

Clinistix Kidney Health Test Kit

clinistix.siemens-healthineers.com/us



A simple at home kidney test can be a fast, accurate, and reliable method to detect abnormalities and monitor kidney health. Prompt detection is crucial in the early stages of kidney disease since there are typically no overt signs or symptoms. If Chronic Kidney Disease (CKD) is detected early and managed appropriately, the deterioration in kidney function can be slowed and the risk of associated cardiovascular complications reduced.¹

Overview

- Clinistix™ Kidney Health Test Kit uses the same dry reagent chemistry as the market-leading, professional-use CLINITEK® Microalbumin 2 Reagent Strips for urinalysis.
- Self-guided test strips are used to detect albumin and creatinine in urine samples and also help users determine whether their albumin-to-creatinine ratio is normal or abnormal.
- Excessive amounts of proteins in the urine are a key marker of kidney damage and of increased risk for renal and cardiovascular disease.

Specifications

- Visually interpreted, no analyzer required; semiquantitative results for albumin and creatinine.
- A table in the package insert helps the user understand the significance of the albumin and creatinine values relative to each other, often known as albumin-to-creatinine ratio (ACR).
- Results in 1 minute.
- Room-temperature storage.
- 18-month shelf life (from date of manufacture).
- Urine sample can be collected mid-stream or dipped.
- FDA 510(k)-cleared: K991315.
- Each strip consists of a 3.25-inch white polystyrene strip (0.4 inches wide) with two reagent pads laminated to the strip.

Shipper and Pallet Configuration

Quantity per case:	24
Shipper internal dimensions:	267 x 181 x 109 mm
Cases per pallet:	198
Pallet dimensions:	1100 x 1040 x 1203 mm

Ordering Information

SMN:	11643376
UPC code:	630414631707
Product name:	Clinistix Kidney Health Test Kit
Number of tests/package:	5 strips
Box dimensions:	43 x 105.5 x 43 mm

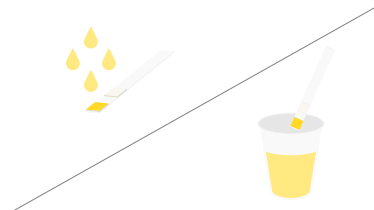
Clinistix Kidney Health Test Kit: How does it work?

1 Apply urine to the strip.

Urinate directly onto the strip. Begin urinating. After some urine has passed, hold the test pads in the urine stream for 1–2 seconds.

OR

Urinate into a clean cup and dip the strip into the sample. Urinate into a clean, dry paper or plastic cup. Dip the test strip into the urine.

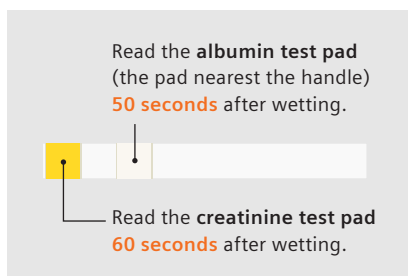


2 Wait.

Start your timer. Lay the test strip, pads up, on a folded tissue.



Leave the test strip on the folded tissue for the time specified below:



3 Read your results.

After waiting for the appropriate time, match the color of each test pad to the color chart for that test on the test strip bottle.



Record your Albumin and Creatinine results where indicated on the package insert.

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

4 Interpret your results.

Determine your albumin-to-creatinine ratio result.

- If your albumin is N, your test result is Normal (N).
- If your albumin 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 results in the table shown in the printed instructions for use:

Date of test	/2022/05/17/						
Test result	N	A					
(Example)							



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

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Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Always consult with your doctor to confirm the diagnosis and advise on treatment.

Footnote:

- World Kidney Day: Chronic Kidney Disease, 2015; <http://www.worldkidneyday.org/faqs/chronic-kidney-disease/>

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