

# LIVER DISEASE TESTS

The test strips enclosed have 10 parameters on each strip. The 2 pads which relate to the detection of liver disease are detailed directly below. The other remaining 8 test pad results are explained in brief at the end of the instructions.

Intended use : For self-testing use  
Product : DUS 10

READ INSTRUCTIONS COMPLETELY BEFORE USING THE TEST

## INTRODUCTION

This Liver Disease test detects the presence of Bilirubin and Urobilinogen in your urine. If you obtain an abnormal result with the first strip, repeat the test using another strip.

## WHAT IS THE LIVER?

The liver is the largest glandular organ in the body, it is situated in the upper abdomen and is protected from injury by the rib cage. The liver has many important functions some of which include:

- The production of bile
- Helps the body to digest fats
- Stores vitamins, iron and other essential nutrients until the body needs them
- Converts the food you eat into energy needed for daily life
- Aids in the removal of toxic substances (e.g. drugs and alcohol) from the bloodstream
- Makes blood proteins

## WHAT CAN GO WRONG WITH THE LIVER?

The liver can repair itself quite easily and can usually function with only a small portion of it working. There is very little evidence of an ageing problem and in the absence of disease the liver functions fully right into old age. There are hundreds of liver disorders but some are quite rare. The most common ones are:

- Alcoholic Liver Disease
- Cirrhosis
- Gallstones

## HOW DO I KNOW IF THERE IS ANYTHING WRONG WITH MY LIVER?

Most liver disease is symptomless and when there are symptoms they are often vague. However, as the disease progresses you may feel generally unwell as well as experiencing any of the following:

- Loss of appetite
- Weight Loss
- Jaundice (Yellowing of the skin and the whites of the eyes)
- Abdominal swelling
- Pain in the right upper abdomen accompanied by pain in the back

## WHY DO I NEED THIS TEST?

Because of its location and many functions, the liver is prone to many diseases such as hepatitis A, B, C, E, alcohol damage, fatty liver and cirrhosis. There are over one hundred types of liver disease and they affect millions of people in the UK. This figure may only be the tip of an iceberg as many cases of liver disease remain undiagnosed. This is because your liver is very resourceful and able to work well enough even when it may be damaged. This means that you may often not 'present' with clear symptoms, or show obvious sign of liver disease or illness. This simple home screening test can help to identify the health of your liver by checking for Bilirubin and Urobilinogen levels in your urine.

## UROBILINOGEN

Is normally present in low concentrations in urine. High levels of Urobilinogen can indicate liver disease or conditions associated with increased breakdown of red blood cells.

## BILIRUBIN

Is a brownish yellow protein usually excreted in bile. It is produced when the liver breaks down old red blood cells. Bilirubin is not usually found in normal urine. The presence of Bilirubin in urine is an early indicator of liver disease, obstruction of the bile duct or hepatitis. If urine contains Bilirubin it can make the colour of urine quite dark.

## PACK CONTENTS

1 or 2 Foils containing 1,2 or 5 test strips  
Comparison Chart  
Instructions

## WARNING AND PRECAUTIONS

For in vitro diagnostic use only.  
All test strips within each foil will need to be used immediately once that foil has been opened.

## STORAGE AND HANDLING

Store in a cool, dry place at temperatures between 2°C ~ 30°C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. As long as the foil pouch has not been opened, the product is stable up to the expiry date printed on the foil. Do not touch test areas of urine reagent strips. Do not open foil pouch until ready to use. All test strips will need to be used immediately once the foil has been opened.

Discolouration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, confirm that the product is within its expiration date and is reacting properly using known negative and positive control materials. Do not use after the expiry date.

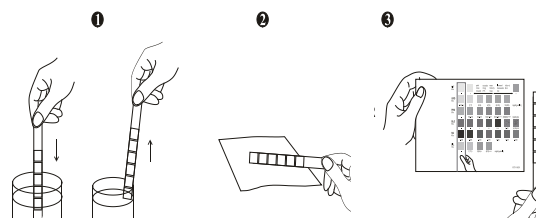
## SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen as soon as possible, with the sample well mixed but not centrifuged. The use of fresh morning urine is recommended for optimal nitrite tests, as well as for the valid determination of bilirubin and urobilinogen, since these compounds are unstable when exposed to light. If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination. If cleanly voided specimens are not collected from females, positive results for leukocytes may be found due to contamination from outside the urinary tract. Skin cleansers containing chlorhexidine may affect protein test results if specimen contamination occurs.

## VISUAL TEST PROCEDURE

The procedure must be followed exactly to achieve reliable results. Do not compare strips with colour chart before the strip is dipped in urine.

