

# Testing options to help identify NAFLD and NASH

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# There is a growing, unmet need in chronic liver disease.

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Non-alcoholic fatty liver disease (NAFLD) is a collective term used to describe a group of conditions where there is an abnormal accumulation of fat in the liver in those who drink little to no alcohol. This may range from a non-serious condition called fatty liver to a potentially serious condition called non-alcoholic steatohepatitis or NASH.<sup>1</sup>

## NAFLD

NAFLD patients with obesity and features of the metabolic syndrome that include insulin resistance, type 2 diabetes mellitus, hypertension and dyslipidemia have a higher risk of progression to NASH. Not all patients have all manifestations of the metabolic syndrome, however. With the development of NASH, the cardio-metabolic profile worsens, leading to a higher risk of cardiovascular events and death.<sup>1,2</sup>

## NASH

NASH is a chronic liver disease characterized by liver cell injury (hepatocellular ballooning) and inflammation as a result of fatty accumulation (steatosis) seen in at least 5% of hepatocytes. This leads to liver scarring and the development of fibrosis (scored F0 to F4). As fibrosis worsens, liver-related morbidity (including cirrhosis and hepatocellular carcinoma) and mortality increase.<sup>2</sup>



80+  
million

Number of people in the United States living with NAFLD<sup>7</sup>

# Symptoms of NASH

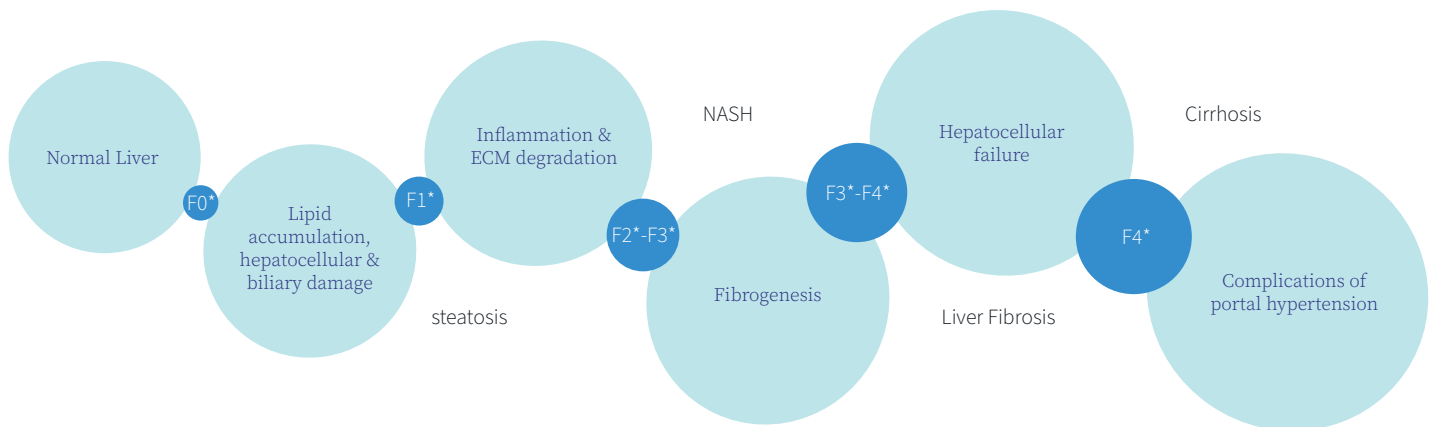
The symptoms of NASH may be very non-specific and can include fatigue, daytime tiredness, or abdominal pain early in the disease. It is usually discovered incidentally due to elevated liver enzymes, abnormal imaging studies or surgery. **As cirrhosis advances**, NASH-specific symptoms are more commonly manifested.<sup>2</sup>

Typically, most people who develop NASH are between 40 and 50 years old, and have one or more of the following health concerns: obesity; insulin resistance and type 2 diabetes; high cholesterol and triglycerides; metabolic syndrome. On the other hand, it is possible for individuals with none of these risk factors to develop NASH.<sup>3</sup>

