Accutest® URS Series Reagent Strips for Urinalysis

Instructions for Use

For In Vitro Diagnostic Use.
Intended for professional use only.
For testing for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Ascorbic Acid, and Leukocytes in human urine. The device is composed of several color pads aligned on a strip. Each pad is employed for testing one assay item by reading the color change of the pad and comparing with the corresponding blocks on a color chart.
The strips are available in the following format:

Products Type	Test Item
URS 11 Cat #UA711	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and **Ascorbic Acid**
URS 10 Cat #UA710B	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH
URS 4 Cat #UA774	Glucose, pH, Protein, Ketone (acetoacetic acid)

INTENDED USE

The Accutest® Series Reagent Strips for Urinalysis are intended for qualitative, semi-quantitative urinalysis. The strips are for in vitro diagnostics use.
The Accutest® Series Reagent Strips for Urinalysis are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

TEST PRINCIPLE

The test is a firm plastic strip. If the test is positive, the test pad should be a uniform purple or pink color.

Glucose	An enzyme, glucose oxidase, catalyzes the formation of gluconic acid and hydrogen peroxide from the oxidation of glucose. Hydrogen peroxide releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes potassium iodide, which causes the color change.
Bilirubin	This test is based on coupling the direct bilirubin with diazotized dichloroaniline in a strongly acid medium, which produces diazotizing colors.
Ketone	The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.
Specific gravity	Electrolytes (M+X-), in the form of salt in urine, react with poly (methyl vinyl ether) and maleic acid (- COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color change.
Blood	This test is based on the peroxidase activity of hemoglobin and myoglobin. Peroxide releases neo-ecotypic oxide[O], then the indicator is oxidized by [O] and causes a color change.
pH	This test is based on a double indicator principle.
Protein	This test is based on the protein-error-of-indicators principle. An ion from the specific pH indicator is attracted by the cation on the protein molecule, which causes the indicator to ionize and change color.
Urobilinogen	This test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acidic medium to produce a pink-red color.
Nitrite	This test depends upon the nitrite diazotize with aromatic amino sulphadiazine to form a diazonium compound. This diazonium compound in turn couples with 1,2,3,4-tetrahydro-benzo(h)quinolin-3-phenol to produce a pink color.
Leucocytes	Granulocytic leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole then reacts with a diazonium salt to form a purple color.
Ascorbic acid	Ascorbic acid, with 1,2-dihydroxy alkenes, under alkaline condition, deoxidizes blue 2,6-dichloroindophenolate form into colorless N-(P-phenol)-2,6-dichloro-P- amine phenol.

WARNINGS AND PRECAUTIONS

Please read ALL the information in this Instruction for Use before performing the test.

- Do not use it after the expiry date.
- Every strip can be used only once.
- Do not remove strip or desiccant(s) from the bottle until immediately before using for testing.
- Replace container cap tightly immediately after removing reagent strip.
- Do not touch test areas of reagent strips.
- Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity.

Please deal with the waste strips according to "Treatment Regulations of Lab Biohazard Materials". Once the canister has been opened, the remaining strips are stable for up to 3 months in humidity conditions lower than 65%RH.

STORAGE AND HANDLING

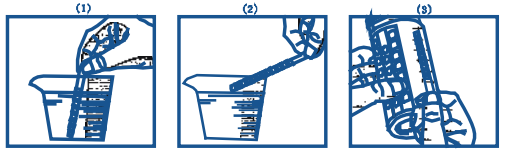
- Store in original bottle and a dry place at temperatures between 2-30°C (36-86°F).
- Do not refrigerate.
- Any unused test strip with discolored test pads should be considered damaged and should be discarded.

DIRECTIONS FOR USE

Collect fresh urine in a clean dry container. Use uncentrifuged urine and mix the sample before testing. The sample should not be more than 2 hours old at the time of testing. Always handle specimens under sanitary conditions.
Note: Water should not be used as negative control. Preservatives will not prevent the deterioration of ketones, bilirubin, or urobilinogen. Bacterial growth from contaminating organisms may affect glucose, pH, nitrite, and blood test results.
Visual reading technique:

1. Immerse all reagent areas in specimen and remove strip immediately.
2. Run the edge of strip against the rim of the container to remove excess urine.
3. Hold strip horizontally or place on a flat surface and compare test areas closely with color chart on bottle label. Record the results.

For a semi-quantitative result read the reagent areas at the time specified on the color chart. The pH and Protein areas may also be read immediately or at any time up to 60 seconds after dipping. For a qualitative result read the reagent areas between 1 and 2 minutes. If a positive result is obtained, repeat the test, reading each reagent at the time specified on the color chart.
The color change after 2 minutes has no diagnostic value.



