Rapichek

Urine Test Strip 10P

Strips for Semi Quantitative Determination of Glucose, Ketone, Protein, pH, Blood, Specific Gravity, Bilirubin, Urobilinogen, Nitrite, Leucocytes in urine

For In-Vitro Diagnostic Use Only. Store at 4°C to 30°C

INTRODUCTION

Rapichek urine test strip is a basic diagnostic tool used to determine pathological changes in a patient's urine in standard urinalysis. Which react (change color) when immersed in, and then removed from, a urine sample. The test can often be read in as little as 60 seconds after dipping. The Urine Test Strips can be used in general evaluation of health, and aids in the diagnosis and monitoring of metabolic or systemic diseases that affect kidney function, endocrine disorders and diseases or disorders of the urinary tract. Urine Test Strips is a medical device intended for the preliminary estimation of glucose, ketone, protein, pH, blood, Specific Gravity, bilirubin, urobilinogen, nitrite, leucocytes in human urine.

This type of analysis is very common in the control and monitoring of various malfunctioning of human body through human urine.

PRODUCT CATEGORY PARAMETER WISE

Name of Product	Blood	BiLirubin	Urobilinogen	Ketone	Protein	Nitrite	Glucose	pH	SG	Leucocyte
Urine Strip 2P					*		*			
Urine Strip 2K				*			*			
Urine Strip 3					*		*	*		
Urine Strip 4	*				*		*	*		
Urine Strip 4S					*		*	*	*	
Urine Strip 5K	*			*	*		*	*		
Urine Strip 10P	*	*	*	*	*	*	*	*	*	*

TEST PRINCIPLE

BLOOD (RBC/µL): This test is based on the peroxidase-like activity of hemoglobin, which catalyzes the reaction of organic hydroperoxide and TMB. The resulting color ranges from yellow to greenish blue.

BILIRUBIN (mg/dL): This test is based on azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. The resulting color ranges from white to dark pink.

UROBILINOGEN (mg/dL): This test is based on a modified Ehrlich reaction, in which 4- diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink color. The resulting color ranges from light tan to pink.

KETONE (mg/dL): This test is based on the reaction of acetoacetic acid (the physiological ketone) with sodium nitroprusside in a strongly basic medium. The colors range from beige or light tan for a 'negative' reading, to pink and pink-purple for a 'positive' reading.

PROTEIN (mg/dL): The test is based on the 'Protein-error' of the indicator. The protein in the urine combines with the blue divalent anionic form of the indicator. This results in the dissociation of the yellow monovalent anion into the blue divalent anion. Although the test strip is buffered to a constant pH, a color change from yellow through green to blue will occur in the presence of protein.

NITRITE (mg/dL): This test is based on diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo dye produced causes a color change from white to pink.

GLUCOSE (mg/dL): 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 potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

pH (pH value): The test is based on the 'Protein-error' of the indicator. The protein in the urine combines with the blue divalent anionic form of the indicator. This results in the dissociation of the yellow monovalent anion into the blue divalent anion. Although the test strip is buffered to a constant pH, a color change from yellow through green to blue will occur in the presence of protein.

SPECIFIC GRAVITY (SG value): The test reflects the ion concentration of urine and correlates well with the refractometric method. In the presence of cat ions, protons are released by a complexing agent and produce a color change in the indicator bromothymol blue from blue via blue-green to yellow.

LEUCOCYTES (WBC/µL): Granulocytic leucocytes contain esterase's that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole then reacts with a diazonium salt to produce a red-purple product.

INTENDED USE

Rapichek Urine Test Strip 2P: Strips for the semi-quantitative determination of Glucose and Protein in urine.

Rapichek Urine Test Strip 2K: Strips for the semi-quantitative determination of Glucose and Ketone in urine.

Rapichek Urine Test Strip 3: Strips for the semi-quantitative determination of Glucose, Protein and pH in urine.

Rapichek Urine Test Strip 4: Strips for the semi- quantitative determination of Glucose, Protein, pH and Blood in urine.

Rapichek Urine Test Strip 4S: Strips for the semi- quantitative determination of Glucose, Protein, pH and Specific gravity in urine.

Rapichek Urine Test Strip 5K: Strips for the semi- quantitative determination of Glucose, Ketone, Protein, pH and Blood in urine.

Rapichek Urine Test Strip 10P: Strips for semi- quantitative determination of Glucose, Ketone, Protein, pH, Blood, Specific Gravity, Bilirubin, Urobilinogen, Nitrite & Leucocytes in urine.

CONTENTS OF KIT

- Urinalysis Test Strips : 100 Nos.
- Desiccant pouch : 01 No.
- Product insert : 01 No.

STORAGE & STABILITY

- Store at room temperature between 4°C to 30°C.
- Do not refrigerate.
- Do not use product after expiration date.
- Do not store the product in direct sunlight.

Note: Once the bottle has been opened, the remaining strips are stable for up to 3 months. Strips removed from the bottle should be used immediately. Stability may be reduced in high humidity condition.

