# Accustrip® URS 10

**CAT. NO: UA870**

**Reagent Test Strips for Blood, Urobilinogen, Bilirubin, Protein, Nitrite, Ketones, Glucose, pH, Specific Gravity and Leukocytes in Urine by the Dip and Read Technique.**

## INDICATIONS FOR USE

The Accustrip® URS 10 Reagent Strip for Urinalysis is a dip-and-read test strip. The product is intended for use as an in vitro diagnostic aid using urine specimens for screening for diabetes, metabolic abnormalities, liver diseases, biliary and hepatic obstructions and diseases of the kidneys and urinary tract. The strip provides qualitative and semi-quantitative tests for blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes by visual comparison with a color chart for each concentration range. The strips may be read visually, requiring no additional laboratory equipment. The test strip may also be read instrumentally using the Accustrip® URS Reader.

## INFORMATION REGARDING CLIA WAIVER

These tests are CLIA waived when read visually and when run on the Accustrip® URS Reader. A certificate of CLIA waiver is required to perform the testing in a waived setting. If the laboratory does not have a Certificate of Waiver, the Application for Certification (Form CMS-116), can be obtained at http://www.cms.hhs.gov/clia/. The form should be mailed to the address of the local State Agency of the State in which the laboratory resides (http://www.cms.hhs.gov/clia/ssa-map.asp). Laboratories with a certificate of waiver must follow the manufacturer's instructions for performing the test. If the laboratory modifies the instructions, the test no longer meets the requirements for waived categorization. A modified test is considered to be high complexity and subject to all CLIA requirements.

## INSTRUCTIONS FOR USE

Make sure to use urine that is not older than 2 hours. Mix well before testing.
Dip all test pads of the reagent strip into the urine for approximately 1 second. Draw the strip across the rim of the container to remove excess urine.
a) If reading visually, start timing. After 30-60 seconds (leukocyte test field after 60 - 120 seconds) compare the reagent areas to corresponding color chart on the bottle label. Hold strip close to color blocks and match carefully. Make sure to read the pads in good light. Color changes that take place after more than 2 minutes are of no significance.
b) If reading instrumentally, carefully follow the directions in the operator's manual.

## PRINCIPLE

**Blood:** The detection is based on the pseudoperoxidative activity of hemoglobin and myoglobin, which catalyzes the oxidation of an indicator by an organic hydroperoxide producing a green color.

**Urobilinogen:** The test paper contains a stable diazonium salt producing a reddish azo compound with urobilinogen.

**Bilirubin:** A red azo compound is obtained in the presence of acid by the coupling of bilirubin with a diazonium salt.

**Protein:** The test is based on the "protein error" principle of indicators. The test zone is buffered to a constant pH value and changes color from yellow to greenish blue in the presence of albumin. Other proteins are indicated with less sensitivity.

**Nitrite:** Microorganisms, which are able to reduce nitrate to nitrite, are indicated indirectly with this test. The principle of Griess reagent is the basis of this test. The test paper contains an amine and a coupling component. A red colored azo compound is obtained by diazotisation and subsequent coupling.

**Ketones:** The test is based on the principle of Legal's test. Acetoacetic acid and acetone form with sodium nitroprusside in alkaline medium a violet colored complex.

**Glucose:** The detection is based on the glucoseoxidase-peroxidase-chromogen reaction. Apart from glucose, no other compound in urine is known to give a positive reaction.

**pH:** The test paper contains indicators which clearly change color between pH 5 and pH 9 (from orange to green to turquoise).

**Specific Gravity:** The test determines the concentration of ions in urine and shows a good correlation to the refractometrical method. The color of the test strip changes from deep blue in urine with low ionic concentration through green to yellow in urines with high ionic concentrations.

**Leukocytes:** The test is based on the esterase activity of granulocytes. This enzyme splits carboxylate. The alcohol constituent released reacts with a diazo salt producing a violet color.

## PERFORMANCE CHARACTERISTICS & EVALUATION SOURCES OF ERROR

**Blood:** The minimum sensitivity of the test strip is 5 to 10 erythrocytes/µl urine corresponding to approx. 0.015 mg hemoglobin/dl urine. Intact erythrocytes are indicated by flecky discolorations of the test field. The color fields correspond to the following values:

0 (negative), ca. 5-10, ca. 50, ca. 250 Ery/µl resp.
hemoglobin concentration out of ca. 10, ca. 50, ca. 250 Ery/µl

Normal concentrations of ascorbic acid (< 40 mg/dl) do not influence the test results. Falsely positive reactions can be produced by a residue of peroxide containing cleansing agents.

**Urobilinogen:** Depending on urine color, 0.5 to 1 mg urobilinogen/dl can be indicated. 1 mg/dl is considered to be the normal excretion rate. Higher values are pathological. A complete absence of urobilinogen in the urine, which is likewise pathological, cannot be demonstrated by the strips, The color fields correspond to the following urobilinogen concentrations;

norm. (normal), 2, 4, 8,12 mg/dl or norm. (normal), 35, 70, 140, 200 µmol/l

The test will be inhibited by higher concentrations of formaldehyde. Exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Too high or falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine. Larger amounts of bilirubin produce a yellow coloration.

