URIPATH series

Reagent Strips for the rapid determination of Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic acid), Specific Gravity, Occult blood, pH, Protein, Nitrite and Leucocytes.

These instructions describe all of the tests within the Uripath series. The combination of test parameters vary according to specific products. Please refer to the appropriate sections before using this product.

INTENDED USE

URIPATH series of reagent Strips are dip-and-read test strips for the rapid determination of Urobilinogen, Glucose, Bilirubin, Ketones, Specific Gravity, Occult blood, pH, Protein, Nitrite and Leucocytes in urine. The test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use only. For professional use only

Health and Safety warnings:

• All patient samples should be treated as potentially infectious and the user should wear appropriate protective equipment when performing the test.
• The reagents which are impregnated into each pad together with average quantities are listed in each section describing the principles of each test.
• Keep out of reach of children.

Analytical precautions:

• Reagent Strips are for diagnostic use only and should not be used for the analysis of body fluids other than urine.
• As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result of method.
• The effects of drugs or other metabolites on the individual tests of the reagent strips are not known in all cases. It is therefore recommended that in case of doubt, the test should be repeated after withdrawal of the potential interfering agent such as medication or vitamin supplement, etc.
• Do not remove desiccant from bottle.
• Do not touch the test areas of the reagent strips.
• Do not open container until ready to use.
• The work area should be clean and free from detergents and other contaminants.
• Each test strip is for single use only.
• The correct reading time shown on the vial label is important for optimal results and readings outside this will invalidate the test.
• Colour changes that appear only along the edge of the test area should be ignored carefil removal of excess urine should eliminate this phenomenon.

COMPOSITION

Kit contents:
100 strips
Desiccant
Instructions for use.

STORAGE AND SHELF LIFE

• Replace the bottle cap immediately and tightly after removing test strips, and keep the vial tightly closed between tests.
• Store in a cool, dry place at temperatures between 15°C and 30°C (59°F and 86°F). Do not store the strips in a refrigerator or freezer.
• Store away from moisture and direct sunlight. When stored in the original container, the product is stable up to the expiry date printed on the bottom of the container.
• Do not use after expiration date.

MATERIALS AND EQUIPMENT REQUIRED BUT NOT PROVIDED.

Urine collection vessel (unused clean and dry)
Absorbent tissue

SPECIMEN

Collect fresh urine in an unused clean and dry vessel. Mix well just before test and do not centrifuge. Test the urine as soon as possible after collection.

If testing cannot be performed immediately refrigerate the specimen and allow it to return to room temperature before testing.

PRINCIPLES OF THE TESTS, PERFORMANCE CHARACTERISTICS AND LIMITATIONS OF THE METHOD

1. Urobilinogen

Chemical Principle: Modified Ehrlich’s reaction. Urobilinogen present reacts with Ehrlich’s reagent to form a red-coloured compound. Colour changes from light orange-pink to dark pink.

Reagents: 4-Methoxybenzenediazonium tetrafluoroborate 2.9mg

Expected Values: The normal urobilinogen range is 0.1 to 1.0 Ehrlich unit/dl. If results exceed the concentration of 2.0 mg/dl, the patient and the urine specimen should be evaluated further.

Detection Limits: The test will detect urobilinogen in concentration as low as 0.1 Ehrlich unit/dl. However, the absence of urobilinogen in the specimen cannot be determined. In patients with elevated urobilinogen excretion, urobilinogen test results correlate closely with Watson-Schwarz spectrophotometer procedures.

Limitation of Test: A positive result on urine from patients with urobilinogenuria or drugs containing azo-gantrisin may give a masking golden colour. The test is not a reliable method for the detection of porphobilinogen

2. Glucose

Chemical Principle: Glucose oxidase catalyzes the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.

Reagents: Glucose oxidase 430U, Peroxidase 200U, Potassium iodide 12mg

Expected Values: Normally no glucose is detectable in urine although the normal kidney excretes a small amount. Approximately 50 mg glucose/dl urine is detectable with this strip. Concentrations of 100 mg/dl may be considered abnormal if found consistently.

