Urinary Tract Infections Test (Urine)
Package Insert
For Self-testing

REF U031-04H
English

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

INTENDED USE

The Urinary Tract Infections Test (Urine) is firm plastic strips onto which several separate reagent areas are affixed. The test is for the qualitative detection of the following analytes in urine: Blood, Protein, Nitrite and Leukocytes. 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's 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 doesn't 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 color.
Blood: This test is based on the peroxidase-like activity of hemoglobin which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting color ranges from orange to green to dark blue.
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 color.
Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators (Tetrabromophenol Blue), The anion produced by pH indicators under given conditions combines with the cation produced by protein, then pH indicators Colors from yellow to green-blue for positive results.

PRECAUTIONS

Read the instructions carefully before performing the test.

- For self-testing *in vitro* diagnostic use only.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- A clean container - uncontaminated by cleaning fluids - to collect urine.
- Keep out of the reach of children.
- Do not use after the expiry date or if the pouch is damaged.
- 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.
- The used test should be discarded according to local regulations.
- In case of difficulties in color identification (such as Daltonism), ask for help in test reading.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30 °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

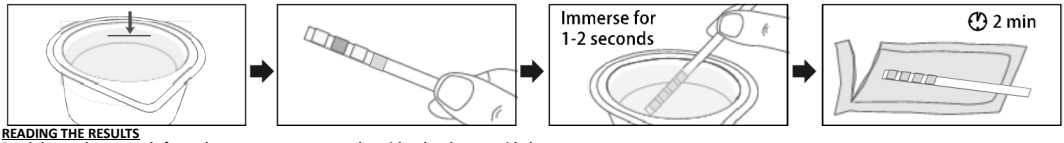
• Test strip • Plastic cup • Color chart • Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

•Timer or a watch with a second hand •Specimen container

PROCEDURE

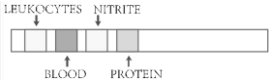
ATTENTION: It's recommended to take a sample of urine for the test in the early morning since it's the most concentrated. The urine used for the test should not come into contact with water from the toilet or any disinfectant or cleaning substances.
For women only: **The test should not be performed during or for three days after your menstrual 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 part of the urine in the supplied plastic cup or using a clean 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 fields**. Once opened the pouch, it is recommended to perform the test **immediately**.
2) Dip the test strip in the urine sample.
ATTENTION: Press the strip and make sure that all four test fields are immersed for about **1-2 seconds.**
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) **Wait for 2 min.** (do not read results after 3 minutes) **Read the result separately for each parameter, compare color with color chart provided.**



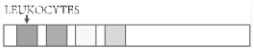
READING THE RESULTS

Read the result separately for each parameter; compare color with color chart provided.
Color changes on the edges of the test pads or color changes after more than 3 minutes have to be ignored.

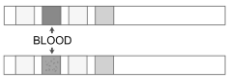
NEGATIVE
The Test field for **LEUKOCYTES** stayed whitish.
The Test field for **BLOOD** stayed mustard yellow
The Test field for **NITRITE** stayed white.
The Test field for **PROTEIN** stayed yellowish.



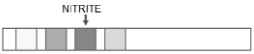
POSITIVE RESULT FOR LEUKOCYTES
If the color of the test field has changed to **purple**, then leukocytes have been found in your urine.



POSITIVE RESULT FOR BLOOD
If the color of the test field has changed to **green** (or some green spots appear on the background), then blood has been found in your urine.



POSITIVE RESULT FOR NITRITE
If the color of the test field has changed to **pink**, then nitrites have been found in your urine.



POSITIVE RESULT FOR PROTEIN
If the color of the test field has changed to **green**, then proteins have been found in your urine.

TECHNICAL NOTES ON PARAMETERS

The Test detects **LEUKOCYTES, BLOOD, NITRITE** and/or **PROTEINE** 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 pad and changing its color to purple.

When taking cephalexin 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 color.

BLOOD: A uniform green color conversion indicates the presence of hemoglobin or hemolyzite erythrocytes; scattered or compacted green spots indicate intact erythrocytes. General urine occult blood attributed to the following three reasons, one is a stone, inflammation, and cancer. On the aspect of inflammation, such as glomerulonephritis, pyelonephritis, cystitis, but may have hematuria, urine occult blood will have occurred. Whether stones kidney, ureter or bladder stones, may cause other situations such as occult blood. The tumor can also cause occult blood, such as benign or malignant tumor of kidney, ureter and bladder.

Menstrual period, constipation may cause a positive result.

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.

PROTEIN: An indicator on the test field reacts with protein in the urine, changing its color to green. They may be found where there is inflammation of the bladder or prostate or bleeding in the urinary tract. Infusions containing polyvinylpyrrolidone may yield a false positive result. Chemical components in the test fields must be viewed as potentially dangerous substances, although they present no hazard provided that all test components are used in accordance with these instructions.

CONTROL PROCEDURE

To serve as good quality control, the instruction must be followed closely when performing the test. Failure to follow directions in 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 color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Each color 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 color such as drugs containing azo dyes (e.g. Pyridium®, AzoGantrisin®, AzoGantanol®), nitrofurantoin (Microdantin®, Furadantin®), and riboflavin.[1] 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 result should be read at 2 min to allow for complete color development. The intensity of the color that develops is proportional to the number of leukocytes present in the urine specimen. High specific gravity or elevated glucose concentrations (≥ 2,000 mg/dL) may cause test results to be artificially low. The presence of cephalexin, 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 color. This test will not react with erythrocytes or bacteria common in urine.[1]

Blood: A uniform green color indicates the presence of myoglobin, hemoglobin or hemolyzed erythrocytes.[1] Scattered or compacted green spots indicate intact erythrocytes. To enhance accuracy, separate color scales are provided for hemoglobin and for erythrocytes. Positive results with this test are often seen with urine from menstruating females. It has been reported that urine of high pH reduces sensitivity, while moderate to high concentration of ascorbic acid may inhibit color formation.

Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction.[2] The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

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 color should be interpreted as a positive result, suggesting the presence of nitrite. Color 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 bacteruria. 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.[3]

Protein: Any green color indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to hemoglobin, globulin and mucoprotein.[1] A negative result does not rule out the presence of these other proteins.

False positive results may be obtained with highly buffered or alkaline urine. Contamination of urine specimens with quaternary ammonium compounds or skin cleansers containing chlorhexidine may produce false positive results. The urine specimens with high specific gravity may give false negative results.

EXTRA INFORMATIONS

WHAT SHOULD I DO IF MY TEST RESULT IS POSITIVE?

Remember that a positive result doesn't mean that all four 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 he/she 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 result on the test field for all four substances is negative. But if you still feel the signs of a UTI or have any other symptom, 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. Ma Junlong, Cong Yulong. The effect of bacteriuria on the determination of urine red blood cells by urine analyzer. Chinese Journal of Medical Examination, 1999, 22(4): 205.
3. Shuai Lihua,Jiujiang Medical Journal 2002, 17 (2): 122.

IVD	For *in vitro* diagnostic use only
2°C 30°C	Store between 2-30°C
	Do not use if package is damaged
EC REP	Authorized representative in EU
REF	Catalog #
	Tests per kit
	Use by
LOT	Lot number
	Manufacturer
	Do not reuse
	Consult instructions for use
	Importer
	Distributor

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