Urine Reagent Strips Instruction

【Product Name】

Urine Reagent Strips

【Model】

KU-14A, KU-12B

Model	Test item
KU-14A	LEU、NIT、URO、BIL、VC、PRO、BLD、pH、SG、GLU、KET、MA、Cr、Ca
KU-12B	LEU、NIT、URO、BIL、VC、PRO、BLD、pH、SG、GLU、KET、MA

【Packing Specification】

100 pieces/bottle

【Intended use】

Urine Reagent Strips is used for qualitative and semi-quantitative detection of nitrite, urobilinogen, bilirubin, vitamin C, protein, occult blood, pH, white blood cells, glucose, ketone body, microalbumin, specific gravity, creatinine and urine calcium in urine. Auxiliary diagnosis of kidney disease, diabetes, urinary infections and other diseases (such as liver metabolism).

【Inspection Principle】

Perform urine analysis based on the chemical reaction principle.

1. Nitrite (NIT): Nitrite reacts with p-aminophenylarsenic acid to form diazonium compounds. The diazo compound is coupled with tetrahydrobenzoquinoline-3-phenol to generate a red azo dye.

2. Urobilinogen (URO): Urobilinogen couples with diazonium salts to form a purple-red dye under strongly acidic conditions.

3. Bilirubin (BIL): Bilirubin is coupled with dichloroaniline diazonium salts in the presence of strong acids to form azo dyes.

4. Vitamin C (VC): Vitamin C has a 1,2-enediol reducing group. Under alkaline conditions, the 1,2-enediol reducing group reduces the oxidized blue 2,6-Dichloroindophenol to the colorless 2,6-Dichlorodiparaffin phenolamines.

5. Protein (PRO): According to indicator protein error method, negative charge of acid-base indicator combines with cations of protein to generate a new compound, causing a color change.

6. Occult blood (BLD): Hemoglobin has peroxidase-like activity, which can decompose peroxide to release new ecological oxygen [O], and which ocidizes indicator to cause a color change.

7. pH: application of acid-base indicator method.

8. Leukocyte (LEU): Pyrrole esters are hydrolyzed by esterases in neutrophils to generate free phenols, which are coupled with phenyldiazonium salts to generate purple azo dyes.

9. Glucose (GLU): Glucose generates gluconic acid and hydrogen peroxide under the action of glucose oxidase, and hydrogen peroxide releases new ecological oxygen [O] under the action of peroxidase, [O] oxidizes potassium iodide, causing a color change.

10. Ketone body (KET): Acetoacetic acid reacts with sodium nitroferricyanide to form a purple-red compound under alkaline condition.

11. Microalbumin (MA): According to the principle of protein error, sulfophthalein dyes have high sensitivity only to microalbumin.

12. Specific Gravity (SG): The methyl vinyl ether-maleic acid copolymer is a weakly acidic (-COOH group) ion exchanger. It reacts with the cations M+ of the electrolyte (M+X-) in urine (with Na^+ Main) to replace hydrogen ions, which react with acid-base indicator, causing a color change.

13. Creatinine (Cr)： Under acidic conditions, creatinine forms complexes with metal ions, and through charge transfer, the indicator develops color.

14. Urine calcium (Ca): Calcium ions react with o-cresolphthalein complex ketone to produce purple-red, and the color depth is proportional to the concentration of calcium ions.

【Main Component】

It is mainly composed of plastic substrate and reagent paper.

Remark:

1. NIT: Test strips contain p-aminophenylarsenic acid, tetrahydrobenzoquinolin-3-ol, buffers and non-reactive substances.

2. URO: Test strips contain diazonium salts, buffers and non-reactive substances.

3. BIL: Test strips contain 2,4-dichloroaniline diazonium salt, buffers and non-reactive substances.

4. VC: Test strips contain 2,6-dichloroindophenol sodium salt hydrate, buffers and non-reactive substances.

5. PRO: Test strips contain tetrabromophenol blue, buffers and non-reactive substances

6. BLD: Test strips contain cumene hydroperoxide and tetramethylbenzidine, buffers and non-reactive substances.

7. pH: Test strips contain bromocresol green and bromoxycresol blue, buffers and non-reactive substances.

