

KETONES/ KETOSIS TESTS

The test strips enclosed have 10 parameters on each strip.
The pad which relates to the detection of ketosis is ketones and is explained below.
The other remaining 9 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

WHAT IS KETOSIS?

On a low-carb diet such as the Atkins Diet, you must aim for a state of ketosis. Ketosis occurs when your body stops burning carbohydrates for energy and switches to burning fat. You should go into this state during the first few days of the plan, as soon as you begin depriving your body of carbohydrates and supplying it with mainly fat and protein. During ketosis, your body produces ketones.

WHY DO I NEED THESE TESTS?

These tests detect ketones in the urine and so will give an indication on whether you are in a state of ketosis or not.

BUT IS THE PRESENCE OF KETONES A SIGN OF DIABETES?

Yes it can be. Usually our body will turn the food we eat into sugar (glucose) and this is used for energy. But if you have diabetes, you may not have enough insulin for the sugar in your bloodstream to be used for fuel. As a result the body will use fat instead and as the fat is broken down, ketones are produced. This is known as Diabetic ketoacidosis (DKA) and can be very dangerous.

Most cases of diabetic ketoacidosis occur in people with type 1 diabetes, although it can also be a complication of type 2 diabetes.

HOW DO I KNOW IF MY POSITIVE KETONES RESULT INDICATES KETOSIS OR KETOACIDOSIS?

To help determine this, each strip also tests for glucose in your urine. If your urine is positive for both glucose and ketones then you should consult your doctor.

You should also seek medical assistance if you have any of the below symptoms (all are signs of ketoacidosis) alongside a positive ketones result:

- passing large amounts of urine
- feeling very thirsty
- vomiting
- abdominal pain

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.

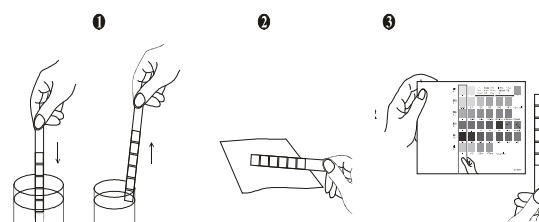
SPECIMEN COLLECTION AND PREPARATION

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.

Ketones Result: The results comparison chart for ketones shows a line of 6 colours starting with a negative result and then five positive ranges which get darker the higher the levels detected. The readings read from 5 mg/dl (0.5mmol/L), 15 mg/dl (1.5mmol/L), 40 mg/dl (3.9mmol/L), 80mg/dl (8mmol/L) and lastly 160mg/dl (16mmol/L). These are indicated by pale pink through to deep burgundy.

Compare the strip to the colour comparison chart. No colour change indicates no ketosis detected. Any shade of pink/purple indicates some level of ketones in the urine.

QUESTIONS AND ANSWERS

Is there a certain time of day when I should carry out the test?

No, the test can be carried out at any time of day. However, be aware that highly concentrated urine may give a false positive result whilst highly diluted urine may give a false negative result. Therefore, it can be better not to use the first urine of the day and to avoid testing after drinking excessive amounts of fluid. You can refer to the specific gravity pad on the strip which will show how concentrated your urine is; specific gravity equal or less than 1.010 indicates dilute urine and readings equal or greater than 1.025 indicate concentrated urine.

What if the sticks don't change colour?

A negative result does not always mean you're not in ketosis. Ketones will spill into the urine only when there is more in the blood than is being used as fuel by the body at that particular moment. If you're keeping your carbs below a certain level, you're probably in ketosis. Some people just use their ketones more efficiently, and indeed make fewer of them, hence their lack of "spill" into the urine. In addition, if you exercised a few hours previously, your muscles would have used up the ketones as fuel, thus there will be no excess. Or if you have had a lot to drink, the urine will be more diluted which may give an inaccurate result.

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.

INTERPRETATION OF ADDITIONAL 9 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.

Urobilinogen: 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. All results lower than 1 mg/dL urobilinogen should be interpreted as normal. If your result is 2mg/dL (35µmol/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.

Bilirubin: Bilirubin is not found in normal urine. The presence of bilirubin in urine is an early indicator of liver disease such as obstruction of the bile duct or hepatitis. Any positive result should be investigated further by your doctor. If you are taking drugs containing chlorpromazine or rifampin, colour reactions may occur on the test pad that might be mistaken for positive bilirubin.

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.

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. Phenosulphonphthalein 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/µl (Intact and lysed WBCs)
Blood:	10-15 RBC/µl (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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