URINE 10P STRIPS

For Professional Use

BHAT Bio-Scan®

A Rapid Test for the Semiquantitative Determination for the Presence & Concentration of Glucose, Bilirubin, Ketone, Sp. Gravity, Blood, pH, Protein, Urobilinogen, Nitrite & Leukocytes in urine.

IVD

Read pack Insert before use provided along with the kit

REF U10P

PARAMETERS : Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH,Protein, Urobilinogen, Nitrite and Leukocytes.

INTENDED USE: Urine 10P Sticks are firm plastic strips to which several different reagent areas are affixed. The strips provides tests for the semi quantitative determination for the presence and concentration of Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. Please refer to the carton and bottle label for specific test parameters of the product you are using. Each strip with reagent areas is ready to use upon removal from the bottle. The entire reagent strip is disposable. No additional equipment is required for testing and the test results are obtained by direct comparison of the test strips with the color blocks printed on the bottle label. The directions must be followed exactly. Accurate timing is essential to obtain reliable results.

CHEMICAL PRINCIPLES OF THE PROCEDURE :

GLUCOSE :

This test is based on a double sequential enzyme reaction. One enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. A second enzyme peroxidase, catalyzes the reaction of hydrogen peroxide with potassium iodide chromogen to oxidize the chromogen to colors ranging from blue-green to greenish-brown through brown and dark brown.

PH :

This test is based on the well known double pH indicator method, where bromothymol blue and methyl red gives distinguishable colors over the pH range of 5-9. The colors range from red-orange to yellow and yellow-green to blue-green.

BILIRUBIN :

This test is based on the coupling of bilirubin with a diazotized dichloroaniline in a strongly acid medium. The colors range from light tan to reddish-brown.

KETONE :

This test is based on the reaction of acetoacetic acid with sodium nitroprusside in a strongly basic medium. The colors range from beige or buff-pink color for a "Negative" reading to pink and pink-purple for a "Positive" reading.

SPECIFIC GRAVITY :

This test is based on the apparent pKa change of certain pretreated polyelectrolytes" in relation to the Ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow-green in urine of higher ionic concentration.

BLOOD :

This test is based on the pseudoperoxidase action of hemoglobin and erythrocytes which catalyzes the reaction 3,3', ,5' - tetra methyl - benzidine and buffered organic peroxide. The resulting colors range from orange to yellow-green and dark green. Very high blood concentration may cause the color development to continue to dark blue.

UROBILINOGEN :

This test is based on a modified Ehrlich reaction in which pdiethylaminobenzaldehyde reacts with Urobilinogen in a strongly acid medium. Colors range from light pink to bright magenta.

PROTEIN :

This test is based on the protein error-of-indicator principle. At a constant pH, the development of any green color is due to the presence of protein. Colors range from yellow for a "Negative" reaction to yellow-green and green to bluegreen for a "Positive" reaction.

NITRITE :

This test depends on the conversion of nitrate to nitrite by the action of Gram negative bacteria in the urine. The nitrate reacts with p-arsanilic acid to form a diazonium compound in an acid medium. The diazonium compound in turn couples with 1,2,3,4-tetrahydrobenzo (h) quinolin to produce a pink color.

LEUKOCYTES :

This tests is based on the action of esterase present in leukocytes,which catalyzes the hydrolysis of an indoxylester derivative. The indoxylester liberated reacts with a diazonium salt to produce a beige-pink to purple color.

STORAGE : Store opened and unopened bottles in a cool, dry place at room temperature (between 15 to 30C) and out of direct sunlight. Do not freeze. Do not use after the expiration date.

PACK SIZE : Available in packs of 100 Tests.

CONTENTS OF THE KIT : Testing devices and silicagel as dehydrant.

MATERIAL REQUIRED BUT NOT PROVIDED : Urine container.

WARNING AND PRECAUTIONS :

1. Remove the strip/s for immediate use only. Replace the cap promptly and tightly after removing the reagent strip.
2. Do not transfer the strips from their original bottle to any other bottle.
3. Do not remove the desiccant from the bottle. Protect against ambient moisture, Light and Heat is essential to guard against altered reagent reactivity.
4. Care must be taken not to touch the test reagent areas of unused strips.
5. Avoid contamination with hydrogen peroxide or any strong oxidizing agent, such as hypo chlorite.
6. Do not combine strips with different lot numbers together.
7. All reagent strips must be used within three months from the date of opening the bottle.
8. Read the Pack Insert carefully before performing the test.
9. The strips are for in vitro diagnostic use only.
10. ALWAYS USE FRESH URINE SAMPLE WITH EACH TEST.

