

For rapid qualitative detection of Leukocytes and Nitrite in human urine.
For self-testing *in vitro* diagnostic use only.

[INTENDED USE]

The Urinary Tract Infections Test (Urine) is a firm plastic strip onto which two separate reagent areas are affixed. The test is for the qualitative detection of the following analytes in urine: Leukocytes and Nitrite. The Urinary Tract Infections Test (Urine) is for single use in self-testing.

[SUMMARY]

A urinary infection represents the most common disease of the urinary tract which includes the urethra, the bladder, the ureter, and the kidneys. Men, women, and children are likely to experience a urinary infection. It is mostly women who suffer from urinary infections, since the short urethra favours the penetration of germs. However, elderly males are also affected if they have an enlarged prostate which obstructs the urine flow. In healthy people, urine is sterile (i.e. it does not contain any micro-organisms). One of the best ways to keep your urinary tract sterile is to empty your bladder completely at regular intervals. Generally, an infection starts in the urethra and may then spread into the upper urinary tract as far as the kidneys. The symptoms vary considerably: burning when emptying the bladder, or a strong urge to urinate. The urine may also be cloudy or have a strong odour.

[PRINCIPLES OF THE EXAMINATION METHOD]

Leukocytes: This test reveals the presence of granulocyte esterases. The esterases cleave a derivatized pyrazole amino acid ester to liberate derivatized hydroxyl pyrazole. This pyrazole then reacts with a diazonium salt to produce a beige-pink to purple colour.

Nitrite: This test depends upon the conversion of nitrate to nitrite by the action of gram-negative bacteria in the urine. In an acidic medium, nitrite in the urine reacts with p-arsanilic acid to form a diazonium compound. The diazonium compound in turn couples with 1 N-(1-naphthyl) ethylenediamine to produce a pink colour.

[PRECAUTIONS]

Read the instructions carefully before performing the test.

- For self-test *in vitro* diagnostic use only.
- Store in a dry place at 4-30°C (39.2-86°F), avoiding areas of excess moisture.
- If the foil packaging is damaged or has been opened, please do not use.
- Use only a clean container - uncontaminated by cleaning fluids - to collect urine.
- Keep out of the reach of children.
- Do not use after the expiry date.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the reagent areas of the test strip.
- For external use only. Not to be taken internally.
- The used test should be discarded according to local regulations.
- In case of difficulties in colour identification (such as Daltonism), ask for help in test reading.

[STORAGE AND STABILITY]

Store as packaged at room temperature or refrigerated (4-30°C).
The test is stable through the expiration date printed on the sealed pouch.
The test must remain in the sealed pouch until use.
DO NOT FREEZE. Do not use beyond the expiration date.

[MATERIALS PROVIDED]

- Test Strip
- Colour Chart
- Package Insert

[MATERIALS REQUIRED BUT NOT PROVIDED]

- Timer or a watch
- Clean Glass or Plastic Cup

[PROCEDURE]

ATTENTION: It is recommended to take a sample of urine for the test in the early morning, as it is the most concentrated. The urine used for the test should not come into contact with water from the toilet or any disinfectant or cleaning substances.

For women only: The test should not be performed during or for three days after your period. The urine sample should not be contaminated with vaginal fluids since this may produce a misleading result.

Do not make any important medical decision without first referring to your doctor.

COLLECT URINE:

Collect urine in a clean glass or plastic cup without any residual detergents. Make sure to fill up the cup with urine.