LIMITATIONS

NOTE: There is the possibility that this test may produce false results. Consult your physician before making any medical decisions.
GLUCOSE: The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. In dilute urine containing less than 0.28mmol/L ascorbic acid, as little as 2.2 mmol/L glucose may produce a color change that might be interpreted as positive. Ascorbic acid concentrations of 2.5 mmol/L or greater and/or high acetoacetic concentrations (l .0mmol/L) may influence the test. Small amounts of glucose may normally be excreted by the kidney. These amounts are usually below the sensitivity of this test.
BILIRUBIN: 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. Medicines that color the urine red or that are themselves red in an acid medium, e.g., phenazopyridine may influence the test. Large ascorbic acid concentration may cause false negatives.
KETONES: The test reacts with acetoacetic acid in urine. It does not react with acetone or -hydroxybutyric acid. Normal urine specimens usually yield negative results with this reagent. False positive results may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.
SPECIFIC GRAVITY: The specific gravity permits determination of urine specific gravity between 1.000 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. For increased accuracy, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Strips read instrumentally are

automatically ad usted for pH by the instrument. The SG test is not affected by ce ain nonionic urine constituents such as glucose or by the presence of radiopaque dye. Highly buffered al aline urines may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (l-7.5g/L) of protein.

BL D: The significance of the Trace rea tion may vary among patients, and clinical udgment is required for assessment in an individual case. evelopment of green spots (intact e throcytes) or green color (free hemoglobin/ myoglobin) on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. Hemoglobin concentration of l 50-620µg/L is approximately equivalent to 5-15/µL intact red blood cells per microlite .

This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The sensitivity of this test may be reduced in urines with high specific gravit . This test is equally sensitive to myoglobin as to hemoglobin. Ce ain oxidizing contaminants, such as hypochlorite, may produce false positive results. icrobial peroxidase associated with urina y tract infection may cause a false positive reaction. Levels of 2.8mmol/L ascorbic acid normally found in urine do not inter ere with this test.

pH: The pH test area measures pH values generally to within l unit in the range of 5.0-8.5.

PR TEIN: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones Protein and mucoprotein. A Negative result does not rule out the presence of these other proteins. Normally no protein is detectable in urine by conventional methods, although a minute amount is excreted by the normal idne . A color matching any bloc greater than Trace indicates significant proteinuria. alse positive results may be obtained with highly buffered al aline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with s in cleansers containing chlorhexidine may also produce false positive results.

UR BILIN GEN: This test area will detect urobilinogen in concentrations as low as 3µmol/L (approximately 0.2 Ehrlich unit/dL) in urine. The normal range with this test is 3-16µmol/L. a result of 33 µmol/L represents the transition from normal to abnormal, and the patient and/or urine specimen should be evaluated further. The absence of urobilinogen cannot be determined with this test.

NITRITE: This test depends upon the conve ion of nitrate (derived from the diet) to nitrite by the action of principally Gram-negative bacteria in the urine. The test is specific or nitrite and will not react with any other substance normally excreted in urine. Pin spots or pin edges should not be interpreted as a positive result. Any degree of uniform pin color development should be interpreted as a positive nitrite test suggesting the presence of l 05 or more organisms per m , but color development is not proportional to the number of bacteria present. A negative result does not prove that there is no significant ba eriuria. Negative results may occur ① when urinary tract in ctions are caused by organisms which do not contain redu tase to convert nitrate to nitrite, when urine has not been retained in the bladder long enough (ur hours or more) for reduction of nitrate to occur or when dietary nitrate is absent. Sensitivity of the nitrite test is reduced for urines with high specific gravity It may resist 2.8mmol/L Ascorbic Acid.

LEUK C TES: Test area reacts with esterase in leukocytes (granulocytic leu ocytes). Normal urine specimens generally yield negative results; positive results (+ or greater) are clinically significant. Individually observed Trace results may be of questionable clinical significance; however Trace results obse ed repeatedly may be clinically significant. Positive results may occasionally be und with random specimens from males due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160mmol/L) or high specific gravity may cause decreased test results.

ASC RBIC ACID: The test area can detect ascorbic acid in urine. Through ascorbic acid detection, we will now the level of ascorbic acid in the body and the effect degree that the ascorbic acid brings to the test on glucose, bilirubin, blood, and nitrite. It will reduce the sensitivity when an oxidant (such as potassium permanganate, hypochlorite) is present in the urine.

