Sample Report, 504960
Patient ID:
Specimen ID: **261-127-9991-0**

DOB: **12/15/1975**
Age: **49**
Sex: **Male**

Patient Report
Account Number: **90000999**
Ordering Physician:

Date Collected: **09/18/2025** Date Received: **09/18/2025** Date Reported: **09/19/2025** Fasting: **Not Given**

Ordered Items: **NASHnext (NIS4)**

General Comments & Additional Information

Clinical Info: NORMAL REPORT

Date Collected: **09/18/2025**

NASHnext (NIS4)

Test	Current Result and Flag	Previous Result and Date	Units	Reference Interval
NIS4 Test[01]	0.30			

<0.36 Lower likelihood of at-risk MASH (1,2)
0.36 - 0.63 Intermediate likelihood
>0.63 Higher likelihood of at-risk MASH (1,2)

"At-risk MASH" is defined as the presence of steatohepatitis with a MASLD activity score (MAS) >=4 and fibrosis stage >=2 (at least moderate fibrosis). Patients with at risk MASH have higher risk of MASH progression leading to liverrelated morbidity.

NASHnext (NIS4) reflects steatohepatitis and fibrosis in a single score from 0.00 to 1.00 based on the results of four individual biomarkers:

1) miR-34a-50: a microRNA contributing to hepatocyte apoptosis, liver fibrosis, and altered lipid metabolism
2) YKL40: glycoprotein associated with activated macrophages and liver fibrosis
3) alpha 2-macroglobulin: protease inhibitor associated with liver fibrosis through inhibition of matrix protein catabolism
4) HbA1c: marker of altered glycemia associated with inflammation and liver fibrosis

Specifically designed to identify at-risk MASH, NIS4 showed robust diagnostic performance in subjects with multiple metabolic disease risk factors (n=702) with an area under receiver operating characteristic curve (AUROC) of 0.80, where <0.36 ruled out at-risk MASH with 82% sensitivity and 63% specificity, and >0.63 ruled in at-risk MASH with 87% specificity and 51% sensitivity.(1)

The independent, FNIH-sponsored NIMBLE study (n=1073) further confirmed NIS4's accuracy for at-risk MASH (AUROC=0.82); by its ability to reflect both MAS and fibrosis, NIS4 outperformed ELF (AUROC=0.77) and FIB-4 (AUROC=0.70) in identifying at-risk MASH.(2)

NIS4 is not impacted by age, sex, body mass index (BMI), ALT, AST, or metabolic comorbidities (type 2 diabetes or obesity).(1,2)

©2025 Laboratory Corporation of America® Holdings
All Rights Reserved - Enterprise Report Version 2.00

This document contains private and confidential health information protected by state and federal law.
If you have received this document in error please call 800-762-4344

Date Collected: **09/18/2025**

NASHnext (NIS4) (Cont.)

Limitations: NASHnext is recommended for patients with suspected at-risk MASH. It is not recommended for patients with other liver conditions, including viral, alcoholrelated or drug-induced hepatitis, genetic or autoimmune liver diseases, and/or extrahepatic cholestasis.

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 2020;5(11):970-985. doi:10.1016/S2468-1253(20)30252-1
2. Sanyal AJ et al. Diagnostic performance of circulating biomarkers for non-alcoholic steatohepatitis. Nat Med 2023;29(10):2656-2664. Doi: 10.1038/s41591-023-02539-6

MASH: Metabolic Dysfunction-Associated Steatohepatitis, renamed from non-alcoholic steatohepatitis (NASH)

MASLD: Metabolic Dysfunction-Associated Steatotic Liver Disease, renamed from non-alcoholic fatty liver disease (NAFLD)

MAS: MASLD activity score, a composite index (0 - 8) that is the sum of steatosis, hepatocellular injury (ballooning), and lobular inflammation scores

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Disclaimer
The Previous Result is listed for the most recent test performed by Labcorp in the past 5 years where there is sufficient patient demographic data to match the result to the patient. Results from certain tests are excluded from the Previous Result display.

Icon Legend
▲ Out of Reference Range ■ Critical or Alert

Performing Labs
01: ES - Esoterix Inc, 4301 Lost Hills Road, Calabasas Hills, CA 91301-5358 Dir: Basel Kashlan, MD
For inquiries, the physician may contact Branch: 800-222-7566 Lab: 800-282-7300

Patient Details
Sample Report, 504960

Phone:
Date of Birth: **12/15/1975**
Age: **49**
Sex: **Male**
Patient ID:
Alternate Patient ID:

Physician Details

LabCorp Test Master
458 South Main Street, BURLINGTON, NC, 27215

Phone: **999-999-9999**
Account Number: **90000999**
Physician ID:
NPI:

Specimen Details
Specimen ID: **261-127-9991-0**
Control ID:
Alternate Control Number:
Date Collected: **09/18/2025 0000 Local**
Date Received: **09/18/2025 0000 ET**
Date Entered: **09/18/2025 1709 ET**
Date Reported: **09/19/2025 1706 ET**

©2025 Laboratory Corporation of America® Holdings
All Rights Reserved - Enterprise Report Version 2.00

This document contains private and confidential health information protected by state and federal law.
If you have received this document in error please call 800-762-4344

