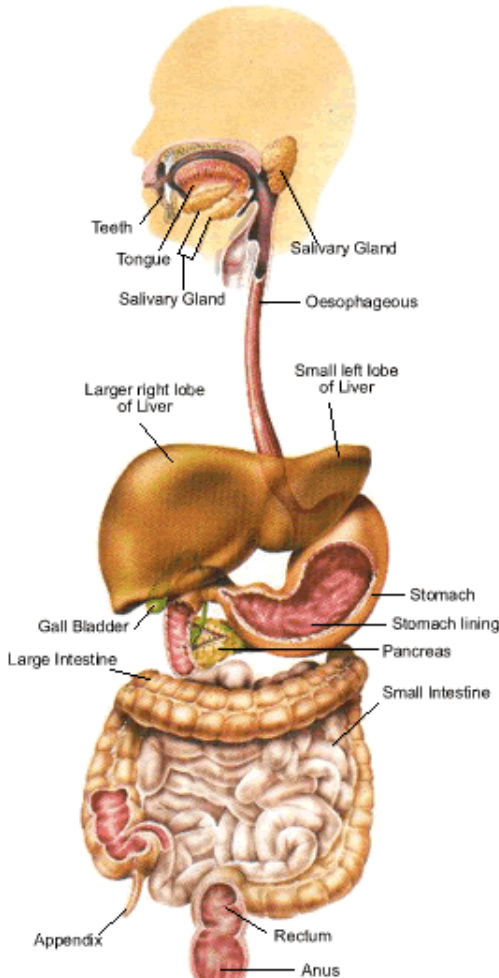


ATLAS HOME LIVER FUNCTION TEST
 For In-Vitro Diagnostic and self testing Use
 Store At room temperature (15-30°C)



INTRODUCTION:

The liver is the largest glandular organ of the body. It weighs about 3 lb (1.36 kg). It is reddish brown in color and is divided into four lobes of unequal size and shape. The liver lies on the right side of the abdominal cavity below the diaphragm (a muscular partition separating the chest and abdominal cavities).



Having a problem with your liver, may cause one or more of the following symptoms:

Symptom 1	Yellowing of the skin and the whites of the eyes. A condition called Jaundice.
Symptom 2	Pain in the right upper abdomen accompanied by pain in the back
Symptom 3	Abdominal swelling
Symptom 4	Weakness and loss of muscle mass
Symptom 5	Light color of feces and/or dark color of urine

The above are the first signs of a liver problem. Jaundice is considered as the most important among them.

Jaundice is caused when excess amount of a compound called bilirubin dissolves in the fat layer under the skin. Bilirubin is a compound that is formed due to the breakdown of Red Blood Cells. It will be carried to the liver by blood vessels and then to the intestines by means of a small duct connecting the liver with the intestine. This duct is called bile duct. Bilirubin can also be stored in the gall bladder which is a very small sac-like organ extending out of the bile duct. In the intestine, bilirubin can be converted to a compound called Urobilinogen by the act of intestinal bacteria. A small percentage of this compound can be reabsorbed to the blood stream. Increased levels of urobilinogen and/or bilirubin in blood will lead to its appearance in urine. Conditions that may increase urobilinogen and/or bilirubin concentration(s) in blood are:

Condition 1	Excessive breakdown of Red Blood Cells. This is common in newborns “Jaundice in newborns”
Condition 2	Obstruction of biliary tract which is associated with gallstones, tumors or liver inflammation which will restrict the movement of bilirubin to the intestine in its way out of the body.
Condition 3	Liver diseases including Hepatitis infection, liver cancer and cirrhosis (a chronic disease that causes the scarring of liver and interferes with the normal functionality of the liver. The major cause is chronic alcoholism).

By means of testing the presence of bilirubin and/or urobilinogen in your urine, which will reflect their concentrations in blood, you will be able to monitor the health status of your liver.

INTENDED USE:

Atlas Liver Function Test provides a dip-and-read test strips that are intended for use to check for Bilirubin and Urobilinogen in urine specimens as an aid in the diagnosis of Liver and gall bladder problems. The test provides results by the visual comparison with color chart printed on the pack.

KIT COMPONENTS:

1. Test strips individually pouched.
2. Package Insert.

STORAGE:

Store at room temperature between 15°-30°(59°-86°F). Do not store the strips in the refrigerator or freezer. Since the test strips are sensitive to specific environmental factors, such as moisture, heat and light, do not expose strips to these factors. Use the strip immediately after removing it from the pouch.

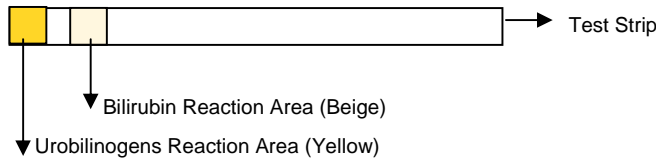
SPECIMEN COLLECTION AND PREPARATION:

- Collect fresh urine sample in a clean and dry disposable container. The container has to be devoid of any detergent traces. Test the urine as soon as possible after collection.

PROCEDURE:

This procedure **MUST BE FOLLOWED EXACTLY** to achieve reliable test results.

