

HI-Quik URINALYSIS REAGENT STRIP PACKAGE INSERT

(For 1 /2 /4 /10 Parameters) Packing: 100 Strips/ bottle

Please carefully read this INSERT before use.

For In-vitro Diagnostic Use only.

SUMMARY

HI-Quik Urinalysis Reagent Strips provide tests for qualitative and semi-quantitative measurement of Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone, Bilirubin, and Glucose in urine. The results on the strips can be read visually and instrumentally.

SPECIMEN COLLECTION AND PREPARATION

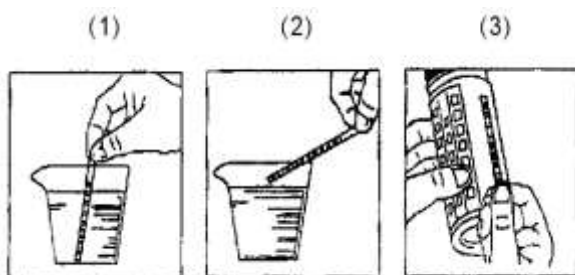
Collect urine in a clean container and test within 1 hour. If test cannot be performed in 1 hour after collection, refrigerate the specimen. Allow the refrigerated specimen to come to RT before testing.

STORAGE

Store at temperatures between 2-30° C avoiding humidity, direct sunlight or heat. Store only in original bottle. Do not remove desiccants. Remove strip from the bottle only at time of testing. Replace cap immediately and tightly after removing strip. Unused strips of opened bottle are stable up to 3 months.

TEST PROCEDURE

1. Remove one strip from the bottle at a time and replace the cap tightly. Do not touch Test Area. Immerse the reagent area of the strip completely in fresh, well mixed urine specimen. Remove the strip quickly.
2. While removing the strip, tap the strip against the rim of container to remove excess urine. Blot the strip on length-wise edge, on absorbent paper.
3. Compare each test area to its corresponding colour blocks shown on colour chart on bottle and read at times specified. Correct Read time is very important for results.
4. Changes in colour after 2 minutes are of no diagnostic use.



REACTION PRINCIPLE:

Leukocytes:

Pyrazole phenol lipid and neutrophil esterase under the hydrolysis, produces free phenol, the free phenol couple reacts with a diazonium salt to produce purple product.

Nitrite:

Nitrite and aromatic amino-sulfanilamide react to diazo compound, and the diazo compound couple reacts with tetrahydro-benzo quinoline-3-phenol, which produces pink product.

Urobilinogen:

Urobilinogen and diazonium salt couple reacts to light pink- dark pink colour.

Protein:

This test is based on the protein-error-of-indicators principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for "Negative" through yellow-green and green to green-blue for "Positive" reactions.

pH:

The test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range. Colors range from orange through yellow and green to blue.

Blood:

This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of diisopropylbenzene dihydroperoxide and 3,3',5,5'-tetra methylbenzidine. The resulting color ranges from orange through green.

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 changes.

Ketone:

This test is based on the development of colors ranging from buff-pink, for a negative reading, to purple when aceto acetic acid reacts with nitroprusside.

Bilirubin:

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

Glucose:

This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with a potassium iodide chromogen to oxidize the chromogen to colors ranging from green to brown.

WARNINGS AND PRECAUTIONS:

1. Water cannot be used as negative quality control liquid.
2. Do not add preservatives in urine.
3. 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.

READ TIME AND RANGE:

Test	Read Time	Visual measuring range
Leucocytes (Cells/ul)	120 seconds	Negative- 500
Nitrite (umol/L)	60 seconds	Negative- Positive
Urobilinogen (umol/L)	60 seconds	3.4- 135
Protein (g/L)	60 seconds	Negative- 20
pH	60 seconds	5- 8.5
Blood (Ery/ul)	60 seconds	Negative- 200
Specific Gravity	45 seconds	1.000-1.030
Ketone (mmol/L)	40 seconds	Negative-16
Bilirubin (umol/L)	30 seconds	Negative -100
Glucose (mmol/L)	30 seconds	Negative -110

INGREDIENTS (Based on dry weight)**Leukocytes:**

0.04%W/W pyrrole amino acid ester;
 0.02%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)

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

EXPLANATION FOR SYMBOLS:

	In-vitro Diagnostic Medical device		Temperature limits
	Consult Instruction for Use		Do not re-use
	Lot number		Manufacturer
	Date of Manufacture		Use by (Expiry)
	No of Tests		Do not use if damaged

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