

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

【INTENDED USE】

Silex UTI strips are for self-testing use. Test strips are dip-and-read test strips for In Vitro Diagnostic Use only for testing above the above items in urine. The test result may provide information regarding the status of kidney function and urinary tract infection. It is measured by comparison of the test paper attached to a plastic strip alongside the colour chart blocks printed on the label.

Caution

After using this test, if you have any symptoms or positive results, you should not take any decision of medical importance without first consulting your medical practitioner.

【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】

Leukocyte: This test pad contains an indoxyl ester and diazonium salt. It is followed by an azo-coupling reaction of the aromatic amine formed by leukocytes esterase with a diazonium salt on the reaction pad. The azo dye produced causes a colour change from beige to violet.

Blood: The test is based on the Pseudo-peroxidase activity of the haem moiety of haemoglobin and myoglobin. The chromogen is oxidized by a hydroperoxide in the presence of haem and changes colour from yellow to blue.

Nitrite: The test is based on the diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo dye produced causes a colour change from white to pink.

Protein: Protein "error of indicators." When the pH is held constant by a buffer, indicator dyes release H⁺ ions because of the protein present and change colour from yellow (or greenish yellow) to blue-green.

【INGREDIENTS】

Each test contains per 5mm² test patch area, the following:

- Leukocyte: Induced Indole amino acid ester 1,3mg
- Blood: Cumene Hydroperoxide 12mg, o-Tolidine 35mg
- Nitrite: P-arsanilic acid 4,5mg
- Protein: Tetrabromophenol blue 0,34mg

【PRECAUTIONS】

For in vitro diagnostic use only. Each test strip is for a single use only.

The desiccant in the strip container is non-toxic for your health but if you inadvertently ingested it, you should drink plenty of water to wash it down.

Used test strips should be wrapped in tissue (or gauze) and then disposed into a waste box to avoid the misuse of the tested strips.

Disposal of all waste materials should be in accordance with local guidelines. Exercise the normal precautions required for handling all laboratory reagents.

【HANDLING PROCEDURE】

Do not open the container until ready to use the test strip(s). Do not remove desiccant from the container(pouch).

Do not touch test areas of urine reagent strips. Keep out of the reach of children.

When stored in the original container (pouch), the product is stable up to the expiry date printed on the pouch.

【STORAGE AND STABILITY】

Store in a cool, dry place at temperatures between 2°C ~ 30°C and a relative humidity of less than 50%.

Do not store the strips in a refrigerator or freezer. Store away from moisture and light.

【MATERIALS PROVIDED】

- Test dipstick • Plastic cup • Colour chart • Package insert • Brand Card

【Caution】 If the packaging is damaged, please do not use.

【MATERIALS REQUIRED BUT NOT PROVIDED】 •Timer or a watch with a second hand

【PROCEDURE】

SPECIMEN COLLECTION AND PREPARATION:

Use only well mixed, non-centrifuged urine. A first-morning specimen is recommended. Collect the specimen in the container provided. Do not add any preservatives. The specimen volume should allow for the complete dipping of all reagent strip areas (e.g. at least 10mL).

If testing cannot be done with an hour after the specimen collection, refrigerate the specimen immediately and let it return to room temperature before testing. Improperly stored (stored over 4hours at RT and refrigerator) urine specimens may give inaccurate results.

PERFORMING THE TEST:

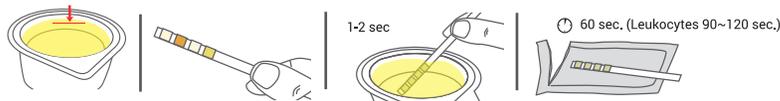
1) Open the foil pouch and take out the test dipstick. Do not touch the test fields. Once the pouch is opened, it is recommended to perform the test immediately.

2) Dip the test dipstick in the urine sample.

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

3)Then remove the test dipstick 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 60 sec (Leukocytes 90~120sec).** Do not read results after 3 minutes. Read the result separately for each parameter. Compare the colour shown on the test strip with the colour chart provided.



【READING THE RESULTS】

Read the result separately for each parameter. Compare the colour shown on the test strip with the colour chart provided. Colour changes on the edges of the test pads or colour changes after more than 2 minutes should be ignored.

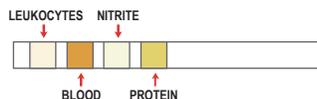
NEGATIVE

The Test field for LEUKOCYTES stays beige.

The Test field for BLOOD stays mustard yellow

The Test field for NITRITE stays white.

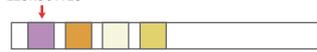
The Test field for PROTEIN stays yellow (or greenish yellow).



POSITIVE RESULT FOR LEUKOCYTES

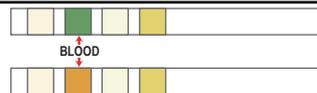
If the colour of the test field has changed to violet, then leukocytes have been found in your urine.