# Prevalence of NAFLD

The prevalence of NAFLD in the United States is reported to be **between 10% and 30%**<sup>5</sup>, and the pooled overall global prevalence of NAFLD diagnosed by imaging was estimated to be greater than 25%.<sup>6</sup> However, the exact prevalence of NAFLD and NASH in an adult population remains difficult to assess due to the lack of a cost-effective and widely available, minimally-invasive diagnostic test, and to the absence of specific symptoms before end-stages. There are many medications in development for the treatment of NASH; diet, lifestyle modifications and exercise are current recommendations.<sup>7</sup>

## NASH Progression



\*NASH Clinical Research Network (CRN) Scoring System

### **NASHnext™** (504960)

Utilizing NIS4™ technology, NASHnext is a blood-based diagnostic test that quantitatively measures **four independent biomarkers** to produce a **score** that identifies, among patients with metabolic factors, those with at-risk NASH, who are at higher risk of disease progression.

### **NAFLD Cascade** (402205)

The NAFLD Advanced Rule-Out Cascade is intended for use in patients with NAFLD and suspected NASH **with advanced fibrosis** that **include subjects with no alcohol** related disorders and any of the **following: elevated** liver function tests, obesity, type 2 diabetes, metabolic syndrome, imaging evidence of fat accumulation, dyslipidemia, **polycystic ovary syndrome**. These patients may be at high risk for progression to advanced liver fibrosis that can cause a fast progression to end-stage liver disease, hepatocellular carcinoma, and liver transplantation. Non-invasive blood biomarkers can help identify those patients using rule-out approach. **Liver biopsy is still required to definitively diagnose patients with NASH and NASH fibrosis.**

### **FIB-4 With Reflex to NASH FibroSure®** (402070)

The **FIB-4 index** is reported to be a simple, accurate, noninvasive, and readily available laboratory test index **that can** help in evaluation of patients with HCV and Non-Alcoholic Fatty Liver Disease (NAFLD) **for the presence of liver fibrosis** indication for liver biopsy, and other liver-related complications.

### **Liver Fibrosis Risk Profile With Hepatic Function Panel, Complete Blood Count (CBC) With Differential, FIB-4, and APRI** (402145)

**This profile** is intended for use in **screening** patients suspected to be at risk for liver fibrosis. **AST to Platelet Ratio Index (APRI)** is reported to be a simple, noninvasive, and readily available laboratory test index that **can stratify patients with HCV and Non-Alcoholic Fatty Liver Disease (NAFLD)** who are at high or low risk for significant fibrosis and cirrhosis with high degree of accuracy. FIB-4 index is reported to be a simple, accurate, noninvasive, and readily available laboratory test index that can help in evaluation of patients with HCV and Non-Alcoholic Fatty Liver Disease (NAFLD) for the presence of liver fibrosis indication for liver biopsy, and other liver-related complications.

### **NASH FibroSure** (550140)

This noninvasive assessment of liver status **in patients with NAFLD** provides quantitative results of **10 biochemicals** in combination with age, gender, height, and weight. These factors are analyzed using a computational algorithm to provide a **quantitative surrogate marker (0.0-1.0) of liver fibrosis** (Metavir F0-F4), **hepatic steatosis (0.0-1.0, S0-S3)**, and **NASH (0.0-0.75, N0-N2)**. **The absence of steatosis (S<0.38) precludes the diagnosis of NASH.**

### **APRI** (385375)

The AST to Platelet Ratio Index (APRI) assay is reported to be a simple, noninvasive, and readily available laboratory test index that can stratify patients with HCV and NAFLD who are at high or low risk for significant fibrosis and cirrhosis with high degree of accuracy. Results from the APRI test include AST, platelet count and the APRI score.

