

BEFORE PERFORMING THE TEST, PLEASE READ THESE INSTRUCTION CAREFULLY

# Urinal Test Analysis, URS 10 Test

Home strip test for testing 10 basic parameters in the urine.  
**Medical device for self-testing.**

The product has received a positive opinion from the "Child Health Center" (Centrum Zdrowia Dziecka)

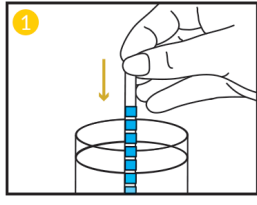
## What is the Urinal test analysis, URS10 Test?

Urinal Test analysis, URS10 Test is a general urine test for home use. Urinal Test analysis, URS10 Test takes the form of a strip, on which there are placed separate reaction fields as ten colored squares. Each of the squares represents one of the parameters (glucose, bilirubin, ketones, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes). Urinal Test analysis, URS10 Test use consists in immersing the test strip in a urine sample and visual comparison of each color field with the color scale, which is located in the package.

## PERFORMANCE OF URINAL TEST ANALYSIS, URS10 TEST?

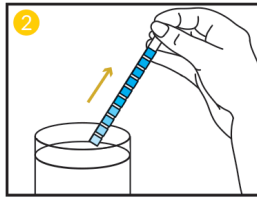
### Stage 1. Collection of urine sample

- » Collect sample of urine coming from the middle stream, preferably from the first morning collection.
- » The urine should be collected in a clean and dry container.

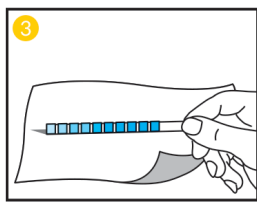


### Stage 2. Test performance

- » Take the test strip out of the bag. The bag also contains desiccant, which should be disposed of.
- » Immerse the test strip in the urine and take it out immediately.



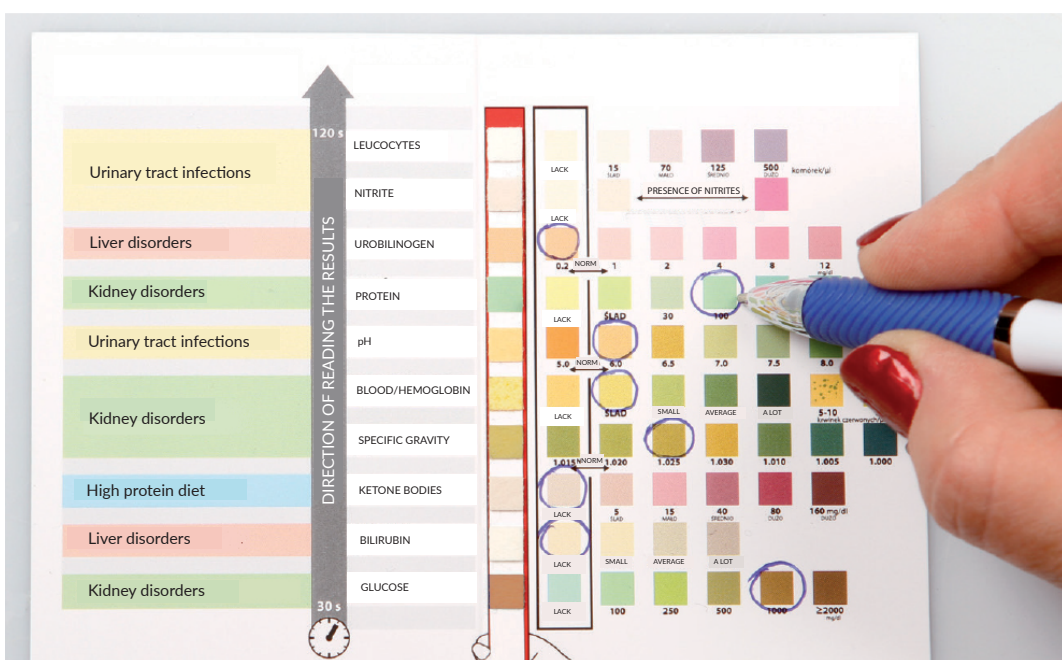
- » While taking the test strip out of the urine, rub its side against the container to remove the excess urine.



