Accutest® URS-10 Urine Reagent Strips

Intended Use

Accutest®URS-10 Urine Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. Accutest® URS-10 Urine Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists both read visually and on the Accutest 50 and Accutest 500 urine analyzers and the Bayer Clinitek® 50, 100, 200, and 500 analyzers.

Accutest® URS-10 Urine 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.

Summary and Explanation of Tests

Accutest® URS-10 Urine Reagent Strips provide tests for Glucose, Bilirubin, Ketone (acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes in Urine.

Test Principles

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 acid medium to produce a pink-red color.
Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strongly acid medium.
Ketone: The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.
Blood: Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide [O]. [O] oxidizes the indicator and causes the color change.
Protein: The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator attracted by a cation on the protein molecule makes the indicator further ionized, which changes its color.
Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the color change.
Leukocytes: Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.
Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium, which causes the color change.
Specific Gravity: Electrolyte (M^+X^-) in the form of salt in urine reacts 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.
pH: This test is based on a double indicator principle that gives a broad range of colors covering the entire urinary pH range.

Reactive Ingredients (based on dry weight at time of impregnation)
Urobilinogen: 0.2% w/w fast blue B salt; 98.0% w/w buffer; 1.8% 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.
Ketone: 5.7% w/w sodium nitroprusside; 64.4% w/w buffer; 29.9% w/w nonreactive ingredients.
Blood: 26.0% w/w diisopropylbenzene dihydro peroxide; 1.5% w/w tetramethyl- benzidine; 35.3% w/w buffer; 37.2% w/w nonreactive ingredients.
Protein: 0.1% w/w tetrabrompenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients.
Nitrite: 1.3% w/w p-arsanilicacid-N-(1-Naphthol)-ethylenediamine; 0.9% w/w tetrahydro -quinoline; 89.6% w/w buffer; 8.2% w/w nonreactive ingredients
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.
Glucose: 1.7% w/w glucose oxidase (microbial, 123U); 0.2% w/w peroxidase (horseradish, 203IU); 71.8% w/w buffer; 0.1% w/w potassium iodide; 26.2% w/w nonreactive ingredients.
Specific Gravity: 4.8% w/w bromthymol blue; 90.2% w/w poly (methyl vinyl ether co maleic anhydride); 5.0% w/w sodium hydroxide.
pH: 3.3% w/w bromcresol green; 55.0% w/w bromthymol blue; 41.7% w/w nonreactive ingredients.

Storage

Strips must be kept in the original bottle. Transfer to any other container may shorten the expiration date of product. Store at temperatures between 2-30 degrees C (39-86 degrees F). Keep away from direct sunlight and moisture. Do not remove desiccants in the bottles. Replace the cap immediately after removing reagent strips. Protect against exposure to light, heat, and ambient moisture to guard against altered reagent reactivity.

Specimen Collection and Preparation

Collect fresh urine in a clean and dry container. Do not centrifuge the urine. Mix the sample well before testing it [1]. The container should allow for complete dipping of all reagent strip areas. Test the urine within four hours after voiding, sooner if testing for bilirubin or urobilinogen [2].

Expected Results

The sensitivity of Accutest®URS-10 Urine Reagent Strips for Urinalysis in testing clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH values, and the lighting conditions when strips are read visually. Visual reading results may not exactly match instrumental reading results because of the difference between the perception of human eyes and the optical instrument. Most visual and instrument readings are within one level of the true value.

Procedure

Gather Materials

- Dry and clean plastic container
- Paper Towel
- Watch with a second hand or stopwatch (if you read the strip visually)
- Urinalysis reagent strips
- Clinitek 50, 100, 200 or 500 Urine analyzer (if you read the strip instrumentally)

Perform Tests

1. Immerse the reagent area of the strip in the urine specimen and take it up quickly and immediately. Start timing if reading visually.
2. Run the edge of the strip against the rim of the container to remove excess urine. Lay the strips on a paper towel with the reagent areas upward.
3. If reading visually, hold the strip up horizontally and compare the reagent areas on the strip to the corresponding color chart on the bottle label at the exact times specified and in good light. Hold the strips close to the color blocks and match carefully. Make note of the result. Color changes after 2 minutes are of no diagnostic value. If reading by instrument, carefully follow the directions given in the instrument operating instruction. The instrument will automatically read each reagent area at a specified time.
4. Dispose of strips with laboratory waste. Do not flush down toilet.

