

KIDNEY FUNCTION TESTS

This Kidney Function Test provides dip-and-read test strips that are intended for use to check for Creatinine, Protein and Specific Gravity in urine specimens as an aid in the diagnosis of kidney diseases and problems. The test provides results by the visual comparison with the enclosed colour chart. If you obtain an abnormal result with the first strip, repeat the test using another strip.

Intended use : For self-testing use
Product : DUS 3C

READ INSTRUCTIONS COMPLETELY BEFORE USING THE TEST

INTRODUCTION

Your kidneys are bean-shaped organs, each about the size of your fist. They are located near the middle of your back, just below the rib cage. Kidneys filter water products and extra water from your blood and produce urine as a result. Urine flows to your bladder through tubes called ureters. Your bladder stores the urine which will pass through the urethra in the process of urination.

The average adult passes between 0.8L and 2.6L per day, depending on the fluids they consume. The volume formed at night is about half that formed in the daytime.

The tiny units inside your kidneys, called nephrons, are the actual filtering unit. Every kidney has about 1 million nephrons.

Most kidney diseases attack the nephrons, altering their ability to filter blood and produce urine.

COMMON CAUSES OF KIDNEY DISEASE:

1. Diabetes
2. High blood pressure
3. Poisons
4. Certain drugs
5. Cancer

WHAT ARE THE TYPES AND SEVERITY OF KIDNEY DISEASE?

1. **Acute Renal Failure (AFR):** This type occurs quickly and suddenly. It can happen as a result of an accident that injures the kidney, losing lots of blood, as well as some poisons and drugs. Acute Renal Failure may lead to permanent loss of kidney function but can still be reversed if your kidneys are not seriously damaged.

2. **Chronic Kidney Disease (CKD):** This type involves the gradual loss of kidney function. It happens slowly and may go unnoticed for years. People with CKD are more susceptible to heart attacks and strokes. Most kidney problems fall under this category.

3. **End-Stage Renal Disease (ESRD):** This condition involves total or nearly total permanent loss of kidney function. Dialysis or transplantation is vital for people with ESRD to stay alive.

WHAT ARE THE SIGNS OF KIDNEY DISEASE?

In the early stages of kidney disease, people do not usually feel sick at all. If it gets worse, sufferers may experience any of the following symptoms:

- Need to urinate more often or less often
- Feel tired or itchy (unable to relax)
- Loss of appetite/experiencing nausea and vomiting
- Hands or feet may swell or feel numb
- Drowsiness or have trouble concentrating
- Darkening of the skin
- Muscle cramps (a painful and involuntary muscle contraction)

HOW CAN YOU CONTROL CHRONIC KIDNEY DISEASE?

During the early stages of kidney disease, patients can take certain steps to make their kidneys last longer. Since CKD patients are susceptible to heart attacks, strokes and anaemia (a condition in which the blood does not contain enough red blood cells), they should make sure to minimize the factors that increase the risk of such conditions. Below are brief notes on how to minimize the risk of CKD:

- Controlling your blood glucose
- Controlling your blood pressure
- Following a low-protein diet
- Maintaining healthy levels of cholesterol in your blood
- Quitting smoking

HOW TO TEST FOR KIDNEY FAILURE?

Kidney failure means that the kidney will lose one or more of the following functions:

1. **Filtering ability:** Normal nephrons act as barriers for red blood cells and large molecules such as proteins. Losing this ability means that protein and/or red blood cells are likely to be seen in urine. Since protein is the first to appear and red blood cells will be a sign of later stage, testing for protein in urine can be considered as a diagnostic tool for kidney failure.

2. **Concentrating ability:** After filtering, the kidney will reabsorb almost 99% of the filtrate back to the blood to retain body water. Losing this ability means that the body will lose more water. Clear signs for this are the increased frequency of urinations and diluted urine. A Specific Gravity test will serve to measure the concentration of the urine.