8. LEU: Test strips contain pyrrole esters and phenyldiazonium salts, buffers and non-reactive substances.

9. GLU: Test strips contain glucose oxidase, horseradish peroxidase and potassium iodide, buffers and non-reactive substances.

10. KET: Test strips contain sodium nitrosoferrocyanide, buffers and non-reactive substances.

11. MA: Test strips contain sulfophthalein dyes, buffers.

12. SG: Test strips contain bromothymol blue and methyl vinyl ether-maleic anhydride copolymer, buffers and non-reactive substances.

13. Cr: Test strips contain tetramethylbenzidine, buffers and non-reactive substances.

14. Ca: Test strips contain o-cresolphthalein complex ketone, buffers and non-reactive substances.

【Storage Conditions and Expiration Date】

1. Stored at 2-30°C for 18 months under dry environment without direct sunlight.

2. The reagent strips are valid for 1 month after the bottle opened.

【Applicable Instrument】

The urine reagent strips is used for Dry Chemistry Urine Analyzer and Automatic Urine Analysis System manufactured by Zhuhai Keyu Biological Engineering Co. ,Ltd.

【Sample Requirement】

1. Collect fresh urine with a clean, dry container and mix the urine well before testing.
2. Sample should be tested within 2 hours.

3. Any operation on the sample must be carried out in a hygienic environment.

4. Water cannot be used as a negative control.

5. Urine preservatives do not prevent the deterioration of ketone bodies, bilirubin, and urobilinogen.

6. Long-term storage of urine sample will lead to false results on glucose, pH, nitrite and occult blood due to bacterial growth.

【Testing Method】

1. Test environment:

A) Temperature: (25±5)℃;

B) Humidity: ≤ 80%.

2. Please follow the instrument user manual for testing.

【Reference Range】

Test item	Reference range	Analytical Range
NIT (μmol/L)	Negative	Neg.-Pos.
URO (μmol/L)	Positive (3.2-17)	3.4-130
BIL (μmol/L)	Negative	Neg.-100
VC (mmol/L)	Negative	0-5.6
PRO (g/L)	Negative	Neg. -3.0
BLD (cell/μL)	Negative	Neg. -200
pH	4.5～8.0	5.0-9.0
LEU (cell/μL)	Negative	Neg.-500
GLU(mmol/L)	Negative	Neg. -55
KET (mmol/L） (Acetoacetic acid)	Negative	Neg. -7.8
MA (g/L)	Negative	Neg. -0.15
SG	1.003-1.030	1.005-1.030
Cr (mmol/L）	（4.4-17.7）	0.9-26.5
Ca (mmol/L）	（2.5-7.5）	1.0-10

【Explanation for Test Results】

NIT

Nitrate reductase of Gram-negative bacteria in the urine reduces nitrate (extracted from food) to nitrite. This test is specific for nitrite and does not react with other substances excreted in normal urine. Pink spots or lines should not be judged positive, and any degree of uniform pink should be judged as a positive result, which indicated that sample has more than 1×10^5 /mL Gram-negative bacteria. However, the degree of color development is not proportional to the number of bacteria. A negative result by itself also does not confirm that a large number of bacteria is not present. Negative may occur in the following situations: 1. Urine does not contain reductase microorganisms that cause nitrate to nitrite conversion. 2. Urine does not remain in the bladder long enough (more than 4 hours) to complete the conversion of nitrate to nitrite. 3. Lack of nitrates in the diet.

For high specific gravity urine samples, the reactivity of this test is reduced. This test item is not disturbed by vitamin C whose concentration is below 1.4 mmol/L.