LEUKOCYTES



POSITIVE RESULT FOR BLOOD

If the colour of the test field has changed to blue (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 blue-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: Normally no leukocytes are detectable in urine. 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 colour to purple.

BLOOD: A uniform green colour conversion indicates the presence of haemoglobin or haemolyzite erythrocytes; scattered or compacted green spots indicate intact erythrocytes. Blood may often be found in the urine of menstruating females.

NITRITE: Gram-negative bacteria in urine convert nitrates from food into nitrite. Nitrite reacts with a chemical in the test field and leaves a pink shade. Normally no nitrite is detectable in urine.

PROTEIN: An indicator on the test field reacts with protein in the urine, changing its colour to green. Normal urine specimens ordinarily contain some protein (<20mg/dL), therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease.

【CONTROL PROCEDURE】

For best results, performance of reagent strips should be validated by testing known negative and positive specimen or controls (e.g., Quantimetrix Dipper Urine Dipstick, Dropper Urine Dipstick, Dip&Spin Urine Dipstick; Bio-Rad qUAntify Plus Control; Thermo SCIENTIFIC MAS UA Control) whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Quality Control materials should be used in accordance with local or national requirements for QC testing.

【PERFORMANCE CHARACTERISTICS】

The repeatability / reproducibility result of Silex UTI strips are above 90%. All of the coefficient of correlation estimated among (MultiStrix 10SG vs Silex UTI strips) is statistically significant at 1% level. Comparative test of between strips (MultiStrix 10SG Vs Silex UTI strips) indicated that there were no significant differences in reactivity of test parameters. A comparison results between professional and laymen revealed a very high concordance of between 80-100%. It results were obtained by 925 samples at 2 hospitals. The values specified for the analytical sensitivity are defined as the concentration of analyte which leads to positive result in >90% of the examined urines.

Test strip	Sensitivity	Specificity
Leukocytes	20 WBC/ μ l	Intact and lysed WBCs
Blood	10 RBC/ μ l(0.03mg/dL haemoglobin)	Intact RBC,Haemoglobin
Nitrite	0.05mg/dL	Nitrite ion
Protein	15mg/dL	albumin

【LIMITATIONS】

As with all tests, definitive diagnostic or therapeutic decisions should not be based on any single (or first) result of method. Substances that cause abnormal urine colour (green, red, dark yellow) may affect the readability of test pads in urinalysis reagent strips.

Urinary ascorbic acid concentrations as low as 40mg/dl can cause interference in specimens with low concentrations of blood and Nitrite.

The effects of drugs or other metabolites on the individual tests are not known in all cases. If in doubt, the test should be repeated after ceasing ingestion of the medication. If the result is the same, **please consult with a doctor.**

Leukocyte: The test result may not always be consistent with the leukocyte cell number by the microscopic examination. High concentration of glucose, high specific gravity, high level of albumin, high concentration of formaldehyde or presence of blood may cause decreased test results. False positive results may occasionally be due to contamination of the specimen by vaginal discharge.

Blood: Elevated specific gravity or protein in urine may reduce the reactivity of the blood test portion. Microbial peroxidase associated with a urinary tract infection may cause false positive results. Ascorbic acid concentrations (>30 mg/dl) may cause false negatives at the low level of blood.

Nitrite: Ascorbic acid (>30mg/dL) may cause a false negative result with low level of nitrite containing (<0.05mg) urine. The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as a positive result. Negative results may occur when urinary tract infections are caused by an organism which does not contain nitrate reductase; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite occur; or when the dietary nitrate is absent.

Protein: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens.

【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 doctor, who will be able to give a more accurate diagnosis and advise on next steps. 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】

- NCCLS (National Committee for Clinical Laboratory Standard) GP 16-A/ ROUTINE URINALYSIS AND COLLECTION TRANSPORTATION AND PRESEVATION OF URINE SPECIMENS; TRNTATIVE GUIDELINE VOL 12-NO 26, EC,1992



DFI CO., Ltd
388-25, Gomo-ro, Jillye-myeon, Gimhae-si,
Gyeongsangnam-do, 50875, Republic of Korea
Tel: 82-55-346-1882 Fax: 82-55-346-1883
Web-site: www.dficare.com



MDS5 GmbH
Schiffgraben 41,
30175 Hannover, Germany



Advena Limited
UK Office, Pure Offices, Plato
Office, Tachbrook Park, Warwick,
United Kingdom, CV34 6WET
T: +44 1926 800153
E: info@advenamedical.com



DTS TRADING INC.LTD
Floor 3, 43-45 St. John Street, London, EC1M 4AN
www.dtstrading.com; www.silextest.com

NOTES ON SYMBOLS



Consult instructions for use



In vitro diagnostic



Use By / Expiry Date (YYYY-MM-DD)



Do not reuse



Store at



Keep away from sunlight



Number of test strips



Caution