3. **Removing by-products:** A major task for the kidneys is to help the body to get rid of metabolism waste products; the most well-known of these are Urea and Creatinine. These two compounds are usually present in the urine at high concentrations. Having those at low level in urine means that they are not filtered and they are still in the blood. Urea is a by-product of protein while Creatinine is a by-product of muscle energy metabolism. Accordingly, the concentration of Urea may be affected by the amount of protein taken in the diet. Base on that Creatinine is considered as a more specific test for kidney failure.

These tests will test for Creatinine, Protein and Specific Gravity to be used as an aid to evaluate kidney function.

PACK CONTENTS

1 or 2 Foils containing 1 or 2 test strips
Colour 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.

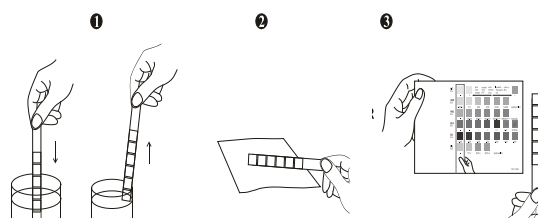
SPECIMEN COLLECTION AND PREPARATION

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.

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 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:

Protein Result

Negative: This is the normal result since urine should not include protein.
Trace: Sometimes having trace amount of protein is considered normal. Repeat the test after several hours. If still having the same result, you should seek medical advice.
30+: This result is not normal. There seems to be a problem with the filtration ability of your kidneys.

Specific Gravity Result

1.000-1.005: This result indicates that your urine is very diluted. The result may be affected by liquid intake. You are advised to repeat the test after 2-3 hours making sure to minimise liquid intake in this period. If you still have the same result, you may have a problem with the concentrating ability of your kidneys and you are advised to seek medical advice.
1.010: This is the same Specific Gravity as the filtrate. You are advised to repeat the test at different times of the day. If you are still having the same result, you may be having a problem with the concentration ability of your kidneys and you are advised to seek medical advice.
1.015-1.025: This indicates a normal result.
1.030: This result also shows that your kidneys are working well. But, having very concentrated urine all the time may reflect a kidney stone problem. It also may be associated with increased Glucose concentration.

Creatinine Result

0-10: This result indicates that Creatinine is not being filtered from the blood. You should seek medical advice as soon as possible.
50+: This shows a normal result which means that your kidneys are working well in eliminating the by-products from your body.

LIMITATIONS OF THE TEST:

Substances that cause abnormal urine colour, such as some drugs may affect the colour development on the strip. The colour development on the reaction areas may be masked, or a colour reaction may be produced on the area 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 (after consultation with your doctor).

Protein: The minimum sensitivity of this test is 10-20mg/dl of protein in urine. Highly buffered alkaline urines (pH 9) may give false negative results. The interpretation of results is also difficult in cloudy urine specimens.

Specific Gravity: Elevated Specific Gravity readings may be obtained in the presence of moderate quantities (100-700mg/dl) of protein. Specific Gravity is also increased when glucose is present in the urine.

Creatinine: Low Creatinine concentration may be associated with adulteration.

QUESTIONS AND ANSWERS:

Q: If the colours of the reaction areas on the test strip are different to how they should be, what should I do?

A: In such cases 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 occurs, contact your local distributor.

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

A: The best results are obtained at 60 seconds. If this time is exceeded it may lead to false readings.

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

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

PERFORMANCE CHARACTERISTICS

The repeatability / reproducibility result of DUS 3C Home Test strips are above 90%.

A comparison results between professional and laymen revealed a very high concordance of between 85-90%. It results were obtained by 909 samples at 2 hospitals.








The values specified for the analytical sensitivity are defined as the concentration of analyte which leads to positive result in >90% of the examined urines. For Specific gravity and Creatinine analytical sensitivity is not applicable.

Test strip	Sensitivity	Specificity
Protein	15-30mg/dL	albumin

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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