Quality Control

Test positive and negative commercial quality controls with each new lot, each new shipment of reagent strips, and when you open a new bottle of reagent strips. Test reagent strips monthly that are stored for more than 30 days. Run positive and negative commercial QC material to ensure reagent strip storage integrity; train new users; confirm test performance; and when patients' clinical conditions or symptoms do not match the results on the test strip. Also, run QC tests per your laboratory procedures. Do not use water as a negative control. For recommendations of control materials and technical questions, call (800) 676-5565, Monday-Friday 8:00am-5:00pm (PST) Compare your QC results to the acceptable results list in the QC manufacturer's labeling. If the QC results are not acceptable, do not test the patient samples until you solve the problem. Repeat QC tests once. If results are still unacceptable, call (800) 676-5565

Important Notes

1. Do not take the strips from the bottle unless they are for immediate use.
2. Do not touch reagent areas of strips.
3. Do not use strips beyond the expiration date
4. Each strip can be used only once.
5. Large amounts of ascorbic acid may effect the test for glucose, bilirubin, nitrite, and blood [2,4].
6. Deterioration may result in discoloration or darkening of the reagent areas of the strip. If this happens, or the test results are questionable or inconsistent with expected results, check and make sure the strips are within the expiration date, and also check results with the control urine.

Limitations

Urobilinogen: The reagent area may react with interfering substances, such as sulfonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminosalicylic acid. False negative results may be obtained if formalin is present and the specimen has been in direct sunlight. The test is not a reliable method for the detection of porphobilinogen [4].
Bilirubin: Medicines that dye urine red and anything that shows red in an acid medium (e.g., phenzaopyridine) may affect the test result. A high concentration of ascorbic acid (49mg/dL) may cause a false negative result.
Ketone: False positive results may occur in highly pigmented urine or those specimens containing a large amount of levodopa metabolites [2].
Blood: Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. A high specific gravity in urine may reduce the sensitivity of the test [2]. Protein: False positive results may be obtained with highly buffered or alkaline urines. Contamination of the urine specimen with quaternary ammonium compounds (e.g., from some antiseptics and detergents) or with cleansers containing chlorhexidine may also produce false positive results [2,4].
Nitrite: A negative result does not rule out significant bacteriuria. False negative results may occur (1) when urine does not contain the organism that caused the conversion from nitrate to nitrite, (2) when urine has not remained in the bladder long enough (up to four hours) for the nitrate to covert into nitrite, or (3) when nitrate in foods is absent. A high specific gravity of

urine may reduce the sensitivity of the test. A 17mg/dL concentration of ascorbic acid or less will not affect the test result [2,4].
Leukocytes: A high glucose concentration (2000mg/dL) or a high specific gravity in urine may reduce the sensitivity of the test. High concentration of oxalic acid may cause decreased test results. Tetracycline may cause decreased reactivity, and high levels of tetracycline may cause a false negative reaction [2].
Glucose: Ascorbic acid concentrations of 10.2mg/dL and/or acetoacetic acid concentrations of 19.4mg/dL or lower will not influence the test [2].
Specific Gravity: Urine nonionic constituents such as glucose or highly buffered alkaline urine may produce low readings compared to other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (750mg/dL). The reagent strip is not suitable for testing newborn because of their low specific gravity (1.002-1.004) [4].
pH: Bacterial growth in a specimen may cause a marked alkaline shift (>8.0), usually because of urea conversion to ammonia.