### **FIB-4** (403604)

The **FIB-4 index** is reported to be a simple, accurate, noninvasive, and readily available laboratory test index that can help in evaluation of patients with HCV and NAFLD for the presence of liver fibrosis, and the indication for liver biopsy, and other liver-related complications. Results from the FIB-4 test **include ALT, AST, platelet count and the FIB-4 score.**



# NAFLD and NASH Related Tests

| Test Name  | Test No. |
|--|----------|
| <b>NASH</b>  |          |
| NASHnext™  | 504960   |
| AST and Platelets with APRI  | 385375   |
| NASH FibroSure®  | 550140   |
| FIB-4  | 403604   |
| Non-Alcoholic Fatty Liver Disease Advanced Fibrosis Rule-Out Cascade   | 402205   |
| Liver Fibrosis Risk Profile with Hepatic Function Panel, Complete Blood Count (CBC) With Differential, FIB-4, and APRI | 402145   |
| FIB-4 with Reflex to NASH FibroSure®   | 402070   |
| <b>Risk of Cardiovascular Disease and Type 2 Diabetes</b>  |          |
| Glucose, Plasma  | 001818   |
| Insulin  | 004333   |
| Hemoglobin (Hb) A1c  | 001453   |
| Lipid Panel Plus ApoB  | 123544   |
| Lipid Panel Plus Inflammation  | 123510   |
| Lipid Panel Plus Diabetes Risk Index   | 123525   |
| Lipid Panel Plus Inflammation and Diabetes Risk Index  | 123559   |
| Lipid Panel Plus Inflammation, Diabetes Risk Index and Apo B   | 123567   |
| NMR LipoProfile® With Insulin Resistance Markers Without Lipids  | 123497   |
| NMR LipoProfile® With Lipids and Insulin Resistance Markers  | 123638   |
| <b>Liver Related Markers</b>   |          |
| Alanine Aminotransferase (ALT/SGPT)  | 001545   |
| Aspartate Aminotransferase (AST/SGOT)  | 001123   |
| Alkaline Phosphatase   | 001107   |
| Alanine Aminotransferase (ALT/SGPT)  | 001545   |
| Aspartate Aminotransferase (AST/SGOT)  | 001123   |
| Alkaline Phosphatase   | 001107   |
| Alanine Aminotransferase (ALT/SGPT)  | 001545   |
| Aspartate Aminotransferase (AST/SGOT)  | 001123   |
| Alkaline Phosphatase   | 001107   |
| <b>ASH</b>   |          |
| ASH FibroSure®   | 550180   |
| Ethyl Glucuronide/Ethyl Sulfate (EtG/EtS), Screen and Confirmation, Urine  | 737610   |
| <b>Hepatitis</b>   |          |
| Hepatitis Panel, Acute   | 322744   |
| Hepatitis A Virus (HAV) Antibody, Total  | 006726   |
| Hepatitis A Antibody, IgM  | 006734   |
| Hepatitis Profile VI (Hepatitis B Profile)   | 058545   |

