

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) comprises firm plastic strips onto which several separate reagent areas are affixed. This device is a nonspecific screening device and is intended to detect abnormal levels of white and red blood cells, nitrite and protein in the urine. Analytes in urine: Leukocytes, Blood, Nitrite and Protein. 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 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 colour.

Blood: This test is based on the peroxidase-like activity of haemoglobin which catalyses the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetramethylbenzidine. The resulting colour 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 colour.

Protein: This reaction is based on the phenomenon known as the "protein error" of pH indicators (Tetrapropenol Blue). The anion produced by pH indicators under given conditions combines with the cation produced by protein, then pH indicators colours from yellow to green-blue for positive results.

PRECAUTIONS

Please read all the information in this package insert 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.
- 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.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle or 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 colour identification (such as Daltonism/colour blindness), ask for help in test reading.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30 °C). The test is stable for use up to the expiry 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
- Plastic cup
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Specimen container

PROCEDURE

ATTENTION:

It is recommended to take a sample of urine for the test in the early morning since 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 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.

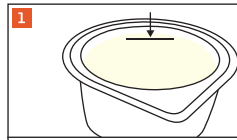
PERFORMING THE TEST:

- 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.
- Dip the test strip in the urine sample.

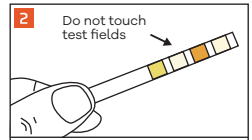
ATTENTION:

Press the strip and make sure that all four test fields are immersed for about 1-2 seconds.

- 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.
- Wait for 2 min. (do not read results after 3 minutes) Read the result separately for each parameter, compare colour with colour chart provided.

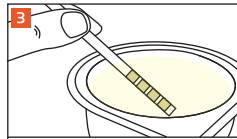


Fill cup with urine

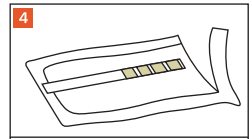


Do not touch test fields

Take test strip from foil pouch



Immerse test strip for 1-2 seconds



Wait 2 minutes, then read results

READING THE RESULTS

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

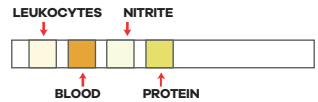
NEGATIVE

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.



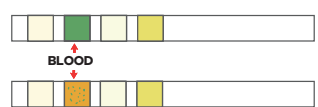
POSITIVE RESULT FOR LEUKOCYTES

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



POSITIVE RESULT FOR BLOOD

If the colour of the test field has changed to green (or some green spots appear on the background), then blood has been found in your urine.



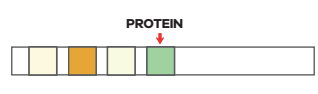
POSITIVE RESULT FOR NITRITE

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



POSITIVE RESULT FOR PROTEIN

If the colour of the test field has changed to green, then proteins have been found in your urine.



For more information contact 2San

Unit 11 Carnforth Business Park,
Oakwood Way, Carnforth,
England, LA5 9FD
E: helpdesk@2san.com
W: www.2san.com

TECHNICAL NOTES ON PARAMETERS

The Test detects **LEUKOCYTES, BLOOD, NITRITE** and/or **PROTEIN** in urine.

LEUKOCYTES: The presence of leukocytes in urine is an important symptom of inflammation of the kidneys and the urinary tract. Proteins react with the pad and change its colour to purple.

BLOOD: A uniform green color conversion indicates the presence of hemoglobin or hemolyzed erythrocytes; scattered or compacted green spots indicate intact erythrocytes. The presence of red cells in your urine may be as a result of a number of conditions and requires further investigation by your doctor. The presence of red cells in urine in menstruating women may provide a positive result that cannot differentiate between contamination of the sample and the presence of blood in the bladder or ureters.

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. 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 colour 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.

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. Interference of 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.

WARNINGS & 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[®]. The colour development on the test pad may be masked or a colour reaction may be produced that could be interpreted as false results.

Taking cephalaxin 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. There are a number of causes of occult blood in the urine. A common and benign cause in women is menstrual period blood. If this applies, repeat the test after your period ends. Other causes of blood in the urine include: kidney, ureter or bladder stones, urinary tract or kidney infections (often also visible to the naked eye) or cancer of the kidneys, ureter or bladder. Menstrual period, constipation may cause a positive result.

Leukocytes: The result should be read at 2 min 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 cephalaxin, 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

Blood: A uniform green colour indicates the presence of hemoglobin, haemoglobin or haemolysed erythrocytes. Scattered or compacted green spots indicate intact erythrocytes.

To enhance accuracy, separate colour scales are provided for haemoglobin 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 colour formation.

Microbial peroxidase, associated with urinary tract infection, may cause a false positive reaction.² The test is slightly more sensitive to free haemoglobin 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 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.³

Protein: Any green colour indicates the presence of protein in the urine. This test is highly sensitive for albumin, and less sensitive to haemoglobin, globulin and mucoprotein.⁴

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.⁵ The urine specimens with high specific gravity may give false negative results.

EXTRA INFORMATION

WHAT SHOULD I DO IF MY TEST RESULT IS POSITIVE?

Remember that a positive result does not 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 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 doctor to arrange a more thorough examination.

BIBLIOGRAPHY





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





APPLICABLE PRODUCTS




This package insert applies to the following products:

PRODUCT NAME	TESTS PER KIT	REF
Urinary Tract Infections Test	1 test kit	AUUTSAT-1
Urinary Tract Infections Test	1 test kit	AUUTSAT-2
Urinary Tract Infections Test	1 test kit	AUUTSAT-3

INDEX OF SYMBOLS

	Consult instructions for use
	For <i>in vitro</i> diagnostic use only
	Store between 2-30°C
	Do not use if package is damaged

	Tests per kit
	Use by
	Lot number
	Manufacturer

	Authorised representative in EU
	Do not reuse
	Catalog #



Hangzhou AllTest Biotech Co., Ltd.

#550, Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 0123

EC REP

MedNet EC-REP GmbH

Borkstrasse 10,
48163 Muenster,
Germany

Distributed by

2San Pty Ltd
Level 35, Tower One,
100 Barangaroo Avenue,
Sydney, NSW 2000, Australia
E: helpdesk@2san.com

Australian Sponsor

2San Pty Ltd,
Level 35 Tower One,
100 Barangaroo Avenue,
Sydney, NSW 2000
Australia

UK Responsible Person

Medimap Ltd
2 The Drift, Thurston
Suffolk IP31 3RT, UK

Number: 14601063002
Revision date: 2023-05-23