UTI TEST

URINARY TRACT INFECTION TEST

Instruction Manual

Diagnox

SUMMARY / INTENDED USE

The Urinox Urinary Tract Infection (UTI) Test Strips by Diagnox® detect Leukocytes and Nitrite in urine. It is used as an aid in the screening of urinary tract infection (UTI).

The test is a firm plastic strip onto which Leukocyte and Nitrite reagent test pads are attached. If the test is positive, the Leukocyte test pad changes color from beige to dark purple, and the Nitrite test pad changes to uniform pink to red.

Individual wrapping of each test strip ensures that each strip is fresh and not altered by atmospheric conditions. Bigger pad and strip size ensure easy testing and convenient handling.

ABOUT URINALYSIS

A urinalysis is a test of urine. Urine is produced by the kidneys. The kidneys filter wastes out of the blood, help regulate the amount of water in the body and conserve proteins, electrolytes, and other compounds that the body can reuse. Therefore, many disorders can be detected by examining the composition of urine.

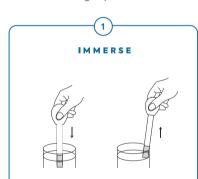
Urinox-UTI Urinalysis Test strips by Diagnox® (dipsticks) check the presence of Leukocytes (LEU) and Nitrite (NIT) in the urine sample. Scientific studies indicate that the presence of either LEU or NIT in urine is a sign of a UTI. This is the same kind of test medical professionals use to assist in diagnosis.

DIRECTIONS FOR USE

Allow the strip and urine specimen to reach room temperature (15-30°C or 59-86°F) before testing. It is recommended to gently wash the genital area thoroughly with soap and water, then rinse well prior to testing.

The test can be used by directly urinating on the strip or immersing it in a urine sample container.

Follow the following steps.

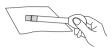


Remove the strip from the sealed pouch, and use it as soon as possible. Hold the end of the strip farthest away from the test pads and begin urinating. After 1 or 2 seconds of passing urine, hold the strip downward with the test pads pointing into the urine stream for 1-2 seconds. Make sure the test pads are entirely wet.

Alternatively, collect a urine sample in a clean and dry container. Dip the test pads of the strip completely into the urine for 1-2 seconds and remove immediately. Run the edge of the strip against the rim of the urine container to remove excess urine.



WAIT



After removing the strip from your urine, immediately bring the edge of the strip into contact with an absorbent material (e.g., a paper towel) to remove excess urine. Lay the strip with the test pad(s) facing upwards and begin timing.



COMPARE



Read the result at 1 minute for Nitrite and 2 minutes for Leukocytes. Compare the test pad(s) to the color blocks on the color chart. Hold the strip close to the color blocks, and carefully match each pad to the color chart for that test.

NOTE:

Use the color chart printed on the pouch.

Do not read results after 3 minutes.

READING THE RESULTS

Use the following tables to interpret the results.

LEUKOCYTES	NITRITE
Negative (-) or Trace (±)	Negative (-)

RESULTS SUGGEST NO SIGN OF A UTI.

When trace (±) LEU occurs or if you have symptoms, test again the following day with your first morning urine using a new test strip. If you get another trace (±) LEU or if you experience symptoms, consult your physician.

LEUKOCYTES	NITRITE
Negative (-) or Trace (±)	Positive (+)

RESULTS SUGGEST A SIGN OF A UTI.

A positive (+) result for nitrite in urine is indicative of bacterial activity in the urinary tract. Consult your physician immediately.

LEUKOCYTES	NITRITE
Positive (+, ++, or +++)	Positive (+)

RESULTS SUGGEST A SIGN OF A UTI.

A positive (+) result for leukocytes and nitrite in urine is indicative of infection and bacterial activity in the urinary tract. Consult your physician immediately.

LEUKOCYTES	NITRITE
Positive (+, ++, or +++)	Negative (-)

RESULTS SUGGEST A SIGN OF A UTI.

Repeat the test after some time using a new test strip. Make sure to wash the genital area thoroughly before testing. If LEU is still positive, consult your physician.

CARE TO KNOW

LEUKOCYTES

Leukocytes (or white blood cells) are the cells of the immune system that protect the body against both infectious diseases and foreign invaders. A few white blood cells (WBCs) are normally present in urine and generally yield negative results. When the number of WBCs in urine increases significantly, this screening test will become positive. The presence of leukocytes (>10 leu/ μ L) in urine may indicate infections in the urinary tract or kidneys.

NITRITES

Normal urine contains chemicals called nitrates. If bacteria enter the urinary tract, nitrates can turn into different, similarly named chemicals called nitrites. Nitrites in urine may be a sign of a urinary tract infection (UTI). To detect a UTI, the presence of Leukocytes in urine is also considered. UTI can be present despite a negative nitrite test.

When you understand better, you feel better.

Our easy-to-understand blogs on urinary tract health provide expert insights and practical advice to help you better understand, prevent, and manage UTIs effectively.



SCAN THIS QR CODE TO ALLOW YOURSELF TO KNOW - ALLOW YOURSELF TO GROW.

MATERIALS

Included in this kit-

- UTI test strips
- Package insert
- · Color chart (on the pouch)

Materials not included (but required)

- Timer or watch
- · Absorbent material (e.g., paper towel)
- Urine collection container (optional)

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.
- Long-term exposure to air may cause inaccurate readings.
- Do not use if the pouch is torn or damaged.
- Do not touch the test pad(s) of the strip.
- Discard any discolored strips that may have deteriorated.

WARNING AND PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For urine testing only.
- · Do not use for blood testing.
- The used strip should be discarded according to local regulations after testing.
- Keep out of the reach of children.
- Do not use after the expiration date.
- For in vitro diagnostic use.
- · Not to be taken internally.

LIMITATIONS AND INTERACTIONS

There is the possibility that this test may produce false results. Consult your physician before making any medical decisions.

Note: The test may be affected by substances that cause abnormal urine color, such as drugs containing azo dyes (e.g., Pyridium®, Azo Gantrisin®, Azo Gantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin. The color development on the test pad may be masked or a color reaction may be produced that could be interpreted as false results.

Leukocytes: The drug tetracycline may cause a false negative result. High protein or elevated glucose in the urine may cause test results to be low.

Nitrite: Any degree of uniform pink to red color should be read as a positive result. Pink spots or pink edges should not be read as a positive result. High ascorbic acid may cause test results to be low.

Note: You may get a negative result if you have a UTI caused by bacteria that do not change nitrate to nitrite, when urine has not been held in the bladder for more than 4 hours, when taking antibiotics, or when your diet does not include nitrates

Please visit

DIAGNOXHEALTH.COM/PRODUCT/UTI

to access detailed information regarding the clinical validation data for this product.

URINOX APP

Keep tabs on your health with the Urinox app.



- RECORD URINALYSIS RESULTS
- **VISUALIZE TRENDS**
- MONITOR PROGRESS
- SHARE REPORTS
- EDUCATIONAL RESOURCES

Make informed decisions about your health and well-being by knowing your urinalysis trends.



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ABOUT DIAGNOX

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: contact@diagnoxhealth.com Diagnox LLC, Plano, TX 75024 - USA 24-hour toll-free number +1 (866) 342 4669