



Healgen® URS Test Strip

Instructions for Use

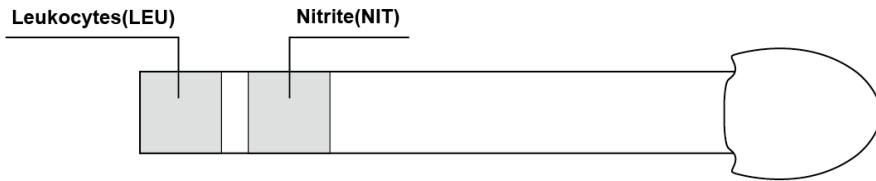
For in vitro diagnostic use only.

INTENDED USE

The Healgen® URS Test Strip is for the qualitative detection of leukocytes (white blood cells) and nitrite in urine as an aid in the screening of a Urinary Tract infection (UTI). It is intended for over-the-counter home use only.

PRINCIPLE

The test is a firm plastic strip onto which Leukocyte and Nitrite test pads are attached. If the test is positive, the test pad should be a uniform purple or pink color.



DETECTION TIME/RANGE

Item	Sensitivity	Reportable range	Read time
Nitrite (mg/dL)	0.05	Negative - Positive	120 seconds
Leukocytes (cells/μL)	15	Negative - 500	120 seconds

REACTIVE INGREDIENTS (based on dry weight at impregnation time)

Leukocytes	<ul style="list-style-type: none"> 4.3% w/w pyrrole amino acid ester 0.4% w/w diazonium salt 92.6% w/w buffer 2.7% w/w nonreactive ingredients.
Nitrite	<ul style="list-style-type: none"> 1.3% w/w p-aminobenzene sulfonamide 0.9% 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol 89.6% w/w buffer 8.2% w/w nonreactive ingredients.

WARNINGS AND PRECAUTIONS

Please read ALL the information in this Instructions for Use before performing the test.

- For *in-vitro* diagnostic use only. Not to be taken internally.
- For human urine testing only. Do not use for blood testing.
- Do not use after the expiration date.
- Keep out of the reach of children.
- Do not open the test strip package until ready to use. The opened strip should be used immediately.
- Used strip should be discarded according to local regulations.
- Analyze results in bright, natural light. Do not analyze under a colored light source to avoid color deviation.

- Do not interpret the results before 60 seconds (1 minute) or past 180 seconds (3 minutes).
- Individuals with color-impaired vision may not be able to adequately interpret test results.
- Diagnosis and treatment should not be based on a single test.

STORAGE AND HANDLING

- Store in a dry place at temperatures between 15-30°C (59-86°F).
- Do not refrigerate.
- Keep out of direct sunlight.
- The test strip should remain in the foil pouch with the drying packet until use.
- Do not touch the test pads of the strip.
- Any unused test strip with discolored test pads should be considered damaged or defective and should be discarded.
- Every strip can be used only once.

MATERIALS

Materials Provided

Test strips Instructions for Use

Materials Required but Not Provided

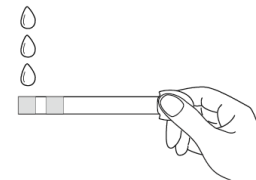
Timer, clock, or watch Absorbent material (e.g., paper towel) Specimen collection container

DIRECTIONS FOR USE

- Remove the test strip from the foil pouch. Retain the foil pouch to use the color chart on the outside to interpret the results. **Do not use the test strip if the pouch is torn or damaged.**
- Hold the end of the test strip 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 completely wet. (Step 1)
- Immediately bring the edge of the test strip into contact with an absorbent material (e.g. paper towel) to remove excess urine. Lay the test strip with the test pads facing upwards and begin timing. (Step 2)
- Interpret results at 120 seconds (2 minutes). Compare the test pads to the color blocks on the foil pouch. Hold the test strip close to the color blocks and carefully match each test pad to the color chart for that test. (Step 3).

