

Product Code : **PKUR002**

Kit Contents : **20, 50 or 100 strips**

Shelf Life: **24 Months**

Kit Components	Quantity (Units)
Test Strips	20, 50 or 100
IFU	1

SUMMARY

Urinalysis Reagent Strips are made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagents for diagnostics. It tests Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ascorbic Acid, Ketone, Bilirubin, Glucose, Microalbumin, Creatinine, Calcium 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 a clean dry container to collect urine and should be shocked before testing and test it within 2 hours. Any operations must be in a clean environment.

TEST CONDITIONS

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

STORAGE

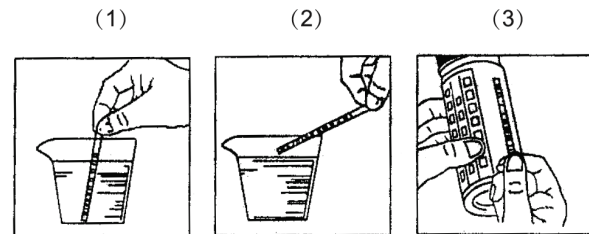
Store between 2-40 °C in dry condition. Keep away from refrigerator direct sunlight. Do not touch the test area of reagent strips. Isolated from damp, light and high temperature for the aim of preserving the reaction activity of reagent.

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 more than 2 minutes have passed are of no diagnostic significance. Results with the leukocytes test portion can be read within 120 seconds.

If reading instrumentally, carefully follow the directions given in the appropriate instrument operating manual.



ANALYZER AND VISUAL ANALYSIS AND SENSITIVITY RANGE

Items	Sensitivity	Analyzer Range	Visual Range
Leukocytes (ca cells/ μ L)	5-15	Neg.-500	Neg.-500
Nitrite (μ mol/L)	13-22	Neg.-Pos	Neg.-Pos
Urobilinogen (μ mol/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/ μ L)	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	0-6.0
Ketone (mmol/L)	0.5-1.0	Neg.-7.8	Neg.-16
Bilirubin (μ mol/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
Creatinine (mmol/L)	0.1-0.9	Neg.->0.9	Neg.-26.5
Calcium (mmol/L)	0.5-2.5	Neg.->2.5	Neg.-10

REACTION PRINCIPLE

Leukocytes:

Pyrrrole phenol lipid and the neutrophil esterase under the hydrolysis, produces free phenol, the free phenol coupled reacts with arenediazonium salts, producing 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:

Urobilinogen 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 in new-born [O], 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 ions, hydrogen ions react with an acid-base indicator, then the color changes.

Ascorbic Acid:

Ascorbic Acid has 1,2-enediol reducing genes, the oxidation state blue 2,6-dichlorophenol indophenol is reduced 2,6-dichlorophenyl 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 [O], oxide potassium iodide, then the color changes.

Microalbumin:

With tolerance principle, use the highly sensitive sulfonephthalein dye.

Creatinine:

It is measured to assess your overall kidney function, creatinine will be showed purple color when reaction with 3,5-Dinitrobenzoic Acid. Color depth is proportional to the concentration of creatinine.

Calcium:

To measure calcium content of 24 hours in urine, normal reference value is 2.5-7.5 mmol/ 24 hour.

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.

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

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

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

2. Clinic significance of positive result of microalbumin

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

(b) 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 immunoturbidimetry.

ATTENTION

Water cannot be used as a negative quality control liquid. Antiseptic of urine cannot prevent the ketone,

bilirubin and urobilinogen from deteriorating. For the long time urine specimen, the test results of glucose, pH, nitrite and blood can be affected because of bacterial growth.

WARNINGS AND PRECAUTIONS

1. Do not remove desiccant from the bottle.
2. Do not touch the test area of Urine Reagent Strips.
3. Do not open the 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 for a 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

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-dimethylamino 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 bromothymol 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
97.2%W/W poly (methyl vinyl ether co maleic anhydride)

Ascorbic Acid:

0.5%W/W 2,6 dichlorophenolindophenol
99.5%W/W non-reaction ingredients

Ketone:

7.1%W/W sodium nitroprusside
92.9%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
15.4%W/W non-reaction ingredients

Microalbumin:

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

Creatinine:

6.5%W/W 3,5-DinitrobenzoicAcid
92.2%W/W buffer
1.3%W/W non-reaction ingredients

Calcium:

5.8%W/W o-cresolphthalein
1.5%W/W buffer
92.7%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.

GRAPHIC AND SYMBOL EXPLANATION



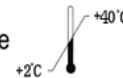
Do not reuse



See instruction for use



In vitro diagnostic use



Store at



Manufacture date



Use by/Expiry date



Lot number

Technical Assistance

For customer support, please contact our Technical Support:
*PathKits Healthcare Pvt Ltd, Plot 28, 29 Sector 18(P),
Gurgaon -122001, India Customer care No.: +91-7303429198
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