



TestCard

Urinary Tract Infection - (UTI)

Urine Self-test Kit

REF TC-UTI

CE 2797

INTENDED USE

TestCard's Urinary Tract Infection - (UTI) Urine Self-test Kit is to be used in conjunction with the TestCard mobile App; to determine likelihood of urinary tract infection. Results are provided through the TestCard mobile App.

Intended for self-testing (testing within a home environment).
For in vitro diagnostic use only.

PRINCIPLE AND SUMMARY OF THE TEST

The kit contains two removable test strips each within a foil pouch testing:

pH – The test pad contains the indicators methyl red, phenolphthalein and bromothymol blue and reacts specifically with H⁺ ions. The most frequent pH values in fresh urine from healthy individuals lie between 5 and 6.

Nitrites – The test is based on the principle of the Griess test and is specific for nitrite. The reaction reveals the presence of nitrite and hence indirectly nitrite-forming bacteria in the urine by a pink-red coloration of the test patch. Even a slight pink is indicative of significant bacteria.

Leukocytes – This test detects Leukocytes in urine by the action of esterase, present in granulocytic leukocytes, which catalyses the hydrolysis of an indoxylcarbonic acid ester to indoxyl. The indoxyl formed reacts with a diazonium salt to produce a purple colour.

The reaction strips should be read using the TestCard App available from the Apple App Store and Android Play Store.



Minimum mobile requirements: A fully functioning iOS 11+ or Android 6+ smartphone device. For a list of supported mobile devices please visit testcard.com/supported-devices

The TestCard App reads and interprets the results from the dipstick to provide guidance. Specific results are available under "more info" which can be shared with your healthcare provider should you wish.

REAGENTS

Each test pad contains per 1cm2 area: **pH** – Bromothymol blue 13.9ug; methyl red 1.2 ug, phenolphthalein 8.6 ug. **Nitrite** – 3-hydroxy-1,2,3,4-tetrahydro-7,8-benzoquinoline 33.5 ug; sulphanilamide 29.1 ug. **Leukocytes** – Indoxylcarbonic acid ester 15.5 ug; methoxymorpholinobenzene diazonium salt 5.5 ug.

PRECAUTIONS

(WARNINGS & PRECAUTIONS, LIMITATIONS OF THE TEST)

- Ensure you follow instructions and read all screens inside the TestCard mobile App throughout the test process.
- Do not remove the test strip from the protective foil pouch until prompted by the mobile App.
- If the foil pouch is not completely sealed, do not use the test.
- Each test strip is intended for single use only, do not reuse the test strip.
- Remove used test strip after use and dispose of safely via normal household waste.
- Do not use the device beyond the expiry date shown on the packaging.
- The foil pouch contains a silica gel pack, do not tamper with the pack, dispose of safely via normal household waste.
- Always consult your doctor or healthcare professional before making any medical decisions resulting from this test.

STORAGE

Store the kit at 2 to 30°C. The test strips are stable up to the expiration date displayed on the packaging whilst the foiled pouch intact. Do not use the test strips after the specified expiration date. Test strips should be used within 2 hours of removal from foil pouch. Extremes of temperature and humidity outside of those recommended may shorten this time.

DISPOSAL

After the test, dispose of any urine sample down the toilet. Outer test card packaging and unused test strips can be recycled (cardboard). Used test strips are not suitable for recycling so should be disposed of safely via normal household waste.

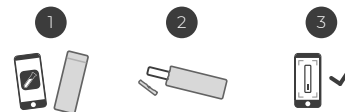
MATERIALS PROVIDED BUT NOT PROVIDED

An Apple or Android smartphone capable of downloading and installing the TestCard App.

Minimum mobile requirements: A fully functioning iOS 11+ or Android 6+ smartphone device. For a list of supported mobile devices please visit testcard.com/supported-devices

HOW TO USE? (PROCEDURE)

Before beginning, the TestCard App should be installed in your smartphone. The App is available from the Apple App Store and Android Play Store.



1. Open/Start the TestCard App and select "Start Test". Follow the instructions provided on screen. Select the "Urinary Tract Infection - (UTI) Kit" product from the list of possible TestCard products.

2. Have your TestCard ready. You'll also need a clean container to collect your urine sample. Any size or type is fine.

Remove a test strip from the packaging and scan the QR code. Briefly dip the test strip in the urine (approx. 1 sec). Do not re-dip the test strip. Follow the instructions provided and select "I've dipped my test".

NB – A mid-stream 'clean catch' sample is best. First thing in the morning often provides the most representative results.

3. When the timer has counted down the flash on your phone will turn on and the scanning screen will be displayed. Follow the instructions in lining up the test strip for scanning. When scanning has been successful the 'Your results are ready' screen will be displayed followed by your results.

HOW TO READ THE RESULT? (INTERPRETATION OF RESULTS)

Possible outcomes:

Negative

Good news, we have not detected a UTI.
You are unlikely to have a UTI but if you have continued symptoms consistent with a UTI we suggest you consult a health professional.

Possible UTI

We have detected that you may have a UTI.
Your urine test indicates that you may have a UTI. We suggest you consult a health professional.

High Possibility

You are very likely to have a UTI.
Your urine test indicates a very real possibility that you have a UTI.
We recommend contacting a health professional as soon as possible.

LIMITATIONS

Nitrite – Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result. Administration of antibiotics or chemical drugs should be discontinued 3 days before performing the test or results may be affected. Large amounts of ascorbic acid decrease the sensitivity of the measurement.

Leukocytes – Formaldehyde (stabiliser) and medication with imipenem, meropenem and clavulanic acid may cause false-positive reactions. If the urine specimen has a pronounced intrinsic colour the reaction colour may be intensified due to an additive effect. Urinary protein excretions in excess of 500 mg/dL and urinary glucose excretions in excess of 1g/dL may diminish the intensity of the reaction colour, as can cephalixin and gentamycin if administered in high daily doses, or boric acid if used as a preservative.

PERFORMANCE CHARACTERISTICS

Analytical range:

pH 5 - 8.5
Nitrites NEG - POS
Leukocytes NEG - 500 LEU/uL

Sensitivity:

Nitrites 13-22 umol/L
Leukocytes – 5-15 LEU/uL

EXPECTED VALUES

Fresh urine from a healthy individual would not be expected to have leukocytes or nitrites detectable and a pH of approximately 6 and therefore report as a 'Negative' result.

CONTACT US FOR FURTHER INFORMATION

For further information on this test or other TestCard tests visit:
testcard.com










For support and complaints please visit:
testcard.com or e-mail support@testcard.com

TestCard's online support area includes:

- FAQs
- How to Videos
- Support Articles

Live chat support is also available in the App and on our website.

MEANING OF THE SYMBOLS ON THE PACKAGE

	Manufacturer
	Use-by date
	Batch number
	Catalogue number
	Store between x and y
	Consult instructions for use
	In vitro diagnostic medical device
	Do not re-use
	EU authorised representative



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