- » Holding the test strip horizontally touch the hygienic tissue to remove excess urine.

### Stage 3. Results reading

- » Place the test strip on a red field on a color scale.
- » Begin reading the results in 30 seconds starting from the bottom, i.e. from GLUCOSE but not later than after 2 minutes.
- » Find the resulting color on the test strip on the color scale, locate and mark by the wheel as pictured below.



## RESULTS INTERPRETATION

Locate the marked result on the color scale for a given parameter in the table of results below:

Marked parameter	Standard	What does the elevated or lowered result mean
Leukocytes (LEU) 120 s	There are no leukocytes in the normal urine	The presence of leukocytes may indicate: » kidney disease » urinary tract infection » tumor (neoplasm)
Nitrites (NIT) 60 s	There are no nitrites in the normal urine	The presence of nitrites may indicate: » urinary tract infection
Urobilinogen (URO) 60 s	Standard 0.2-1 mg/dL	Elevated levels of urobilinogen may indicate: » liver disorder » cirrhosis » Hepatitis
Protein (PRO) 60 s	There are no proteins in the normal urine	Elevated protein level may indicate: » kidney damage » infection » tumor » high blood pressure » heart failure » diabetes » lupus erythematosus » glomerulonephritis » leukemia » multiple myeloma » poisoning (e.g. by copper or lead) » pre-eclampsia (a complication in pregnancy) » the condition after strenuous exercise
pH 60 s	The average pH value is 6.0	Alkaline urine pH (pH > 7) may indicate: » urinary tract infection » kidney stones » the use of vegetable or milk diet Acidic urine (pH < 7) may suggest: » acidosis » diabetes » kidney stones » gout » fever
Blood (BLO) 60 s	There is no blood in the normal urine	Presence of blood may indicate: » kidney damage » damage to the urinary tract
Specific gravity (SG) 45 s	The correct value should be between 1.015 and 1.022 g/mL	A low specific gravity may indicate: » diabetes » renal disorder A large specific gravity may indicate: » kidney disease » excessive water loss
Ketones (KET) 40 s	There are no ketones in the normal urine	Elevated ketones level may indicate: » diabetes or poorly controlled diabetes » fasting » vomiting » fever » low carbohydrate diet
Bilirubin (BIL) 30 s	There is no bilirubin in the normal urine	Elevated bilirubin level may indicate: » disease of liver and bile ducts » Hepatitis » jaundice
Glucose (GLU) 30 s	There is no glucose in the normal urine	Elevated protein level may indicate: » diabetes or poorly controlled diabetes » acute renal failure

## STORAGE AND STABILITY OF THE TEST

Urinal Test Analysis, URS10 TEST package contains 2 tests, 1 color scale used to read the results and instructions for use. Each test is packaged in a separate foil bag. The bag contains a desiccant, which should be discarded. Urinal Test Analysis, URS10 tests should be stored at 2-30°C, in their original packaging. Packaging should not be exposed to direct sunlight or frozen. The test strip must be removed from the bag just before the test performance. Do not use the test after the expiration date. Do not use the test if the foil package is damaged. Do not use discolored tests.

## IMPORTANT NOTES

Remove the used test as every other household waste. Do not make any decision of medical relevance without first consulting your doctor.

## FREQUENTLY ASKED QUESTIONS

### Are the results obtained with the Urinal test Analysis, URS10 TEST reliable?

Yes, the results obtained with the Urinal Test Analysis, URS10 tests are just as reliable as the results obtained in the analytical laboratory, where exactly the same test strips are used. The difference is how the results are read. In the analytical laboratory obtained results are read using an electronic reader, and using the Urinal Test Analysis, URS10 Test the laboratory results on the color scale.

### Why do the Urinal test Analysis, URS10 TEST?

Many diseases are asymptomatic in the initial period. Before noticeable changes occur in the blood, the first signs of many diseases appear in the urine. Urinalysis is a basic research carried out in medical practice. It serves not only the assessment of health status, but also monitoring and controlling the status and work of many important organs such as the kidneys or liver. Urinalysis is also basic test ordered in suspected urinary tract infections.

