

LIVER-Screen®

Ref. 999984W-3L

Self-testing device for the assessment of liver physiological status in whole blood

GENERAL POINTS

The Liver is an essential organ of the body having a critical role for health. It helps break down food, clean blood, produce proteins and store energy.

In case of liver problems, a number of symptoms may appear including dark urine or light-coloured stool, no desire to eat, yellowish eyes or skin (jaundice), swelling in your belly, weakness or feeling very tired. There might be many reasons for a problem occurrence in liver such as hepatitis, side effects of certain medications, cirrhosis due to heavy drinking, overweight especially in case of diabetes or high blood pressure.

Many tests could be performed on the liver but the most commonly used tests are transaminases (ALT and AST) enzymes assessment. These enzymes are released in the blood by the liver in response to damage or disease.

LIVER-Screen® is a rapid immunodiagnostic test for the immunological detection of increased transaminase (both ALT and AST) levels from a finger prick whole blood sample. The test consists on a plastic housing containing one stick having two distinct zones for transaminases detection (red colour when positive) and one control zone (blue colour).

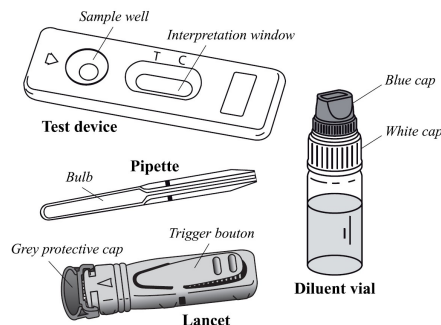
PRESENTATION

The box contains the material necessary to perform a test:

- 1 sealed aluminium pouch containing:
1 test device, 1 plastic pipette and 1 desiccant bag.

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used.

- 1 sterile lancet for blood sampling.
- 1 dropper bottle containing 1 mL of diluent.
- 1 instruction leaflet.



Not provided necessary material: absorbent cotton and alcohol 70 % vol. or alcohol pad.

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic. External use only. DO NOT SWALLOW.
2. Carefully read the instructions before performing the test. The test is only interpretable if the instructions are carefully respected. Follow strictly the indicated time, whole blood and diluent quantities.
3. Store between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
5. Do not re-use LIVER-Screen® test.
6. Keep out of the reach of children.
7. After use, all components can be discarded in a dustbin.

PROCEDURE

Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

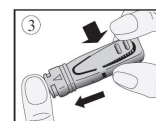
1. Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.



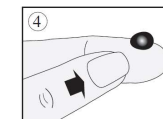
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.
3. Prepare the lancet. Hold the lancet without touching the trigger button. Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished ① & ②.



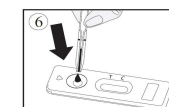
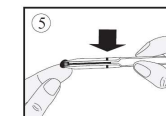
4. Clean the end of the middle finger or ring finger with cotton dampened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button③.



6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample ④.

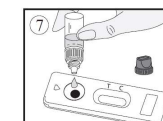


8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥.



10. Wait 30-40 sec for the blood being totally absorbed into the sample well. Unscrew the blue cap of the diluent dropper bottle (leave the white cap tightly screwed) and add the diluent as follows:

Hold the diluent dropper bottle vertically and slowly add exactly 4 drops in the sample well of the device⑦ with an interval of 2-3 seconds between each drop.



11. Read the result after 10 minutes. Do not interpret after 15 minutes.

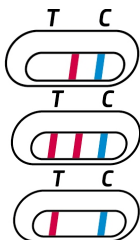
RESULTS INTERPRETATION

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

1. Positive result

In addition to the blue colour line (C), one or two red colour line(s) appear(s) in the detection zone (T) as indicated below.

This result means that either one or both transaminases levels are higher than the norm (80 IU/L) and that **you should consult a doctor.**



2. Negative result

Only one blue coloured line appears in the control zone (C). This result means that the transaminases concentrations are normal and **the liver is functioning correctly.**



3. Invalid result

If there is no blue colour line in the control zone (C) whatever the line(s) appearing or not in the detection zone (T), the test is invalid. It is recommended to repeat the test with another LIVER-Screen® device and a new blood sample.

