Urine Strips -2 Para (Glucose and Ketone)

For the Semi-quantitative detection of Glucose, and Ketone.

INTENDED USE

2 Para Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. 2 Para Urine Test Strips provide test for the semi-quantitative determinations of Glucose, and Ketone. 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 is 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 PRINCIPLE

Glucose : The test is based on a double sequential enzyme reaction One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide with O-Toludine chromogen to oxidize the chromogen to color ranging from blue to dark brown

Ketone: This test is based on the reaction between acetoacetic acid present in urine with nitroprusside. The colors range from buff-pink, for a "Negative" reading to purple for positive sample.

REAGENT COMPOSITON

Glucose: 10.54% w/w glucose oxidase (aspergilius, 250 IU), 0.2% w/w Peroxidase (horseradish, 2,500 IU), 0.07% w/w, O-Toludine and 84.3% non reactive ingredients.

Ketone: 4.5% w/w sodium nitroprusside and 95.5% w/w buffer.

Materials Provided
1. 2 Para urine test strips
2. Color label chart
3. Instructions for use.

Materials required but not provided
1. Urine collection cup
2. Clock or timer.

PRECAUTIONS

1. For in vitro diagnostic use only.
2. Do not touch areas of strips.
3. After removing a test strip, replace cap on bottle promptly.
4. Working area should be free of detergents and other contaminants.

STORAGE
1. Storage at room temperature between 15 – 30° C (59-89 F) and out of direct sunlight.
2. Do not use after expiry date
3. Do not refrigerate or freeze.
4. Store all test strips in the original bottle. Do not remove the desiccant from bottle.
5. Close the bottle cap tightly after each use.

SPECIMEN COLLECTION

1. Urine should be collected in a clean container, either plastic or glass. Do not centrifuge.
2. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately.
3. It is especially important to use fresh urine to obtain optimal test results for bilirubin and urobilinogen.

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. Do not remove strips from the bottle until immediately before it is used for testing. Replace cap immediately and tightly after removing reagents strips.

GOOD LABORATORY PRACTICE
1. Urine collection containers are to be clean with no contamination.
2. The urine chemistry analyzer is to be cleaned daily. The instrument is first turned on, an optical calibration and self-test procedure must be performed.
3. Each day, the laboratory must run a negative and positive control before each routine test.

TEST PROCEDURE
1. Bring specimens to room temperature before use.
2. Remove 2 Para strip from the bottle. Replace cap immediately.
3. Inspect the strip. (Discoloration or darkening of reagent test areas 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 lengthwise edge on absorbent paper.
6. Compare the optimal results carefully with the color chart on the bottle label in a good light.
7. 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 secs 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.

LIMITATIONS
Glucose: Large amounts of ketone bodies (50 mg/dl or greater) may decrease color development.

Ketone: Color reactions that could be interpreted as "Positive" may be obtained with urine specimens containing medium or large amounts of phenyl ketone.

Expected values:
Glucose: The kidney normally excretes small amounts of glucose. Concentrations of as little as 0.1 gm/dl glucose, read either at 10-30 seconds may be scientifically abnormal if found consistently.

Ketone: Normally no ketone is present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting. Pregnancy and frequent exercise.

NORMAL VALUE REFERENCE

Glucose	Negative
Ketone	Negative

PERFORMANCE CHARACTERSTICS
Studies comparing the 2 Para Urine analysis Strip and other commercially available strips resulted in greater than 99% agreement with 60 urine samples.

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.

GLOSSARY OF SYMBOL

	Consult Instruction for Use
REF	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight

India office
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