

The Urinalysis Reagent Strips Manual

User's Instruction

【Products Name】 Reagent Strips

【Model】 V-10A、V-11A、V-11B、V-11C、V-11D、V-11F、V-11G、V-14A、V-14B、V-14F。

【Packing Specification】 100 pcs / bot. , 25 pcs / bot. , 10 pcs / box ,1 pcs / bag etc.

【Intended Use】

For Semi-quantitative detection in urine uric bravery, glucose, ketone body, bilirubin, ascorbic acid, protein, nitrite, pH value, occult blood, specific gravity, white blood cells, calcium, creatinine, and trace albumin project

Clinically, it is mainly used for the diagnosis of nephropathy, diabetes, urinary infection and other diseases (such as liver metabolism).

【The Principle】 In the test paper area, the specific color reaction of the tested objects was observed, and the color change of the test paper area was identified by the color map of the same color or urine analyzer, and the test results were given.

【Principal Component】

The Main Components of Reagent Strips

Items	The Composition (w/w)
Glucose	Glucose oxidase 2.2%; Peroxidase 1.0%;
Bilirubin	2,4 - Dichloroaniline diazo tetrafluorate 0.02%; Buffer 35.3%;
Ketone	Sodium nitroferricyanide 2.1%;
Ascorbic acid	2,6 - Dichlorophenol sodium salt 0.03%;
specific gravity	Bromothymol blue 0.08%;
Blood	Hydroxyl isopropyl benzene 0.3%; Tetramethylbenzidine 0.27%;
pH	Methyl red 0.01%; Bromothymol blue 0.04%;
Protein	Tetrabromophenol blue 0.06%;
Urobiligogen	Fast blue B salt 0.06%
Nitrite	P-aminophenyl arsenic acid 0.06%; 1,2,3, 4-tetrahydrobenzene and quinoline-3-phenol 0.01%;
Leukocytes	Amino acid ester pyrrole derivative 0.07%; Diazo 0.04%;
Calcium Ions	Ethylene glycol bis (2-aminoethyl) tetraacetic acid 0.17%; 8-hydroxyquinoline 1.0%;

Creatinine	Peroxyhydroxyl isopropylbenzene 0.14%; Tetramethylbenzidine 0.04%;
Micro-Albumin	3,4,5,6 - Tetrabromophenolphthalein 0.02%;

【Storage Conditions & Validity Period】

Keep it in the cool, dark, dry place preservation with the room temperature 2~30 °C. The reagent strips is valid for 24 months. Please keep in the original bottle. Do not remove the desiccant in the bottle.

【Sample Request】

Fresh, no preservative, no centrifuge urine sample, before the test, the sample storage time must not exceed 4 hours; The urine samples should be thoroughly mixed before the test.

【Methods】

Please test under 20 to 28 °C condition, relative humidity is not higher than 80% . After taking out the strips, cover the caps, then completely submerged in the urine sample, take out after 1 to 2 seconds, on the blotting paper to wipe off excess urine, according to the test after the time stated on the label placement results compared with the same color map visual colorimetric and slide the stage or in the urine analyzer, according to the operation procedures for testing.。

【Reference Value】 (Reference Range)**Reference Range**

Item	Reference Range
pH	5.0~9.0
SG	1.010~1.025
GLU (mmol/L)	<2.8
Bil (μmol/L)	Negative
KET (mmol/L)	0
Ascorbic acid (mmol/L)	0~5.6
Blood (cells /μL)	0~20
Protein (g/L)	0~0.30
URO (μmol/L)	3.3~16
Nitrite (μmol/L)	0~18
LEU (cells /μL)	0~15

Creatinine (mg/dL)	25~250
Calcium ions (g/L)	0~0.15
MALB (mg/L)	<20

Note: Due to differences in geography, race, gender and age, it is recommended that each laboratory set up its own reference range.

