Urine Reagents Strips 10 parameters (Urinalysis)

IVD CE

PRODUCT CODE
US001

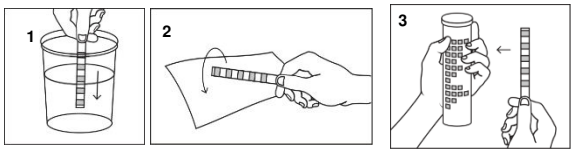
Intended Use
Urine Reagent Strips (US) are used for quick and simultaneous semiquantitative and qualitative screening of multiple urine parameters in one easy testing format. The testing range can be any combination of the following parameters:
Blood, Urobilinogen, Bilirubin, Protein, Nitrite, Ketone, Glucose, pH, SG, and Leukocytes.

Clinical Significance
Preliminary screening test for diabetes, liver disease, haemolytic diseases, urogenital and kidney disorders and metabolic abnormalities during routine examinations, and for use in general preventative medicine.

Specimen Collection
Collect urine in a clean container and test as soon as possible. **Do not centrifuge**. The use of urine preservatives should be avoided. If testing cannot be performed within one hour after voiding, refrigerate the specimen immediately at 2°C – 4°C and test within 4 hours. Allow refrigerated urine specimen to return to room temperature (15°C – 25°C) before testing.

Procedure
Before use, ensure that the test strips and container are not damaged, and that the expiry date and maximum storage temperature have not been exceeded. In these cases, the container and test strips must be discarded. Use fresh midstream urine less than 4 hours old. Always collect midstream urine into a clean, dry container, free of detergents.
Remove one strip from the container taking care not to touch the reagent areas. Immediately close the container securely using the original cap.

1. Briefly (one second only) dip all reagent areas into the urine sample.
2. Remove the test strip and **blot the side of the test strip on absorbent paper** to remove excess urine.
3. After 60 seconds, compare the test strip reagent areas with the colour scale on the label (after 60 – 120 seconds for leukocytes).



Proper reading times are critical for optimal results. Coloration appearing along the edges of the test pads or developing after more than two minutes after immersion has no diagnostic value. Visual interpretation should take place in diffuse daylight.

Clinical Use, Test Principles, Expected Values and Limitations

Blood: Intended to detect occult blood in urine. Occult blood indicates urological or kidney diseases. Microhaematuria does not affect the colour of urine and is only detectable microscopically or by chemical detection methods. The detection of blood is based on the pseudo-peroxidative activity of haemoglobin and myoglobin, which catalyse the oxidation of an indicator by an organic hydroperoxide and a chromogen to produce a green colour. Intact erythrocytes are indicated by punctual colorations (spots) on the test pad and, haemoglobin and myoglobin by a uniform green coloration. Large concentrations of ascorbic acid may cause lower readings in urine containing occult blood. False positive results are usually caused by residues of peroxide, chlorine or tertiary ammonium compounds used as disinfectants, detergents or cleaning agents. False positives may also be caused by formalin or by the activities of microbial oxidase from urogenital tract infections. The significance of a positive result varies from patient to patient and should be evaluated in the overall clinical assessment of the patient. The colour fields correspond to the following values: neg (negative), approx. 5-10, approx. 50, approx. 300 Ery/µL.
Interpretation: When a result falls between values, read to the lowest colour block. Any "trace values" should be reported as negative.
Detection range: 5 – 300 Ery/µL.

