QUANTON BIOLIFE SCIENCES
YOUR PARTNER IN PRECISION MEDICINE

Urine Strips -12 Para (Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Microalbumin and Creatinine)

For the Semi-quantitative detection of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Microalbumin and Creatinine

INTENDED USE

12 Para Urine Test Strips contains solid phase reagent areas affixed to a plastic stick. They are provided as a dry reagent. 12 Para Urine Test Strips provide test for the semi-quantitative determinations of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocyte, Microalbumin and Creatinine. 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.

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

Blood: This test is based on the peroxidase like activity of hemoglobin which catalyzes the reaction of cumene hydroperoxide and 3, 3’, 5, 5’ tertramethybenxidene. The resulting color ranges from orange through green to dark to dark blue.

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

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.

Protein: The test is based on the protein error-of-indicators principle. At a constant Ph, the development of any green color is due to the presence of protein. Colors range from green to green-blue for “Positive reaction”.

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.

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

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

Microalbumin: At a constant pH, albumin binds with sulfonephthalein dye to develop of any blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad

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.

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

Ketone: 4.5% w/w sodium nitroprusside and 95.5% w/w buffer.
Specific Gravity: 5.0% w/w Bromothymol blue, 58% w/w polymethl viny ether, 15.0% w/w sodium hydroxide and 22.0% w/w non reactive ingredients.

Blood: 6.6% w/w cumene hydroperoxide, 2.0% w/w 3,3’,5,5’ tetramethylbenzidine, and 91.4% w/w non reactive ingredients.
Protein: 1.5% w/w tetrabromophenol blue and 98.5% w/w non reactive ingredients.

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

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

Protein: 0.3% tetrabromophenol blue, 99.7% Buffer

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

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

Microalbumin: 1.9% w/w sulfonephthalein color; 94.2% w/w buffer; 3.9% w/w non-reactive ingredients.

Creatinine: 2.5% w/w copper sulfate; 4.5% w/w benzidine; 56.4% buffer; 36.6% w/w non-reactive ingredients.

Materials Provided
1. 12 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.

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TEST PROCEDURE

1. Bring specimens to room temperature before use.
2. Remove 12 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.

pH: Excessive urine on the test strip may wash the acid buffer from the neighboring 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.

Urobilinogen: A stable diazonium salt reacts almost immediately with urobilinogen to give a red azo dye. No discoloration of the test area or colors lighter than that shown for 1 mg/dl constitutes a positive i.e. pathologic, 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.

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.

Bilirubin: large dose of antibiotic. And ascorbic acid

Nitrite: Pink colour is not relation to number of bacteria; there are many bacteria which do not convert the nitrate to nitrite.

Leukocyte: high colored urine, present of getamycin, also due to >500mg/dl protein in urine. Gives false test.

Microalbumin: At a constant pH, albumin binds with sulfonephthalein dye to develop of any blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

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.

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

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

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.

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

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

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.

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

Leukocyte: Normal urine gives negative result.

Microalbumin: At a constant pH, albumin binds with sulfonephthalein dye to develop of any blue color. The resulting color ranges from pale green to aqua blue.

Creatinine: In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

NORMAL VALUE REFERENCE

Glucose	Negative
Bilirubin	Negative
Ketone	Negative
Blood	Negative
Protein	Negative
Urobilinogen	0.2 ~ 1 mg/dl (1 mg/dl = approx. 1 EU)
Specific Gravity	1.003 – 1.040
Nitrite	Negative
Leukocyte	Negative
Microalbumin:	detects concentration as low as 10 mg/L.
Creatinine:	detects concentration as low as 100 mg/L

PERFORMANCE CHARACTERSTICS

Studies comparing the 12 Para Urinalysis Strip and other commercially available strips resulted in greater than 99% agreement with 60 urine samples.

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.

GLOSSARY OF SYMBOL

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

Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2, Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.
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