SPECIMEN : Fresh Urine

SPECIMEN COLLECTION AND PREPARATION : Collect fresh urine in a clean container and test it as soon as possible. If testing cannot be done within one hour after voiding, refrigerate the specimen immediately. Refrigerated specimen must be brought to room temperature before testing. Do not centrifuge. The use of urine preservatives is not recommended. Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant changes in pH. A shift to alkaline pH may cause false positive results with the protein test area. Urine containing glucose may decrease pH as organisms metabolize the glucose. Contamination of the urine specimen with skin cleanser containing chlorohexidine may affect protein test results. The user should determine whether the use of such
skin cleansers is warranted.

TEST PROCEDURE :

1. Collect fresh urine specimen in a clean dry container. Mix Well Immediately before testing.
2. Remove from the bottle only enough strips for immediate use and replace the cap tightly. Completely immerse reagent areas of the strip in FRESH well mixed urine. Remove the strip immediately to avoid dissolving out the reagents.
3. While, Removing, run the edge of the entire length of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent possible mixing of chemicals from adjacent
reagent areas and / or contaminating the hands with urine.
4. Compare the reagent areas to corresponding Color chart on the bottle label at the times specified. HOLD STRIP CLOSE TO COLOR BLOCKS AND MATCH CAREFULLY. Avoid laying the strip directly on the color chart, as this will result in the urine sailing the chart.
5. Do not use the same urine sample more than once, as the urine may have been contaminated with the dissolving of the different reagent areas.

EXPECTED VALUES

Glucose : Small amounts of glucose are normally excreted by the kidney. Concentrations as little as 0.1 g/dl glucose, read either at 10 or 30 seconds, may be significantly abnormal if found consistently. At 10 seconds, results should be interpreted qualitatively; for semi-quantitative results, read at 30 seconds only.

Bilirubin : Normally, no bilirubin is detectable in urine by even the most sensitive method. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation. Atypical colors (colors produced which are different than the negative or positive color blocks shown on the Color Chart) may indicates that bilirubin derived bile pigments are present in the urine sample and are possibly masking the bilirubin reaction.

Ketone : Normally, no ketones are present in urine. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In starvation diets, or in other abnormal carbohydrate metabolism situation, ketones appear in the urine in excessively large amounts before serum ketones are elevated.

Specific Gravity : Random urine may vary in specific gravity from 1.003-1.040+. Twenty four hour urine from normal diets and normal fluid intake will have a specific gravity of 0.016-1.022. In severe renal damage, the specific gravity is fixed at-1.010, the value of the glomerular filtrates.

Blood : Any green spots or green color developing on the reagent area within 40 seconds is significant and the urine should be examined further. Blood is frequently,
but not invariably found in the urine of menstruating females.

pH : new born: 5-7 thereafter 4.5-8 average=6.

Protein : In 24 hour urine, 1-14 mg/dl of protein may be excreted by the normal kidney A color matching any color block greater than trace indicates significant proteinuria. For urine with high specific gravity, the test area may most closely match the trace color block even though only normal concentration of protein are present. Clinical Judgment is needed to evaluate the significance of trace results.

Urobilinogen : In a healthy population, the normal urine urobilinogen range obtained with this test is 0.2-1.0 Ehrlich Unit/dl. A result of 2.0 EU/dl may be of clinical significance and the same patient sample should be evaluated further.

Nitrite : The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 10 or more organisms/ml. There are occasional urinary tract infections from organisms which do not contain reductase to convert nitrate to nitrite.

Leukocytes : Normal urine specimens generally yield negative results with this test. A trace result may be of questionable clinical significance and it is recommended that the test be repeated using a fresh sample from the same patient. Repeated trace and positive results are of clinical significance.

SPECIFICITY : The performance characteristics of U10P reagent strips have been determined both in the laboratory and in clinical tests. Parameters of importance to the user are sensitivity, specificity, accuracy and precision. Generally, U10P reagent strips have been developed to be specific for the constituent to be measured with the exception of interferences listed above. For visually read strips, accuracy is a function of the manner in which the color blocks on the bottle label are determined and the discrimination of the human eye in reading the test. Precision is difficult to assess in a test of this type because of the variability of the human eye. It is for that users are encouraged to develop their own standards of performance.