**Bilirubin:** The minimum sensitivity of the test strip is 0.5 to 1 mg bilirubin/dl urine. The color fields correspond to the following values:

0 (negative), 1(+), 2(++), 4(+++) mg/dl or 0 (negative), 17(+), 35(++), 70(+++) µmol/l

Some urine contents can produce a yellow coloration of the test strip. Ascorbic acid and nitrite in higher concentrations inhibit the test. Exposure of the urine to light for a longer period of time may lead to lowered or falsely negative results. Too high or falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine.

**Protein:** The minimum sensitivity of the test strip is 10 mg protein/dl urine. The color fields correspond to the following ranges of albumin concentrations:

negative, 30,100 and 500 mg/dl or negative, 0.3, 1.0 and 5.0 g/l

Falsely positive results are possible in alkaline urine samples (pH > 9), after infusions with polyvinylpyrrolidone (blood substitute), after intake of medicaments containing quinine and also by disinfectant residues in the urine sampling vessel. The protein coloration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

**Nitrite:** The test detects concentrations from 0.05 to 0.1 mg nitrite/dl urine. Every pink color indicates a bacterial infection of the urinary tract. The color intensity depends only on the nitrate concentration, but does not provide information about the extent of the infection. A negative result does not preclude an infection of the urinary tract, if bacteria, which cannot produce nitrite, are present. Falsely negative results can be produced by high doses of ascorbic acid, by antibiotic therapy and by very low nitrate concentrations in urine as the result of low nitrate diet or strong dilution (diuresis). Falsely positive results can be caused by the presence of diagnostic or therapeutic dyes in the urine.

**Ketones:** Acetoacetic acid reacts more sensitively than acetone. Values of 10 mg/dl acetoacetic acid or 50 mg/dl acetone are indicated. The color fields correspond to the following acetoacetic acid values:

0 (negative), 25(+), 100(++) and 300(+++) mg/dl or
0 (negative), 2.5(+), 10(++) and 30(+++) mmol/l

Phenylketones in higher concentrations interfere with the test, and will produce variable colors. ß-Hydroxybutyric acid is not detected. Phthalein compounds interfere by producing a red coloration.

**Glucose:** Pathological glucose concentrations are indicated by a color change from green to bluish green. Yellow or greenish test fields should be considered negative or normal. The color fields correspond to the following ranges of glucose concentrations:

neg. (yellow), neg. or normal (greenish), 50, 150, 500 and ≥ 1000 mg/dl or
neg. (yellow), neg. or normal (greenish), 2.8, 8.3, 27.8 and ≥ 55.5 mmol/l

An inhibitory effect is produced by gentisic acid. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents.

**pH:** The pH value of fresh urine of healthy people varies between pH 5 and pH 6. The color scale gives a clear distinction of pH value between pH5 and pH 9.

**Specific Gravity:** The test permits the determination of urine specific gravity between 1.000 and 1.030. Urine from adults with normal diets and fluid intake will have a density of 1.015 -1.025. The chemical nature of the test strip may cause slightly different results from those obtained with other methods when elevated amounts of certain urine constituents are present, e.g. the increase of urine specific gravity because of high glucose concentrations of > 1000 mg/dl (> 56 mmol/l) cannot be detected by the specific gravity test field. Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein. Highly buffered alkaline urines may cause low readings.

**Leukocytes:** The test records values starting from approx. 10-25 leukocytes/µl urine. Changes in color that can not be assigned to the negative reference field and faint violet colors after 120 seconds must be evaluated as positive. The color reference fields correspond to the following leukocyte concentrations:

negative (normal), 25, 75, 500 leukocytes/µl

A weakened reaction can be expected in the case of proteinuria at over 500 mg/dl and a glucose concentration of over 2 g/dl as well as in the case of patients taking preparations containing cephalexin and gentamycin. Bacteria, trichomonads and erythrocytes do not react with this test. Formaldehyde (as a preservative) can result in a false positive reaction. Excretion of bilirubin, nitrofurantoin or other strongly-colored compounds may disguise the color of the reaction. Tests with female patients have shown that vaginal discharge can cause a false positive reaction.

