Accutest® URS-4 Urine Reagent Strips

Intended Use

Accutest®URS-4 Urine Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. Accutest® URS-4Urine Reagent Strips are for single use in professional near patient (point-of-care) facilities and centralized laboratory locations by medical technologists read visually.

Accutest® URS-4 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-4 Urine Reagent Strips provide tests for Glucose, Protein, Nitrite and Leukocytes in Urine.

Test Principles

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 catalyze 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.

Reactive Ingredients (based on dry weight at time of impregnation)

Protein: 0.1% w/w tetrabrompenol blue; 97.4% w/w buffer; 2.5% w/w nonreactive ingredients.
Glucose: 1.7% w/w glucose oxidase (microbial, 123U); 0.2% w/w peroxidase (horseradish, 203U); 71.8% w/w buffer; 0.1% w/w potassium iodide; 26.2% 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.

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-4 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.

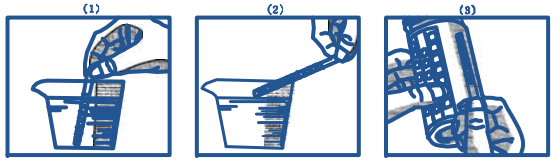
Procedure

Gather Materials

- Dry and clean plastic container
- Toilet paper
- Watch with a second hand or stopwatch (if you read the strip visually)
- Urinalysis reagent strips

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. 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

Remove one strip from the bottle and check against the color blocks on the color chart. If the color of the reagent area is darker than the lowest block on the chart (except for specific gravity and pH), the strip is unusable. Discard the strip and check all strips from the bottle before using or discard the bottle. When a new bottle is first opened, use two strips to test known negative and positive specimens or controls. Water should NOT be used as a negative control.

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. [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

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].
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].
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].

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].

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.
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.
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.

Performance Characteristics

The performance characteristics of the strips are determined by clinical analysis and study. The results from visual readings and 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-4 Urin e Reagent Strips and Bayer Multistix 4 SG Reagent Strips.

Analyte	% Agreement		
Glucose	96.9 % (1467/1514)	Leukocytes	98.6 % (1492/1514)
Protein	99.9 % (1513/1514)	Nitrite	98.2 % (1487/1514)

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.

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.

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.

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-4 Urine Reagent Strips

Test Pad	Sensitivity	Output Value
		Visual Read
Protein (mg/dL)	15-30	Neg - 2000
Glucose (mg/dL)	50-100	Negative - 2000
Nitrite (mg/dL)	0.08-0.1	Negative - Positive
Leukocytes (Leu/µL)	5-15	Negative - 500

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.

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URS 4
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Urine Reagent Strips

Notes on Symbols and Marks

Store at | LOT Batch code | Use by (expiration date) | Single use

Please read package insert | IVD In Vitro Diagnostic Use

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