Glucose : This test is specific for glucose; no substance excreted in urine other than glucose is known to give a positive result. The reagent area does not react with lactose, galactose, fructose, nor reducing metabolites of drugs; e.g. salicyclates and nalidixic acid. This test may be used to determine whether the reducing substance found in urine is glucose. Approximately 100mg/dl glucose in the urine is detectable.

Bilirubin : The test has a sensitivity of 0.4 - O.8mg/dl bilirubin in urine. The test is considered specific for bilirubin in urine.

Ketone : The ketone test area provides semi-quantitative results and reacts with acetoacetic acid in urine. This test does not react with beta-hydroxybutyric acid or acetone. The reagent area detects as little as 5-10mg/dl acetoacetic acid in urine.

Specific Gravity : The specific gravity test permits determination of urine specific gravity between 1.000 and 1.030. In general, the specific gravity test correlates within 0.005 with values obtained with the reflective index method.

Blood : At the time of reagent manufacture, this test when read as instructed has a sensitivity to free hemoglobin of 0.015 mg/dl or 5-10 intact red blood cells/µl in urine. This test is slightly more sensitive to free hemoglobin and myoglobin than to intact erythrocytes.

pH : The pH test area permits quantitative differentiation of pH values to one unit within the range of 5-9. pH reading are not affected by variation in the urinary buffer concentration

Protein : The test area is more sensitive to albumin than to globulin, hemoglobin, Bence-Jones proteins and mucoprotein; a negative result does not rule out the presence of these other proteins. The test area is sensitive to l5mg/dl albumin.
Depending on the inherent variability in clinical urine lesser concentration may be detected under certain conditions.

Urobilinogen : This test will detect urobilinogen in concentrations as low as 0.2 EU/dl in urine. The absence of urobilinogen in the specimen being tested cannot be determined with this test.

Nitrite: At the time of reagent manufacture, this test has a sensitivity to sodium nitrite of 0.075 mg/dl. Comparison of the reacted reagent area on a white background may aid in the detection of low levels of nitrite and will not react with substances normally excreted in the urine.

Leukocytes : This test can detect as low as 10-15 WBC/ul. This test will not react with erythrocytes or bacteria common in urine.

LIMITATIONS OF PROCEDURE : Comparison to the color chart is dependent on the interpretation of the individual. It is therefore, recommended that all laboratory personnel interpreting the results of these strips be tested for color blindness. As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single test result or method.

Glucose : Moderate amounts of ketone bodies (40mg/dL or greater) may decrease color development in urine containing small amounts of glucose (75~125 mg/dl) However, such concentration of ketone simultaneously with such glucose is metabolically improbable in screening. The reactivity of the glucose test decreases as the SG of the urine increases. Reactivity may also vary with temperature.

Bilirubin : Reactions may occur with urine containing large doses of chlorpromazine or rafampen which might be mistaken for positive bilirubin. Indican (Indoxyl sulfate) and metabolites of Lodine may cause false positive or atypical color; ascorbic acid (25mg/dL or greater) may cause false negative results.

Ketone : Color reaction that could be interpreted as "positive" may be obtained with urine specimens containing MESNA or large amounts of phenyl ketones or Ldopa metabolites.

Specific Gravity : The chemical nature of the specific gravity test may cause slightly different results from the those obtained with the specific gravity methods when elevated amounts of certain urine constituents are present. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (100-750 mg/dl) of protein.

Blood : The sensitivity of the blood test is reduced in urine with high specific gravity and/ or high ascorbic acid content. Microbial peroxidase, associated with urinary tract infection may cause false positive reactions.

pH : If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as "running over" may occur, in which the acid buffer from the protein area run onto the pH area, causing a false lowering in the pH result.

Protein : False positive results may be obtained with highly alkaline urine. Contamination of the urine specimen with quartemary ammonium compounds may also produce false positive results.

Urobilinogen : The test area will react with interfering substances known to react with Ehrlich's reagent, such as porphobillinogen and p-aminosalicyclic acid. This test is not a reliable method for the detection of porphobilinogen. Drugs containing ako-dyes (e.g. Azo Gantrising) may give a masking golden color. The absence of urobilinogen cannot be determined with the test.

Nitrite : The pink color is not quantitative in relation to the number of bacteria present. Any degree of pink coloration should be interpreted as a positive nitrite test suggestive of 10 or more organisms/ml. There are occasional urinary tract infections from organisms which do not contain reductase to convert nitrate to nitrite.

