

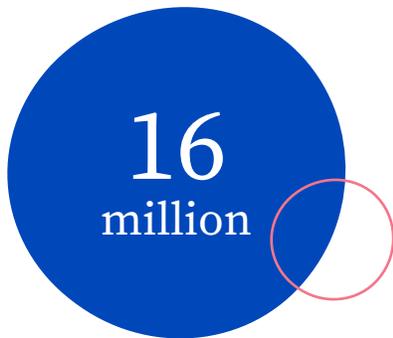
NON-ALCOHOLIC STEATOHEPATITIS (NASH)

NASHnext™: Non-invasive testing for diagnosing NASH



At Labcorp, we believe that proper testing can help identify those with NASH that are at risk for progressing to end-stage liver disease.

Non-alcoholic steatohepatitis, or NASH, is an advanced form of non-alcoholic fatty liver disease (NAFLD). It is estimated that more than 16 million people in the United States are living with NASH, and the prevalence of NASH will increase by 63% by the year 2030.⁴



Number of people in the
U.S. living with NASH⁴



- ✓ More accurate results.
- ✓ Fewer invasive procedures.
- ✓ Better outcomes.

Invasive liver biopsy has been the clinical standard to formally diagnose NASH and determine the state of the disease, and no extensively validated, non-invasive diagnostic tests were available. **Until now.**

NASHnext™, utilizing NIS4™ technology developed by GENFIT, is a non-invasive blood test, utilizing a proprietary scoring system to help identify patients with both NASH and liver fibrosis.

Its performance is shown to be superior to many available tests¹, and data has also revealed that NASHnext is able to identify patients with NASH and liver fibrosis independent of age, sex, body mass index (BMI), aminotransferase levels (ALT or AST), or metabolic comorbidities (type 2 diabetes or obesity). Currently, NASHnext is the only widely-available assay whose diagnostic performance is not impacted by these parameters.¹

GENFIT's groundbreaking NIS4™ technology combines results from four independent biomarkers (miR-34a, a2M, YKL-40/CHI3L1, and HbA1c) into one score, and can be used to identify at-risk NASH (NAS \geq 4 and F \geq 2) in patients with features of metabolic syndrome.¹⁻³



NASH is a silent epidemic, with many people not even knowing they have this disease. Most who have NASH feel fine and probably don't know they have it. Its most basic symptoms – fatigue, mild pain – aren't uncommon for even the healthiest people.

As the disease progresses, however, and liver damage gets worse, they may start to see a worsening of symptoms. If left unchecked, the results can be devastating: NASH may lead to cirrhosis of the liver.

Treating NASH isn't perfect. While lifestyle changes – eating healthier, losing weight, exercise – are all recommended, there is no standard treatment for patients, and nor is there a cure.

NASHnext™ is poised to change current clinical practice, and advance the treatment paradigm for patients with this disease. Armed with the result of NASHnext, you can better counsel your patients on the necessary lifestyle changes and the advisability of the new treatment options soon to become available.

Candidates for the NASHnext test are patients who drink little to no alcohol and have one or more of the following risk factors^{5,6}:

- Hypertension
- Type 2 Diabetes
- Obesity
- Heart Disease
- Insulin Resistance
- High Blood Lipid Levels
- Polycystic ovary syndrome (PCOS)

Test Name	Test No.	Patient Preparation	Specimen	Container	Storage
NASHnext™	504960	Patient must be fasting at least 12 hours before testing	4 mL whole blood and 4 mL serum divided into two tubes	Whole Blood: Lavender-top (EDTA) tube, green-top (heparin) tube or gray-top (sodium fluoride) tube Serum: Gel-barrier tube	Room temperature whole blood; Refrigerated serum; Frozen serum

For more details regarding specimen collection and test details, [visit the Test Menu on Labcorp.com](#).

References

1. Harrison SA, et al. A blood-based biomarker panel (NIS4) for non-invasive diagnosis of non-alcoholic steatohepatitis and liver fibrosis: a prospective derivation and global validation study. *Lancet Gastroenterol Hepatol*.5:11;970-985.
2. Younossi ZM, Koenig AB, Abdelatif D, Fazel Y, Henry L, Wymer M. Global epidemiology of nonalcoholic fatty liver disease-Meta-analytic assessment of prevalence, incidence, and outcomes. *Hepatology*. 2016;64(1):73-84.
3. Portillo-Sanchez P, Brill F, Maximos M, Lomonaco R, Biernacki D, Orsak B, Subbarayan S, et al. High Prevalence of Nonalcoholic Fatty Liver Disease in Patients With Type 2 Diabetes Mellitus and Normal Plasma Aminotransferase Levels, *J Clin Endocrinol Metab*. 2015;100(6):2231–2238
4. American College of Gastroenterology website. Non-alcoholic Fatty Liver Disease (NAFLD). <https://gi.org/topics/fatty-liver-disease-nafld/>. Accessed May 29, 2020.
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6. Kumarendran B, O'Reilly MW, Manolopoulos KN, Toulis KA, et al. Polycystic ovary syndrome, androgen excess, and the risk of nonalcoholic fatty liver disease in women: A longitudinal study based on a United Kingdom primary care database. *PLoS Med*. 2018 Mar 28;15(3):e1002542.

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

