

PRATHAM[®] Urine Strip-2 Parameters

For the semi-quantitative detection of 2 Parameters in human urine samples.

INTENDED USE

The Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. Urine Test Strips provide test for the semi-quantitative determinations of Glucose and Protein.

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 is essential to provide optimal results.

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

TEST PRINCIPAL

- **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.
- **GLUCOSE (mg/dL):** This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of glycolic 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.

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 2-30°C.
- 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 than 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 must 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 area 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.

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

Results		Negative (-)	Trace (±)	Positive				
				+	++	+++	++++	
Protein	Conc. (mg/dL)	0	10	30	100	300	1000	
Glucose	Conc. (mg/dL)	0	100	250	500	1000	2000	

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.
- 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) <i>Included cross-reactive samples</i>	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

- A.H. Free and H.M. Free "Urinalysis critical discipline of clinical science "CRC Critical Reviews in Clinical Laboratory Sciences, 481-531, 1972.
- H. Free et.Al., "A comparative study of qualitative tests for ketones in urine and serum: Clin. Chem., 4,323, 1958.
- 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
 In-vitro diagnostic use	 Keep away from Sunlight	 Reference Catalogue Number
 Storage Condition		