



# NASH-FibroTest

Estimating NASH, Steatosis and Fibrosis in NAFLD (non-alcoholic liver disease) patients

NASH-FibroTest is a liver panel including 3 non-invasive tests: NashTest 2, SteatoTest 2 and FibroTest, along with 2 additional tests: ActiTest and AshTest.



## Rational for NASH-FibroTest (NashTest 2 + SteatoTest 2 + FibroTest)

NASH-FibroTest is a liver panel used in the diagnosis and the follow-up of liver NASH, steatosis and fibrosis/cirrhosis with one standard blood sample, done at a local laboratory:

- **NashTest 2:** estimates the liver inflammation as a quantitative assessment<sup>1</sup> of steatohepatitis and the prediction of liver outcome<sup>2</sup>
- **SteatoTest 2:** estimates the liver steatosis<sup>3</sup>
- **FibroTest:** estimates the liver fibrosis<sup>5</sup>, predicts the long-term liver-related mortality<sup>6</sup>

Clinicians need the 3 diagnoses to take a decision for treatment and/or followup.<sup>7-8</sup>

### NashTest 2

NashTest 2 is constructed using updated histological consensus on NASH definition.<sup>9</sup> It is a quantitative test, assessing the severity of the liver inflammation (NASH), without the need of BMI.

The absence of glucose assay makes NashTest 2 more robust in patients with type 2 diabetes.

### SteatoTest 2

Hepatic steatosis, which is assessed by the SteatoTest 2, is a build-up of fat in the liver, which frequently causes elevated levels of gamma-GT and transaminases.<sup>10</sup> SteatoTest is recommended by EASL, EASD and EASO for the management of non-alcoholic liver disease.<sup>11</sup> SteatoTest 2 is equivalent to the SteatoTest (non-inferiority) but is more convenient (no BMI).<sup>3</sup>

### FibroTest:

#### Reference test

FibroTest is recommended by the EASL, EASD and EASO for the management of non-alcoholic liver disease.<sup>11</sup> FibroTest is the reference test for liver fibrosis and cirrhosis (recommended by AASLD<sup>10</sup>, EASL-ALEH<sup>12</sup>, CASL<sup>13</sup>, APASL<sup>14</sup> and WHO<sup>15</sup> in chronic liver diseases).

## Why monitor the liver of NAFLD patients ?

NASH-FibroTest evaluates NASH<sup>1</sup>, steatosis<sup>3</sup>, fibrosis (incl. cirrhosis)<sup>5</sup> and therefore the risk of liver cancer in populations with either: metabolic-related factors (i.e. overweight, hypertension, dyslipidemia or type 2 diabetes)<sup>5,16-17</sup> with coronary artery disease<sup>4</sup> or with ultrasound steatosis<sup>5</sup>.

## NASH-FibroTest comes with 2 additional tests

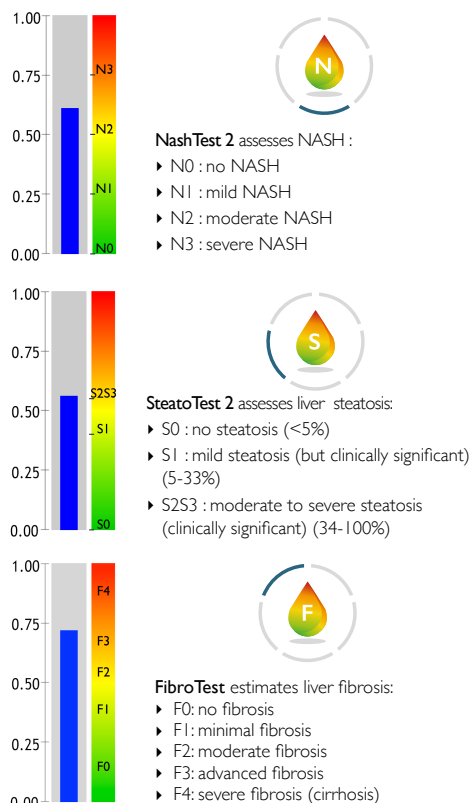
ActiTest and AshTest will also be provided along with NASH-FibroTest as additional tests since they may be very useful when NAFLD is associated with chronic viral hepatitis (ActiTest) or alcohol consumption (AshTest).

	FibroTest	Transient Elastography	APRI	FIB-4
Applicability	●	●	●	●
All stages performance	●	●	●	●
Inflammatory activity false positive	●	●	●	●
Observer variability	●	●	●	●
Cost	●	●	●	●
Prognosis	●	●	●	●

FibroTest benchmark in direct comparisons, in intention to diagnose<sup>18</sup>

NASH-FibroTest is the **only package on the market** combining the EASL recommended non-invasive blood-based tests for both steatosis and fibrosis.

## A complete NASH panel based on a blood sample (no BMI)



## Additional tests:

- ActiTest** estimates necroinflammatory activity:

  - ▶ A0: no activity
  - ▶ A1: minimal activity
  - ▶ A2: moderate activity
  - ▶ A3: severe activity

**AshTest** assesses inflammation due to alcohol:

  - ▶ H0 : no alcoholic steatohepatitis
  - ▶ H1 : moderate alcoholic steatohepatitis
  - ▶ H2 : significant alcoholic steatohepatitis
  - ▶ H3 : severe alcoholic steatohepatitis

**Assays (done at a local lab):** Alpha-2 macroglobulin, Haptoglobin, Apolipoprotein A1, Total Bilirubin, GGT, ALT, AST, Cholesterol, Triglycerides, Fasting Glucose, age, sex - according to BioPredictive precautions of use (biopredictive.com)

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