CYSTI'TEST®
Rapid hygienic test for the detection of nitrites and leukocytes in urine
Ref.: TR-URI-002
User manual

INDICATION FOR USE

CYSTI'TEST® is a rapid test for the qualitative detection of 2 parameters (leukocytes, nitrites) in urine samples.
CYSTI'TEST® is a rapid test for professional use that helps in the diagnosis of urinary tract infections.

INTRODUCTION

Urinary tract infections are quite common situations, affecting both adults and children. Some are benign, such as simple acute cystitis in women; Others have a potentially serious course with a risk of kidney infection (pyelonephritis) on a stone (lithiasis) that requires an emergency consultation.
CYSTI'TEST® allows a rapid examination to be carried out that can guide the diagnosis of simple acute urinary tract infection in the absence of risk factors (pregnancy, severe kidney failure, immunosuppression, age > 65 years).
CYSTI'TEST® allows urine to be tested for nitrites and leukocytes in a single examination.

PRINCIPLE OF THE TEST

CYSTI'TEST® is a rapid hygienic test carried out using a urine strip to which reagent squares are attached, capable of changing colour in the presence of certain substances. The urine strips are interpreted using the colour chart printed on the jar containing the urine strips. The reading is done after a reaction time of 2 minutes. By comparing the colour of each square to this colour chart, it is possible to interpret the presence or absence of certain elements.

Parameter	Principle	Composition
Nitrite	The test depends on the diazotation of nitrite with aromatic amino sulfonamide to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol to produce a pink color.	1.3% w/w of 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol; 89.6% w/w buffer; 9.1% w/w non-reactive ingredients
Leukocyte	Granulocyte leukocytes in the urine contain esterases that catalyze the hydrolysis of the amino acid ester pyrrole to release 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to form a purple color.	4.3% w/w pyrrole-derived amino acid ester; 0.4% w/w of diazonium salt; 92.6% w/w buffer; 2.7% w/w non-reactive ingredients

EQUIPMENT PROVIDED

- 1 jar of 25 urine strips with color chart
- 25 hygienic bottles for urine collection and urine dipstick interpretation
- 25 zip plastic bags
- 1 user manual including a simplified operating procedure

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

STORAGE AND STABILITY

The kit can be stored at room temperature between 2 and 30°C.
Do not store it in the refrigerator, do not freeze it. Keep away from direct sunlight.
Store the strips in their original jar. Do not remove the desiccant bag(s). REMOVE THE STRIP FROM THE JAR ONLY IMMEDIATELY BEFORE USING IT FOR THE TEST. Replace the cap immediately on the jar and screw it on firmly after removing the strip. After opening the jar, the urine strips should be used within 18 months without exceeding the expiry date indicated on the jar.

WARNINGS AND PRECAUTIONS

- For professional in vitro diagnostic use only.
- Urine strips should remain in their tightly sealed jar until they are used.
- Do not use the kit after the expiration date.
- Urine strips and urine collection bottles are for single use.
- Do not touch the reactive squares of the urine strips with your fingers.
- Wear appropriate protective clothing, gloves, and eye/face protection when handling the contents of this kit. The equipment used must be disposed of in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

- Collect fresh urine in the bottle provided and place it in the zipped plastic bag provided in the kit. The amount should be between the "Min" and "Max" markings on the vial label. Remove excess urine if the fill level exceeds the "Max" line.
- The sample must not have been collected more than 2 hours before the test is performed.

PROCEDURE

1. Homogenize the sample before performing the test.
2. Remove the small soft rubber stopper on the lid and insert a urine strip into the vial, arrows down, with the reagent squares visible from the outside.
3. Put the small soft rubber stopper back on the lid.
4. Tilt the urine collection bottle for 1 second so that the test strip reagent squares are completely soaked with urine.
5. Place the bottle upright on a flat surface. Ensure that all test squares have been soaked with urine.
6. Wait 2 minutes and read the test result through the bottle, comparing the colour of the reagent squares to the colour chart on the label of the strip jar.

INTERPRETATION OF THE RESULTS

Refer to the colour chart printed on the jar containing the strips.

Parameter	Principle	Results	Limitations of the test
Nitrite	Conversion of nitrate (derived from food) to nitrite by the action of mainly Gram-negative bacteria in the urine, most commonly E. coli.	Any uniform pink color should be interpreted as a positive nitrite test suggesting the presence of bacteria. The development of color is not proportional to the number of bacteria present.	The test is specific to nitrites and does not react with any other substance normally found in urine. Pink spots or pink edges should not be interpreted as a positive result. Negative results can occur when the UTI is caused by organisms that cannot convert nitrate to nitrite; when urine has not been retained in the bladder long enough (four hours or more) for nitrate reduction to occur, or when dietary nitrates are absent.
Leukocyte	Result of the reaction of granulocyte leukocyte esterase with diazonium salt.	The "Traces" result observed individually can be considered doubtful. The "Traces" result observed in an iterative manner should be considered positive. Any color ranging from pink to purple of intensity greater than "Traces" is positive. The presence of leukocytes in the urine is linked to a urinary tract infection.	False positive results can sometimes be found when urine is contaminated by vaginal discharge or high glucose concentrations (160 mmol/L). High blood concentrations (>200 hem/leu) can decrease the intensity of the result.

BOUNDS

- Failure to follow the procedure may adversely affect the performance of the test and/or invalidate the test result.
- PROTECTING THE STRIPS FROM AMBIENT MOISTURE, LIGHT AND HEAT IS ESSENTIAL TO PREVENT CHANGES IN THEIR REACTIVITY. The deterioration may cause the reactive squares to become discoloured. If this is the case, the strips should not be used.
- The sensitivity of the test is reduced for high-density urine.
- As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory results have been evaluated.
- The test must be used according to the regulations in force.

PERFORMANCE

The performance of the **CYSTI'TEST®** test was evaluated in a comparative prospective clinical study, conducted on 3 sites and involving 100 individuals.

Parameter	Reading time	Limit of Detection (LOD)	Measuring range	Precision (± 1 deviation in colour intensity)
Nitrite	2 min	0.06-0.1 mg/dl	Negative or Positive	>80%
Leukocyte	2 min	20-25 leu/µl	Negative at 500 leu/µl	>80%

SYMBOL LEGEND

	Read the user manual		Number of tests per kit		Maker
IVD	For in vitro *diagnostic use* only		Expiry date		Do not reuse
2°C 30°C	Store between 2 and 30°C	LOT	Lot number	REF	Reference
CE	CE marking				

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