

**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 outside 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 sanitary environment.

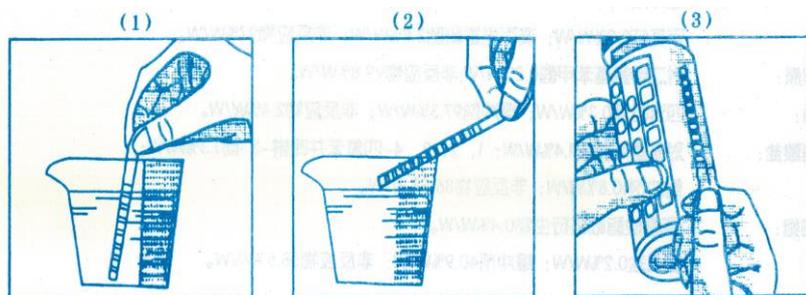
**Attention**

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.

**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.

**Test Conditions**

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

**Storage**

Store between 2-30°C 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.

## Limitation of Procedures

Just like all the laboratory tests, the diagnosis results and treatment protocols cannot be decided only by any single diagnostic method.

## 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-benzoquinoline-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 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 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- dichloro phenol 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 change.

**Microalbumin:** with tolerance principle, use the high sensitive sulfonephthalein dye.

### Analyzer and visual analysis and sensitivity range

Items	Sensitivity	Analyzer Range	Visual Range
Leukocytes (ca cells/ $\mu$ L)	5-15	Neg.-500	
Nitrite ( $\mu$ mol/L)	13-22	Neg.-Pos	
Urobilinogen ( $\mu$ mol/L)	3.2-16	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/ $\mu$ L)	5-15	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 ( $\mu$ mol/L)	8.6-17	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

## Ingredients

(based on dry weight at time of impregnation)

Leukocytes	pyrrole amino acid ester	0.04%W/W
	diazonium salt	0.02%W/W
	buffer	40.9%W/W
	non-reaction ingredients	58.5%W/W
Nitrite	p-arsanilic acid	1.4%W/W
	tetrahydro benzoquinoline	1.3%W/W
	buffer	10.8%W/W
	non-reaction ingredients	86.5%W/W
Urobilinogen	p-diethylamino benzaldehyde	0.2%W/W
	non-reaction ingredients	99.8%W/W
Protein	tetrabromophenol blue	0.3%W/W
	buffer	97.3%W/W
	non-reaction ingredients	2.4%W/W
pH	methyl red	0.2%W/W
	bromthymol blue	2.8%W/W
	non-reaction ingredients	97.0%W/W
Blood	diisopropylbenzene dihydroperoxide	6.8%W/W
	tetramethyl-benzidine	4.0%W/W
	buffer	48.0%W/W
	non-reaction ingredients	41.2%W/W
Specific Gravity	bromothymol blue	2.8%W/W
	poly (methyl vinyl ether co maleic anhydride)	97.2%W/W
Ascorbic Acid	2,6 dichlorophenol indophenols	0.5%W/W
	non-reaction ingredients	99.5%W/W
Ketone	sodium nitroprusside	7.1%W/W
	buffer	92.2%W/W
Bilirubin	2,4-dichloroaniline diazonium salt	0.4%W/W
	buffer	37.3%W/W
	non-reaction ingredients	62.3%W/W
Glucose	glucose oxidase (microbial, 123U)	16.3%W/W
	peroxidase (horseradish, 203U)	0.6%W/W
	potassium iodide	7.0%W/W
	buffer	60.7%W/W
	non-reaction ingredients	16.7%W/W
Microalbumin	sulfonephthalein dye	2.2%W/W
	buffer	96.0%W/W
	non-reaction ingredients	1.8%W/W

## 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.

## Graphic and Symbol Explanation



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