URINE STRIP 4 PARAMETER

METHOD – MANUAL- DIP STICKS
PRODUCT CODE – US13

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for semi quantitative detection of Glucose, Protein, Ketone and pH in urine samples.

INTENTED 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 Protein & Ketone. The test results may provide information regarding the status of carbohydrate metabolism, Kidney function, liver function 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, catalyses the formation of gluconic acid and hydrogen peroxide with Potassium Iodide chromogen to oxidize the chromogen to colour ranging from blue to dark brown

Protein: The test is based on the protein error-of-indicators principle. At a constant pH, the development of any green colour is due to the presence of protein. Colours range from green to green-blue for "Positive reaction".

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

pH: This test is based on a double indicator principle that gives a broad range of colours covering the entire urinary pH range. Colours range from orange through yellow and green to blue.

REAGENT COMPOSITION

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

Protein: 0.3% tetrabromophenol blue, 99.7% Buffer

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

MATERIALS PROVIDED

1. Urine test strips
2. Colour label chart
3. Instructions for use.

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 ^{0}F) and out of direct sunlight. Do not use after expiry date. Do not refrigerate.
2. Store all test strips in the original bottle. Do not remove the desiccant from bottle. Close the bottle cap tightly after each use.

SPECIMEN COLLECTION

Urine should be collected in a clean container, either plastic or glass. Do not centrifuge. If testing cannot be done within an hour after voiding, refrigerate the specimen immediately. Urine collection containers are to be cleaned leaving with no contamination.

RECOMMENDED HANDELING 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. Do not use the strip if discoloration occurs.
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 colour 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 colour 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 colour blocks printed on the bottle label.

LIMITATIONS

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

Protein: False positive results may be obtained with alkaline urine.

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

pH: Excessive urine on the test strip may wash the acid buffer from the neighbouring protein reagent on the pH area and change the pH reading to an acid pH.

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.

Protein: Normally urine specimens contain some protein, (0.4 mg/dl) therefore, only persistent levels of urine protein indicate kidney or urinary tract disease.

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.

pH: new born : 5-7, thereafter: 4.5-8. Average 6.0.

NORMAL REFERENCE VALUES

Glucose	Negative
Protein	Negative
Ketone	Negative

SYMBOLS:


Read Instruction for use

In Vitro Diagnostic Use Only


Manufactured by


Expiry Date


Storage Temperature

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