
| Gamma GT | 0.9 IU/l | Triglycerides | 1.5 mmol/l |

Serum Biomarkers:
Results

SCORES

Test Name:

With description for each test

Result:

Scores and classification

0.43

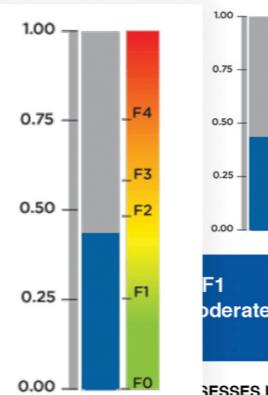
Results:

Blue robust charts providing the level of fibrosis, inflammation and steatosis

Recommendations:

For better usage of the test

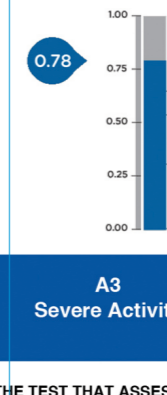
FIBROTEST



FIBROSIS:

Scarring caused by the liver's reaction to hepatitis virus attack, fat or alcohol. Liver fibrosis is usually compared to a scar which spreads in the liver.

ACTITEST

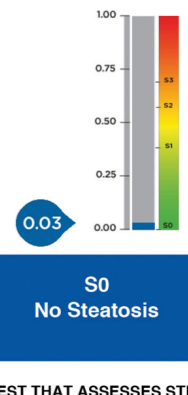


IS THE TEST THAT ASSESSES INFLAMMATION:

ACTIVITY:

Inflammation of the liver caused by viral infections, fatty liver or alcohol.

STEATOTEST



IS THE TEST THAT ASSESSES STEATOSIS:

STEATOSIS:

Accumulation of fat in the liver, caused by metabolic anomalies (cholesterol, triglycerides, diabetes, overweight). Steatosis is commonly referred to as fatty liver.

INTERPRETATION/RECOMMENDATIONS

INTERPRETATION:

- Your result for the SAF score is S0-A3-F1.
- This score indicates that you have no or minimal steatosis, a severe inflammation activity and a minimal or moderate fibrosis.
- Consult your physician for further evaluation.

PRECAUTIONS:

- The reliability of results is dependent on compliance with the preanalytical and analytical conditions recommended by DDA.
- The tests have to be deferred for: acute hemolysis, acute hepatitis, acute inflammation, extra hepatic cholestasis.
- The advice of a specialist should be sought for interpretation in chronic hemolysis and Gilbert's syndrome.
- The test interpretation is not validated in liver transplant patients.
- Isolated extreme values of one of the components should lead to caution in interpreting the results.
- In 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 33% variability rate for one fibrosis stage.