

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



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 work as filters that 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.

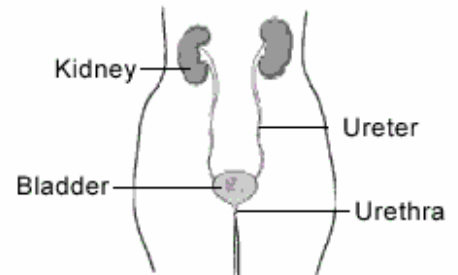
The average adult passes between 0.8L and 2.6L per day, depending on the fluids a person consumes. The volume formed at night is about half that formed in the day time.

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



WHAT ARE THE TYPES AND SEVERITY OF KIDNEY DISEASES?

- Acute Renal Failure (ARF):** This type occurs quickly and suddenly. It is caused as a result of an accident that injures the kidney, losing lots of blood, some poisons and drugs. These conditions may lead to permanent loss of kidney function. Acute renal failure can still be reversed if your kidneys are not seriously damaged.
- Chronic Kidney Disease (CKD):** This type involves the gradual loss of kidney function. It happens slowly and may remain asymptomatic for years. People with CKD are more susceptible to heart attacks and strokes. Most kidney problems are under this category.
- 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 A KIDNEY DISEASE?

At early stages of a kidney disease, people usually do not feel sick at all. If your kidney disease gets worse you may experience one of the following symptoms:

- You may need to urinate more often or less often.
- You may feel tired or itchy (unable to relax).
- You may lose your appetite or experience nausea (the state that precedes vomiting) and vomiting.
- Your hands or feet may swell or feel numb (lacking sensation).
- You may get drowsy (showing lack of attention) or have trouble concentrating.
- Your skin may darken.
- You may have muscle cramps (a painful and involuntary muscle contraction).

HOW CAN YOU CONTROL CKD?

At early stages of a kidney disease, you may be able to take certain steps to make your kidneys last longer. Since CKD patients are susceptible to heart attacks, strokes and anemia (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:

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

HOW TO TEST FOR KIDNEY FAILURE?

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

- Filtering ability:** Normal nephrons acts as barriers for Red blood cells and large molecules such as proteins. Losing this ability, means that protein and/or RBCs are likely to be seen in urine. Since the protein is the first to appear and RBCs will be a sign of later stage. Testing protein in urine can be considered as a diagnostic tool for kidney failure.
- Concentrating ability:** after filtering, kidney will reabsorb almost 99% of the filtrate back to the blood to retain body water. Losing this ability means that the body will loose more water. Clear signs for this are the increased frequency of urinations and diluted urine. Specific gravity test will serve as a measure of how much the urine is concentrated.
- By products removing:** a major task for the kidneys is to help the body getting rid of metabolism waste products. The most famous 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 kept in blood. Urea is a by-product of protein while creatinine is a by-product of muscle energy metabolism. Accordingly, 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.

INTENDED USE:

Atlas Kidney Function Test provides a 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 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°F-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.

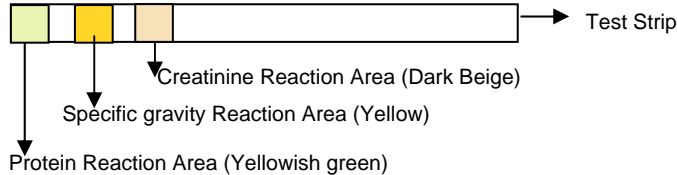
SPECIMEN COLLECTION AND PREPARATION:

- 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 Creatinine, Specific gravity and Protein. Dark beige reaction area is for creatinine, yellow reaction area is for specific gravity and yellowish green is for protein. 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:

Protein Result					
Negative	Trace	30	100	300	2000 or more
This is the normal result since urine should not include protein.	Some times 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.	This result is absolutely abnormal. You are most probably having a problem with the filtration ability of your kidneys			
	Some times protein may be associated with Urinary tract infection. To exclude this factor you can use 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 much diluted. This result may be affected by liquid intake. So, you are advised to repeat the test after 2-3 hours and you should make 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 kidney and you are advised to seek medical advice.	This is the same specific gravity for the filtrate. You are advised to repeat the test at different timers 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 since urine should be concentrated.	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 Atlas Kidney Stones Test (coming soon). It is also may be associated with increased Glucose concentration. You can use Atlas Diabetic Check to exclude this factor.	

Creatinine Result					
Negative	10	20	50	100	200
This result indicates that Creatinine is not filtered from 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 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.

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 turbid 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.

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: 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 a 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 minimized, 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 in treatment.
- Avoid pain pills that may make your kidney disease worse. Check with your doctor before taking any medicine.

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

A: Here are some points regarding your diet that may help controlling 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 wastes out of the blood but leave protein. Impaired kidneys may fail to separate the protein from the wastes. 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 dietitian 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 buildup 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 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 have also problems with blood pressure?

A: In addition to the kidney role in controlling body water content, and removing waste by-products, kidneys 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 and so 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 for 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. 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 center three times per week for 3 to 4 hours.

Q: What is Transplantation?

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

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