TEST OWLIVER:

Results report

OWLiver® NAFLD Diagnostic Test

Sample internal code:
External reference:
Sample type:
Sample collection date:

Physician Name:
Hospital:
Report issue date:

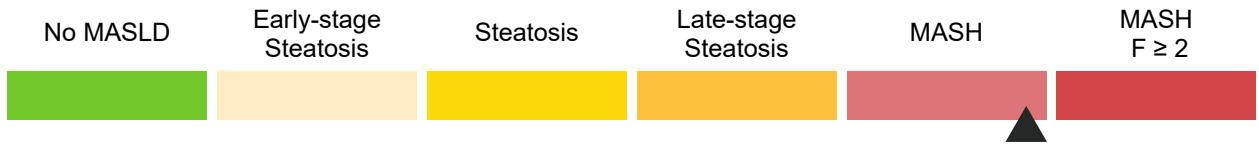
Patient Data

BMI: ALT: AST:

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



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

The analysis is based on the results obtained from three 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
OWLiver® MASLD	**0.997 ***	**0.50**
MASEF® at-risk MASH	**0.326**	**0.33**
OWLiver® MASH	**1 ***	**0.50**

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

- OWLiver® MASLD algorithm: differentiates between non fatty liver and MASLD. A score ≥ 0.5 means MASLD.
- MASEF® at-risk MASH algorithm: among patients with MASLD, identifies those with MASH and fibrosis ≥ 2. A score ≥ 0.33 means MASH with fibrosis grade 2 or higher (at-risk MASH).
- OWLiver® MASH algorithm: among patients with MASLD, discriminates between steatosis and MASH. A score ≥ 0.5 means MASH.

[1] The test has been developed with samples with a BMI greater than or equal to 25 kg/m^2.

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

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

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OWLiver panel description

The OWLiver® Test is an Annex III (self-marked) IN VITRO DIAGNOSTIC medical device that has been developed and patented complying with directive 98/79/CE.

The OWLiver® test consists of a fasting blood lipidomic analysis, which allows the measurement of a panel of biomarkers, all of them lipids. These biomarkers are a reflection of the amount of fat and inflammation in the liver, as well as the degree of fibrosis 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 three algorithms.

The OWLiver® test has been developed to estimate the stage of MASLD and is based on a prospective study in which patients had previously been diagnosed by means of the reference test for this disease, the liver biopsy. The study with which the OWLiver® test was developed was a multi-center and multi-ethnic study in patients with a body mass index greater than 25 kg/m^2 and with different degrees of type 2 diabetes mellitus, including non-diabetics, controlled diabetics and diabetics with poor glycemic control.

Laboratory Manager

References

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