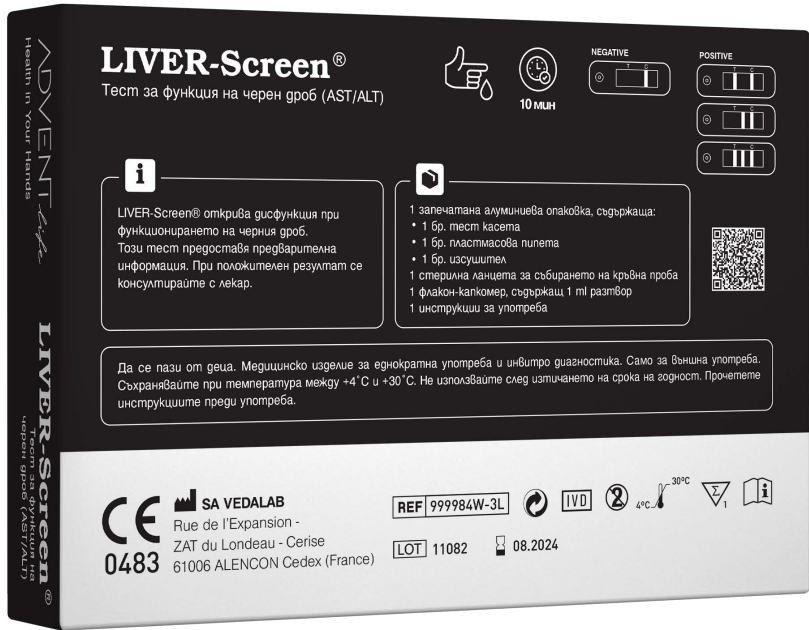


Self-testing device for assessing of the physiological status of the liver in whole blood (AST/ALT) (at-home liver function test)

-  FAST
-  EASY
-  ACCURATE



Our ambition is to make healthcare widely accessible by empowering self-care globally.

Driven by our spirit of innovation, **Advent Life** specialises in self-tests for a wide range of medical conditions, while also offering other products that allow everyone to take health into their own hands. We enable people to take the first step themselves and at their own convenience.

Advent Life focuses on bringing the best from the world while prioritising safety and easy-to-use products. We design premium brands that are delivered to pharmacies, hospitals, laboratories, public organisations and government institutions.

For more information, visit www.adventlife.net.

FUNCTIONS OF THE LIVER

The Liver is an essential organ of the body and has a critical role for our health. It helps break down food, clean blood, produce proteins and store energy. There might be many reasons for a problem occurring in the liver such as hepatitis, side effects of certain medications, cirrhosis due to heavy drinking, overweight especially in case of diabetes or high blood pressure.

WHAT ARE TRANSAMINASE ENZYMES AST AND ALT?

Many liver tests can be performed, but the most commonly used tests are to evaluate transaminase enzymes (ALT and AST). These enzymes are released into the blood by the liver in response to injury or disease.

WHAT ARE THE SYMPTOMS?

If there is liver damage, a number of symptoms may occur:

- Dark urine
- Light stools
- Lack of appetite
- Yellowing of the eyes or skin (jaundice)
- Abdominal swelling
- Weakness
- Feeling very tired

SELF-TESTING DEVICE FOR ASSESSING THE PHYSIOLOGICAL STATUS OF THE LIVER IN WHOLE BLOOD

PURPOSE

In case of liver damage, 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 the transaminases when their concentration is over 80 IU/L according to the *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 test device. A control line capturing the reagent excess appears as a blue coloured line under the C mark of the test device.

*International Federation of Clinical Chemistry.

FAST AND RELIABLE RESULTS

Time: 10-15 minutes.

Store between +4°C and +30°C. Do not freeze!

1 test per box.

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

Easy to read results.

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 occur.

CLINICAL EVALUATION RESULTS

Sensitivity: 98.40 %

Specificity: 100 %

Accuracy: 98.80 %

PROVIDED MATERIALS:

- 1 sealed aluminum pouch containing:
- 1 test device
- 1 plastic pipette
- 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

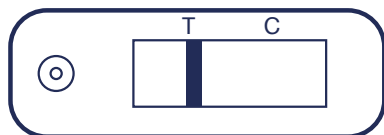
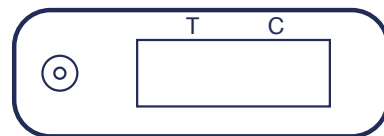
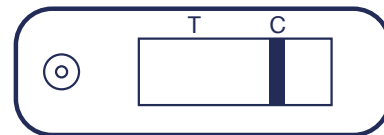
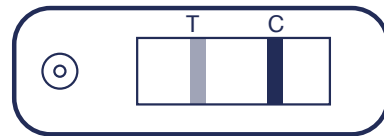
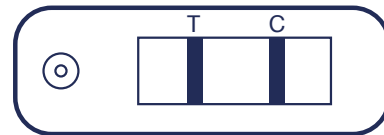
REQUIRED MATERIALS NOT PROVIDED:

Absorbent cotton and alcohol 70% vol. or alcohol pad.



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 hands with a clean towel.
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them within 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 $\frac{1}{4}$ of the way until you feel it separate from the lancet and then continue twisting it (2-3 rotations). Don't pull just twist and discard the cap when finished.
4. Clean the end of the middle finger or ring finger with cotton moistened with alcohol. Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. Press the platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button.
6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.
8. Without pressing the blood drop that has formed, put the plastic pipette in contact with the blood sample. The blood migrates into the pipette through capillarity to the line indicated on the pipette. You may rub your finger again to obtain more blood if the line is not reached. Avoid air bubbles as much as possible.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb.
10. Wait 30-40 sec for the blood to be completely 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 device with an interval of 2-3 seconds between each drop.
11. Read the result after 10 minutes. Do not interpret after 15 minutes.



Positive: 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.

Negative: 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.

Invalid: If there is no blue colour line in the control zone (C) whether other lines appear 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.

NOTE:

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

IMPORTANT INFORMATION

www.adventlife.net

This test is exclusively intended for in vitro diagnostic. External use only. DO NOT SWALLOW.

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.

Store between +4°C and +30°C. Do not freeze.

Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.

Do not re-use LIVER-Screen® test.

Keep out of the reach of children.

After use, all components can be discarded in a dustbin.