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CE

"See Now" Urine Strips 10 parameters

For in vitro Diagnosis Use Product Code: SN 13.1

INTENDED USE

This "See Now "Urine Strips 10 parameters are made for urine analysis of both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. It tests Bilirubin, Urobilinogen, Ketone, Glucose, Protein, Blood, Nitrite, pH, Specific Gravity, , Leukocytes, 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.

REACTION PRINCIPLE

Bilirubin: The direct bilirubin and dichlorobenzene diazonium <u>coupled</u> <u>react</u> to azo dyes in acid medium.

Urobilinogen: Urobillinogen and <u>diazonium salt</u> coupled react to <u>purplish</u> red compounds

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

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

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

Blood: <u>Hemoglobin</u> acts as peroxides. It can cause peroxidase release new-born [0], which causes the color change.

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

pH: Applied to acid alkali indicator method.

Specific Gravity: methyl vinyl ether, <u>maleic copolymer</u> are weak acid (-COOH) <u>ion exchange bodi</u>es, and the electrolyte (M^+X^-) in the form of salt in urine, the M^+ (main are Na $^+$) reacts with ion exchange bodies, produces <u>hydrogen ion</u>, <u>hydrogen ion</u> reacts with <u>acid-base indicator</u>, then the color change.

Leukocytes: Prrole phenol lipid and the <u>neutrophil</u> esterase under the <u>hydroly</u>sis, produces free phenol, the free phenol coupled reacts with <u>arenediazonium salts</u>, produce purple azo dyes.

MATERIALS PROVIDED

- 100 strips/bottle
- insert

SPECIMEN COLLECTION AND STORAGE

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.

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.





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.

STORAGE AND STABILITY

Store between 2-30 $^{\circ}$ C in dry condition. Keep away from <u>refrigerator</u> 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.

Ambient temperature: 20 $^{\circ}$ C-30 $^{\circ}$ C, relative humidity≤80%, the best test temperature: 23 $^{\circ}$ C-27 $^{\circ}$ C

PRECAUTION

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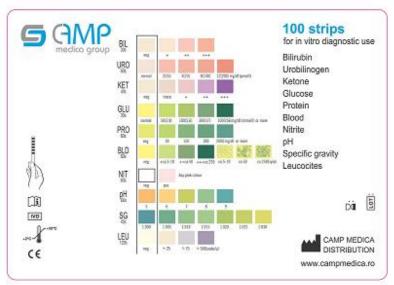
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LIMITATION OF PROCEDURE

Just like all the <u>laboratory test</u>s, the diagnosis results and treatment protocols cannot be decided only by any single diagnostic method.

ANALYZER AND VISUAL ANALYSIS AND SENSITIVITY RANGE

Items	Detection Range	
Bilirubin (µmol/L)	17 - 70	
Urobilinogen (µmol/L)	ol/L) 35-200	
Ketone (mmol/L)	2.5 - 30	
Glucose (mmol/L)	2.8 -56	
Protein (g/L) 0.3 - 5		
Blood (Ery/µL)	5 - 250	
Nitrite (mg/d/L)	0 - 0.05	
pH pH 5.0- pH 9.0		
Specific Gravity 1.000 - 1.030		
Leukocytes (Leuko/µL)	25 - 500	



INGREDIENTS (based on dry weight at time of impregnation)

Bilirubin	2,4-dichloroaniline diazonium salt	0.4%W/W
	buffer	37.3%W/W
	non-reaction ingredients	62.3%W/W
Urobilinogen	p-diethylamino benzaldehyde	0.2%W/W
	non-reaction ingredients	99.8%W/W
Ketone	sodium nitroprusside	7.1%W/W
	buffer	92.2%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
Protein	tetrabromophenol blue	0.3%W/W
	buffer	97.3%W/W
	non-reaction ingredients	2.4%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
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
рН	methyl red	0.2%W/W
	bromthymol blue	2.8%W/W
	non-reaction ingredients	97.0%W/W
Specific	bromothymol blue	2.8%W/W
Gravity	poly (methyl vinyl ether co maleic	97.2%W/W
	anhydride)	
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