Bilirubin: Intended to measure the levels of bilirubin conjugates in urine. Measurement of bilirubin and its conjugates are used in the diagnosis and treatment of certain liver and bile diseases. The test for bilirubin is based on the coupling of bilirubin with a diazonium salt under acidic conditions. Normally no bilirubin is detected in the urine even by the most sensitive methods. The slightest discoloration of the reagent area constitutes a positive (i.e. pathologic) result. Concentrations of 0.5 mg/dL and more result in a red-orange peach colour and indicate the early stage of a liver disease. The pH of the urine does not affect the test reaction. False negatives may be produced by metabolites of drugs that give a colour at low pH, by the presence of nitrites and/or ascorbic acid concentrations in excess of 25 mg/dL (1.4 mmol/L). Indoxyl sulphate may also interfere with the interpretation of a negative or positive bilirubin reading. The presence of urobilinogen can enhance the sensitivity of the test field whilst urine indicane may cause atypical coloration. The colour fields correspond to the following values:neg (negative), 1(+), 2(++), 4(+++) mg/dL or neg (negative), 17(+), 35(++), 70(+++) µmol/L.
Interpretation: When a result falls between values, read to the lowest colour block.
Detection range: 1 – 4 mg/dL (17 – 70 µmol/L).

Glucose: Intended to measure glucose (glucosuria) in urine. Glucose measurement is used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and hyperglycaemia. This test is based on the specific glucose oxidase (GOD) – peroxidise (POD) reaction with a chromogen. Apart from glucose, no other compound in the urine is known to give a positive reaction. It is independent of pH and not affected by presence of ketone bodies. Test reactivity, however, decreases as the SG of the urine increases. Reactivity is inhibited by low temperature. Small amounts of glucose are filtered by healthy kidneys, therefore changes in the coloration of less than 50 mg/dL (2.8 mmol/L) are considered normal. The inhibitory effects of ascorbic acid has been largely eliminated for glucose readings higher than 150mg/dL. Other inhibitory substances include gentisic acid and pH values higher than 5. False positive results are usually caused by residues of peroxide, chlorine or tertiary ammonium compounds used as disinfectants, detergents or cleaning agents. The colour fields correspond to the following values: normal, 50, 150, 500 and ≥1000 mg/dL, or normal, 2.8, 8.4, 28 and ≥ 56 mmol/dL.
Interpretation: When a result falls between values, read to the nearest colour block. Repeat the test the following day when "trace values" are reported.
Detection range: 50 – 1000 mg/dL (2.8 – 56 mmol/L).

Ketones: Intended to detect ketones in urine. Identification of ketones is used in the diagnosis and treatment of acidosis of ketosis and for monitoring patients with diabetes. Based on the principle of Legal's test, this test reacts with acetoacetic acid and acetone in alkaline solution to form a violet coloured complex. Normal urine specimens usually yield negative results, however, detectable levels may be observed during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. The test does not react with ß-hydroxybutyrate. Captopril, Mesna (sodium-2-mercapto-ethane sulfonate) and other substances containing sulfhydryl groups may produce false-positive results. Phenyl ketones in high concentrations will cause variable colours. Phthalein compounds and anthrachinone derivates interfere with the test by producing a red coloration which may mask the reaction of ketones. The colour fields correspond to the following acetoacetic acid values: neg (negative), 25(+), 100(++) and 300(+++) mg/dL, or neg (negative), 2.5(+), 10(++) and 30(+++) mmol/dL.
Interpretation: When a result falls between values, read to the nearest colour block.
Detection range: 25 – 300 mg/dL (2.5 – 30 mmol/L).

Leukocytes: Intended to detect leukocytes in urine. A positive leukocyte result indicates an inflammatory disease of the kidneys and the urinary tract and suggests the need for further investigation. The reaction is based on the release of leukocyte esterase from lysed neutrophils, which react with an ester, producing a pyrrole compound. The pyrrole reacts with a diazonium salt yielding a violet colour. Urine from healthy subjects do not contain any leucocytes. Any positive result is to be considered as clinically relevant. The reaction is not affected by bacteria, trichomonads or erythrocytes present in the urine. Formaldehyde (stabilizer) may cause false-positive reactions. If the urine specimen has a pronounced intrinsic colour (for example due to the presence of bilirubin or nitrofurantoin), the reaction colour may be intensified due to an additive effect. False positive results may be caused by contamination with vaginal secretions. Urinary protein excretions > 500 mg/dL and urinary glucose excretions > 2 g/dL may diminish the intensity of the reaction colour, as can cephalexine, cephalothine, tetracycline and gentamicin if administered in high daily doses. The colour fields correspond to the following values: neg (negative), approx. 25, approx. 75 and approx. 500 Leukocytes/µL.
Interpretation: When a result falls between values, read to the nearest colour block. Trace values should be repeated on the next urine sample. Detection range: 25 – 500 Leukocytes/µL.