- 1) Dip the strip into the urine up to the test area, ensuring all reagent pads are fully immersed. Dip for no more than two seconds.
- 2) Draw the edge of the strip along the brim of the vessel to remove excess urine; be careful not to allow the test areas to touch the brim of the vessel. Turn the strip on its side and tap once on a piece of absorbent material to remove any remaining urine; excessive urine on the strip may cause the interaction of chemicals between adjacent reagent pads, so that an incorrect result may occur.
- 3) Compare the colours of the reagent pads after exactly 60 seconds (Leukocytes after 90-120 seconds) with the colour chart on the vial label under good light. While comparing, keep the strip horizontal to prevent possible mixing of chemicals when excessive urine is present.



## RESULTS:

Test results should be read at 60 seconds but no longer than 2 minutes as this could give an inaccurate reading.

**Urobilinogen Results:** The results comparison chart for urobilinogen shows a line of 5 colours starting with 2 normal results and then three positive ranges which get darker the higher the levels detected. The readings read from 0.1 mg/dl (1.6µmol/L) up to 8mg/dl (131µmol/L) and are indicated by a peach colour through to dark pink.

**Bilirubin Results:** The results comparison chart for bilirubin shows a line of 4 colours starting with a negative result and then three positive ranges which get darker the higher the levels detected.

Compare the strip to the colour comparison chart. Compare each test individually, and if the colour pad on the strip is the same colour as the negative reading on the comparison chart then no urobilinogen or bilirubin has been detected in your urine.

If there is a small change of colour, repeat the test again the following day and if a similar result appears again then you should consult your doctor for advice. A high level means that the test has found excess urobilinogen or bilirubin in your urine. This does not always mean that you have a liver condition. However, it is very important that you visit your doctor to discuss your test result.

If the result was negative this means at this time no excess urobilinogen or bilirubin was found in your urine. If the result is negative and you do not have any symptoms, you do not need to do anything else. However, you should visit your doctor if the result was negative but you are experiencing any of the associated symptoms mentioned above.

## QUESTIONS AND ANSWERS

### At what time of the day the test should be performed?

This test can be done any time of the day. Try to minimise liquid intake one hour before doing the test.

### If I dipped the strip in urine for more than a second will this affect the result?

If you left the strip in the urine for 2-3 seconds this will not affect the result but if left for more than 5 seconds the results could be inaccurate.

### Why should I use a fresh sample for this test?

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

## INTERPRETATION OF ADDITIONAL 8 TEST PAD RESULTS

Results are obtained and interpreted by comparing the colour of the test pads on the strip with the colour blocks printed on the colour chart. In the event of unexpected or questionable results, confirm that the strips have been used before the expiry date printed on the pack then repeat the test using a new strip.

If the results are outside the normal levels (see below), consult your doctor.

## NOTE: DO NOT TAKE ANY MEDICAL DECISION WITHOUT CONSULTING YOUR DOCTOR.

**Nitrite:** Nitrite is not detectable in normal urine. Positive nitrite can be indicative of urinary tract infection. Any degree of uniform pink to red colour should be interpreted as a positive result and you should consult your doctor. Viewing the test against a white background may help the detection of low levels of nitrite, which might otherwise be missed. Pink spots or pink edges should not be interpreted as a positive result.

**Protein:** Up to 14 mg/dL of protein may be excreted by a normal kidney. Higher than normal levels of protein in urine may indicate a variety of disorders including diseases of the kidney and urinary tract. In older patients, high protein levels may occasionally indicate heart problems. If your result is 30mg/dL (0.3g/L) or more, consult your doctor.

**Specific Gravity:** Urine collected at different times of day may vary in specific gravity from 1.003-1.035. Specific gravity equal or less than 1.010 indicates dilute urine and readings equal or greater than 1.025 indicate concentrated urine. Low readings may simply be due to excessive liquid intake and high readings may be due to insufficient drinking causing dehydration. However, persistent low readings can be due to kidney problems and continuous high readings can be indicative of underlying clinical problems relating to the kidney and possibly the heart and should be checked by your doctor. High protein levels in urine (more than 300mg/dL) can cause high specific gravity results.

**Blood:** The presence of red blood cells or haemoglobin in urine can indicate diseases or damage to the kidneys or urinary tract. A positive (+) result may be seen as either a uniform colour change of the test pad or the appearance of green spots on the test pad (see colour chart). If either type of positive result is obtained, consult your doctor.

