

ATLAS HOME KIDNEY FUNCTION TEST

For in-vitro diagnostic and self-testing use
Store at room temperature (15-30°C)

REF 70022001

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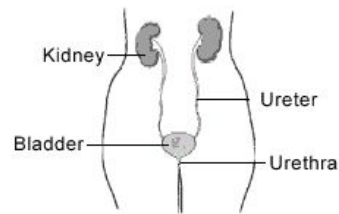
15°C - 30°C

INTENDED USE:

The Atlas 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 visual comparison with a colour chart printed on the pack.

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 a 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 DISEASES?

1. **Acute Renal Failure (ARF):** 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 a 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
- Feeling tired or itchy (unable to relax)

- Loss of appetite/experiencing nausea and vomiting
- Hands or feet may swell or feel numb
- Drowsiness or 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 minimise the factors that increase the risk of such conditions.

Below are brief notes on how to minimise 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 them 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. Based on that, Creatinine is considered as a more specific test for kidney failure.

Based on the above, Atlas is providing a urine test for Creatinine, Protein and Specific Gravity to be used as an aid to evaluate kidney function.

KIT COMPONENTS:

1. Test strips individually pouched
2. Package insert

PRECAUTIONS:

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 be harmful.
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 remainder of the test.
10. Do not freeze.

11. At the end of the test, wrap everything you have used in a plastic bag and throw it 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.

STORAGE:

- Store at room temperature between 15°-30° (59°F-86°F).
- Do not store the strips in the refrigerator or freezer.
- Do not expose strips to moisture, heat and light before use.
- Use the strip immediately after removing it from the pouch.

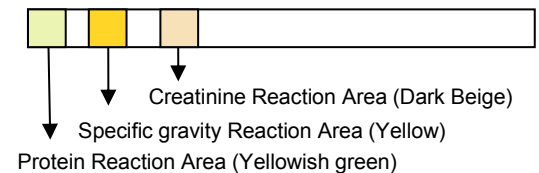
SPECIMEN COLLECTION AND PREPARATION:

Collect fresh urine sample in a clean and dry disposable container. Make sure there are no traces of detergent on the container. 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 pack.
2. Prepare the urine specimen.
3. Remove the strip from the pouch. Familiarise yourself with the position of the reaction area of Creatinine, Specific Gravity and Protein. The dark beige reaction area is for Creatinine, the yellow reaction area is for Specific Gravity and yellowish green is for protein. Also, familiarise yourself with the colour 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. Compare the colours of the reaction on the strip with those of the chart. While comparing, keep the strip in a horizontal position to avoid possible mixing of colours between the reaction areas on the strip.
8. Identify the best colour match on the colour chart and the corresponding concentration range. A change in colour 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:

Protein Result					
Negative	Trace	30	100	300	2000 or more
This is the normal result since urine should not include protein.	Sometimes having a trace amount of protein is considered normal. Repeat the test after several hours. If still having the same result, you should seek medical advice.	This result is not normal. There seems to be a problem with the filtration ability of your kidneys.			
	Sometimes protein may be associated with a Urinary Tract Infection. To exclude this factor you can use the Atlas UTI Test				

Specific Gravity Result				
1.000	1.005	1.010	1.015 - 1.025	1.030
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 minimize 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.		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.		This indicates a normal result. This result also shows that your kidneys are working well. But, having very concentrated urine all the time may reflect a kidney stone problem. You can exclude this result by using the Atlas Kidney Stones Test (coming soon). It also may be associated with increased Glucose concentration. You can use the Atlas Diabetic Check to exclude this factor.

Creatinine Result					
Negative	10	20	50	100	200
This result indicates that Creatinine is not being filtered from the blood. You should seek medical advice as soon as possible.		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 areas 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 increased with the glucose 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 (1 minute); 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 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.

Q: What can I do about kidney disease?

A: Unfortunately, chronic kidney disease often cannot be cured. But if you are in the early stages of kidney disease, you may be able to make your kidneys last longer by taking certain steps. You will also want to be sure that risks for heart attack and stroke are minimised, since CKD patients are susceptible to these problems.