URO

This test item can detect urobilinogen with a concentration as low as 3 μmol/L in urine. The normal content of urobilinogen should be 3.2 to 17 μmol/L. A result of 33 μmol/L may be the junction (critical) of the transition from normal to abnormal and further examination of the patient or urine sample is required. The negative result of this test does not confirm the absence of urobilinogen in the sample.

Bilirubin

Under normal circumstances, the most sensitive method cannot detect the presence of bilirubin in urine. The presence of trace amounts of bilirubin in the urine is sufficient to suggest that it is abnormal and requires further investigation.

Medications that stain urine red, or that appear red in an acidic environment, such as phenazopyridine, may interfere with bilirubin tests. High concentrations of vitamin C may lead to false negatives.

VC

This reaction zone is used to detect vitamin C in urine.

The test of this project can understand the level of vitamin C in the human body and evaluate the influence of vitamin C on the determination results of glucose, bilirubin, occult blood and nitrite test paper.

When urine contains chlorinating agents (such as potassium permanganate, hypochlorite, etc.), it will affect the sensitivity of this test.

PRO

This test item is used for the detection of albumin in urine. The test strips have low sensitivity to mucin and globulin, generally 0.3 g/L or higher to be detected.

Visible hematuria (≥5 mg/dL) may also give false-positive results.

BLD

The emergence of borderline reactions has different meanings for different patients. The identification of individual cases requires clinical examination to confirm the diagnosis.

Green spots (intact erythrocytes) and green appearance (hemoglobin/myoglobin) in the reaction zone within 60 seconds of loading indicate that the patient should be examined further. Occult blood often appears in the urine of menstruating women. Hemoglobin 150 μg/L-620 μg/L is approximately equivalent to 5-15 /μL of intact red blood cells.

This test item is very sensitive to hemoglobin, so it can be used to supplement microscopy. The sensitivity of this test strip will be reduced for high specific gravity urine. It has the same sensitivity to hemoglobin and myoglobin. Certain oxidizing contaminants, such as hypochlorite, can cause false positives. Discharge that accompanies a urinary tract infection can also cause false-positive results. This area is not disturbed by the concentration of vitamin C below 5.0 mmol/L.

pH

The experimental measurement range is from pH 5.0 to pH 9.0.

LEU

This test item reacts with esterases in Leukocyte (neutrophils). A normal urine sample should generally be negative under this test. A positive result ("+" or greater) is clinically significant. A single borderline result is clinically suspicious, but if repeated clinically, the significance is very important, and occasionally positive results are obtained in randomly selected female urine samples due to contamination by vaginal discharge. Higher glucose concentrations

(160 mmol/L) or high specific gravity urine will reduce the test results.

GLU

The detection of glucose in this area is specific, and no other substances in the urine can be found to make the test paper a false positive result. When the vitamin C concentration is ≥2.8 mmol/L or the acetoacetic acid concentration is ≥1.0 mmol/L, the sample with glucose concentration of 3-7 mmol/L may have false negative results.

KET

This test item reacts with acetoacetic acid in the urine and does not react with acetone or beta-hydroxybutyric acid. Normal urine generally only gives a negative result. False positives may be produced in urine samples containing pigment or large amounts of levodopa metabolites.

MA

The test item is used for the detection of microalbumin in urine. The test result of 0.15 g/L indicates clinical proteinuria. Microalbumin test strips can sensitively detect albumin in urine and are nine times less sensitive to other proteins than albumin.

SG

Specific gravity test strips test the specific gravity of urine between 1.000 and 1.030.

In general, the error between the test results and the results obtained by the refractive index method is within 0.005.

To improve its accuracy, add 0.005 to the visual count of urine specific gravity when the pH of the urine is equal to or greater than 6.5.

The urine analyzer automatically adjusts for this when reading the test strip.

The test is unaffected by some non-ionic components of urine, such as glucose, nor is it affected by opaque dyes, highly buffered alkaline urine will give low readings relative to other methods.

