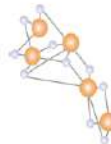


Ana-Chek® URINE STRIPS 4P (P+G+K+pH)



ANAMOL
THE ORIGINAL MAKERS

METHOD – MANUAL DIP-STICKS
PRODUCT CODE – US10

INSTRUCTIONS FOR USE

INTENDED USE: Test for semi quantitative detection of 4 parameters (Protein+Glucose+Ketone+pH) in urine samples.

INTRODUCTION

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

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".

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

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

Protein: 1.5% w/w tetrabromophenol blue and 98.5% w/w non-reactive ingredients.

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

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

pH: 0.2% w/w methyl red, 2.8% w/w Bromothymol blue, 97% buffer.

MATERIALS PROVIDED

1. Ana-Chek® Urine test strips 4P
2. Colour label chart
3. Instructions for use.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Urine collection cup
2. Clock or timer.

PRECAUTIONS AND HANDLING

For in vitro diagnostic use only. Do not touch areas of strips. After removing a test strip, replace cap on bottle promptly. Working area should be free of detergents and other contaminants. The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory

requirements. Read the instructions given on the labels and instructions for use carefully before using the kit.

STORAGE

Storage at room temperature between 15 – 30 °C (59-89 °F) and out of direct sunlight. Do not use after expiry date Do not refrigerate or freeze. 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. It is especially important to use fresh urine to obtain optimal test results for bilirubin and urobilinogen.

TEST PROCEDURE

1. Bring specimens to room temperature before use.
2. Remove Ana-Chek® urine 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 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

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

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

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

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

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

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.

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.

NORMAL REFERENCE VALUES

Protein	Negative
Glucose	Negative
Ketone	Negative
pH	6.0

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.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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GMP
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