

U-PROTEIN

URINE PROTEIN
TEST STRIPS

Instruction
Manual

Diagnox

ABOUT THE PRODUCT

The urine protein test strips by Diagnox® check the presence and approximate concentration of protein in the urine. Protein is not normally present in the urine at detectable levels. While several non-alarming issues can temporarily spike protein levels in urine, scientific studies indicate that chronically elevated protein in urine could be due to serious health conditions, including kidney disorders, heart diseases, and various infections. Also, protein in urine during pregnancy may indicate preeclampsia that requires medical attention. Urine protein testing is a vital part of a routine urinalysis by healthcare providers to diagnose diseases, monitor the health of organs, and track treatment regimens.

Diagnox Urine protein test strips are designed to make regular and repeated testing both convenient and affordable, allowing you to take preemptive actions to protect your health and seek timely medical help if your urine protein levels are unusually high.

Individual packing of each test strip helps to keep each strip fresh and immune from humidity and moisture, ensuring a reliable test for every use. Individually packaged dipsticks also offer an extended shelf life, convenient handling, and easy storage.

INTENDED USE

Diagnox urine protein test strips are intended for qualitative (presence or absence) and semiquantitative measurement (estimate of the quantity) of protein excreted in the urine.

ABOUT URINALYSIS

A urinalysis is a test of urine. Urine is produced by the kidneys. Kidneys filter wastes out of the blood, help regulate the amount of water in the body and conserve a balance of nutrients, including proteins, electrolytes, and other compounds that the body can reuse. Therefore, by examining the composition of urine, we can learn a lot about our bodies.

Excess amounts of protein in the body can be tested through urinalysis using a dipstick test. When immersed in a urine sample, the reagent pad on the dipstick changes color as it reacts with urine. With six different levels, the Diagnox urine protein test can detect the presence and concentration of protein in urine from trace to large amounts. This is one of the quickest, most affordable, and simpler ways to test. It is the same kind of test medical professionals frequently use in their practice.

WHAT IS PROTEIN IN URINE?

Proteins are large molecules that our bodies require to function properly. Protein can be found in all body parts. The kidneys filter extra water and wastes from the blood to produce urine. The tiny filters in the kidneys prevent large protein molecules from exiting the body via urine. In ideal circumstances and with healthy kidneys, the protein should be utilized by the body, e.g., to build and maintain muscles and fight infections. However, protein may leak into the urine if these filters are not working properly. When urine protein is elevated, it is referred to as proteinuria, which may indicate renal or tubular disorders.

CAUSES OF PROTEIN IN URINE?

Relatively benign or temporary medical conditions that can cause elevated protein levels in the urine include dehydration, inflammation, low blood pressure, intense exercise stress, aspirin therapy, and exposure to cold temperatures.

More serious medical conditions can also cause proteinuria, such as:

- Certain immune disorders, including lupus and Goodpasture's syndrome.
- Acute kidney inflammation (glomerulonephritis).
- Plasma cell cancer (multiple myeloma).
- Cardiovascular disease or cardiac infection such as endocarditis.
- The destruction of red blood cells, which causes hemoglobin to release into the bloodstream (intravascular hemolysis).
- Preeclampsia (proteinuria combined with hypertension in pregnancy).
- Poisoning.
- Trauma.
- Kidney cancer.
- Congestive heart failure.
- Protein buildup in organs (amyloidosis).
- Kidney Stones.
- Diabetes.
- High blood pressure (hypertension).

The above causes can cause damage to the kidneys. Kidney disease often has no early symptoms. One of its first signs may be proteinuria which is generally detected by a urine dipstick test. Your healthcare provider may order other tests to evaluate how well your kidneys are functioning.

STORAGE & HANDLING

- Store in a dry place at 2-30°C (36-86°F).
- Do not freeze. Keep out of direct sunlight.
- The strip should remain in the sealed pouch until use.
- Do not use if the pouch is torn.
- Do not touch the test pad of the strip.
- Discard any expired or discolored strips that may have deteriorated.

HOW ACCURATE IS THIS TEST?

Diagnox urine protein test offers clinical-grade accuracy. The analytical performance of the protein reagent pad with urine controls in a multi-site study demonstrates a mean test accuracy of 96.67% (percentage exact match) when reading strips visually (n=180).



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TO LEARN MORE
ABOUT THE CLINICAL
VALIDATION DATA.

URINOX MOBILE APP

Keeping a log of your test results will help you stay proactive with your health. The free Urinox mobile app will help you analyze your health trends and share results with your physician. By eliminating guesswork, you can make well-informed decisions about your health.



