ImmunoScience INDIA

ImmunoQuick

UTS 10

Strips for semi quantitative Determination of Glucose, Ketone, Protein, pH, Blood, Specifice Gravity, Bilirubin, Urobilinogen, Nitrite, Leucocytes from Urine

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

INTENDED USE AND SUMMARY

ImmunoQuick Urine strips are plastic strips on to which several separate reagent pads are laminated for semi quantitative detection of various analytes from human urine. Depending on the product being used, ImmunoQuick Urine strips provides test for Glucose, Ketone, Protein, pH, Blood, Specific Gravity, Bilirubin, Urobilinogen, Nitrite, Leucocytes in human urine. Test results aid in providing information regarding the status of Carbohydrates metabolism, kidney function, liver function, acid-base balance and urinary tract infection. The product is intended for professional, in vitro diagnostic use only.

Test Item / Product Name	Blood	Billirubin	Uribilinogen	Ketone	Protein	Nitrite	Glucose	pH	Specific Gravity	Leucocytes
UTS 1G Urine Test Strips -1G							-			
UTS 2P Urine Test Strips -2P					-		-			
UTS 2K Urine Test Strips -2K				-			-			
UTS 3 Urine Test Strips -3					-		-	-		
UTS 4 Urine Test Strips -4	-				-		-	-		
UTS 4S Urine Test Strips -4S					-		-	-	-	
UTS 5K Urine Test Strips -5K	-			-	-		-	-		
UTS 10 Urine Test Strips -10	-	-	-	-	-	-	-	-	-	-

PRECAUTIONS AND IMPORTANT PROCEDURES FOR HANDLING OF TEST STRIPS

1. The directions must be followed exactly. Accurate result reading time is essential to provide optimal results.
2. Do not reuse the test strips.
3. The reagent strips must be kept in the bottle with the cap tightly closed to maintain test reactivity. Unused strips must remain in the original bottle.
4. Do Not remove desiccant from bottle. Do not remove strip from the bottle until immediately before it is to be used for testing.
5. Replace cap tightly immediately after removing test strip.
6. Do not touch areas of test strip.
7. To obtain optimal results, it is necessary to use fresh well-mixed uncentrifuged urine.
8. Dip test areas in urine completely, but briefly, to avoid dissolving out the reagents.
9. Protection of test strips against ambient moisture, light and heat is essential to guard against altered reagent reactivity.
10. Discoloration or darkening of reagent areas may indicate deteriorations, so, do not use the test strip.
11. Disposal of all waste material should be in accordance with good laboratory procedures

STORAGE

Store at 4° C to 30° C temperature. Do not use product after expiry date. Do not store the bottle 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 conditions.

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. pH & glucose of urine containing glucose may decrease as organisms metabolize the glucose. Contamination of the urine specimen with skin cleansers containing chlorhexidine may affect protein (and to a lesser extent, specific gravity and bilirubin) test results.

TEST PROCEDURE

1. Allow the strip, urine specimen, and/or controls to reach room temperature (20-30°C) prior to testing.

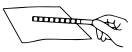
2. Remove the strip from the closed container and use it as soon as possible. Immediately close the container tightly after removing the required number of strip(s). Completely immerse the reagent areas of the strip in fresh, well-mixed urine for 1-2 seconds and immediately remove the strip to avoid dissolving the reagents. See illustration 1 below.

3. While removing the strip from the urine, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position and bring the edge of the strip into contact with an absorbent material (e.g. a tissue paper) to avoid mixing chemicals from adjacent reagent areas and to remove excess urine. See illustration 2 below.

4. Compare the reagent areas to the corresponding color blocks on the color chart at the specified times. Hold the strip close to the color blocks and match carefully. See illustration 3 below.

Note: Read results at 60 seconds. Do not read result after 60 seconds.

1



2

3

SENSITIVITY/LIMIT OF DETECTION

Test Area	Result							
	Unit	Neg(-)	Trace(±)	+	++	+++	++++	
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	0.25	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	S.G. value	1.000	1.005	1.010	1.015	1.020	1.025	1.030
Leucocytes	Conc. (WBCs/µl)	0		25	75	500		

QUALITY CONTROL

1. For best results, performance of reagent strips should be confirmed by testing known positive and negative specimens/controls.
2. Test QC as per your laboratory policies and follow local, state and federal regulations.
3. 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.
4. Test the strips monthly that are stored for more than 30 days.
5. 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.