WARNING & PRECAUTIONS

- Instruction must be followed as per given in product insert prior to test perform.
- Do not use expired kit.
- Use separate or cleaned containers for each sample to avoid cross contamination.
- After strips removing from bottle for test performing, the remaining strips must be kept in original bottle with silica gel and replace the cap tightly closed to maintain test reactivity.
- Do not throw away used strip any were discard it in proper way.

• Urine Reagent Strips are for in vitro diagnostic use only. Do not touch test areas of Urine Reagent Strips.
• Do not re-use the test strips.
• Do not use any human body fluid as a specimen other than urine.
• All materials used in the assay and samples should be disposed off in accordance with established safety procedures.
• Spills should be decontaminated promptly with IPA or any other suitable disinfectant.

SPECIMEN COLLECTION AND PREPARATION/ PRECAUTIONS

A urine specimen must be collected in a clean and dry container and tested as soon as possible. Do not centrifuge. The use of urine preservatives is not recommended. If testing cannot be done within an hour after sample collection, refrigerate the specimen immediately and let it return to room temperature before testing. Prolonged storage of urine at room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease in pH as organisms metabolize the glucose. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein test results.

TEST PROCEDURE

• Allow all kit components and specimen to room temperature (20°C-30°C) prior to performing test.
• Collect urine in a clean container and test it as soon as possible. Do not centrifuge.
• Remove the test strips from the closed containers and use it as soon as possible. Close the container tightly after removing the required number of strips. Completely immerse the reagent areas of the strips in fresh well mixed urine for 1 to 2 seconds and immediately remove the strip. (See illustration 1 below).
• While removing the strips from the urine, run the edge of the strip against the rim of the urine container and wipe the excess urine, hold the strip in horizontal position and bring the edge of the strip into contact with absorbent materials (e.g., Tissue paper) to avoid mixing chemical from adjacent reagent areas and to remove excess urine. (See illustration 2 below).
• Wait for reaction and read the results at 60 seconds. Do not read results after 60 seconds.
• Compare the reagent area to corresponding color band on the color-chart label provided in the surface of bottle. (See illustration 3 below).

ILLUSTRATION-1 ILLUSTRATION-2 ILLUSTRATION-3

RECOMMENDED HANDLING PROCEDURES

All unused strips must remain in the original bottle. Transfer to any container may cause reagent strips to deteriorate and become non-reactive. Do not remove desiccant from bottle. Do not open container until ready to use. Opened bottles should be used within 3 months after first opening.

SENSITIVITY & LIMIT OF DETECTION

Test Parameters \ Results		Negative (-)	(±)	Positive +	++	+++	++++	
Blood	Conc. (RBCs/µL)	0		10	50	250		
Bilirubin	Conc. (mg/dL)	0		0.5	1	3		
Urobilinogen	Conc. (mg/dL)	0.1 ◄ Normal ►		1	4	8	12	
Ketone	Conc. (mg/dL)	0	5	10	50	100		
Protein	Conc. (mg/dL)	0	10	30	100	300	1000	
Nitrite	Conc. (mg/dL)	0		0.5	Any degree of uniform pink color			
Glucose	Conc. (mg/dL)	0	100	250	500	1000	2000	
pH	pH value	5.0	6.0	6.5	7.0	7.5	8.0	9.0
Specific Gravity	SG value	1.000	1.005	1.010	1.015	1.020	1.025	1.030
Leucocyte	Conc. (WBCs/µ)	0		25	75	500		

LIMITATION OF PROCEDURES

• As with all diagnostic tests, a definitive clinical diagnostic should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
• Knowledge of the effects of drugs or their metabolism upon the individual tests is not yet complete. In doubtful cases it is therefore advisable to repeat the test after discontinuing a particular drug. Large amounts of ascorbic acid in the urine can produce artificially low to false negative results for nitrite and bilirubin.
• In clinical specimens, the sensitivity depends upon the variability of color perception; the presence or absence of inhibitory factors typically found in urine, the specific gravity, and the pH; and the lighting conditions when the products is read visually, because the color of each test area changes as the analyte concentration increase, the percentage of specimens detected as positive will increase with analyte concentration.
• 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.

QUALITY CONTROL

• For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls.
• Test QC as per your laboratory policies and follow local, state and federal regulations.
• Test commercially available positive and negative quality controls with each new lot, each new shipment of strips, and when you open a new bottle of reagent strips. Please note: Water is NOT an appropriate negative control.
• Test the strips monthly that are stored for more than 30 days.
• Run QC tests to ensure reagent storage integrity; train new users; confirm test performance; when clinical conditions or symptoms do not match the results obtained on the test strips.

REFERENCES

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Manufactured By : **PATHOZYME DIAGNOSTICS**
An ISO 9001:2015 & 13485:2016 | CE & GMP Certified Company

Expiry Date | IVD In-vitro Dignostics Use | 4°C 30°C Storage | Mfg. Date | LOT Batch Number | See Package Insert | Keep Dry | Keep Away from Sun Light | Do not Reuse

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