Ana-Chek® URINE STRIPS 10P

METHOD – MANUAL DIP-STICKS
PRODUCT CODE – US08

ANAMOL
THE ORIGINAL MAKERS

INSTRUCTIONS FOR USE

INTENDED USE: Test for semi quantitative detection of 10 parameters 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, 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 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

Leukocyte: This test is based on the action of esterase present ion leukocyte, which catalyses the hydrolysis of an indoxyl ester derivative. The indoxyl ester liberated reacts with diazonium salt to produce a being-pink to purple colour.

Nitrite: This test depends on the conversion of nitrate to nitrite by the action of gram-negative bacteria in the urine. The nitrite reacts with p-arsenilic acid to form a diazonium compound in an acidic medium. The diazonium compound in turn couples with 1, 2, 3, 4-tetrahydrobenzo quinoline to produce pink colour.

Urobilinogen: A stable diazonium salt reacts almost immediately with urobilinogen to give a red azo dye. No discoloration of the test area or colours lighter than that shown for 1 mg/dl constitute normal findings.

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".

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.

Blood: This test is based on the peroxidase like activity of haemoglobin which catalyses the reaction of cumene hydroperoxide and 3, 3', 5, 5' tetramethylbenzidine. The resulting colour ranges from orange through green to dark to dark blue.

Specific Gravity: The test is based on the apparent PKa change of certain pre-treated polyelectrolytes in reaction to ionic concentration. In the presence of an indicator, colours range from deep blue-green in urines of low ionic concentration through green and yellow seen in urines of increasing ionic concentration.

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.

Bilirubin: The test for bilirubin is based on the coupling of bilirubin with a diazonium salt to give an azo dye. Even the slightest pink coloration constitutes a positive i.e., pathologic, result.

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

REAGENT COMPOSITION

Leukocyte: 0.4% w/w indoxyl derivative, 0.2% w/w diazonium salt, 99.4% Buffer.

Nitrite: 1.4% w/w p-arsenilic acid, 98.6% Buffer.

Urobilinogen: Methoxybenzene diazonium salt 67.7 mg and 99.4% w/w buffer.

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

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

Blood: 6.6% w/w cumene hydroperoxide, 2.0% w/w 3,3',5,5' tetramethylbenzidine, and 91.4% w/w non-reactive ingredients.

Specific Gravity: 5.0% w/w Bromothymol blue, 58% w/w polymethyl vinyl ether, 15.0% w/w sodium hydroxide and 22.0% w/w non-reactive ingredients.

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

Bilirubin: Dichlorobenzene diazonium salt 16.7 µg and 99% w/w non-reactive ingredients.

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.

MATERIALS PROVIDED

1. Ana-Chek® Urine test strips 10P
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

Leukocyte: High coloured urine, present of gentamycin, also due to >500mg/dl protein in urine gives false test.

Nitrite: Pink colour is not relation to number of bacteria; there are many bacteria which do not convert the nitrate to nitrite. Large amount of ascorbic acid may interfere.

Urobilinogen: A stable diazonium salt reacts almost immediately with urobilinogen to give a red azo dye. No discoloration of the test area or colours lighter than that shown for 1 mg/dl constitutes a positive i.e. pathological result. Other urinary constituents produce a more or less intense yellow discoloration. Reactions may occur with urine specimens containing large doses of chlorpromazine, which might be mistaken for positive Bilirubin

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

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.

Blood: A false positive can sometime occur when the bacteria are present in urine. Ascorbic acid or protein may reduce the reactivity of the blood test. Strong oxidizing substances such as hypochlorite may produce false positive results.

Specific Gravity: Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein (100-700 mg/dl). Specific gravity is increased with glucose in urine.

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

Bilirubin: Large dose of antibiotic, large amount of ascorbic acid may interfere.

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

EXPECTED VALUES

Leukocyte: Normal urine gives negative result.

Nitrite: Normally there is no presence of nitrite. Nitrite positive is shown in case of urinary tract infection.

Urobilinogen: In this test normal range is 0.2-1.0 mg/dl. If results exceed the concentration of 2.0 mg/dl., the patient and /or urine specimen should be evaluated further.

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.

Blood: Any green spots or green colour that appears on the reagent area within 60 seconds indicates blood has been detected and the needs further investigation.

Specific gravity: In normal adult random urine specific gravity may be from 1.003 to 1.040. Specific gravity will shift according to kidney dysfunction.

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.

Bilirubin: Normally no Bilirubin is detectable in urine by even the most sensitive methods. Typical colours may indicate that Bilirubin derived bile pigments are present in the urine sample.

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

Leukocyte	Negative
Nitrite	Negative
Urobilinogen	0.2 - 1 mg/dl (1 mg/dl = ~ 1 EU)
Protein	Negative
pH	6.0
Blood	Negative
Specific Gravity	1.003 - 1.040
Ketone	Negative
Bilirubin	Negative
Glucose	Negative

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	IVD	In Vitro Diagnostic Use
LOT	Lot Number		Read Instructions Before Use
REF	Catalogue Number		Storage Temperature
	Manufacturing Date	Σ	Number of Tests / Volume
	Expiry Date	2	Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE

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