SPECIFIC PERF RMANCE CHARACTERISTICS: Specific per ormance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors; the variability of color perception, the presence or absence of inhibitory factors typically found in urine, specific gravit , pH, and the lighting conditions when the product is read visually. Each color bloc or instrumental display value represents a range of values. Because of specimen and reading variabilit specimens with analyte concentrati ns that fall between nominal levels may give results at either level. esults at levels greater than the second positive level r the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

DETECTION AND TEST RANGE OF URINALYSIS STRIPS

Analyte	Lab Assay Range		Reportable Range	
	Metric Units	SI Units	Metric Units	SI Units
Glucose	0 - 5500 mg/dL	0 - 305 mmol/L	Neg - 2000 mg/dL	Neg - 111 mmol/L
Protein	0.3 - 5000 mg/dL	0.003 -5 0 g/L	Neg - 2000 mg/dL	Neg - 20 g/L
Ketone	0.2 - 350 mg/dL	0.019 - 34 mmol/L	Neg - 160 mg/dL	Neg - 16 mmol/L
Blood	0 - 350 cell/µL	0 - 350 cell/µL	Neg - 200 cell/µL	Neg - 200 cells/µL
Bilirubin	0 - 18.8 mg/dL	0 - 321 µmol/L	Neg - 6 mg/dL	Neg - 103 µmol/L
Nitrite	5.0 - 2000 mg/dL	0.02 – 9.09 µmol/L	Neg or Pos	Neg - Pos
Leukocytes	0 - 800 cells/µL	0 - 800 cells/µL	Neg - 500 cells/µL	Neg - 500 cells/µL
Urobilinogen	0.01 - 18.75 mg/dL	0.17 - 317 µmol/L	0.2 - 8 mg/dL	3.2- 131 µmol/L
Ascorbic acid	1 - 230 mg/dL	0.06 - 13 mmol/L	0 - 100 mg/dL	0 - 5.7 mmol/L
pH	0 - 14.0	0 - 14.0	5.0 - 8.5	5.0 - 8.5
Specific Gravity	1.000 - 1.040	1.000 - 1.040	1.000 - 1.030	1.000 - 1.030

REACTIVE INGREDIENTS (based on dry weight at time of impregnation)

Protein: 0.1% m/m tetrabromphenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients

Blood: 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethylbenzidine; 35.3% w/w buffer. 37.2 %nonreactive ingredients.

Glucose: 1.7% w/w glucose oxidase (microbial.123U); 0.2 % w/w peroxidase (horseradish. 203 TU); 0.1% w/w potassium iodide; 71.8% w/w buffer; 26.2% w/w nonreactive ingredients.

Ketone: 5.7% w/w sodium nitroprusside; 29.9% w/w nonreactive ingredients;64.4% w/w buffer.

Leukocytes: 4.3% w/w pyrrole amino acid ester; 0.4% w/w diazonium salt; 92.6% w/w buffer; 2.7% w/w nonreactive ingredients.

Nitrite: 1.3% w/w p-arsanilicacid; 0.9% N-(1-Naphthol)-ethylenediamine; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients.

Specific Gravity: 4.8% w/w bromothymol blue; 90.2% w/w poly (methyl vinyl ether co maleic anhydride); 5.0% w/w sodium hydroxide.

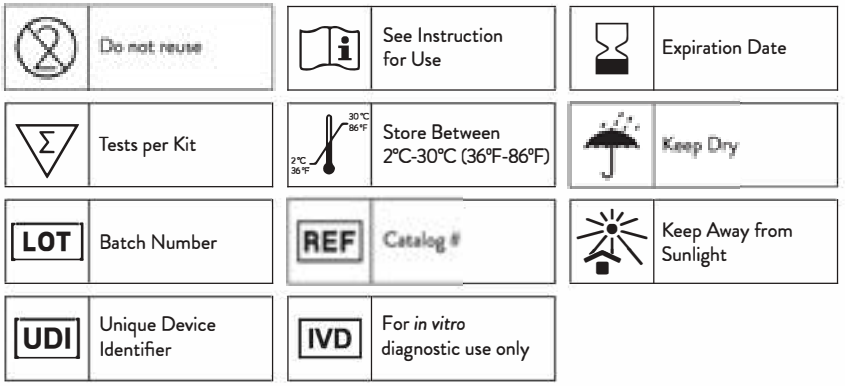
pH: 3.3% w/w bromocresol green; 55.0% w/w bromothymol blue; 41.7% w/w nonreactive ingredients

Bilirubin: 0.6% w/w 2.4-dichlorbenzene amine diazonium salt; 57.3% w/w buffer; 42.1% w/w nonreactive ingredients.

Urobilinogen: 0.2% w/w p-diethylamino benzaldehyde; 98.0% w/w buffer; 1.8% w/w nonreactive ingredients

Ascorbic acid: 0.8% w/w 2,6-dichloroindophenolate hydrate; 40.7% w/w buffer; 58.5% w/w nonreactive ingredients.

INDEX OF SYMBOLS



ASSISTANCE

If you have any questions regarding the use of this product, please call our Technical Support Number +1-800-676-5565.

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