Nitrite: Intended to detect the presence of nitrite in urine. Detection of nitrite in the urine aids in the treatment of urinary tract infections of bacterial origin. The test is based on the principle of Griess's test and is specific for nitrite. The reaction reveals the presence of nitrite and hence indirectly of nitrite-forming (Gram Negative) bacteria in the urine by a pink discoloration of the test patch. Even a slight pink coloration is indicative of significant bacteriuria. Prolonged urinary retention in the bladder (4-8 hours) is essential in order to obtain an accurate result.

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A negative result does not preclude a bacterial infection (insufficient incubation, urinary tract infection due to bacteria not containing nitrite reductase). Administration of antibiotics or chemical drugs including vitamin C should be discontinued 3 days before the test. False positive results usually occur with stale urines in which nitrite has been formed by bacterial contamination of the urine specimen and in urines containing dyes such as beetroot and pyridinium derivatives. False negative results can be caused by various factors including vitamin C, low nitrate content diet, bacteria not containing nitrate reductase, significant diuresis, and insufficient incubation time in the bladder. A reaction pad showing red or blue borders should not be interpreted as a positive result.
The colour fields correspond to the following values: neg (negative) and pos (positive).
Interpretation: When a result falls between values, read to the nearest colour block. Any purple colour (even faint) should be reported as a positive result.
Detection range: 0.05 – 0.1 mg/dL or 6.5 – 13 µmol/L

pH: Intended to estimate the pH of urine. Estimation of urinary pH is used to determine the alkalinity or acidity of urine and aids in the monitoring of patients on specific diets. Abnormal urinary pH values relate to many renal and metabolic disorders. Persistently high pH values may be indicative of urinary tract infections. The pH reaction is based on an indicator that changes colour from 5 to 9. The pH of healthy individuals varies between pH 5 and pH 6. Bacterial contamination may lead to false results. The colour fields correspond to the following values: pH 5, pH 6, pH 7, pH 8, and pH 9.
Interpretation: When a result falls between values, read to the nearest colour block.
Detection range: pH 5 – pH 9.

Protein: Intended to detect the presence of protein in the urine. Identification of urinary protein is used in the diagnosis and treatment of renal diseases. The test is based on the "protein error" principle of the indicator. The test is especially sensitive to albumin and less sensitive to other proteins. Normally, no protein is detectable in the urine of healthy individuals. Trace values (for example values between negative and 30 mg/dL) should be reported as negative. False positive results are obtained with urine of high alkalinity, urine with high specific gravity, and urine containing quinine, polyvinylpyrrolidone (PVP), detergents or quaternary ammonium compounds (disinfectant residue in the urine collection vessel). The colour fields correspond to the following values: neg (negative), 30, 100 and 500 mg/dL, or neg (negative), 0.3, 1.0 and 5.0 g/L.
Interpretation: When a result falls between values, read to the lowest colour block. Any "trace values" should be reported as negative.
Detection range: 30 – 500 mg/dL (0.3 – 5.0 g/L).