LIMITATION OF PROCEDURES

1. 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.
2. 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.
3. 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.

ACTIVE INGREDIENTS, CHEMICAL PRINCIPLES, EXPECTED VALUES AND LIMITATIONS OF THE TEST

I. BLOOD

1. Test strip contains Tetramethyl benzidine, Cumene hydroperoxide. This test is based on the peroxidase like activity of hemoglobin, which catalyzes the reaction of organic hydroperoxide and TMB. The resulting colors ranges from yellow to greenish blue.
2. When hemoglobin appears in urine, it indicates some kind of kidney disease or some kind of urinary tract disorder. Development of green spot (intact erythrocytes) or green color (free hemoglobin/myoglobin) on the test area within 60 seconds indicates the need for further investigation. This test is highly sensitive to hemoglobin and thus complements the microscopic examination.
3. Ascorbic acid concentration of 50 mg % or greater may cause a false negative reaction. Captopril concentration of 100 mg % or greater may cause a false negative reaction. Certain oxidizing contaminates such as hypochloride may produce false positive results Microbial peroxidase associated with urinary tract infection may cause a false positive reaction.

II. BILIRUBIN

1. Test strip contains: sodium nitrite substituted aniline diazonium salt. this test is based on azo-coupling reaction of bilirubin with a diazonium salt on an acid medium to form an azodye. The resulting color ranges from white to dark pink.
2. Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficient abnormal to require further investigation.
3. Ascorbic acid concentration of 25 mg % or greater may cause a false negative reaction.
4. Nitrite concentration of 0.1 mg% or greater may cause of false negative reaction.

III. UROBILINOGEN

1. Test strip contains 4-methoxybenzene diazonium. This test is based on a modified Ehrlich reaction, in which 4-methoxybenzene diazonium in conjugation with a color enhancer reacts with urobilinogen in a strongly acid medium toproduce a pink color. The resulting color ranges from white to pink.
2. The normal urobilinogen range is 0.1 to 1.0 Ehrlich unit/dl. If results exceed the concentration of 2.0 mg/dl, the patient and the urine specimen should be evaluated further.
3. Formaldehyde concentration of 1%(v/v) may cause a false negative reaction. A typical color reactions color reaction may be obtained in the presence of 1000 mg% concentrations of p-aminosalicyclic acid. p- aminobenzoic acid concentration of 100 mg % cause a false positive reaction.

IV. KETONE

1. Test strip contains Sodium nitroprusside. This test is based on the development of colors ranging from off white for negative reading to purple when acetoacetic acid reacts with nitroprusside.
2. Ketone bodies should not be detected in normal urine specimen with this test strip. The test reacts with acetoacetic acid or acetone in urine. it does not react with B-hydroxybutyric acid.

3. False positive results may occur with highly pigmented urine specimens. 2- Mercaptoethane sulfanic acid concentration of 10 mg %, Captopril concentration of 50 mg %, Phenylpyruvic acid concentration of 100 mg % and Phenylsulfanphthalein concentration of 0.05 mg% may cause a false positive reaction.

V. PROTEIN

1. Test strip contains Tetrabromphenol blue. This test is based on protein error of indicators principle. when the pH is held constant by a buffer, indicator dyes release H+ ions because of the protein present. Color changes from yellow for negative to green for positive reaction.
2. Normal urine specimens ordinarily contain some protein. Therefore, only persistent elevated levels of urine protein indicate significant proteinuria and thus further clinical testing is needed to evaluate the significant of results.
3. False positive results may be found in strongly basic urine. Chlorohexidine concentration of 0.25 % (v/v) may cause a false positive reaction.

VI. NITRITE

1. Test strip contains P- arsanilic acid. 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.
2. Normally nitrite is not present in urine. The reaction reveals the presence of nitrite and hence indirectly of nitrite- forming bacteria in the urine. Bacteria is generally due to infection of the kidneys, ureter and bladder in the urethra. Pink spots or pink edges should not be interpreted as a positive result.
3. Ascorbic acid concentration of 25 mg% greater may cause false negative reaction.