## REACTIVE INGREDIENTS

(minimum quantity resp. activity/cm² at time of expiry)

| | | | | | |
|---|---|---|---|---|---|
| **Blood:** | | **Nitrite:** | | **pH:** | |
| tetramethylbenzidine | 59µg | sulfanilic acid | 80µg | methyl red | 2.8µg |
| cumene hydroperoxide | 253µg | quinoline derivative | 25µg | bromothymol blue | 10µg |
| **Urobilinogen:** | | **Ketones:** | | **Specific Gravity:** | |
| diazonium salt | 28µg | sodium nitroprusside | 116µg | bromothymol blue | 12µg |
| | | | | copolymer | 295µg |
| **Bilirubin:** | | **Glucose:** | | **Leukocytes:** | |
| diazonium salt | 26µg | glucoseoxidase | 3.2U | carboxylic acid ester | 10.6µg |
| | | peroxidase | 0.2U | diazonium salt | 4.4µg |
| **Protein:** | | o-tolidine | 65µg | | |
| tetrabromophenol blue | 7.5µg | | | | |

## DIRECTIONS

In any case, in order to establish a final diagnosis and prescribe an appropriate therapy, the results obtained with test strips should be verified with other medical results.

The effect of medications or their metabolic products on the test is not known in all cases. In case of doubt it is recommended not to take the medications and then repeat the test. Any change of medication should be approved by the patient's physician.

Only use well-washed and clean vessels for urine collection. The presence of usual urine preservatives will not affect the test results,

Remove only as many test strips as are required, and reseal the container immediately after use. Do not touch the test paper. Avoid exposing the strips to sunlight and moisture. Store the container below +30 °C in a dry place. The test strips are stable, when stored properly up to the date of expiry indicated.

## SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean container and test samples as soon as possible. If testing cannot be completed within one (1) hour after sample collection, REFRIGERATE THE SPECIMEN IMMEDIATELY AND LET IT RETURN TO ROOM TEMPERATURE BEFORE TESTING. Nitrite results are best optimized by using a first morning specimen or one which has incubated in the bladder for four (4) hours or more.

Prolonged exposure of unpreserved urine to room temperature may result in microbial proliferation with resultant changes in pH and false positive nitrite test. A shift to alkaline pH may cause false positive results in the protein test area. Urine containing glucose may decrease in pH as organisms metabolize glucose. Bacterial growth from contaminating organisms may cause a positive blood reaction due to the peroxidases produced,

Preservatives do not prevent deterioration of ketones in the sample. Some preservatives do not adequately protect glucose from being metabolized by contaminating or infecting organisms. Do not use formaldehyde as a urine preservative as it may produce unreliable results.

## PROCEDURE - MUST BE FOLLOWED EXACTLY TO ACHIEVE RELIABLE TEST RESULTS

1. Collect FRESH urine specimens in a clean, dry container.
2. Remove one strip from aluminum container and replace cap. COMPLETELY immerse strip in FRESH urine and remove immediately to avoid the dissolving out of reagents.
3. When removing, run the edge of the strip against the rim of the urine container to remove excess urine. Hold the strip in a horizontal position to prevent mixing of chemicals from adjacent reagent areas and/or soiling of hands with urine.
4. Compare test areas to the corresponding color charts on the bottle label. HOLD STRIP CLOSE TO Color BLOCKS-MATCH CAREFULLY.

If reading instrumentally, carefully follow the directions in the operator's manual.

Some colors continue to become more intense for a short time and then fade. For this reason, the best time for comparison is AFTER 30 SECONDS AND BEFORE 60 SECONDS. Color changes that take place after more than 2 minutes are of no significance.

## QUALITY CONTROL

Test at least one known negative and one known positive specimen or control, whenever a new bottle of strips is first opened, for each new shipment, for each new lot or at least monthly. Do not use water as negative control. Positive and negative control solutions provide a convenient basis for a quality control program. Contact the service number below for ordering information. If proper results are not obtained, consult your local product representative or contact Customer Service by calling (800) 676-5565 for advise on testing techniques and results.

## RESULTS

Results with test strips are obtained in clinically meaningful units directly from the color chart comparison.
If reading instrumentally, carefully follow the directions in the operator's manual.

## STORAGE AND STABILITY HANDLING

Accustrip® URS 10 test strips should be stored between 39 – 86°F (4 - 30°C) in a COOL, DRY place. Do not freeze.
Properly stored, the strips are stable until the date of expiration.

## RECOMMENDED PROCEDURES FOR HANDLING

Unused test strips must remain in the original container. Desiccant material in the cap will keep dipsticks moisture free. Transfer to any other container may cause reagent strips to deteriorate and become non reactive. Replace cap immediately and tightly after removing dipstick. Do not touch reagent areas of test strip with your fingers. Do not allow dipsticks to come in contact with detergents which may be found in specimen containers and other contaminating substances found in work areas.

## WARNING AND PRECAUTIONS

PROTECTION AGAINST MOISTURE, LIGHT AND HEAT IS ESSENTIAL. ALTERED REAGENT ACTIVITY MAY RESULT IF CARE IS NOT TAKEN. Discoloration or darkening of reagent areas may indicate deterioration. DO NOT USE STRIP IF THIS OCCURS. In this event, check to see that the unopened expiration date stamped on the vial has not been passed or examine vial for evidence of exposure to moisture, light or heat. Store strips out of reach of children!

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Rev. 06/2008 / Axxxxxx / xxx/x


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Jant Pharmacal Corporation
Encino, California 91436 USA