Sample Report, 504960
Patient ID:
Specimen ID: **261-127-9992-0**

DOB: **12/15/1975**
Age: **49**
Sex: **Male**

Patient Report
Account Number: **90000999**
Ordering Physician:

labcorp

Date Collected: **09/18/2025** Date Received: **09/18/2025** Date Reported: **09/19/2025** Fasting: **Not Given**

Ordered Items: **NASHnext (NIS4)**

General Comments & Additional Information

Clinical Info: ABNORMAL REPORT

Date Collected: **09/18/2025**

NASHnext (NIS4)

Test	Current Result and Flag	Previous Result and Date	Units	Reference Interval
▲ **NIS4 Test** [01]	**0.72** **High**			

<0.36 Lower likelihood of at-risk MASH (1,2)
0.36 - 0.63 Intermediate likelihood
>0.63 Higher likelihood of at-risk MASH (1,2)

"At-risk MASH" is defined as the presence of steatohepatitis with a MASLD activity score (MAS) >=4 and fibrosis stage >=2 (at least moderate fibrosis). Patients with at risk MASH have higher risk of MASH progression leading to liverrelated morbidity.

NASHnext (NIS4) reflects steatohepatitis and fibrosis in a single score from 0.00 to 1.00 based on the results of four individual biomarkers:

1) miR-34a-50: a microRNA contributing to hepatocyte apoptosis, liver fibrosis, and altered lipid metabolism
2) YKL40: glycoprotein associated with activated macrophages and liver fibrosis
3) alpha 2-macroglobulin: protease inhibitor associated with liver fibrosis through inhibition of matrix protein catabolism
4) HbA1c: marker of altered glycemia associated with inflammation and liver fibrosis

Specifically designed to identify at-risk MASH, NIS4 showed robust diagnostic performance in subjects with multiple metabolic disease risk factors (n=702) with an area under receiver operating characteristic curve (AUROC) of 0.80, where <0.36 ruled out at-risk MASH with 82% sensitivity and 63% specificity, and >0.63 ruled in at-risk MASH with 87% specificity and 51% sensitivity.(1)

The independent, FNIH-sponsored NIMBLE study (n=1073) further confirmed NIS4's accuracy for at-risk MASH (AUROC=0.82); by its ability to reflect both MAS and fibrosis, NIS4 outperformed ELF (AUROC=0.77) and FIB-4 (AUROC=0.70) in identifying at-risk MASH.(2)

NIS4 is not impacted by age, sex, body mass index (BMI), ALT, AST, or metabolic comorbidities (type 2 diabetes or obesity).(1,2)

©2025 Laboratory Corporation of America® Holdings
All Rights Reserved - Enterprise Report Version 2.00

This document contains private and confidential health information protected by state and federal law.
If you have received this document in error please call 800-762-4344

Date Collected: **09/18/2025**

NASHnext (NIS4) (Cont.)

Limitations: NASHnext is recommended for patients with suspected at-risk MASH. It is not recommended for patients with other liver conditions, including viral, alcoholrelated or drug-induced hepatitis, genetic or autoimmune liver diseases, and/or extrahepatic cholestasis.

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 2020;5(11):970-985. doi:10.1016/S2468-1253(20)30252-1
2. Sanyal AJ et al. Diagnostic performance of circulating biomarkers for non-alcoholic steatohepatitis. Nat Med 2023;29(10):2656-2664. Doi: 10.1038/s41591-023-02539-6

MASH: Metabolic Dysfunction-Associated Steatohepatitis, renamed from non-alcoholic steatohepatitis (NASH)

MASLD: Metabolic Dysfunction-Associated Steatotic Liver Disease, renamed from non-alcoholic fatty liver disease (NAFLD)

MAS: MASLD activity score, a composite index (0 - 8) that is the sum of steatosis, hepatocellular injury (ballooning), and lobular inflammation scores

This test was developed and its performance characteristics determined by Labcorp. It has not been cleared or approved by the Food and Drug Administration.

Disclaimer
The Previous Result is listed for the most recent test performed by Labcorp in the past 5 years where there is sufficient patient demographic data to match the result to the patient. Results from certain tests are excluded from the Previous Result display.

Icon Legend
▲ Out of Reference Range ■ Critical or Alert

Performing Labs
01: ES - Esoterix Inc, 4301 Lost Hills Road, Calabasas Hills, CA 91301-5358 Dir: Basel Kashlan, MD
For inquiries, the physician may contact Branch: 800-222-7566 Lab: 800-282-7300

Patient Details
Sample Report, 504960

Phone:
Date of Birth: **12/15/1975**
Age: **49**
Sex: **Male**
Patient ID:
Alternate Patient ID:

Physician Details

LabCorp Test Master
458 South Main Street, BURLINGTON, NC, 27215

Phone: **999-999-9999**
Account Number: **90000999**
Physician ID:
NPI:

Specimen Details
Specimen ID: **261-127-9992-0**
Control ID:
Alternate Control Number:
Date Collected: **09/18/2025 0000 Local**
Date Received: **09/18/2025 0000 ET**
Date Entered: **09/18/2025 1710 ET**
Date Reported: **09/19/2025 1719 ET**

©2025 Laboratory Corporation of America® Holdings
All Rights Reserved - Enterprise Report Version 2.00

This document contains private and confidential health information protected by state and federal law.
If you have received this document in error please call 800-762-4344