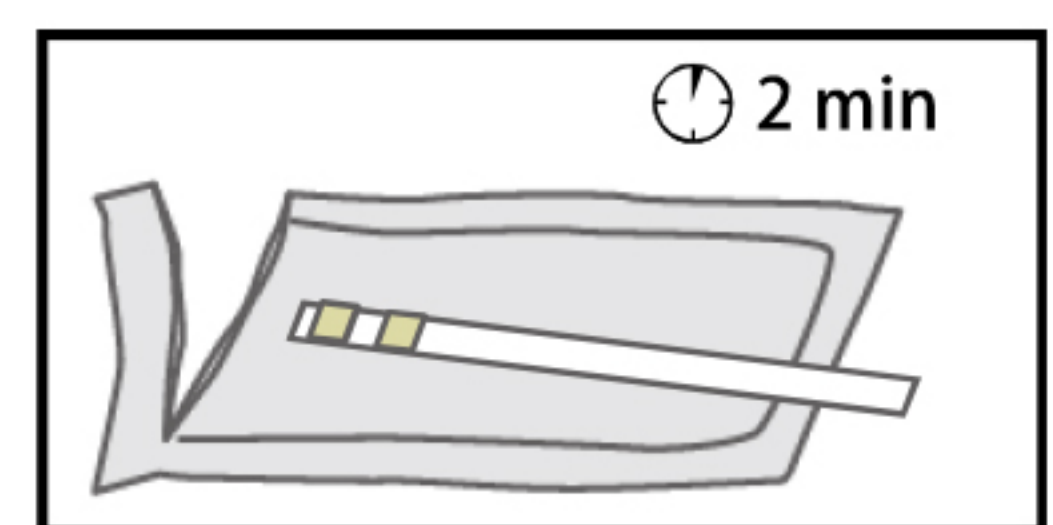
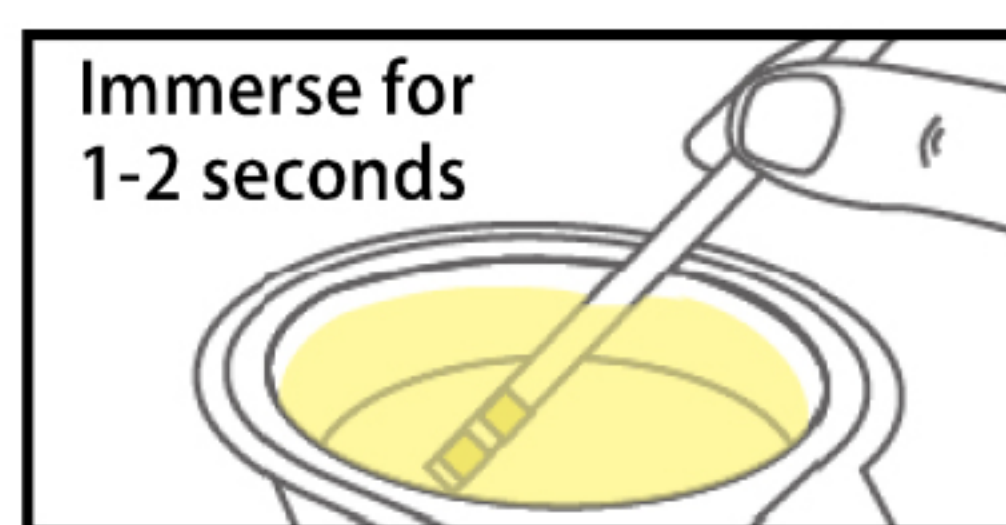
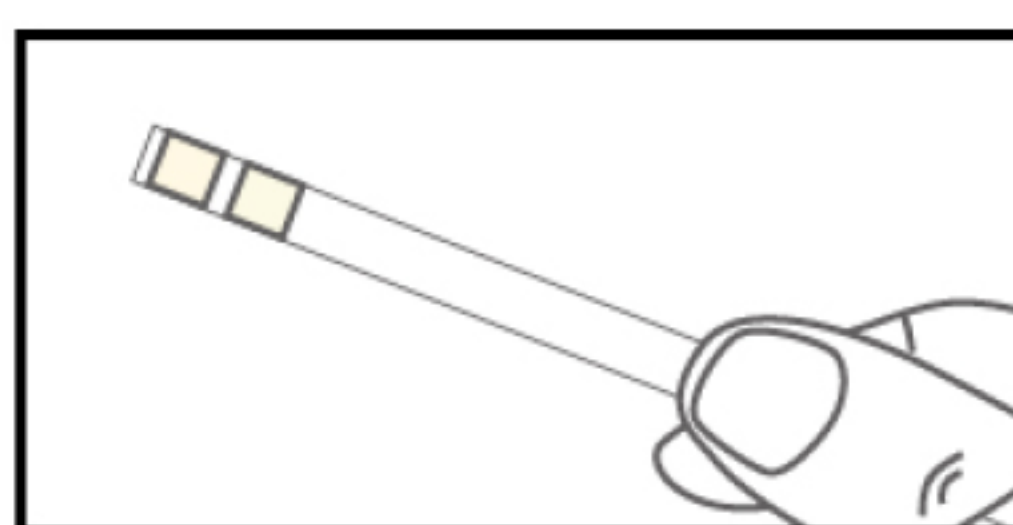
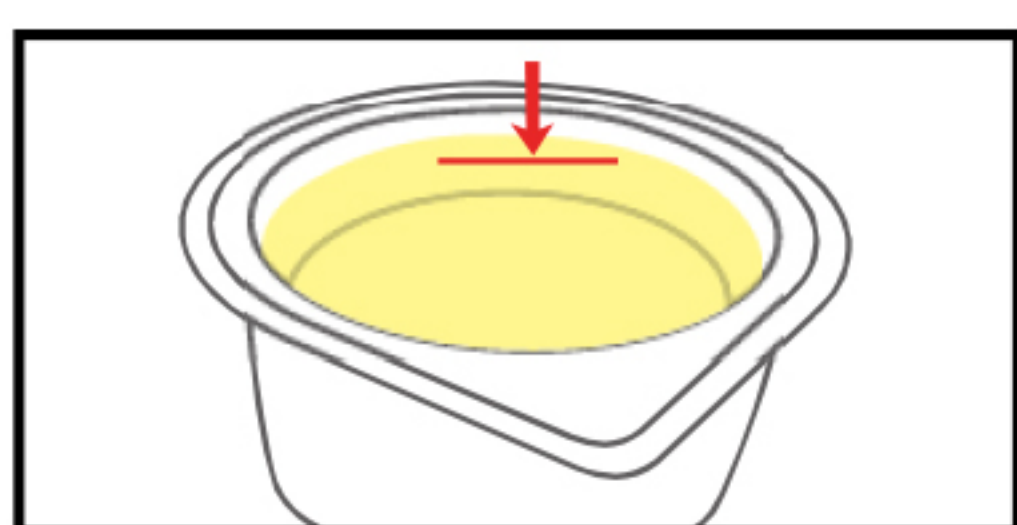
PERFORMING THE TEST:

- 1) Open the foil pouch and take out the test strip. **Do not touch the test pads.** Once the pouch is opened, it is recommended to perform the test **immediately.**
- 2) Dip the test strip in the urine sample.

ATTENTION: Hold the end of the test strip farthest away from the test pads and dip the test strip in the urine sample for **1-2 seconds**, ensuring all test pads are fully immersed in the urine.

- 3) Then remove the test strip and wipe off any surplus urine against the rim of the container or with an absorbent material (e.g. a paper towel) to avoid mixing chemicals from adjacent reagent areas.
- 4) Lay the strip with the test pads facing up on a flat surface and begin timing. **Wait for 2 min** (Do not read results after 3 minutes).

ATTENTION: Read the result separately for each parameter, compare colour with the colour chart provided.



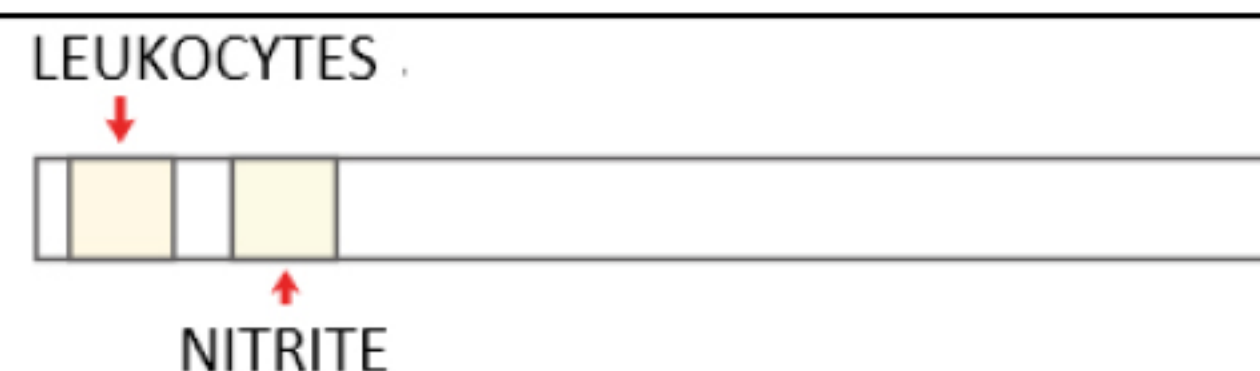
[READING THE RESULTS]

Read the result separately for each parameter; compare the test pad colour with colour chart provided. Colour changes on the edges of the test pads or colour changes after more than 3 minutes should be disregarded.

NEGATIVE

The Test field for **LEUKOCYTES** stayed whitish.

The Test field for **NITRITE** stayed white.



POSITIVE RESULT FOR LEUKOCYTES

If the colour of the test pad has changed to **purple**, then leukocytes have been found in your urine.



