URINALYSIS REAGENT STRIP USER'S GUIDE

Manufacture date Use by/Expiry date

LOT Lot number

SUMMARY

Urinalysis Reagent Strips are made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. It tests Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood,Specific Gravity,Ascorbic Acid, Ketone, Bilirubin, Glucose, Microalbumin in urine. Please refer to the out-side box and bottle label for the specific test parameters of the product you are using. Please read this direction carefully before using.
The results on the strips can be read visually and instrumentally.

SPECIFICATIONS

100 strips/bottle

SPECIMEN COLLECTION AND PREPARATION

Use only clean dry container to collect urine and should be shocked before testing and test it within 2 hours. Any operations must be in the clean environment.

TEST CONDITIONS

Ambient temperature: 20℃-30℃, relative humidity≤80%, the best test temperature: 23℃-27℃.

STORAGE

Store between 2-30℃ in dry condition. Keep away from refrigerator direct sunlight. Do not touch test area of reagent strips. Isolated from damp, light and high temperature for the aim of preserving the reaction activity of reagent.

TEST PROCEDURE

1. Remove one strip from the bottle and replace the cap immediately.
2. Immerse the reagent area of the strip in the urine specimen and take it out quickly.
3. Wipe off excess urine against the rim of the specimen container.
4. Read the test results carefully within 60 seconds in a good light and with the test area held near the appropriate color chart on the bottle label. Changes in color that appear only along the edges of the test pads or after moving than 2 minutes have passed are of no diagnostic significance. Results with leukocytes test portion can be read within 120 seconds.
If reading instrumentally, carefully follow the directions given in the appropriate instrument operating manual.

(1) (2) (3)

GRAPHIC AND SYMBOL EXPLANATION

Do not reuse See instruction for use

IVD In vitro diagnostic use +30℃ +2℃ Store at

ANALYZER AND VISUAL ANALYSIS AND SENSITIVITY RANGE

Items	Sensitivity	Analyzer Range	Visual Range
Leukocytes (ca cells/μL)	5-15	Neg.-500	Neg.-500
Nitrite (μmol/L)	13-22	Neg.-Pos	Neg.-Pos
Urobilinogen (μmol/L)	3.2-16	3.4-135	3.4-135
Protein (g/L)	0.15-0.3	Neg.-3.0	Neg.-20.0
pH	—	5.0-9.0	5.0-8.5
Blood (ca cells/μL)	5-15	Neg.-200	Neg.-200
Specific Gravity	—	1.005-1.030	1.000-1.030
Ascorbic Acid (mmol/L)	0.5-0.6	0-5.0	0-5.0
Ketone (mmol/L)	0.5-1.0	Neg.-7.8	Neg.-16
Bilirubin (μmol/L)	8.6-17	Neg.-100	Neg.-100
Glucose (mmol/L)	2.8-5.5	Neg.-55	Neg.-55
Microalbumin (g/L)	0.10-0.15	Neg.->0.15	Neg.-0.15

REACTION PRINCIPLE

Leukocytes:

Prrole phenol lipid and the neutrophil esterase under the hydrolysis, produces free phenol, the free phenol coupled reacts with arenediazonium salts, produce purple azo dyes.

Nitrite:

Nitrite and aromatic amino-sulfanilamide react to diazo compound, and the diazo compound coupled reacts with tetrahydro-benzo quinoline-3-phenol, which produces azo dyes.

Urobilinogen:

Urobillinogen and diazonium salt coupled react to purplish red compounds.

Protein:

The protein based on a certain indicator negative charge attracts protein cationic, ionizing causes the color change.

pH:

Applied to acid alkali indicator method.

Blood:

Hemoglobin acts as peroxides. It can cause peroxidase release new-born [0], which causes the color change.

Specific Gravity:

methyl vinyl ether, maleic copolymer are weak acid (-COOH) ion exchange bodies, and the electrolyte (M+ X-) in the form of salt in urine, the M+ (main are Na+) reacts with ion exchange bodies, produces hydrogen ion, hydrogen ion reacts with acid-base indicator, then the color change.

Ascorbic Acid:

Ascorbic Acid has 1,2-enediol reducing genes, the oxidation state

blue 2,6-dichlorophenol indophenol is reduced 2,6- dichlorophenol amine.