Detection Limits: Approximately 50 mg/dl of glucose is detectable. The test is highly specific for glucose. The reagent area does not react with lactose, galactose, fructose or reducing metabolites of salicylates and nalidixic acid.

Limitation of Test: Ascorbic acid (more than 50 mg/dl) and ketone bodies (more than 40 mg/dl) may cause a false negative for a specimen containing a small amount of glucose (<100 mg/dl). But the combination of such ketone levels and low glucose levels is metabolically improbable in screening. Reactivity of the test decreases as the specific gravity and pH of urine increases and may also vary with temperature.

3. Bilirubin

Chemical Principle: Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azo-dye. Colour changes from light tan to beige or light pink.

Reagents: 2,4-dichlorobenzene diazonium 2.3mg

Expected Values: Normally no bilirubin is detectable in urine by even the most sensitive methods. Even trace amounts of bilirubin are sufficiently abnormal to require further investigation.

Detection Limits: The test has a sensitivity of 0.5mg/dl bilirubin.

Limitation of Test: Metabolites of drugs, such as pyridium and serenium, which give a colour at low pH, may cause false positives. Indican indoxyl sulphate can produce a yellow-orange to red colour response, which may interfere with the interpretation of negative or positive bilirubin readings. False positive results may be obtained in the presence of diagnostic or therapeutic dyes in test urine. Ascorbic acid concentrations of 25 mg/dl or greater may cause false negatives.

4. Ketones

Chemical Principle: Legal’s test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide to produce a colour change from beige to purple.

Reagents: Sodium nitroprusside 23.0mg

Expected Values: Ketone bodies should not be detected in normal urine specimens with this reagent.

Detection Limits: Some high specific gravity and low pH urines may give reactions up to and including trace level. Clinical judgment is needed to determine the significance of reactions at the trace level.

Limitation of Test: Positive results (trace or less) may occur with highly pigmented urine specimens or those containing large amounts of levodopa metabolites. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise in ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism. Ketones may appear in urine in large amounts before serum ketone is elevated.

5. Specific Gravity (SG)

Chemical Principle: Ionic solutes present in the urine cause protons to be released from a poly electrolyte. As the protons are released the pH decreases and produces a colour change of bromothymol blue from blue-green to yellow-green.
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Reagents: Bromothymol blue 1.3mg; Poly (methyl vinyl ether/ maleic acid) anhydrous 140.5mg
Expected Values: Adults random urines vary in SG from 1.003 to 1.040. The first morning specimen should have a SG between 1.015 and 1.035. Newborns random specimens vary between 1.002 and 1.004. In severe renal damage the SG is fixed at 1.010, the value of the glomerulus’s filtrate.
Detection Limits: The specific gravity test permits determination of urine SG between 1.000 and 1.030.
Limitation of Test: Highly buffered alkaline urines may cause low reading of result. Elevated SG readings may be obtained in the presence of moderate quantities of protein. SG is also increased with glucose in the urine.

6. Occult blood
Chemical Principle: The test is based on the pseudo-peroxidase activity of the haem moiety of haemoglobin and myoglobin. The chromogen is oxidized by a hydroperoxide in the presence of haem and changes colour from yellow to blue.
Reagents: Hydroperoxide 35mg
Expected Values: The significance of trace reaction may vary among patients and clinical judgment is required for assessment in individual cases. When haemoglobin appears in urine it indicates kidney disease or a urinary tract disorder. Blood may often be found in the urine of menstruating females.
Detection Limits: The test is slightly more sensitive to free haemoglobin and myoglobin than to intact erythrocytes. The sensitivity may be reduced in urines with high specific gravity and those containing ascorbic acid. The appearance of green spots on the reagent test area indicates the presence of intact erythrocytes in the urine.
Limitation of Test: Elevated specific gravity or elevated protein may reduce the reactivity of the blood test. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations of 40 mg/dl or greater may cause false negatives at trace levels.