VII. GLUCOSE

1. Test strip contains Glucose oxidase, peroxidase, potassium iodide. This test is based on the specific glucose -oxidase/peroxidase reaction.

$$\text{Glucose} + O_2\,(\text{air}) \xrightarrow{\text{GOD}} \text{Glucuronic acid} + H_2O_2$$

$$H_2O_2 + \text{Chromogen} \xrightarrow{\text{POD}} \text{Oxidized chromogen} + H_2O$$

2. Color changes from light blue for negative to brown for positive reaction.
3. Normally no glucose is detectable in urine although the normal kidney excretes a minute amount.
4. Certain oxidizing contaminants, such a hypochlorite, may produce false positive results. Ascorbic acid concentration of 50 mg % or greater may cause false results negative. Ketone bodies reduce the sensitivity of the test. The reactivity of the glucose test decrease as the S.G. of urine increases.

VIII. pH

1. Test strip contains Methyl red and Bromothymol blue. This test is based on the double indicator principle that gives a broad range of colors covering the entire urinary pH range from orange through yellow and green to blue color.
2. Both the normal and abnormal urinary pH range is from 5.0 to 9.0. The pH of urine is an important indicator of certain metabolic, kidney, gastrointestinal and respiratory factors.

IX. SPECIFIC GRAVITY (S.G.)

1. Test strip contains Bromothymol blue. The test reflects the ion concentration of urine and correlates well with the refractometric method. In the presence of cations, protons are released by a complexing agent and produce a color change yellow colored pad containing the indicator bromothymol blue from green (for 1.000) to yellow (up to 1.030).
2. The S.G. test permits determination of urine S.G between 1.000 and 1.030.
3. The chemical nature of test may cause slightly different results from those obtained with other specific gravity methods when elevated amounts of certain urine constituents are present, highly buffered alkaline urines may cause low reading relative to other method. Elevated specific gravity readings may be obtained in the presence of moderate quantities (500mg%) of protein.

X. LEUCOCYTE

1. Test strip contains pyrrole amino acid ester, diazonium salt. Granulocytic leucocytes contain esterases 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.
2. Normally no leucocyte is detectable in urine. Individually observed trace or positive results are clinically significant.
3. If the urine specimen has a pronounced intrinsic color (for example due to the presence of bilirubin or nitrofurantoin), the reaction color may be intensified due to an additive effect. Glucose concentration of 2 g % greater, protein concentration of 500 mg % or greater may cause false negatives. A typical color reaction may be obtained in the presence of 1 mg% or greater concentrations of bilirubin.

SPECIFIC PERFORMANCE CHARACTERISTICS

Performance characteristics are based on clinical and analytical studies and depend upon several factors like variability of urine specimens the presence or absence of inhibitory and matrix factors typically found in urine and the laboratory conditions in which the product is used (e.g. lighting, temperature and humidity). Each color block or instrumental result represents a range of values, because of specimen and reading variability specimens and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results will usually be within one level of the true concentrations, Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments as stated above. Sensitivity/limit of detection shows the generally detectable levels of the analytes in the contrived urines however because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.

ImmunoQuick Urine strips are tested and results compared with commercially available product. Results found 100 % agreement with comparative kit.

REFERENCES

1. Dolphe kutter the urine test strip of the future clinica chimica acta 297(2000) 297-304.
2. Penders J, Fiers T, Delanghe JR. Quantitative evaluation of urinalysis test strips. Clin chem. 2002 Dec; 48(12):2236-41.
3. Buhling KJ, Dudenhausen JW. Test Strip analysis and urinary sediment. Dtsch Med Wochenschr. 2002 Aug 16;127(33):1718, author reply 1718.
4. Winkens RA, Leffers P, Degenaar Cp, Houben AW. The reproducibility of urinalysis using multiple reagent test strips. Eur J Clin Chem Clin Biochem. 1991 Dec;29(12):813-8.

IVD	In Vitro Diagnostic Use
	Manufacturer
	Manufacturing Date
	Expiry Date
LOT	Lot Number
30°C 4°C	Store at 4°C to 30°C
2	Single Use
Σ	Number of tests in the pack
	Do not use if pouch or kit damaged
	This side Up
i	Read package insert before use

MANUFACTURED BY

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