Ketone:

The acetoacetate and sodium nitroprusside cause reaction in alkaline medium, which produces purplish red compounds.

Bilirubin:

The direct bilirubin and dichlorobenzene diazonium coupled react to azo dyes in acid medium.

Glucose:

The glucose catalyzes the gluconate and peroxide hydrogen under the action of the glucose oxidase.Hydrogen peroxide catalyzes new-born [0], oxide potassium iodide, then the color change.

Microalbumin:

With tolerance principle, use the high sensitive sulfonephthalein dye.

THE COMMON QUESTIONS FOR MICROALBUMIN TESTING

1. The reason for the testing of microalbumin

The assay of microalbumin has the early detection for several diseases.

(1) Practical value for patient of high blood pressure: the excretion rate of microalbumin for high blood pressure patient is obviously higher than one for normal person. The increasing microalbumin is the important forecast parameter for cardiovascular disease.

(2) Microalbumin can forecast the development of diabetic nephropathy is the presence of microalbumin in urine, it is very helpful for diabetes patients to take earlier measures to protect the function of kidney.

(3) The assay of microalbumin is the sensitive indicator for diabetic complication of microvessel.

2. Clinic significance of positive result of microalbumin

(1) If the strips has the positive result on microalbumin, it is necessary to test urine specimen consecutively for several days. If microalbumin is casually present, it could be physical proteinuria. For example, it might be caused from diet, exercise or stress.

(2) If the positive result is consecutively present, or the positive result on blood a microalbumin simultaneously or positive result on glucose and microalbumin simultaneously, it is suggested that the result of microalbumin should be confirmed by the method of immune turbidimetry.

ATTENTION

Water cannot be used as negative quality control liquid.Antiseptic of urine cannot prevent the ketone, bilirubin and urobilinogen from deteriorated. For the long time urine specimen, the test results of glucose, pH, nitrite and blood can be affected cause of bacterial growth.

WARNINGS AND PRECAUTIONS

1. Do not remove desiccant from the bottle.
2. Do not touch test area of Urine Reagent Strips.
3. Do not open container until ready to use.
4. The use of urine preservatives can prevent the decomposition of ketone, bilirubin and urobilinogen in the urine.
5. Do not store the sample long time (one hour or longer) before testing.

INGREDIENTS

(based on dry weight at time of impregnation)

Leukocytes:
- 0.4%W/W pyrrole amino acid ester;
- 0.2%W/W diazonium salt;
- 40.9%W/W buffer
- 58.5%W/W non-reaction ingredients

Nitrite:
- 1.4%W/W p-arsanilic acid;
- 1.3%W/W tetrahydro benzoquinoline
- 10.8%W/W buffer
- 86.5%W/W non-reaction ingredients

Urobilinogen:
- 0.2%W/W p-diethylamino benzaldehyde
- 99.8%W/W non-reaction ingredients

Protein:
- 0.3%W/W tetrabromophenol blue
- 97.3%W/W buffer
- 2.4%W/W non-reaction ingredients

pH:
- 0.2%W/W methyl red
- 2.8%W/W bromthymol blue
- 97.0%W/W non-reaction ingredients

Blood:
- 6.8%W/W diisopropylbenzene dihydroperoxide
- 4.0%W/W tetramethyl-benzidine
- 48.0%W/W buffer
- 41.2%W/W non-reaction ingredients

Specific Gravity:
- 2.8%W/W bromothymol blue
- 90.2%W/W poly (methyl vinyl ether co maleic anhydride)

Ascorbic Acid:
- 0.5%W/W 2,6 dichlorophenol indophenols
- 99.5%W/W non-reaction ingredients

Ketone:
- 7.1%W/W sodium nitroprusside
- 92.2%W/W buffer

Bilirubin:
- 0.4%W/W 2,4-dichloroaniline diazonium salt
- 37.3%W/W buffer
- 62.3%W/W non-reaction ingredients

Glucose:
- 16.3%W/W glucose oxidase (microbial, 123U)
- 0.6%W/W peroxidase (horseradish, 203U)
- 7.0%W/W potassium iodide
- 60.7%W/W buffer
- 16.7%W/W non-reaction ingredients

Microalbumin
- 2.2%W/W sulfonephthalein dye
- 96.0%W/W buffer
- 1.8%W/W non-reaction ingredients

LIMITATION

Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test or method.