7. pH
Chemical Principle: Double indicator system. Indicator’s methyl red and bromothymol blue are used to give distinct colour changes from orange to green to blue. (pH 5.0 to 9.0)
Reagents: Methyl red 0.05mg; Bromothymol blue 0.5mg
Expected Values: Urine values generally range from pH 5 to 9. The pH of urine is an important indicator of certain metabolic, kidney, gastrointestinal and respiratory factors.
Detection Limits: The test measures pH values generally to within 1 unit in the range of 5-9.
Limitation of Test: Excessive urine on the test strip may wash the acid buffer from the neighbouring protein reagent onto the pH area and affect the pH reading. See Method (below).

8. Protein
Chemical Principle: The test is based on the “protein error” principle of indicators. When pH is held constant by a buffer, indicator dyes release H’ ions because of the protein present and change colour from yellow to blue-green.
Reagents: Tetrabromophenol blue 0.34mg
Expected Values: Normal urine specimens ordinarily contain some protein therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace level or over indicate significance proteinuria and thus further clinical testing is needed to evaluate the significant of results.
Detection Limits: This test has detection limit of 10-15 mg/dl protein.
Limitation of Test: False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens

9. Nitrite
Chemical Principle: The test is based on the diazotation reaction of nitrite with an aromatic amine to produce a diazonium salt. This is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo-dye produced causes a colour change from white to pink.
Reagents: P-arsanilic acid 4.5mg; T-(1-naphthyl) ethylene-diamine 2HCl 5.5mg
Expected Values: Normally no nitrite is detectable in urine and the presence of nitrite indicates the presence of bacteria that may be caused by infection of the kidneys, urethra, or bladder.
Detection Limits: Comparison of the reacted reagent area against a white background may aid in the detection of low levels which may otherwise be missed. Any degree of uniform pink colour development should be interpreted as suggesting the presence of 10’s bacteria/ml, but colour development is not proportional to the number of bacteria present.
Limitation of Test: The test is specific for nitrite and will not react with any other substance normally excreted in urine. The nitrite test detects only nitrate reducing bacteria. Any degree of uniform pink colour development should be considered positive, however, pink spots or pink edges should not be interpreted as a positive result. The specimen should not be more than 4 hours old at the time of the test. Urine that has been stored for longer periods of time is likely to give a false negative or a false positive result. The latter can be shown to be due to bacterial contamination.

10. Leucocytes
Chemical Principle: This test pad contains an indoxyl ester and diazonium salt. It is followed by an azo-coupling reaction of the aromatic amine formed by leucocyte esterase with a diazonium salt on the reaction pad. The azo-dye produced causes a colour change from beige to violet.
Reagents: Indole amino acid ester 1.3mg; Diazonium 1.55mg
Expected Values: Normally no leucocytes are detectable in urine.
Limitation of Test: The test result may not always be consistent with the leucocyte cell number found by microscopic examination. High concentration of glucose, high specific gravity, high level of albumin, high concentration of formaldehyde, or presence of blood may cause decreased test results. High concentration of oxalic acid of trace of oxidizing agents may cause false negative results.

PROCEDURE
The procedure must be followed exactly to get accurate results.
Remove a single strip from the container and replace the cap immediately.
Inspect the strip for signs of deterioration. If the reagent areas are discoloured or darkened do not use.
Refer to illustrations below for the following steps.

a) Dip the strip into the urine up to the test area for no more than 1 second.
b) Draw the edge of the strip along the brim of the vessel to remove excess urine taking care to ensure that the test areas do not touch the vessel.
c) Turn the strip on its side and tap once on a piece of absorbent material to remove any remaining urine. Excessive urine on the strip may cause the interaction of chemicals between adjacent reagent pads, so that an incorrect result may occur.
d) After the required time compare the test results carefully with the colour chart under good light. While comparing, keep the strip horizontally to prevent possible mixing of chemicals when excessive urine is present.

QUALITY CONTROL
The strips must be properly stored and handled before and during the testing. Sources of error are outlined under the limitation of Test. Each laboratory should establish its own goals for adequate standards of performance.