【Interpretation of Results】

GLU:

This area is the glucose - specific test, and no other substances in urine have been found to produce positive results. The content of vitamin C was lower than 0.28mmol/L urine sample, higher than 2.2mmol/L of glucose, and the test paper color change was positive. There was no interference in the area of urine with a vitamin C of less than 2.84mmol/L or Ketone of less than 4mmol/L. When the proportion of urine is increased, the sensitivity of the glucose test paper decreases, and the sensitivity can be changed by temperature. In normal circumstances, a small amount of glucose may be excreted by the kidney, but its concentration is generally lower than the sensitivity of the detection in this area.

BIL:

In normal conditions, the most sensitive method can not detect the bilirubin in normal urine. The presence of a small amount of bilirubin in the urine is sufficient to indicate its abnormality and requires further examination. The atypical color in urine may indicate the abnormality of bile pigment, which should be further tested (e.g. using ICTOTEST™ reagent tablets). The metabolites of some drugs can be produced in a low pH value, such as pyridine and ethylenic acid, which can cause false positive reactions. No less than 1.42mmol/L of vitamin C can cause false negative results.

Ascorbic Acid:

Ascorbic acid excreted by urine is about half of the intake, and about 20 to 40mg of ascorbic acid is excreted daily. If the ascorbic acid test is positive, it should be retested after 24 hours of non-ingestion of foods or drugs containing ascorbic acid. Ascorbic acid can inhibit the reaction of glucose, latent blood, bilirubin, nitrite and other projects, and produce false negative. When the ascorbic acid content in urine is equal to or greater than 2.8mmol/L, the blood, bilirubin and nitrite can produce false negative. The

reductive substance in urine may cause the test to be false negative.

KET:

The test only detected acetic acid in urine, but did not react with pyruvate or beta-hydroxybutyric acid in urine. Some SG and low - pH urine can improve the reactivity and detection of microketone. Normal urine test results are usually negative, and false positive results (trace) can be seen in the pigment samples or samples containing a large number of L dopa metabolites.

Blood:

The little results should be judged according to the specific situation. The presence of green dots (complete red blood cells) or green (free hemoglobin/myoglobin) in the test area in 60 seconds means further examination of the patient. This test of hemoglobin is extremely sensitive, can complement each other with microscopy, but if the test area changes green and shows that the red blood cells in urine has burst, compared with that of microscopy results may have bigger difference. This test is of the same sensitivity to hemoglobin and myoglobin (150-620 μ g/L hemoglobin concentration is equivalent to 5-15 complete red blood cells/ μ L). Menstruation women are often positive for this test. A high proportion of urine may reduce the sensitivity of the test. Certain oxidative pollutants such as hypochlorite can result in

false positives. Peroxidase in microorganisms associated with urinary tract infection can result in false positive results. The level of vitamin C that is common in urine does not interfere with this test.

pH :

The pH value in the pH test area is usually within one unit.

SG:

The ratio between 1.005 and 1.030 can be determined. This method is very close to the refraction index method, and the error is within 0.005. This test is not affected by certain non-ionic substances such as glucose in urine. High concentration alkaline urine can result in low detection results, and urine containing protein (1-7.5g/L) can result in high detection results.

URO:

This area can detect the concentration of urine in urine to 3 mol/L (about 0.2 Ehrlich unit /dL). The

normal range of this test is 3-16 moles per liter. The result of a 33 mmol /L represents a transition from normal to abnormal, and the patient or his urine specimen should be further examined. Strip the response increased with the temperature increasing, the optimal temperature of the reaction is 22 to 26 °C. A high concentration of p-aminobenzoic acid in urine may cause atypical color reaction. Formaldehyde in the urine may lead to false negative. Some dark substances, such as azo pigments and riboflavin, can cover the color changes of the paper strips. The negative results of this test do not confirm that there is no urinogen in the sample.