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DIRECTIONS FOR USE

Start with a freshly collected urine sample in a clean, dry container. Tear open the sealed bag and remove the strip. Hold the strip without touching the test pad.


1



IMMERSE

Immerse the strip into the urine sample and remove it immediately by dragging the edge of the strip against the container rim to remove excess urine. Alternatively, hold the strip in the urine stream just enough to wet the test pad.

2



WAIT

Start timing.

Remove excess urine by blotting the side of the strip on a paper towel. Place the strip horizontally on a paper towel.

Results are ready to read 60 seconds after the pad is wet.

3









COMPARE

Compare the color of the test pad to the provided color key to find the closest color match. Read the results carefully in a good light. Change in the color that appears after 2 minutes is of no diagnostic significance.

COLOR CHART

A positive dipstick test for protein will result in a pad color that is bright green, sea green, turquoise, or dark green. The intensity of the color of the reagent pad will correlate with the protein concentration in the urine. Use the following color key to interpret your test results.

	-	Negative		
	+/-	Trace		
	1+	0.3 g/L	30 mg/dL	300 mg/L
	2+	1.0 g/L	100 mg/dL	1,000 mg/L
	3+	3.0 g/L	300 mg/dL	3,000 mg/L
	4+	≥ 20 g/L	≥ 2,000 mg/dL	≥ 20,000 mg/L

1g=1000mg 1L=10dL

WHAT DO THE RESULTS IMPLY?

A normal amount of protein in the urine is less than 150 milligrams (mg) per day. If you have more than 150 mg of protein in your urine per day, it is generally considered proteinuria. If you have 3 to 3.5 grams of protein in the urine per day, it is generally considered nephrotic-range proteinuria.

Persistently elevated levels of protein in the urine may be a sign of urological or nephrological disorders, such as kidney

disease or kidney damage caused by other conditions. Occasionally, protein in urine is an early sign of chronic kidney disease (CKD), although you can have CKD and have normal levels of protein in your urine.

While protein in urine is generally considered serious, a non-negative protein level in your urine sample does not always indicate that you have a medical problem that requires treatment. Urine protein levels can temporarily rise due to strenuous exercise, diet, dehydration, stress, pregnancy, and other factors. However, it is important to consult with your doctor if your test results are positive, especially if repeated testing shows protein in the urine.

Scientific studies suggest that the protein in your urine is related to the severity of kidney damage. However, more tests are usually required to determine what is causing the damage.

If your test results are positive, it is generally a good idea to continue to test your urine multiple times a day to know if it was an acute episode or if the protein is persistently elevated in the urine. A "24-hour urine sample test", for example, provides better and more complete results as the amount of protein in urine can change throughout the day.

Consult your physician to discuss your test results. Your healthcare provider may recommend other urinalysis tests to determine the cause of protein in urine and prescribe an appropriate treatment.

LIMITATIONS AND INTERACTIONS

Urine tests can sometimes give false results for different reasons, as explained below.

Possible causes of false positives:

- An old urine sample.
- Non-sterile urine containers. Detergents, antiseptics, and quaternary ammonium compounds used to clean urine containers can cause false positives.
- Highly buffered alkaline urine (e.g., due to medications, supplements, or a vegetarian diet that cause alkaline urine).
- Dipstick left in the urine sample for too long. (Dip for 1 - 2 seconds only)
- Certain medications and substances, such as phenazopyridine, polyvinylpyrrolidone, and chlorhexidine gluconate (commonly found in skin cleansers), may cause false positives.
- The presence of blood or high levels of bilirubin may interfere with the accuracy of the test.
- Highly pigmented or concentrated urine.
- Contamination of the urine with vaginal discharge, semen, heavy mucus, pus, and blood can give false positives.

Possible causes of false negatives:

- Very dilute urine sample. By testing multiple times daily, urine protein variations throughout the day can be monitored.
- Proteins other than albumin in the urine can give false negatives. The dipsticks are more sensitive to albumin than to other proteins.



We believe that promoting and sharing knowledge is a form of care. With this mission, we make it easy for people to take charge of their own health.

Listen to your body and get to know yourself to own yourself.

Being the protagonist of your well-being is having information at the palm of your hand. With that in mind, we provide innovative health tests that provide accurate results along with simple-to-understand information and all the support needed for you to connect the dots and be aware of your health. After all, good decisions come from good information.

It is knowledge from the inside out that guides us to look after ourselves and others around us, raising awareness for better health for all.

Diagnox

Care to Know. Know to Care.

QUESTIONS?

For questions, please contact us at:

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