ASTAM DIAGNOSTICS

PRODUCT INSERT

REF US10

PRATHAM® *Urine Strip-10 Parameters*

For the semi-quantitative detection of 10 Parameters in human urine samples.

INTENDED USE

The Urine Test Strips contains solid phase reagent areas affixed to aplastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocyte. The test results may provide information regarding the status of carbohydrate metabolism, Kidney function, liver function, acid base and urinary tract infection.

SUMMARY AND EXPLANATION

The urinalysis test strips are ready to use upon removal from the bottle. The entire reagent strips are disposable, No additional laboratory equipment is necessary for testing. The directions must be followed exactly. Accurate timing essential to provide optional results.

The strips are packaged in a plastic bottle, containing desiccant. The bottle must be capped tightly to maintain reagent activity.

TEST PRINCIPAL

- **BLOOD (RBC/uL):** 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-diethylaminobenzaldehyde 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 strips 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 azocoupling 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 glucose acid and hydrogen peroxide from the oxidation of glucose. A second enzyme, peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide 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/uL):** Granulocytic leucocytes contain esterases that catalyze the hydrolysis of the derivatized pyrrole amino esterases that catalyze the hydrolysis of the derivatized pyrrole amino acid ester to liberate 3-hydroxy-5-phenyl pyrrole. This pyrrole. This pyrrole then reacts with a diazonium salt to produce a red-purple product.

MATERIAL PROVIDED

1. Urine test strips
2. Desiccant Pouch
3. Color label chart
4. Instructions for use.

MATERIAL REQUIRED BUT NOT PROVIDED

Timer and Urine collection container etc.

STORAGE AND STABILITY

- Store at room temperature between 2-30ºC.
- Do not use product after expiration date.
- Do not store the product in direct sunlight.
- The product shelf-life is 24 months from date of manufacturing.
- Once the bottle has been opened; the remaining strips are stable for up to 06 months.

WARNING & PRECAUTION

- 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 then urine.
- Use of disposable gloves and bio-hazardous clothing while running the test.
- The test shall be performed by competent person only.
- 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

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.

RECOMMENDED HANDLING PROCEDURE

All unused strips mus remain in the original bottle. Transfer to another container may cause reagents strips to deteriorate and become unreactive. Remove strips from the bottle just before it is used for testing. Replace cap immediately and tightly after removing reagents strips.

TEST PROCEDURE

1. Bring specimens to room temperature before use.
2. Remove urine strip from the bottle. Replace cap immediately.
3. Inspect the strip. (Discoloration or darkening of reagent test are as may indicate deterioration. Do not use the strip).
4. Immerse test areas of the strip completely in urine and remove immediately to avoid dissolving of reagents.
5. To remove excess urine, run the edge of the strip against rim of the urine container. Hold the strip in horizontal position to prevent possible mixing of chemicals from adjacent reagent areas. Excess urine may also be removed by gently blotting the length wise edge on absorbent paper.
6. Compare the optimal results carefully with the color chart on the bottle label in a good light.

1. **NOTE:** The optimal reading time of each test parameter varies from 30 to 60 seconds. Changes in color that appear only in the edges of the test areas or after more than 60 seconds are of no clinical significance.

RESULTS

The results are obtained by dipping the strips in urine and direct comparison of the test strip with the color blocks printed on the bottle label.

SENSITIVITY & LIMIT OF DETECTION

Test Parameters \ Results		Negative	Trace	Positive				
		(-)	(±)	+	++	+++	++++	
Blood	Conc. (RBCs/uL)	0		10	50	250		
Bilirubin	Conc. (mg/dL)	0		0.5	1	3		
Urobilinogen	Conc. (mg/dL)	(normal) 0.1	(normal) ↔	(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				
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/uL)	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.

SPECIMEN 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).

Samples	Positive	Negative	Sensitivity & Specificity
Positive (N=150)	149	1	Sensitivity: 99.3% Specificity: 100%
Negative (N=150) *Included cross-reactive samples*	0	150	
Total	149	151	

N= Number of samples tested.

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 control 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.
- 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.

BIBLIOGRAPHY

1. A.H. Free and H.M. Free "Urinalysis critical discipline of clinical science "CRC Critical Reviews in Clinical Laboratory Sciences, 481-531, 1972.
2. H. Free et.Al., "A comparative study of qualitative tests for ketones in urine and serum: Clin. Chem., 4,323, 1958.
3. J.M. Wilson and G.Hunger "Principles and practice of screening for disease "Public Health Papers Bo. 34, World Health Organization, Geneva, 1986.

SYMBOLS

Read instructions for use	Name of Manufacturer	For single use only
No. of test	Expiry Date of Kit.	Date of manufacturing of IVD Kit
IVD In-vitro diagnostic use	Keep away from Sunlight	REF Reference Catalogue Number
Storage Condition		

ASTAM DIAGNOSTICS

Manufactured By:
ASTAM DIAGNOSTICS PVT. LTD.
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