Specific Gravity: Intended to provide an estimation of renal ability (urine concentration or urine dilution). The specific gravity of urine varies with fluid intake and can be an indicator of certain disorders. Highly diluted urine (SG 1.000) can indicate a failure of the renal concentration ability. Specific gravity can also serve as an indicator of urine tampering when screening for drug abuse. The test reaction is based on a colour change correlating with the concentration of ions present in the urine. This allows for urine density to be estimated between 1.000 and 1.030. The normal value varies between 1.015 and 1.025. Since pH has an influence on the test, the reaction has been optimised for urine with a pH of 6. Highly alkaline urine (pH >8) will yield slightly lower results, while highly acidic urine will yield slightly higher results. The test is not affected by glucose or urea. The colour fields correspond to the following values: 1.000, 1.005, 1.010, 1.015, 1.020, 1.025 and 1.030.
Interpretation: When a result falls between values, read to the nearest colour block.
Detection range: 1.000 – 1.030.

Urobilinogen: Intended to detect and estimate urobilinogen in urine. Urobilinogen (a bile pigment degradation product of red cell haemoglobin) is used in the diagnosis and treatment of liver diseases and haemolytic disorders. The test principle is based on the coupling of a stabilised diazonium salt with urobilinogen to form a red azo compound. The normal urobilinogen concentration in urine ranges from 0.1 – 1.8 mg/dL (1.7 – 30 µmol/L). Any value higher than 2 mg/dL (35 µmol/L) is considered pathological. The urinary pH does not affect the test. Traces of formaldehyde in the urine and exposure of urine to light may cause lowered or falsely negative results. Beetroot and drug metabolites which give a colour at a low pH (azo dyes, p-aminobenzoic acid, phenazopyridine) may cause false positive results. The colour fields correspond to the following values:
normal, 2, 4, 8 and 12 mg/dL, or 0 (negative), 0.3, 1.0 and 5.0 g/L.
Interpretation: When a result falls between values, read to the lowest colour block.
Detection range: 2 – 12 mg/dL (35 – 200 µmol/L).

Reagent Composition

BLD: Tetramethylbenzidine 0.5%; Cumene hydroperoxide 1.8%

UBG: Diazonium salt 0.1%
BIL: Diazonium salt 0.05%
PRO: Tetrabromophenol blue 0.05%**;** Buffer 4.7%
NIT: Tetrahydrobenzo[h]quinoline 0.04%; Sulfanilamide 0.1%
KET: Nitroprusside 0.2%; Buffer 30%
GLU: GOD 2.1%; POD 1.0%**;** O-Tolidine 0.2%
pH: Methyl red 0.16%; BTB 0.18%
LEU: N-Tosyl ester 0.06%**;** Diazonium salt 0.02%
SG: BTB 0.25%

Storage and Stability

Urine reagent strips are packaged along with a drying agent contained in the cap of the plastic container. Containers must be kept tightly closed at all times. Keep product away from sunlight and humidity at all times. Store the containers in a cool dry place. Under proper conditions unopened test strips are stable up to the expiry date printed on the packaging. **Once opened, the product must be used within 6 months**.

Notes

- All results should be considered in conjunction with a proper clinical assessment. Positive results should preferably be confirmed by other laboratory methods. In the case of monitoring, results should always be discussed with a clinician before any action is taken.
- Do not interpret results after 60 seconds (120 seconds for leucocytes) as this may lead to false results.
- Do not allow urine or urine collection vessels to be contaminated by residues of cleaning agents or disinfectants, as these cause false-positive results.
- Measurements may not accurately reflect current conditions if the urine has been in the bladder for several hours.
- For single use only. Do not use more than once.
- The product is intended for professional use only, not for self-testing.
- Do not use with any fluids other than urine, including water.
- STORE IN A DRY PLACE AWAY FROM HEAT OR DIRECT SUNLIGHT. ALWAYS KEEP BETWEEN 2C and 30C
- Avoid contact with mucous membranes. Do not swallow.
- Please observe standard laboratory practice when handling urine reagent strips and urine. Always read results in good lighting conditions.
- It is recommended to use Negative and Positive Control Solutions in a quality control programme.
- Keep out of reach of children. Discard used strips in a medically and environmentally responsible manner.

Symbols and Abbreviations:

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

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