| Test Name   | Test No. |
|---|----------|
| Hepatitis B Core Antibody, Total  | 006718   |
| Hepatitis B Surface Antibody, Qualitative   | 006395   |
| Hepatitis B Surface Antigen (HBsAg) Screen, Qualitative                                 | 006510   |
| Hepatitis B Virus (HBV), Quantitative, DNA Real-time PCR, (Nongraphical)                | 551610   |
| Hepatitis B Virus (HBV) Genotyping Plus Drug Resistance                                 | 551750   |
| Hepatitis B Virus (HBV) Genotype  | 551710   |
| Hepatitis C Virus (HCV) Antibody With Reflex to Quantitative Real-time PCR              | 144050   |
| Hepatitis C Virus (HCV), Quantitative, Real-time PCR (Nongraphical)                     | 550080   |
| Hepatitis C Virus (HCV), Quantitative, Real-time PCR (Graphical)                        | 550070   |
| Hepatitis C Virus (HCV), Quantitative, RNA PCR (Nongraphical) With Reflex to Genotyping | 550090   |
| Hepatitis C Virus (HCV), Quantitative, RNA PCR (Graphical) With Reflex to Genotyping    | 550100   |
| Hepatitis C Virus (HCV) Genotyping, Nonreflex   | 550475   |
| Hepatitis C Virus (HCV) GenoSure® NS3 / 4A  | 550540   |
| Hepatitis C Virus (HCV) NS5A Drug Resistance Assay                                      | 550325   |
| Hepatitis C Virus (HCV) NS5B Drug Resistance Assay                                      | 550505   |
| Hepatitis C Virus (HCV) FibroSure®  | 550123   |
| Hepatitis C Virus (HCV) Genotype 3 NS5A Drug Resistance Assay                           | 550603   |
| Hepatitis B Surface Antigen, Quantitative, Monitor                                      | 007130   |
| <b>Other</b>  |          |
| α-Fetoprotein (AFP), Tumor Marker   | 002253   |
| α-Fetoprotein (AFP), Tumor Marker (Serial Monitor)                                      | 480012   |
| α-Fetoprotein (AFP) With AFP-L3%, serum   | 141300   |
| Thyroid Peroxidase (TPO) Antibodies   | 006668   |
| Actin (Smooth Muscle) Antibody (ASMA)   | 006643   |
| Mitochondrial (M2) Antibody   | 006650   |
| Liver-Kidney Microsomal (LKM) Antibodies  | 163980   |
| Soluble Liver Antigen (SLA) IgG Antibody  | 007441   |
| α1-Antitrypsin, Serum (preferred) or plasma   | 001982   |
| α1-Antitrypsin Deficiency, DNA Analysis   | 511881   |
| α1-Antitrypsin Phenotyping, Serum   | 095653   |
| Ammonia, Plasma   | 007054   |
| Bilirubin, Total and Direct   | 001214   |
| Ceruloplasmin   | 001560   |
| Copper, Serum or Plasma   | 001586   |
| Copper, Urine   | 003343   |
| γ-Glutamyl Transferase (GGT)  | 001958   |
| Hereditary Hemochromatosis, DNA Analysis  | 511345   |

# Power of the Combined

## Labcorp and Covance by Labcorp working to bring NASH technologies to the forefront

Superior testing options with NASHnext™, NASH FibroSure®, NAFLD cascade, and more through Labcorp

- 15 NAFLD/NASH studies in 5 years, with 4 global phase 3 studies in progress at Covance by Labcorp
- 4,000+ biopsy-confirmed patients recruited by Covance by Labcorp, plus metrics on 700+ sites across 28 countries
- 31 NAFLD/NASH and NASH cirrhosis studies currently being conducted in our labs as of 2019

Drug development leadership & medical testing expertise makes Covance by Labcorp & Labcorp your choice for NASH collaboration



### References

1. American College of Gastroenterology website. Non-alcoholic Fatty Liver Disease (NAFLD). <https://gi.org/topics/fatty-liver-disease-nafld/>. Accessed October 3, 2019.
2. Non-Alcoholic Steatohepatitis. Understanding NASH, A Major Public Health Issue. The NASH Education Program.
3. National Institute of Diabetes and Digestive and Kidney Diseases website. Symptoms & Causes for NAFLD & NASH. <https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/symptoms-causes>. Accessed March 15, 2021.
4. Vernon G, Baranova A, Younossi ZM. Systematic review: the epidemiology and natural history of non-alcoholic fatty liver disease and non-alcoholic steatohepatitis in adults. *Aliment Pharmacol Ther* 2011;34:274-285.
5. Younossi ZM, Koenig AB, Abdelatif D, et al. Global epidemiology of nonalcoholic fatty liver disease—Meta-analytic assessment of prevalence, incidence and outcomes. *Hepatology* 2016; 64(1):73-84
6. National Institute of Diabetes and Digestive and Kidney Diseases website. Treatment for NAFLD & NASH. <https://www.niddk.nih.gov/health-information/liver-disease/nafld-nash/treatment>. Accessed October 3, 2019.
7. Estes C, Razavi H, Loomba R, Younossi Z, Sanyal AJ. Modeling the epidemic of nonalcoholic fatty liver disease demonstrates an exponential increase in burden of disease. *Hepatology*. 2018 Jan;67(1):123-133.

For more information about NASH-NAFLD  
and how it can benefit your patients,  
visit [Labcorp.com/NASH](https://www.labcorp.com/NASH)