Expected Values/Reference Ranges
Expected values for a "normal" healthy population and abnormal populations are listed below for each test. Expected values are referenced to European Urinalysis Guidelines, The Clinical Analysis Of Urine Recent Period and Compendium – Urinalysis With Test Strips [2,4,5].
Urobilinogen: Urobilinogen is normally present in urine at concentrations up to 1.0 mg/dL (1 Ehrlich unit/dL). A level of 2mg/dL in urine is the critical value, representing the transition from normal to abnormal, which requires a further check on patients and specimens. Evaluation of both the bilirubin and urobilinogen results helps in the differential diagnosis of jaundice, as well as other liver and biliary disorders.
Bilirubin: Normally, even the most sensitive method cannot detect bilirubin in healthy urine. It is abnormal to have even a little bilirubin in urine, which requires further inspection.
Ketone: Normal urine specimens usually produce negative results in the test. In ketoacidosis, starvation, fasting, pregnancy and frequent strenuous exercise, ketones may appear in urine and may produce positive results [4].
Blood: The 'trace' reaction may vary among patients. Clinical judgments are required for individual cases. The presence of green spots (intact erythrocytes) or green color (hemoglobin/myoglobin) on the reagent area within 60 seconds after dipping indicates the need for a further diagnostic check. Erythrocytes are often, but not always, found in the urine of menstruating females.
Protein: The reagent area is more sensitive to albumin than to globulins, hemoglobin, Bence-Jones protein, and muco-protein. Therefore a 'Negative Result' is not sufficient to indicate that these proteins do not exist in urine. Normally protein is not detectable in urine with conventional methods, although a minute amount of protein is excreted through normal kidney function. Protein in urine is indicated when the color is darker than the plus/minus mark on the chart.
Nitrite: Gram-negative bacteria in urine converts nitrate (derived from foods) into nitrite. The reagent strip is specific to nitrite and will not react with other substances in urine. Any degree of uniform pink color development should be taken as a positive result. The degree of color development and the number of bacteria are not in direct proportion.
Leukocytes: The reagent area of the strip reacts with esterase in leukocytes (granulocyte leukocytes). Normal urine specimens generally yield negative results. Positive results (+ or greater) are clinically significant. Individual 'trace' results are clinically questionable, and it is very important that 'trace' results be confirmed in a repeated test.
Glucose: Normally, a small amount of glucose may be excreted through the kidneys. The amount is usually below the sensitivity of the reagent test. Results at the first positive level may be significantly abnormal if found consistently.
Specific Gravity: The normal specific gravity of urine ranges from 1.003-1.030. If the specific gravity of random urine is 1.023 or greater, the concentrating ability of the kidneys can be considered normal.
pH: The normal pH of urine can range from 4.6 to 8.0. Certain dietary conditions can produce acid or alkaline urines, which can be useful in the treatment, or some calculi [4]

Performance Characteristics
The performance characteristics of the strips are determined by clinical analysis and study. The results from visual readings and instrumental readings represent an actual range of analyte concentrations. Because of the variety of the specimens and reading methods, the values obtained from the results of tests may have errors compared to the actual values of the specimens. Visual reading results may not exactly match the instrumental reading results because of the inherent difference between the perception of human eyes and the optical instruments.

The following table shows the +/-1 color block % Agreement using 1514 samples in laboratory comparison studies between Accutest® URS-10 Urine Reagent Strips and Bayer Multistix 10 SG Reagent Strips.

	% Agreement	Analyte	% Agreement
Urobilinogen	98.2% (1486/1514)	Bilirubin	97.6 % (1477/1514)
Ketone	98.6 % (1492/1514)	Blood	96.3 % (1458/1514)
Protein	99.9 % (1513/1514)	Nitrite	98.2 % (1487/1514)
Leukocytes	98.6 % (1492/1514)	Glucose	96.9 % (1467/1514)
pH	89.0 % (1348/1514)	Specific Gravity	95.2 % (1441/1514)