1. Check that the product is within the expiration date shown on the kit pack.
2. Prepare the urine specimen.
3. Remove the strip from the pouch. Familiarize yourself with the position of the reaction area of Bilirubin and Urobilinogens. Beige reaction area is for bilirubin while yellow reaction area is for Urobilinogens. Also, familiarize yourself with the color chart on the pack



4. Dip the test strip in the urine until the reaction areas are completely immersed for no more than 1 second.
5. Remove the dipstick from the urine and tap the strip on the rim of the cup to remove excess urine and place it horizontally with the reaction areas facing up.
6. Leave the strip for 30-60 seconds for the reaction to take place.
7. Read the results by comparing the colors of the reaction on the strip with those of the chart. While comparing, keep the strip in a horizontal position to avoid possible mix of colors between the reaction areas on the strip.
8. Identify the best match color on the color chart and the correspondent concentration range. A change in color that appears only along the edges of the reaction areas indicates that the reaction did not take place properly so we recommend redoing the test with another strip. Results read after 60 seconds are not valid.

RESULTS:

The results are obtained by direct comparison of test strip with the color chart printed on the pack. See the table below for interpretation of the results.

HOW TO DETERMINE POSITIVE OR NAGTIVE VALUES:

Any color other than the color indicating negative result is considered positive. Refer to the results table below to see the clarifications of the obtained result.

		Bilirubin Result	
		Positive	Negative
Urobilinogen Result	Positive	You probably have one of the conditions mentioned in <i>table 2</i> . By means of this test you will not be able to distinguish between these conditions and so you are advised to seek medical advice as soon as possible.	Normal urine specimens ordinarily give a light tan or slight pink color. This should be considered normal. Having high concentrations of Urobilinogen while bilirubin is negative is a highly unlikely result. You are advised to repeat the test using fresh urine sample and a new strip. If the result is still the same, you are advised to test for Bilirubin and Urobilinogen in a clinical lab to confirm the results.
	Negative	You probably have <i>condition 2</i> in <i>table 2</i> and particularly, the cause will be the presence of stones in the bile tract. While other conditions such as tumors and inflammation can cause biliary tract obstruction, these conditions will also cause the increase in bilirubin concentration too and therefore such conditions can be excluded. Anyway, you are advised to seek medical advice soon.	Normal. You probably have no problem with your liver. If you are still having any of the symptoms mentioned in table one other than <i>symptom 1</i> , you are probably having a problem not related to liver. If Jaundice is appearing, repeat the test using new fresh sample and new strip. If the result is still negative, seek medical advice soon.

LIMITATIONS OF THE TEST:

Substances that cause abnormal urine color, such as some drugs may affect the color development on the strip. The color development on the reagent pad may be masked, or a color reaction may be produced on the pad that could be interpreted visually as a false positive. It is therefore recommended that in case of doubt, the test should be repeated after stopping the medication.

Bilirubin: Since the bilirubin in specimens is sensitive to light, exposure of the urine specimens to light for a long period of time may result in a false negative.

Ascorbic acid concentration of 25-50mg/dl may also cause false negatives. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. False positive results may be obtained in the presence of diagnostic or therapeutic dyes in the test urine.

Urobilinogen: the strip cannot demonstrate a complete absence of Urobilinogen in the specimen being tested. Normal urine specimens ordinarily give a light tan or slight pink color. Higher concentration of formalin may give false negative result.

PRECAUTIONS & WARNINGS

1. Please read all the information in this leaflet before performing the test.
2. Do not use the test after the expiration date.
3. If the package is not completely sealed do not use the test.

4. Do not open the test foil pouch until it has reached room temperature and you are ready to start the test.
5. The test should be performed in a well-lit area.
6. Use the test device immediately after opening it.
7. Do not touch the test area. This could affect results and may also impose personal hazards.
8. Use a disposable sample container to be discarded after performing the test.
9. The pouch contains a Silica Gel pack to absorb humidity. Do not open the pack. Throw it away with the remaining of the test.
10. Do not freeze.
11. At the end of the test, wrap every thing you have used in a plastic bag and throw away in the bin. Do not forget to wash your hands properly.
12. The remaining sample should be discarded and flushed in the toilet.
13. Keep out of the reach of children.
14. For *in vitro* diagnostic and self-testing use. Not to be taken internally.

QUESTIONS AND ANSWERS:

Q: If the colors of the reaction areas on the test strip are different than what they should be, what shall I do?

A: In such case you are advised not to use this strip since it will not give accurate results. You have to use a new strip. If the same problem is seen, contact your local distributor.

Q: If results are read after more than one minute, are the results still reliable?

A: Best results are obtained at 60 seconds (1min.), if this time is exceeded, the results will not remain the same and may lead to false readings.

Q: At what time of the day the test should be performed?

A: This test can be done any time of the day. Try to minimize liquid uptake one hour before doing the test.

Q: Why should I use fresh sample for this test?

A: Bilirubin and Urobilinogen are sensitive to light and can be decomposed if left for long time. Accordingly, results may not reflect the actual concentration of these two compounds in the urine sample since they would have been partly decomposed.

Q: Is there any indication of urine color?

A: Presence of bilirubin in urine will make the color of urine quite dark. In this case the color is almost brownish orange. Other compounds and some kinds of food may cause urine coloration. So, urine color should not be used as a sole criteria for testing bilirubin.

Q: What is hepatitis?

A: Hepatitis is an inflammation in the liver that can be caused by infections with various organisms including bacteria and viruses (Hepatitis A, B, C...etc.) or parasites. Chemical toxins such as alcohol, drugs, and poisonous mushrooms can also damage the liver and cause it to become inflamed.

Q: What is "Biliary Tract Obstruction"?

A: Biliary tract obstruction involves the blockage of any duct that carries bile (Bilirubin and other salts) from the liver to the gallbladder or from the gallbladder to the small intestine. This may be caused by biliary stones, tumor in the liver or inflammation of the liver. Jaundice and pain in the upper right abdomen that is accompanied with a pain in the back are the most important symptoms of such condition.

ATLAS MEDICAL

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