TEST OWLIVER:

Results report

OWLiver® MASLD Spectrum Diagnostic Test

Patient Name:
Sample internal code:
Sample type:
Sample collection date:

DOB:
Physician Name:
Hospital:
Report issue date:

Patient Data

BMI:

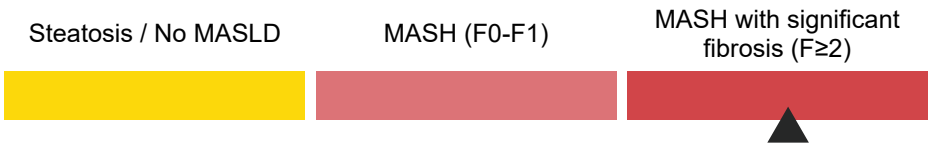
Gender (M/F):

Enzyme	Value	Unit	Reference range
ALT:		U/L	[0 - 55]
AST:		U/L	Male: [5 - 51]; Female: [5 - 34]

MASLD evaluation - TEST RESULT

Based on the lipidomic analysis and the clinical data provided, the analysis of the OWLiver® Test has determined the following result, which should be evaluated by your doctor:

MASH WITH SIGNIFICANT FIBROSIS (F≥2)



Graphical representation of the test result, highlighting the MASLD stage of the patient.

The analysis is based on the results obtained from two algorithms expressed on a probability scale of 0 to 1. In case any of the algorithms has a positive score, an asterisk (*) will appear to its right:

ALGORITHM	PATIENT SCORE	CUTOFF
MASEF® at-risk MASH	**0.695 ***	**0.33**
OWLiver® MASH	**-**	**0.50**

Chart 1: Score of the algorithms comprising the OWLiver® Test

- MASEF® at-risk MASH algorithm: among MASLD patients, detects patients with higher risk of disease progression, that is patients with MASH, NAS ≥4, and F≥2. A score ≥ 0.33 means at-risk MASH.
- OWLiver®-MASH algorithm: discriminates between MASH and not-MASH (in this category are included no MASLD and Steatosis). A score ≥ 0.5 means MASH.

Notes:
MASLD: Metabolic dysfunction-Associated Steatotic Liver Disease.
MASH: Metabolic dysfunction-Associated Steatohepatitis.
At-risk MASH: Metabolic dysfunction-Associated Steatohepatitis with fibrosis grade 2 or higher.

The serum sample shall be kept for seven days for such checks as may be deemed appropriate. After this time the sample will be destroyed.

Luxor™ Scientific Medical Laboratories

Luxor Scientific
1327 Miller Road, Suite F, Greenville, SC 29607
www.luxorscientific.org
T. 864-568-8940
E. clientservices@luxorscientific.org

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OWLiver panel description

OWLiver® is listed as PLA code 0344U by the American Medical Association (AMA) and CIMA Sciences is the proprietary. Performance characteristics were determined by LUXOR Scientific LLC with CLIA NUMBER 42D2120659.

The OWLiver® test consists of a fasting blood lipidomic analysis, which allows the measurement of a panel of biomarkers. These biomarkers are a reflection of the amount of fat and inflammation in the liver, as well as the degree of fibrosis of the liver and, therefore, make it possible to establish the degree of development of metabolic liver disease.

The lipids of the OWLiver® test are determined by high performance liquid chromatography coupled with mass spectrometry (UHPLC-MS). The relative concentrations of these lipids, together with the clinical data provided by the prescriber, are jointly analyzed in two algorithms.

Laboratory Manager

References

1. 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
2. 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
3. M. Noureddin *et al.,* "Serum identification of At-Risk MASH: The Metabolomics-Advanced steatohepatitis fibrosis score (MASEF)", Hepatology, 2024 Jan 1;79(1):135-148. doi: 10.1097/HEP.0000000000000542. Epub 2023 Jul 24
4. M. Noureddin *et al.,* "At-risk NASH identification using an algorithm that combines FIB-4 + MASEF (Metabolomics-Advanced StEatohepatitis Fibrosis score).", Hepatology, Oct. 2023. doi: 10.1097/HEP.0000000000000580
5. P. Iruzubieta *et al.,* "One-step non-invasive diagnosis of metabolic dysfunction-associated steatohepatitis and fibrosis in high-risk population.", United European Gastroenterol J., 2024;12(7):919-929. doi:10.1002/ueg2.12589

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