### Who is mostly exposed to the urinary tract infections?

#### WOMEN

Infections of the urinary system occur more often in women than in men. It is facilitated by a short urethra and the small distance between the anus and the mouth of the urethra. In men, Urinary tract infections are also promoted by sexual activity (during the intercourse the bacteria can penetrate into the urethra) and the use of spermicides (facilitating the introduction of bacteria into the urethra).

#### CHILDREN

The second group of most frequently exposed to urinary tract infections are children. Urinary tract infection in children is second (after respiratory infections) childhood disease. Because of the specific symptoms, UTI (urinary tract infection) remains untreated, in many cases, which leads to serious complications. Urinary tract infection in children should be treated with an antibiotic, so its early diagnosis and initiation of appropriate treatment is very important.

### Who should do the Urinal Test Analysis, URS10 TEST?

» Patients in the case of raised temperature with no evidence of the source of infection

- » Patients with frequent urinary tract infections
- » Patients with chronic kidney disease
- » Patients on drastic slimming diets
- » Women who use vaginal contraceptives
- » Women with recurring problems of incontinence
- » Frequent users of public swimming pools

### How often should I perform urinalysis?

People from the group of increased risk of developing a urinary tract infection should performed the URS10 Test prophylactically once every three months. In case of any problems with your urinary tract, as soon as possible to do the test and see a doctor. Prophylactically, in healthy individuals it is recommended to make the test once a year.

### Does the performance of Urinal Test Analysis, URS10 TEST require a special collection and preparation of urine sample?

When taking urine sample for test strips of URS10 Test you should be guided by the same rules that apply when the urine is submitted to the analytical laboratory. For testing, use a urine sample derived from a mid-stream, preferably from the first morning collection. It is important that the urine is taken after overnight (at least 5h) break in urination, and it is collected in a clean and dry container.

### Can I read the results after 2 minutes?

No, do not read results after 2 minutes. Research has shown that the results obtained after two minutes are unreliable.

### What parameters should be particularly considered:

Suspecting urinary tract infection	» leukocytes » nitrites » pH » specific gravity
Suspecting kidney disease	» leukocytes » nitrites » pH » blood » specific gravity » glucose
With liver disease	» urobilinogen » bilirubin
Applying slimming diet	» ketone bodies
When performing prophylactic test of general health condition (recommended annually)	» all parameters

## INFORMATION ABOUT THE TEST ACTION, METHOD AND COMPOSITION

**Glucose:** test is based on an enzymatic reaction that occurs between glucose oxidase, peroxidase and a chromogen. Glucose is first oxidized to later in the presence of peroxidase in the reaction of hydrogen peroxide with chromogenic potassium iodide produce a gluconic acid and hydrogen peroxide in the presence of glucose and oxidase. On the degree of oxidation of the chromogen depends the color saturation level of the test field from green to brown. Glucose should not occur in normal urine. The small amounts of glucose can be excreted by the kidneys. If even small amounts of glucose to 100 mg/dL consistently recur in the urine, it is necessary to take into account that there are irregularities.

**Bilirubin:** This test is based on the reaction of bilirubin with a diazonium dichloroaniline in a strongly acidified environment. Different levels of bilirubin cause proportionate to its concentration in the urine pink color saturations on the test strip. In the normal urine bilirubin is not detected, even using very sensitive methods. The detection of even trace amounts of bilirubin requires additional testing. Obtaining abnormal reading (other than the color indicating a positive or negative on the color scale) may indicate the presence of bile pigments in urine, which can cover up the reaction of bilirubin.

**Ketones:** This test is based on the color reaction of ketones with sodium nitroprusside and acetoacetic acid. As a result of these reactions there occurs color saturation from light pink if the results are negative to dark pink or crimson in the case of positive results. Ketones are not present in normal urine. Detectable levels of ketone bodies may, however, be demonstrated in conditions physiologically aggravating the body such as fasting, pregnancy and frequent, intense effort. When using slimming diets or in the case of other carbohydrate metabolism disorders, ketone bodies in urine appear in elevated concentrations before appearing in the serum.