Note: Strenuous exercise can cause blood to appear in urine and blood is often found in the urine of menstruating women. A uniform colour change indicates the presence of haemoglobin or broken red blood cells in the urine. Green spots on the test pad indicate the presence of intact red blood cells (erythrocytes)

**Glucose:** The kidney normally excretes small amounts of glucose. Concentrations of 100mg/dl may be considered as abnormal if found consistently and may indicate diabetes. The results comparison chart for glucose shows a line of 6 colours starting with a negative result (pale blue) and then five positive ranges which get darker the higher the levels detected through to dark brown. If you get a positive result, consult your doctor.

**Ketones:** Ketone bodies should not be detected in normal urine specimens with this reagent. The results comparison chart for ketones shows a line of 6 colours starting with a negative result (pale pink) and then five positive ranges which get darker the higher the levels detected through to deep burgundy. If you get a positive result, this may indicate diabetes and you should consult your doctor.

**pH:** Urine values generally range from pH 5 to 9. Results that are either too high or low can indicate that your body will form kidney stones. If you receive a highly acidic or highly alkaline result, consult your doctor.

**Leukocytes:** Normally no leukocytes are detectable in urine. A positive result for leukocytes is indicative of a urinary tract infection. If leukocytes are found in your urine sample the colour of the test strip will change colour and go dark pink or purple. If you get a positive result, consult your doctor.

## LIMITATIONS OF PROCEDURE

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result. Substances that cause abnormal urine colour may affect the readability of test pads in urinalysis reagent strips.

**Nitrite:** Ascorbic acid (>30mg/dL) may cause false negative result with low level of nitrite containing (<0.03mg) urine. The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as a positive result. Negative result may occur when urinary tract infections are caused by organisms which do not contain nitrate reductase; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite occur; or when dietary nitrate is absent.

**Protein:** False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens.

**Urobilinogen:** The absence of urobilinogen in the specimen cannot be determined. The test area will react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid. Drugs containing azo gantrisin may give a masking golden colour. The test is not reliable method for the detection of porphobilinogen.

**Blood:** Elevated specific gravity or protein in urine may reduce the reactivity of the blood test portion. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations (>30 mg/dl) may cause false negatives at the low level of blood.

**Specific Gravity (SG):** High-buffered alkaline urine may cause diminished result, whereas high-buffered acidic urine may cause slightly elevated result.

**Bilirubin:** Metabolites of drugs, such as pyridium and selenium, which give a colour at low pH, may cause false positives. Indican (indoxyl sulphate) can produce a yellow-orange to red colour response, which may interfere with the interpretation of negative or positive bilirubin readings. Ascorbic acid (> 30mg/dl) may cause false negative result.

**Glucose:** High SG (>1.020) with high pH urine and ascorbic acid (more than 40mg/dl) may cause a false negative for specimen containing small amount of glucose (100mg/dl). Reactivity may be influenced by urine SG and temperature.

**Ketones:** Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Some high SG and low pH urine may give false positive result. Phenolsulphonphthalein may cause false positive result.

**pH:** If the excessive urine is remain on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affect the pH portion, then pH result may be decreased than the actual. This phenomenon is called "run-over effect."

**Leukocytes:** The test result may not always be consistent with the leukocyte cell number by the microscopic examination. High concentration of glucose, high specific gravity, high level of albumin, high concentration of formaldehyde or presence of blood may cause decreased test results. False positive results may occasionally be due to contamination of the specimen by vaginal discharge.

## PERFORMANCE CHARACTERISTICS

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of colour perception; the presence or absence of inhibitory and matrix factors typically found in urine; and the laboratory conditions in which the product is used (e.g., lighting, temperature and humidity). Each colour block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between normal levels may give results at either level. Results will usually be within one level of the true concentration. The following list shows the generally detectable levels of the analytes in contrived urines; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.








## TEST PAD AND SENSITIVITY (SPECIFICITY)

Glucose:	75-125mg/dL (Glucose)	Protein:	15-30mg/dL (albumin)
Bilirubin:	0.8-1.0mg/dL (Bilirubin)	Nitrite:	0.05-0.1mg/dL (Nitrite ion)
Ketones:	5-10mg/dL (Acetoacetic acid)	Leukocytes:	20-25 WBC/ $\mu$ l (Intact and lysed WBCs)
Blood:	10-15 RBC/ $\mu$ l (haemoglobin)		

## BIBLIOGRAPHY

- NCCLS (National Committee for Clinical Laboratory Standard) GP 16-A/ ROUTINE URINALYSIS AND COLLECTION TRANSPORTATION AND PRESERVATION OF URINE SPECIMENS; TENTATIVE GUIDELINE VOL 12-NO 26, EC.1992

## NOTES ON SYMBOLS

	Number of test strips		Do not reuse
	In vitro diagnostic		Store at
	Consult instructions for use		Keep away from sunlight
	Use By /Expiry Date		

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