POSITIVE RESULT FOR NITRITE

If the colour of the test pad has changed to **pink**, then nitrites have been found in your urine.



[TECHNICAL NOTES ON PARAMETERS]

The Test detects **LEUKOCYTES** and **NITRITE** in urine.

LEUKOCYTES: The presence of leukocytes in urine is an important symptom of an inflammation of the kidneys and the urinary tract, protein react with the test pad and changes its colour to purple. When taking cephalixin and cephalothin, or high concentration of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction colour.

NITRITE: Gram-negative bacteria in urine convert nitrate from food into nitrite. Nitrite reacts with a chemical in the test field and leaves a pink shade. The test result may be distorted if urine does not stay for long in the bladder, due to hunger, a vegetable-free diet or antibiotic treatment. Comparing the test on a white background may aid in the detection of low nitrite levels, which might otherwise be missed.

[CONTROL PROCEDURE]

To serve as quality control, the instruction must be followed closely when performing the test. Failure to follow the directions in this package insert may yield inaccurate test results.

[PERFORMANCE CHARACTERISTICS]

Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, this test has been developed to be specific for the parameters to be measured with the exceptions of the interferences listed. Please refer to the Limitations section in this package insert. Interpretation of visual results is dependent on several factors: the variability of colour perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each colour block on the chart corresponds to a range of analyte concentrations.

[LIMITATIONS]

Note: The Urinary Tract Infections test (Urine) may be affected by substances that cause abnormal urine colour such as drugs containing azo dyes (e.g. Pyridium®, AzoGantrisin®, AzoGantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.¹ The colour development on the test pad may be masked or a colour reaction may be produced that could be interpreted as false results.

LEUKOCYTES: The result should be read at 2 minutes to allow for complete colour development. The intensity of the colour that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations ($\geq 2,000$ mg/dL) may cause test results to be artificially low. The presence of cephalixin, cephalothin, or high concentrations of oxalic acid may also cause test results to be artificially low. Tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. High urinary protein may diminish the intensity of the reaction colour. This test will not react with erythrocytes or bacteria common in urine.¹

NITRITE: The test is specific for nitrite and will not react with any other substance normally excreted in urine. Any degree of uniform pink to red colour should be interpreted as a positive result, suggesting the presence of nitrite. Colour intensity is not proportional to the number of bacteria present in the urine specimen. Pink spots or pink edges should not be interpreted as a positive result. Comparing the reacted reagent area on a white background may aid in the detection of low nitrite levels, which might otherwise be missed. Ascorbic acid above 30 mg/dL may cause false negatives in urine containing less than 0.05 mg/dL nitrite ions. The sensitivity of this test is reduced for urine specimens with highly buffered alkaline urine or with high specific gravity. A negative result does not at any time preclude the possibility of bacteriuria. Negative results may occur in urinary tract infections from organisms that do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder for a sufficient length of time (at least 4 hours) for reduction of nitrate to nitrite to occur; when receiving antibiotic therapy or when dietary nitrate is absent.²

[EXTRA INFORMATION]

WHAT SHOULD I DO IF MY TEST RESULT IS POSITIVE?

Remember that a positive result does not mean that both substances have been detected in your urine. Even if your result is positive for just one of them, it is most likely that something is wrong in your urine, even if the reason may not be a urinary infection. Get in touch promptly with your own doctor, who will be able to give a more accurate diagnosis. When you visit your doctor, please take these instructions with you so that they will be better informed as to the type of test you have performed.

WHAT SHOULD I DO IF MY TEST RESULT IS NEGATIVE?

Remember that your test result is only negative if the results on the test pad for both substances are negative. If you still feel the signs of a UTI or have any other symptoms, then contact your own doctor to arrange a more thorough examination.

[BIBLIOGRAPHY]

1. Henry JB, et al. Clinical Diagnosis and Management by Laboratory Methods, 20th Ed. Philadelphia. Saunders. 371-372, 375, 379, 382, 385, 2001.
2. Shuai Lihua Jiujiang Medical Journal 2002, 17 (2): 122.

Index of Symbols

	Consult Instructions for Use
	For <i>in vitro</i> diagnostic use only
	Store between 4-30°C
	Do not use if package is damaged

	Tests per kit
	Use by
	Lot Number
	Manufacturer

	Authorized Representative
	Do not reuse
	Catalog #

Hangzhou AllTest Biotech., Ltd
#550, Yin Hai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018, P. R. China

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CE 0123

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SC-317C
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