Urobilinogen: This test can detect urobilinogen in concentrations as low as 0.2mg/dL (approximately 0.2 EU/dL); therefore, most normal urines will give a slightly pink reaction. The absence of urobilinogen in the specimen cannot be determined.
Bilirubin: The test has a sensitivity of 0.5mg/dL bilirubin. Bilirubin in urine indicates liver disease before any clinical signs are usually evident.
Ketone: In 90% of urines tested, acetoacetate acid at 5.0 mg/dL will produce a positive reaction. The strip does not react with hydroxybutyric acid and acetone and acetoacetic acid.
Blood: The test is specific for hemoglobin and myoglobin. In 90% of urines tested, hemoglobin or erythrocytes concentrations of 5 Ery/µL will produce a positive result.
Protein: In 90% of urines tested, albumin concentrations of 0.15 g/L or greater will produce a color change. The test pad is more sensitive to albumin than globulin, Bence-Jones proteins, and mucoproteins.
Nitrite: The test has a sensitivity of 0.08-0.1 mg/dL nitrite ion in urine of normal excreted in urine. Comparison of the reacted area against a white background may aid in the detection of low levels of nitrite. A negative result doesn't mean the existence of bacteria in a large amount. A negative result may occur (1) when urine doesn't contain organisms that cause the conversion from nitrate to nitrite; (2) when urine has not remained in the bladder long enough (four hours or more) to let the nitrate covert into nitrite; or (3) the nitrate in foods is absent.
Leukocytes: Urinary tract infection in up to 90% of all patients can be detected by analysis of random urine specimens. A positive reaction (small or greater) at less than the 2 minutes reading time may be regarded as a positive indication of leukocytes in urine.
Glucose: In 90% of urines tested, glucose concentrations of 80 mg/dL or greater will produce a positive result. Sugars other than glucose will not react with the reagent. If the color appears somewhat mottled at the higher glucose concentrations, match the darkest color to the blocks.
Specific Gravity: The reagent strips test urine specimens for specific gravity between 1.000 and 1.030. In general, the mean error between the results of the strip test and results from the refractive index method is only 0.005. For increased accuracy 0.005 may be added to readings from urine samples with pH equal to or greater than 6.5. Strips read instrumentally are automatically adjusted for pH by the instrument.
pH: Strip tests for pH measure pH values from 5.0-8.5 visually and 5.0-8.5 instrumentally generally to within one level of the expected result.

The sensitivity of the strips on clinical urine specimens may vary depending upon several factors, such as the variability of color perception, specific gravity, pH value, and the lighting conditions when the strips are read visually. Test sensitivities and output values are given in the following table.

Sensitivity and Output Values of Accutest®URS-10 Urine Reagent Strips

Test Pad	Sensitivity	Output Value	
		Instrumental Read	Visual Read
Urobilinogen (mg/dL)	0.2-1.0	0.2 - 8.0	0.2 - 8.0
Blirubin (mg/dL)	0.2-0. 5	Negative - Large	Negative - Large
Ketone (mg/dl)	5-10	Negative - 80	Negative - 160
Blood (Ery/µL)	5-15	Negative - 200	Negative - 200
Protein (mg/dL)	15-30	Neg - 300	Neg - 2000
Nitrite (mg/dL)	0.08-0.1	Negative - Positive	Negative - Positive
Leukocytes (Leu/µL)	5-15	Negative - 500	Negative - 500
Glucose (mg/dl)	50-100	Negative - 1000	Negative - 2000
Specific Gravity	——	1.005 - 1.030	1.000 - 1.030
pH	——	5.0 - 8.5	5.0 - 8.5

Bibliography

1. "Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline"; NCCLS Document GP16-A (ISBN 1-56238-282-9); 1995. NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA19087, USA.
2. "European Urinalysis Guidelines", The Scandinavian Journal of Clinical & Laboratory Investigation, Scand J Clin Lab Invest-Vol. 60-Supplement 231.2000.
3. "Operating Rules Of Clinical Test" (Rev.2), The Ministry of Health of P.R.C. Publishing. Yingwu Ye, Yusan Wang.
4. "The Clinical Analysis of Urine Recent Period", The Science and Technology Publishing House, Yu Long Cong, Jun Long Ma, Editors; 1998; pp. 37-81, 96-97.
5. "Compendium – Urinalysis with Test Strips" Roche Diagnostic, Combur® Reagent Strips.

Notes on Symbols and Marks

Store At | LOT Batch Code | Use By (expiration date) | Single Use
IVD In Vitro Diagnostic Use | Please Read Package Insert | Rev.: AUG 2012

accutest® URS 10 10 Parameter Urine Reagent Strips

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