CIMA Sciences, LLC

OWLiver® NAFLD Diagnostic Test

Results report

Prescriber's Contact Information

Physician Name:	Postal/Zip Code:
E-mail:	Telephone number:
Hospital/Medical Center:	Department:
Address:	Laboratory:
City:	

Patient Identification Data

Reference Number:

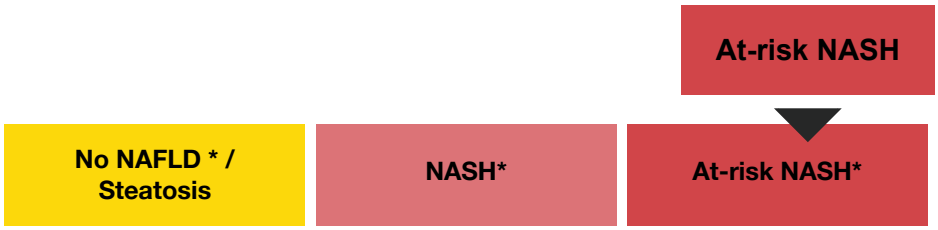
Sample (serum) collection date (DD/MM/YY): Gender (M/F): Age:

Weight (kg): Height (m): BMI (kg/m^2):

Transaminase (U/L): ALT AST

NAFLD* evaluation

Evaluation result:



Graphical representation of the test result. This represents the patient's liver state as **No NAFLD** or specifies the **NAFLD** stage of the patient.

***Notes:**
NAFLD: Non-Alcoholic Fatty Liver Disease.
NASH: Non-Alcoholic Steatohepatitis.
At-risk NASH: NASH, NAFLD Activity Score (NAS) ≥ 4 and fibrosis (F) ≥ 2.

Based on the sample and data supplied, the OWLiver® Panel analysis has determined the above result, which must be assessed by the prescribing physician.

OWLiver® is a blood test carried out under fasting conditions, which measures a panel of biomarkers all of them lipids, using ultrahigh-performance liquid chromatography and mass spectrometry (UHPLC-MS). Such biomarkers are a reflection of the amount of fat, inflammation and fibrosis in the liver and, hence, allow to determine the degree of severity of NAFLD. The relative concentrations of these biomarkers are analyzed in two algorithms that generate the OWLiver® NASH and OWLiver® at-risk NASH scores. These scores allow to classify the patient's liver state as at-risk NASH, NASH or not-NASH (including in this category no NAFLD and steatosis stages). Test is marketed in US by CIMA Science, LLC.

Signature, Laboratory Manager
25th of March 2022

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OWLiver®
NAFLD Diagnostic Test

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Results

Reference Number:

ID	No NAFLD range	Patient's observed values
Met_01_01	0.975 - 3.287	1.386
Met_01_02	0.774 - 2.841	1.122
Met_01_03	1.018 - 2.908	1.639
Met_01_04	0.549 - 1.798	1.528
Met_01_05	1.224 - 2.027	1.108
Met_01_06	1.218 - 3.006	1.688
Met_01_07	0.486 - 1.664	5.376
Met_01_08	0.477 - 1.272	1.665
Met_01_09	0.575 - 1.661	3.957
Met_01_10	1.027 - 2.227	6.205
Met_01_11	1.276 - 3.074	1.968
Met_01_12	1.221 - 5.916	1.145
Met_01_13	0.911 - 2.346	0.835
Met_01_14	2.023 - 8.008	1.408
Met_01_15	2.301 - 9.132	0.888
Met_01_16	2.666 - 9.057	2.230
Met_02_01	1.329 - 3.662	2.474
Met_02_02	0.416 - 1.409	4.469
Met_02_03	1.106 - 2.127	2.682
Met_02_04	0.559 - 2.136	1.733
Met_02_05	1.747 - 4.671	1.286
Met_02_06	1.950 - 9.113	1.703
Met_02_07	1.401 - 4.668	6.930
Met_02_08	1.514 - 3.988	2.128
Met_02_09	1.048 - 2.254	3.478
Met_02_10	0.774 - 1.767	1.795
Met_02_11	1.457 - 6.866	1.775
Met_02_12	0.994 - 13.632	1.145

Chart 1: **Metabolites used in the test**

ALGORITHM	PROBABILITY
OWLiver® NASH	-
OWLiver® at-risk NASH	0.750

Chart 2: Individual probabilities of the algorithms comprising the OWLiver® Panel

Explanation of the OWLiver® Panel

* The analysis is based on the results obtained from two algorithms expressed on a probability scale of 0 to 1.
- A first algorithm, OWLiver® NASH, discriminates between NASH and not NASH (in this category are included no NAFLD and Steatosis). The cutoff is 0.5.
- A second algorithm, OWLiver® at-risk NASH, detects patients with higher risk of disease progression, that is patients with NASH, NAS ≥4, and F≥2. The cutoff is 0.33.

Evaluation result:
At-risk NASH

The score in this test was developed to estimate a patient's NAFLD state and is based on a prospective study in which patients had been previously NAFLD staged using the gold-standard diagnostic method for this disease: invasive liver biopsy. The patients included in the development of the test were multi-ethnic, non-diabetic, controlled diabetic or uncontrolled diabetic and had a BMI greater than 25 kg/m^2. OWLiver®'s technical specifications are available upon request.

Note: The remaining patient sample will be appropriately disposed of in 3 months unless otherwise requested.

References:

M. Noureddin *et al.,* "Serum-based Metabolomics Advanced StEatohepatitis Fibrosis Score (MASEF) for the non-invasive identification of patients with non-alcoholic steatohepatitis with significant fibrosis", J Hepatol, vol. 73, Suppl. 1, Aug. 2020
P. Ortiz *et al.,* "Serum metabolomics-based steatohepatitis score for the non-invasive identification of patients with non-alcoholic steatohepatitis (NASH) in multiethnic, including type 2 diabetes mellitus population", J Hepatol, vol. 75, Suppl. 2, Jun. 2021

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