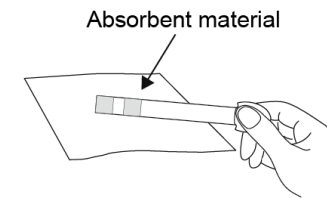
Note: Do not read results after 180 seconds (3 minutes).

STEP 1



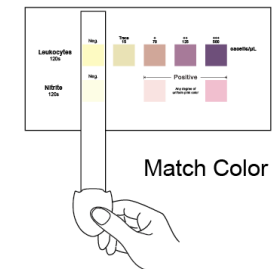
1-2 Seconds

STEP 2



120 Seconds (2 Minutes)

STEP 3



Match Color

INTERPRETATION OF RESULTS

Interpret the results by comparing the test pads to the color blocks on the foil pouch. Match the color of the test pad to the closest color block on the foil pouch.

TEST STRIP RESULTS		RECOMMENDATIONS
Leukocytes (LEU)	Nitrite (NIT)	
Negative	Negative	No sign of UTI detected. However, if you still have symptoms, consult your physician; there are some cases of UTI that the test may not detect.
Trace	Negative	Results suggest additional testing is required. Test again the following day with a new strip. If you have symptoms or if you get another trace leukocyte result, consult your physician.
Negative or Trace	Positive	Results suggest a sign of a UTI. Consult your physician immediately.
Positive +, ++,+++	Positive	Results suggest a sign of a UTI. Consult your physician immediately.
Positive +, ++,+++	Negative	Results suggest a sign of a UTI. Repeat the test next time you urinate using a new test strip. Make sure to wash the genital area first. If LEU is still positive, consult your physician.

LIMITATIONS

There is the possibility that this test may produce false results. The test may be affected by medication or dietary supplement that may change urine color. Do not use test strips if you observe abnormal urine colors (such as bright yellow or green). Do not use test strips while taking antibiotics. Consult your physician before making any medical decision.

Note:

- Leukocytes:** High glucose ($\geq 1000\text{mg/dL}$) or high Vitamin C ($\geq 150\text{mg/dL}$) in urine may cause test results to be low. Urine with a $\text{pH} \geq 8.0$ may cause a false positive leukocyte reading. Dehydration may cause false negative leukocyte reading.
- Nitrite:** High Vitamin C ($\geq 150\text{mg/dL}$) in urine may cause a false negative nitrite reading. Any degree of uniform pink color should be read as a positive result. You may get a negative result if you have 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.

PERFORMANCE CHARACTERISTICS

The performance characteristics of the test strips are based on both laboratory and clinical tests. The sensitivity of the test depends upon several factors, such as the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions under which the test strip is interpreted.

FREQUENTLY ASKED QUESTIONS

Q: What are the common symptoms of UTI?

A: The common symptoms of UTI include burning or pain during urination, frequent urination, fever, and back or groin pain.

Q: Can I have UTI without symptoms?

A: Yes, UTI can occur without symptoms in young children, pregnant women, and the elderly.

Q: Do I have to test with my first-morning urine?

A: Although you can test at any time of day, your first-morning urine would contain the most bacteria if UTI is present. Avoid testing during your menstrual period.













Q: Will common foods, alcohol, or medications affect my test results?

A: Generally, no. Most substances will not interfere with the test. Consult your physician if you are taking antibiotics. However, some medications can affect the color of your urine, making it difficult to match your results with the color chart on the foil pouch. Large quantities of Vitamin C may cause false negative results.

Q: I received an abnormal result; What should I do now?

A: We recommend you contact your physician or healthcare professional.

INDEX OF SYMBOLS

	Do not reuse		See Instruction for Use		Expiration Date
	Tests per Kit		Store Between 2°C-30°C (36°F-86°F)		Keep Dry
	Batch Number		Catalog #		Keep Away from Sunlight
	Unique Device Identifier		For <i>in vitro</i> diagnostic use only		Manufacturer

ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number 1-866-982-3818 (9:00a.m. to 5p.m. CDT).

Revision Date: 2023-07-06