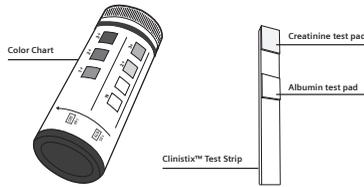


Clinistix™ Kidney Health Test Kit

EN Test Strips for the Determination of Albumin and Creatinine in Urine.



Directions:

Before you start the test: Gather the materials you will need:

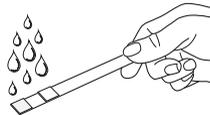
- Timer or watch with a second hand
- Bottle of Kidney Health Test Kit test strips
- Folded Tissue
- Pen or Pencil
- Clean, dry paper or plastic cup (optional)

Read all directions:

- Remove a test strip from the bottle and **replace cap immediately and tightly**.
- Check the color of the test pad closest to the handle. Compare it to the color blocks for albumin on the bottle label. If the pad is darker than the first color block (labeled "N"), discard the test strip.

Note: Testing can be done on urine passed at any time of the day, although the first urine sample in the morning is best.

Step 1: Apply urine to pads.

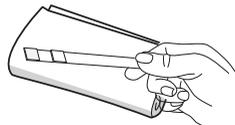


- Begin urinating. After some urine has passed, hold the test pads in the urine stream for **1-2 seconds**. Make sure both test pads are wetted.
- (If you prefer, you may collect your urine in a clean, dry cup. Then dip the test strip in the urine.)

Step 2: Start timing.



- Lay the test strip, pads up, on a folded tissue.



- Wait 50 seconds. (You may notice a "burst" of color on the albumin pad that fades within several seconds after dipping. Ignore this color unless it remains until the 50 second reading time.)

Step 3: Read the test results.



- Read the albumin test pad (the pad nearest the handle) 50 seconds after wetting, then read the creatinine pad 60 seconds after wetting. (It is important to read each pad at the exact time given.) Match the color of each test pad to the color chart for that test (the color chart is found on the bottle label).
- Record your readings below. (Ignore any color change after you have read the test pads at 50 and 60 seconds.)

Date of Test	2022/05/17					
Creatinine (60 sec.)	2+					
Albumin (50 sec.)	N					

(Example)

- Dispose of the test strip with your household waste. Do not flush down the toilet.

Understanding your test results:

- If your albumin reading is "N", your test result is Normal (N).
- If your albumin reading is anything else, use the following table to determine your test result:

Albumin Reading:	Creatinine Reading:		
	1+	2+	3+
N	N	N	N
1+	A	A	N
2+	A	A	A
3+	A	A	A

Locate the square in the table that corresponds to both the creatinine reading (column-down) and the albumin reading (row-across). The test result is Normal (N) or Abnormal (A).

Record your test result:

Date of Test	2022/05/17					
Test Result	N					

(Example)

Notify your doctor if your result is "A" (Abnormal).

Frequently Asked Questions:

Should I test my urine more than once?

The albumin level in urine changes from day to day. Therefore your doctor may recommend that you test your urine three different times over a three-to-six month period.

Why should I test my urine?

Some people are at risk of developing kidney disease, and an abnormal albumin result may be an early sign of the disease. When the disease is detected at an early stage, it is more easily treated.

People who are at risk include those who:

- have diabetes or hypertension; or
 - have been exposed to chemicals that can cause damage to the kidneys or suffer from immune disorders.
- An abnormal albumin result can also be important information for your doctor if you are pregnant.

What does an abnormal test result mean?

A single abnormal result may not mean anything. However, you should notify your doctor any time you obtain an abnormal result. Tell your doctor if you have a urinary tract infection or a fever, or if the urine was tested after strenuous exercise, as these conditions can cause a temporary increase in the albumin level in your urine.

Will common foods, alcohol, or medication affect my test results?

Generally, no. Most substances will not interfere with the test. However, some medications can affect the color of your urine, making it difficult to match the pad colors to the color chart. If this happens, contact your doctor. You may also obtain a falsely high creatinine result if you are taking the drug Tagamet® (cimetidine). If your urine is noticeable bloody, do not use this test.

Why is the creatinine test important?

The creatinine reading gives an indication of how concentrated or dilute the urine is. A higher level of albumin may be detected in concentrated urine, but the level may still be completely normal. By comparing the albumin reading to the creatinine reading, you can determine if the albumin result is normal or abnormal without worrying about when the urine was passed.

How accurate is Clinistix?

The Clinistix Kidney Health Test Kit test strips have the same test pads as are on the test strips used by doctors and clinical labs (CLINITEK® Microalbumin). Clinistix Kidney Health Test Kit was evaluated in studies where solutions were tested by untrained micros and healthcare workers. Agreement between the two groups was 84% for the albumin-to-creatinine ratio.

Storage and handling:

- Store the bottle at room temperature 59–86°F (5–30°C), and away from direct light.
- Do not refrigerate.
- Do not remove the desiccant (drying) packet.
- Keep the cap tightly closed.

Important:

- Use the test strips before the expiration date (📅) on the bottle.
- Use each test strip only once (🔄).
- Do not leave the bottle open.
- For *in vitro* (external) diagnostic (IVD) use.

Questions of a medical nature should be discussed with your doctor. If you have questions about this product, call the Customer Service Department of Siemens Healthcare Diagnostics (U.S. customers only) at 1-877-777-6415 between 8:00 AM and 8:00 PM Eastern Time, Monday through Friday.

Trademarks: Clinistix is a trademark of Siemens Healthcare Diagnostics.

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Product No.: 11643376

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ARTWORK DETAILS				
Job ID #:	625-2	Mechanical Drawing:	N/A	
Description:	Clinistix Kidney Health Test Kit	Size:	200 mm W x 265 mm H	
REF/Catalog #:	11643376	NUMBER OF COLORS		
Artwork Part #/ Finished Label #:	11643404 Rev. A			
Packaging Level / Type :	IFU (Instruction for use)	Black 0/0/0100	XXXX	XXXX
Notes:	OTC			
		XXXX	XXXX	XXXX
Plant:	OEM - Kimball	TINTS		
Languages:	EN/US			
		XX% Black	XX% XXXX	XX% XXXX