Leukocytes : Highly colored urine and the presence of the drugs cephalexin (Keflex) and gentamicin have been found to interfere with this test. High urinary protein of 500 mg/dl or above diminish the intensity of the reaction color. Elevated glucose concentration or high specific gravity may cause decreased results.

Leukocytes : This test can detect as low as 10-15 WBC/ul. This test will not react with erythrocytes or bacteria common in urine.

BIBLIOGRAPHY :

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NOTE:: Even after the best effort is made to supply the product as per the sample submitted but due to continuous R & D, the company reserves the right to improve/change any specifications/components without prior information/notice to the buyer

LIMITED EXPRESSED WARRANTY OF MANUFACTURER

The manufacturer limits the warranty to this test kit, as much as that the test kit will function as an in vitro diagnostic assay within the Nature of Sample, Procedure limitations and specifications as described in the product instruction manual, when used strictly in accordance with the instructions contained. The manufacturer disclaims any warranty expressed or implied including such expressed or implied warranty with respect to merchantability, fitness for use or implied utility for any purpose. The manufacturer's liability is limited to either replacement of the product or refund of the purchase price of the product and in no case liable to claim of any kind for an amount greater than the purchase price of the goods in respect of which damages are likely to be claimed. The manufacturer shall not be liable to the purchaser or third parties for any injury, damage or economic loss, howsoever caused by the product in the use or in the application there of.

REAGENT	READ TIME	COMPOSITION	DESCRIPTION
Bilirubin	30 seconds	0.4% w/w dichloroaniline; diaznium salt and buffer	Detects very small amount of Bilirubin in urine (Concn, not available)
Blood	40 seconds	6.6%w/w cumene hydroprusside 4% w/w 3, 3`,5, 5`tetramethyl benzidene 89.4% w/w buffer and non reactive ingredients	Detects upto non haemalyzed trace
Urobilinogen	60 seconds	2.9% w/w p-diethyl aminobenzaldehyde buffer and non-reactive ingredients	Detects upto 0.2 Ehrich / dl
Nitrite	60 seconds	1.4% w/w p-arsanilic acid buffer and non-reactive ingredients	Detects very small amount of Nitrite (Concn, not available)
Leukocytes	1-2 Minutes	0.4% w/w indoxyl ester derivative 0.2% w/w diazonium salt 99.4% w/w buffer non-reactive ingredients	Detects very small amount of Leukocytes (Concn, not available)
Glucose (GLU)	30 seconds	1.5% w/w glucose oxidase; 0.5% w/w peroxidase; 10.0% w/w potassium iodide; 75.0% non-reactive ingredients	Detects glucose as low as 50-100 mg/dL (2.5-5 mmol/L).
Ketone (KET)	40 seconds	5% w/w sodium nitroprusside; 95% w/w buffer	Detects acetoacetic acid as low as 2.5-5 mg/dL (0.25-0.5 mmol/L)
Specific Gravity (SG)	45 seconds	2.5% w/w bromthymol blue indicator, 17.5% w/w buffer and non-reactive ingredients, 55% poly (methyl vinyl ether/ maleic anhydride); 25% sodium hydroxide	Detects urine specific gravity between 1.000 ad 1.030. Results correlate with values obtained by refractive index method within = 0.005
pH	60 seconds	0.5% w/w methyl red sodium salt, 5% w/w bromthymol blue; 94.5% w/w non-reactive ingredients	Permits the quantitative differentiation of pH values within the range of 5-9
Protein (PRO)	60 seconds	0.3% w/w tetrabromophenol blue; 99.7% w/w buffer and non-reactive ingredients	Detects albumin as low as 7.5-20 mg/dL (0.075 - 0.2 g/L)

BS ISO-15223-1:2012(E) MEDICAL DEVICES SYMBOL

2°C 30°C	Temperature Limitation	2001-06	Date of Manufacture	IVD	In vitro Diagnostic Device
LOT	Batch Code		Company name & address		Consult Instructions For Use
	Use by	Company	Company Name	EC REP	Authorised Representative in European Community
	Do Not Reuse	Σ	Sufficient for		KEEP AWAY FROM SUNLIGHT
	KEEP DRY	NON STERILE	NON-STERILE	CONTROL −	NEGATIVE CONTROL
CONTROL +	POSITIVE				

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