QUESTIONS AND ANSWERS

How does LIVER-Screen® work?

In case of liver injury, transaminases (ALT and/or AST) are released by the liver in the blood stream. LIVER-Screen® rapid test detects these transaminases thanks to specific immunological reagents for each of both transaminases when their concentration is over 80 IU/L according to *I.F.C.C. international reference method. LIVER-Screen® test uses a couple of antibodies detecting specifically transaminases (ALT and/or AST) by producing one or two coloured test lines, in case of abnormal concentration, under the T mark of the cassette. A control line capturing the reagent excess appears as a blue coloured line under the C mark of the cassette.

*International Federation of Clinical Chemistry.

When should the test be performed?

In case of liver problems, a number of symptoms may appear including dark urine, light coloured stool, no desire to eat, yellowish eyes or skin, swelling in your belly, weakness or feeling very tired.

It is recommended to perform LIVER-Screen® screening test. LIVER-Screen® test could be performed any time of the day.

Can the results be incorrect?

The results are accurate as long as the instructions are carefully respected.

Nevertheless, the result can be incorrect if LIVER-Screen® test gets wet before test performing or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box allows making sure the collected blood volume is correct.

How to interpret the test?

LIVER-Screen® test should be considered as positive when, in addition to a blue line, one or two red lines, corresponding to each transaminase (ALT and AST), appear. Hepatic problems may indeed lead to an increased concentration of one transaminase only.

What is the blue line that appears under the mark C (Control) for?

When this blue line appears, it only means that the test has been performed well.

If I read the result after 15 minutes, will the result be reliable?

No. The result should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

What do I have to do if the result is positive?

If the result is positive, it means that the ALT and/or AST transaminase level in blood is higher than the norm (80 IU/L) and that you should consult a doctor to show the test result. Then, the doctor will decide whether additional analysis should be performed. Although ALT and AST level concentration is valuable in the diagnosis of liver disease, it should be used in combination with other hepatic enzymes (alkaline phosphatase, lactate dehydrogenase, gamma-glutamyl transferase...) activity levels and other blood analytes such as urea, creatinine or bilirubin to evaluate the liver function. The increase in transaminases activities could be due to many others reasons (ex: intensive exercise, overweight...). Only a doctor could make a diagnosis after considering clinical investigation and additional test results.

What do I have to do if the result is negative?

If the result is negative, it means that the ALT and/or AST transaminase level is below 80 IU/L and is within the norm. However, if the symptoms persist, it is recommended to consult a doctor.

What is the accuracy of LIVER-Screen®?

Evaluation report performed on LIVER-Screen® test shows an overall agreement of 89.2% [84.8 - 92.7%] ** with the clinical chemistry reference method. Although this test is reliable, false positive or false negative results could be obtained.

****CI 95%: 95% Confidence Interval**

Information on liver problems :

http://www.doctissimo.fr/html/sante/analyses/ana_enzymes08.htm
<https://www.ncbi.nlm.nih.gov/books/NBK425/>
<https://www.mayocliniclabs.com/test-catalog/Clinical+and+Interpretive/8360>

Sterile lancet: **STERILE R**  1639

Owen Mumford Ltd
Brook Hill, Woodstock, Oxfordshire
OX20 1TU (UK)

EC REP GERMANY

Owen Mumford GmbH, Alte Häge 1,
63762 Großostheim, Germany

	Read the instructions before use	IVD	For in vitro diagnostic use		Do not reuse
	Store between +4°C and +30°C	LOT	Batch number		Expiration date
	Manufacturer	EC REP	Authorized EU representative		

 **VEDA-LAB**
Rue de l'Expansion - ZAT du Londeau -
Cerisé - BP 181 - 61006 ALENCON Cedex
(France)

 0483

CHANGES DESCRIPTION

Changes type :

- N/A	Not Applicable (creation)
- Technical change	Addition, revision and/or removal of information related to the product.
- Administrative	Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
Administrative	EC REP for Owen Mumford

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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