**Specific gravity:** The test is based on pKa changes in certain polyelectrolytes depending on the concentration of ions. At low ion concentration, the indicator will turn deep blue-green, with elevated concentrations of ions it will become green or yellow-green. Specific gravity of randomly tested samples of urine ranges from 1.003 to 1.035. Specific gravity of daily urine of an adult, healthy man, normally eating and drinking is in the range from 1.016 to 1.022. In the case of severe renal damage the specific gravity of the urine is approximately 1.010 of glomerular filtration value.

**Blood:** This test is based on the activity of hemoglobin, which, like the peroxidase catalyzes the diisopropylbenzene di-hydroperoxide and 3,3', 5,5 - tetramethylbenzidine. Range results of this test colors oscillate from orange to green and dark blue. Occurrence of any green spots on the test field or the development of color in the direction of the green within 60 seconds indicates the need for additional tests. Blood is often, but not always, detected in the urine of women during menstruation.

**pH:** The test is based on the principle of double indicator providing a wide range of colors corresponding to the full range of urinary pH. Colors results develop within the ranges from orange to yellow and from green to blue. Range of neonatal urine pH is 5.0 to 7.0. In other cases, 4.5 to 8.0, the average pH value is 6.0.

**Protein:** The reaction is based on the phenomenon known as the "protein error" of pH indicators, where a highly buffered indicator can change color in the presence of proteins (anions), while the indicator releases hydrogen ions to the protein. At constant pH, the appearance of any shade of green indicates the presence of protein. Colors range from yellow to yellow-green is negative. Appearance of color from green to green-blue indicates positive results. Protein in the amount of 1-14 mg/dL may be excreted by healthy kidneys. Test field giving a score higher than that corresponding to trace amounts of protein means significant proteinuria. For urine with high specific gravity, the test may give a score indicating the presence of trace amounts of protein, although its actual presence is in the correct concentration. Upon detection of trace amounts of protein the urine should be tested in the analytical laboratory.

**Urobilinogen:** This test is based on a modified Ehrlich reaction occurring between p-diethylaminobenzaldehyde and urobilinogen under strongly acidic conditions, which results in a pink color. Urobilinogen is one of the main ingredients in the synthesis of heme and substance normally present in urine. In the normal urinary concentration of urobilinogen is 0.2-1.0 mg / dL (3,5-17\µmol/L). Obtaining a result of 2.0 mg / dL (35 pmol/L) may be of clinical relevance and requires further research.

**Nitrites:** The test uses the transition of nitrate to nitrite as a result of action of gram-negative bacteria in urine. In the acidic environment nitrites contained in urine react with p-arsanilic acid, forming diazonium compound which on reaction with 1N-(1-naphthyl)-ethylenediamine gives rise to pink color. Nitrites are not detected in normal urine. The test for this component may be positive in some infections, depending on how long the urine was kept in the bladder before testing. When the time was short, reactions with nitrite are found only in 40% of cases the infection, during prolonged stops (at least 4 h) - in 80% of cases.

**Leukocytes:** the test uses granulocyte esterase in the presence of urine. Esterases split the amino acid ester derivatives of pyrazolu releasing hydroksypyrazole. Pyrazole then react with diazonium salts, causing the appearance of colors from beige-pink to crimson. In the normal urine this reaction does not occur. The detection of trace amounts of leukocytes in urine is not clinically significant. In the event of such a result it is recommended to repeat the test on a fresh sample of urine. Confirmation of positive or trace results may be of clinical relevance.

Date of the last revision of the instruction: 20.06.2022

Version 5 AC/EN

## METHOD LIMITATIONS

**Glucose:** the reaction field does not react with lactose, galactose, fructose, and other metabolites, as well as metabolites of drugs having reducing ability (e.g., salicylates and nalidixic acid). Sensitivity of the test may be reduced for urine samples of high specific weight (> 1.025) and ascorbic acid at a concentration of  $\geq 25$  mg/dL. High levels of ketones  $\geq 100$  mg/dL can cause false negative results in samples containing small amounts of glucose (50-100 mg/dL).