When the urine contains protein (1 g/L-7.5 g/L), the specific gravity reading can be high.

Cr

The normal urine creatinine concentration of adults is 0.6 to 2.0 g/24 hours (the test result of the test paper is about 4.4 to 17.7 mmol/L). Random urine creatinine test results vary widely, from 0.9 mmol/L to 26.5 mmol/L. Concentrated urine and morning urine have higher levels of creatinine (test results on dipsticks may be higher than 17.7 mmol/L). Dilution of urine due to polyuria, excess water intake, or other conditions results in typically low-concentration urine (test results ≤50 mg/dL). Visible hematuria (≥50 mg/dL) or cimetidine may result in falsely high creatinine concentration results.

Ca

A large amount of magnesium ions (>10 mmol/L) can cause high urinary calcium measurement results.

【Limitations of Test Methods】

1. As with all laboratory tests, the determination of diagnosis and treatment cannot be based on any single diagnostic method.
2. The application of test strips is based on clinical analysis and research. For clinical urine samples, the sensitivity depends on the following factors: variability of color recognition, specific gravity, changes in pH value, etc.
3. The result actually is not a certain concentration, but a range. Due to the variability of urine samples and readings, the value of the analyte obtained by the test may deviate from the actual value. For protein, glucose, ketone bodies, and urobilinogen tests, the deviation of positive values above the second positive level is usually within a "+".
4. Visible hematuria, medicine that turn urine red or its red in acidic environments, such as phenazopyridine, urine containing pigments or large amounts of levodopa metabolites, certain oxidative contaminants such as hypochlorite, the secretions, vaginal excretions that appear along with urinary tract infectious, high concentrations of vitamin C, acetoacetic acid, etc. that may affect the test results.

【Product Performance Index】

1. Accuracy

The difference between the test results of each concentration of the test strip test item and the corresponding reference solution label value shall not exceed one order of magnitude in the same direction, and there shall be no reverse difference. Positive reference solutions must not give negative results, and negative reference solutions must not give positive results.

2. Repeatability

The consistency of the test detected results is not less than 90%.

3. Detection limit

The first non-negative magnitude of each test item should be positive except the specific gravity and pH.

4. Analytical specificity

Interfering substance within certain concentration does not interfere with test results.

【Precautions】

1. This product is for in vitro diagnostic use only.
2. The test strips must be stored in the original cylinder.
3. The strips should be used within the expiry date of the product.
4. Each test strip is for one-time use.
5. The desiccant should not be removed from the cartridge.
6. The test strip should not be taken out of the cylinder unless it is used immediately.
7. The test strip should be stored in a dry environment of 2°C-30°C.
8. Avoid direct sunlight and do not touch the reaction zone of the test strip.
9. The test strip must be isolated from the surrounding environment of moisture, light and heat in order to protect the reactivity.
10. Deterioration of the test strip can lighten or darken the color of the reaction zone. When the test results are in doubt or inconsistent with expected results, determine if the test strip has expired and test it with a quality control solution.
11. For used test strips, please refer to the laboratory microbial hazardous materials treatment method.

【Index of symbol】

IVD	In vitro diagnostic medical device	Σ	Contains sufficient for <n> tests
	Consult instructions for use		Do not re-use
	Date of manufacture		Manufacturer
LOT	Batch code		Use-by date
n	Stacking limit by number		Temperature limit
	Keep away from sunlight		Keep dry
	Biological risks		
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		
EC REP	Authorized representative in the European Community		

【Reference】

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3. Luo Jialing, Dong Fang, Li Lin, et al. Evaluation of Clinical Application of Urine Dry Chemical Analysis [J]. Chinese Journal of Misdiagnosis, 2001, 1(10):1583-1584.

4. Chen Shenglin. Factors influencing the determination of urine by dry chemical method [J]. Journal of Clinical Laboratory, 2000, 18(1):59.

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【Approval and revision date of the instruction】

October 26, 2022