

INTEX[®] Uriscreen 10

Instructions for use

Reagent Strips for the rapid determination of:

Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic Acid), Specific Gravity, Occult blood, pH, Protein, Nitrite, Leukocytes

1 INTENDED USE

INTEX[®] URISCREEN 10 Reagent Strips are dip-and-read test strips for In Vitro Diagnostic Use only for testing above items in urine. Test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. It is measured by comparison of test paper attached to a plastic strip with the colour chart blocks printed on the vial label. When tested visually, and referred to the directions of analyzer in case of using instrument, the directions must be followed exactly.

2 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 2°C ~ 30°C (36°F ~ 86°F). Do not store the strips in a refrigerator or freezer.
- Store away from moisture and 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.

3 ANALYTICAL PRECAUTIONS

- For in vitro diagnostic use only.
- For professional use only.
- 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 test 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 test areas of urine reagent strips.
- Do not open container until ready to use.
- The work area should be clean and free from detergents and other contaminants.
- Keep out of reach of children.
- 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 careful removal of excess urine should eliminate this phenomenon.

4 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.

5 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 section describing the principles of each test.

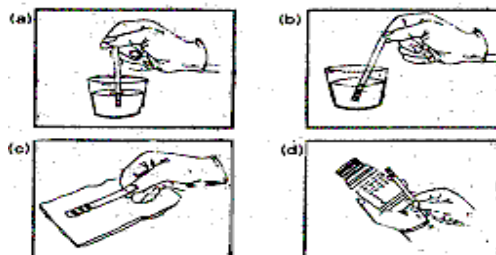
6 QUALITY CONTROL

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.

7 TEST PROCEDURE

The procedure must be followed exactly to get accurate results.

1. Remove a strip from the vial and replace the cap immediately; inspect the strip. If reagent areas are discolored or darkened, do not use the strip.
2. 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; at this time, don't make the test areas touched to the brim of 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 proper time compare the test results carefully with the color chart on the vial label under good light. While comparing, keep the strip horizontally to prevent possible mixing of chemicals when excessive urine is present.



8 REAGENT AREA INFORMATION

1. UROBILINOGEN

Chemical Principle: Modified Ehrlich's reaction. Urobilinogen present reacts with Ehrlich's reagent to form a red-colored 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, urobilingen test results correlate closely with Watson-Schwartz spectrophotometer procedures.

Limitation of Test: The test area will react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid. Drugs containing azo gantrisin may give a masking golden color. The test is not 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. The kidney normally excretes small amounts of glucose. Approximately 50mg glucose /dl urine is detectable with this strip.

Concentrations of 100mg/dl may be considered as abnormal if found consistently.

Detection Limits: Approximately 50mg/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 50mg/dl) and ketone bodies(more than 40mg/dl) may cause a false negative for a specimen containing a small amount of glucose (100mg/dl). But the combination of such ketone levels and low glucose levels is methobologically improbable in screening. Reactivity of the test decreases as the specific gravity and pH of urine increases and may also vary with tem perature.

3. BILIRUBIN

Chemical Principle: Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. Color 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 pyridum and serenium, which give a color at low pH, may cause false positives. Indican indoxyl sulfate 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 25mg/dl or greater may cause false negatives

4. KETONES

Chemical Principle: Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricanide 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 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. 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 the acid buffer from the neighboring protein reagent onto the pH area and change the pH reading to an acid pH although the urine being tested is originally neutral or alkaline. This is called the "run-over" phenomenon.

6. OCCULT BLOOD

Chemical Principle: The test is based on the Pseudo-peroxidase activity of the haem moiety of hemoglobin 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 hemoglobin appears in urine it indicates kidney disease or a urinary tract disorder. This test is highly sensitive to hemoglobin (it is slightly less so to intact erythrocytes) and thus complements the microscopic examination. Blood may often be found in the urine of menstruating females.

Detection Limits: The test is slightly more sensitive to free hemoglobin 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. SPECIFIC GRAVITY (SG)

Chemical Principle: Ionic solutes present in the urine cause protons to be released from a polyelectrolyte. As the protons are released the pH decreases and produces a colour change of bromothymol blue from blue-green to yellow-green.

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 1.025. Newborns random specimen vary between 1.002 ~1.004. In severe renal damage the SG is fixed at 1.010, the value of the glomerulus's filtrate.

Detection Limits: The SG test permits determination of urine SG between 1.000, 1.005, 1.010, 1.015, 1.020, 1.025, 1.030. Highly buffered alkaline urines may cause low reading of result.

Limitation of Test: Elevated SG readings may be obtained in the presence of moderate quantities of protein. SG is also increased with glucose in the urine.

8. PROTEIN

Chemical Principle: Protein "error 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 diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It 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) ethylenediamine 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, ureter, and bladder of urethra.

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. The test is specific for nitrite and will not react with any other substance normally excreted in urine.

Limitation of Test: 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. Any degree of uniform pink color development should be interpreted as suggesting the presence of 10^5 /ml, but colour development is not proportional to the number of bacteria present. 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 bacteria contamination.

10. LEUKOCYTES

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 leukocytes 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 leukocytes are detectable in urine. Individually observed trace the results may be questionable clinical significance.

Detection Limits: The test is generally capable of detecting 20~25 WBC/ μ l as a trace.

Limitation Of Test: The test result may not always be consistent with the leukocyte cell number by the 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 or trace of oxidizing agents may cause false negative results.

9 SYMBOLS

	Article number		For single use only
	Lot number		Expiry date
	Storage		Content
	Only for in vitro diagnostics		Instructions for use

INTEX[®] Uriscreeen 10		
	100 Teststrips	UR80100



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