**Bilirubin:** bilirubin is not present in normal urine, so to obtain a positive result, meaning even trace amounts, indicates a pathology and requires additional testing. Reagent reactions can occur with samples containing large amounts of chlorpromazine or rifampicin, which can produce false positive results. The presence of bile pigments, bilirubin derivatives, may hinder obtaining reliable results, this situation manifests itself by receiving unusual colors on the indicator. High concentrations of ascorbic acid may reduce the sensitivity of the test.

**Ketones:** test field does not react with acetone and  $\beta$ -hydroxybutyric acid. False positives "trace" results may occur in the highly colored or containing sulfhydryl groups urine.

**Specific gravity:** organism acidification by ketone bodies or elevated protein level (above 300mg/dL) can produce increased results. The test results are not affected by nonionic urine components such as glucose. If the pH of the urine sample is 7 or more, its specific gravity should be increased by 0.005.

**Blood:** uniform blue color indicates the presence of myoglobin, hemoglobin, or hemolyzed erythrocytes. The emergence of distributed or regular blue spots indicates the presence of intact erythrocytes. To increase the accuracy of the test a separate color scales for hemoglobin and erythrocytes were indicated. Blood is often found in the urine of women during menstruation. High urine pH may decrease the sensitivity of the test, and medium to high concentrations of ascorbic acid can inhibit the saturation of color. The presence of peroxidase associated with bacterial infection of the respiratory tract can produce false positive results. The test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

**pH:** if you do not comply with the instruction for use and excess urine remains on the strip, there may occur the phenomenon of "passage" in the sense that the acidic buffer from the protein reagent filtrates to the pH test field, lowering the pH. Different urinary buffer concentrations do not interfere with the test results.









**Protein:** any shade of green indicates the presence of protein in the urine. The test is highly sensitive to albumin and less sensitive to hemoglobin, globulins and mucoproteins. A negative result does not exclude the presence of these proteins. Urine highly buffered or alkaline can produce false positive results. Urine samples contaminated with quaternary ammonium compounds or agents for cleaning the skin containing chlorhexidine may produce false positive results. Urine with high specific gravity may give false negative results.

**Urobilinogen:** all results below 1 mg/dL are interpreted as normal. A negative result does not exclude the presence of urobilinogen. The test may react with interfering substances known as Ehrlich's reagent, such as p-aminosalicylic acid and sulfonamide. Formalin may cause false negative results. The test is not used for detection of porphobilinogen.

**Nitrites:** the test is specific for nitrites and will not react with any other substance excreted in the urine. The emergence of any color saturation uniformly pink to red indicates a positive result, i.e. the presence of nitrite. The color intensity is not proportional to the amount of bacteria present in the urine sample. Pink spots or pink coloring of the edges of the test field should not be interpreted as a positive result. It is advisable to compare the resulting color on a white ground, which can help to spot the result for the low level of nitrite. Ascorbic acid at a concentration above 30 mg/dL can cause false negative results in urine containing less than 0.05 mg/dL of nitrite. The sensitivity of this test is deteriorated in the case of strong alkaline urine sample or a high specific gravity. To obtain accurate results, you should not take antibiotics for three days before testing. Negative results may be obtained in the case of urinary tract infections caused by microorganisms not containing reductase converting nitrate to nitrite; if the urine is not sufficiently long (at least 4 hours) kept in the bladder so that there was a reduction of nitrate to nitrite; when the antibiotic therapy was used, or when the diet lacks nitrates.

**Leukocytes:** results should be read within 60-120 seconds to full color saturation. Color intensity is proportional to the amount of leukocytes in urine. High specific gravity or elevated glucose levels (above 2000 mg/dL) may understate the result. The presence of cephalixin, cephalothin, or a high concentration of oxalic acid may also understate the results. Tetracycline may cause a decrease in reactivity and high concentration of the drug may cause a false negative result. High levels of protein can reduce the intensity of the color. Test does not respond to red blood cells or bacteria commonly found in the urine.

## SYMBOLS

	Prior to test performance carefully read the instruction		For in vitro diagnostics
	For single use only		Store at temperature 2-30°C
	Serial number		Expiry date
	Number of tests in the set		Warning

**Manufacturer:**  
Aleja Stanów Zjednoczonych 61A  
04-028 Warsaw, Poland  
www.hydrex.pl  
www.controly.eu

 **controly**  
medical devices

 1434