Nit :

This area is specific to nitrite and does not react with any other normal excretion in urine. The pink reaction was positive and indicated that the bacterial content in the urine was more than 105 /mL, but the color of the test paper was not directly proportional to the bacterial content. Negative result does not mean do not contain bacteria in the urine, when the urine in the bladder retention time less than 4 hours to make the reduction of nitrate, lack of nitrate or diet, even if the bacteria in the urine, the results may also be negative; Urine samples containing non-nitrate transformed bacteria may also be negative. High proportion of urine can reduce the sensitivity of this test. For samples containing a small amount of nitrite (equal to or less than 13 μ /L), the concentration of vitamin C in urine is equal to or greater than 1.4mmol/L, producing false negative results.

LEU:

In this area, the esterase reaction in white blood cells (neutrophils), other types of white blood cells did not result in positive results. Normal urine is usually negative. Positive results (" + "and above) have clinical significance. The results of "trace" in clinical significance are suspicious, but the results of "trace" in multiple samples of the same person may be problematic. "Positive" results were found in samples contaminated with vaginal secretions. High glucose (> 160mmol/L) urine or high proportion of urine may result in lower test results. In the urine, the results of the test may also be reduced by the presence of vanillin drugs, ethylenic acid or high concentration of oxalic acid. Tetracycline may reduce the reactivity of the test, and the high concentration of drugs can cause false negative results. The yellow urine caused by nitrofurantoin can mask the reaction color of the paper strip. Any abnormal results of urine color can affect the test results.

Protein, Micro-Albumin:

The sensitivity of the reagent area to albumin is higher than the sensitivity to globulin, hemoglobin, Benzoic protein and mucin, so a negative result does not exclude the presence of these proteins. Highly buffered urine or alkaline urine can cause false positive results. Samples contaminated with quaternary ammonium compounds (such as from some disinfectants or cleaners) or chloride-containing skin disinfectants can also cause false positive results.

Creatinine:

This area could not detect the disappearance or decrease of creatinine, and the negative results did not confirm that creatinine was not present in the sample. In the urine, such antibiotics as pyruvate, acetic acid and penicillin G, cephalothiphene and cefoxitin, can cause high test results.

Calcium ions:

This area cannot detect the loss or decrease of calcium ions, and the negative result does not confirm that there is no calcium ion in the sample. In urine, a large amount of magnesium ions (greater than 10mmol/L) can result in high test results. Protein, Microalbumin. The sensitivity to albumin in the reagent area was higher than that of globulin, hemoglobin, BCTC and mucin, so the negative results did not exclude the presence of these proteins. High levels of urine or alkaline urine can result in false positives. False positive results can also be caused by samples contaminated with quaternary ammonium compounds (such as disinfectants or detergents) or chlorinated skin disinfectants.

【The limitations of the test Method】

As with all laboratory tests, any diagnosis or treatment cannot be based on a single test or test result.

For clinical urine samples, the sensitivity of the test depends on the differences in color perception, the presence of inhibiting factors in urine, the proportion of urine, and the lighting conditions of the color. The test results displayed by the instrument represent a numerical range. The test method is semi-quantitative, and the test result may be one of the levels when the concentration of the sample is between two adjacent levels. In the product performance index, the concentration is usually detectable, but in some cases, the lower concentration may be obtained due to the inherent differences in clinical urine.

[Notes]

This product is a disposable product. Do not touch the test area of the paper strip with your hand.

The product is only for professional use, only for in vitro diagnosis.

After taking the test strip, the bottle cap should be tightly sealed for storage. Do not take out the desiccant in the bottle. If the test strip tube is not tightly closed for a long time, the remaining test strip will deteriorate and become invalid. Any degree of powdering of LEU test pad will indicate the test strip has deteriorated and expired and cannot be used anymore.

All samples and test strips after use should be collected and disused after centralized sterilization.

【The Mark】



Please read the instruction carefully before using.



Represents In Vitro Diagnostic Reagent.



Disposable.



Follow with the EU IVD Medical Device Directive 98/79/EC.



Production Time.



Production Batch

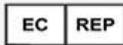


Shelf Life



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