- If you have diabetes, watch your blood glucose closely to keep it under control. Consult your doctor for the latest treatments.
- Avoid painkillers that may make your kidney disease worse; check with your doctor before taking any medicine.

Q: Do I need to have a special diet to control the progress of kidney disease?

A: Here are some points regarding your diet that may help control the progress of the diseased kidneys and also reduce the other risks associated with kidney disease:

Protein: Protein is important to your body. It helps your body repair muscles and fight disease. Protein comes mostly from meat. As discussed in an earlier section, healthy kidneys take waste out of the blood but leave protein. Impaired kidneys may fail to separate the protein from the waste. Some doctors tell their kidney patients to limit the amount of protein they eat so that the kidneys have less work to do, but you cannot avoid protein entirely. You may need to work with a dietician to find the right food plan.

Cholesterol: Another problem that may be associated with kidney failure is too much cholesterol in your blood. High levels of cholesterol may result from a high-fat diet. Cholesterol can build up on the inside walls of your blood vessels; the build-up makes pumping blood through the vessels harder for your heart and can cause heart attacks and strokes.

Sodium: Sodium is a chemical found in salt and other foods. Sodium in your diet may raise your blood pressure, so you should limit foods that contain high levels of sodium. High-sodium foods include canned or processed foods like frozen dinners and hot dogs.

Potassium: Potassium is a mineral found naturally in many fruits and vegetables, like potatoes, bananas, dried fruits, dried beans and peas, and nuts. Healthy kidneys measure potassium in your blood and remove excess amounts. Diseased kidneys may fail to remove excess potassium, and with very poor kidney function, high potassium levels can affect the heart rhythm.

Q: Does smoking affect the progress of kidney disease?

A: Smoking not only increases the risk of kidney disease, it also contributes to deaths from strokes and heart attacks in people with CKD. You should try your best to stop smoking.

Q: Why do most people with kidney disease also have problems with blood pressure?

A: In addition to the kidneys' role in controlling body water content, and removing waste by-products, they also produce a hormone called Renin. This hormone plays a major role in regulating blood pressure. A diseased kidney may lose the ability to produce this hormone, thus affecting the blood pressure.

Q: Does the kidney produce other hormones and what are their roles?

A: Kidneys also produce the active form of Vitamin D and a hormone called erythropoietin.

- The active form of Vitamin D helps maintain calcium for bones and a normal chemical balance in the body
- Erythropoietin, or EPO, stimulates the bone marrow to make red blood cells

Q: What happens if my kidneys fail completely?

A: Complete and irreversible kidney failure is called End-Stage Renal Disease, or ESRD. If your kidneys stop working completely, your body fills with extra water and waste products. This condition is called Uremia. Your hands or feet may swell and you will feel tired and weak because

your body needs clean blood to function properly. Untreated Uremia may lead to seizures or coma and will ultimately result in death. If your kidneys stop working completely, you will need to undergo dialysis or kidney transplantation.















Q: What is dialysis?


A: Dialysis is the process of passing your blood through a machine that filters away waste products. The clean blood is returned to your body in a continuous circulation. Dialysis is usually performed at a dialysis centre three times a week for 3 to 4 hours.

Q: What is Transplantation?

A: This means that a kidney from a donor is to be implanted in your body. The kidney that you receive must be a good match for your body. The more compatible the new kidney, the less likely your immune system is to reject it. Your immune system protects you from disease by attacking anything that is not recognised as a normal part of your body. So your immune system will attack a kidney that appears "foreign." You will take special drugs to help trick your immune system so it does not reject the transplanted kidney.

SYMBOLS USED IN THE LABELING OF THE DEVICE:

	Product Reference No.		Single use. Do not re-use.
	For in-vitro diagnostic use.		Do not use if the pouch is damaged.
	For Self-Testing use.		Store at 15 - 30°C.
	Caution.		Number of tests in the pack.
	Read product insert before use.		Manufacturer.
	Lot (batch) number.		Expiry date.
	Manufacturer telephone number.		Manufacturer fax number.

 **ATLAS MEDICAL**
William James House, Cowley Road, Cambridge, CB4 0WX, UK
Tel: ++44 (0) 1223 858 910, Fax: ++44 (0) 1223 858 524

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