HENRY SCHEIN®

Urispec® 11-Way

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

For *in vitro* diagnostic use.

INDICATIONS FOR USE

The Urispec® 11-Way 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 specific gravity, leucocytes, glucose, protein, blood, nitrite, pH, ketones, bilirubin, ascorbic acid and urobilinogen by visual comparison with a color chart for each concentration range.

The strips may be used visually, requiring no additional laboratory equipment for testing. The strips can also be read instrumentally using OneStepPlus or Urispec® Plus urine strip readers.

INSTRUCTIONS FOR USE

Dip the reagent strip for approximately 1 second into the fresh urine. Draw it across the rim of the container to remove excess urine. After 30 to 60 seconds (leucocyte test field after 60 – 120 seconds) compare the test strip with the colour scale. The best time for comparison is after 30 seconds. Colour changes that take place after more than 2 minutes are of no significance. The urine should not be more than 4 hours old when tested.

PRINCIPLE

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

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 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 colour 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 coloured 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 coloured complex.

Ascorbic acid: The detection is based on the decolouration of Tillmans reagent. In the presence of ascorbic acid a colour change takes place from blue to red.

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 colour 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 colour of the test strip changes from deep blue in urine with low ionic concentration through green to yellow in urines with high ionic concentrations.

Leucocytes: 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 colour.

PERFORMANCE CHARACTERISTICS AND EVALUATION SOURCES OF ERROR

Blood: The minimum sensitivity of the test strip is 5 erythrocytes/µL urine corresponding to approx. 0.015 mg hemoglobin/dL urine. Intact erythrocytes are indicated by flecky discolourations of the test field. The colour 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

Larger amounts of ascorbic acid which may be present in urine after a high intake of vitamin C (e.g. vitamin tablets, antibiotics or fruit juices) can lead to lower or falsely negative results. In addition an inhibitory effect is produced by gentisic acid. Falsely positive reactions can also be produced by a residue of peroxide containing cleansing agents.

Urobilinogen: In dependence upon the urine colour 0.5 to 1 mg urobilinogen/dL urine are 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 colour 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, higher 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 colouration.

Bilirubin: The minimum sensitivity of the test strip is 0.5 to 0.75 mg bilirubin/dL urine. The colour 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 colouration 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, higher 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 colour 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 colouration may be masked by the presence of medical dyes (e.g. methylene blue) or beetroot pigments.

Nitrite: The test detects concentrations from 0.05 mg nitrite/dL urine. Every pink colour indicates a bacterial infection of the urinary tract. The colour 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 antibiotics 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 5 mg/dL acetoacetic acid or 50 mg/dL acetone are indicated. The colour 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 colours. ß-Hydroxybutyric acid is not detected. Phthalein compounds interfere by producing a red colouration.

Ascorbic acid: The colour fields correspond to the following values:

0 (negative), 10(+) and 20(++) mg/dL or
0 (negative), 0.6(+) and 1.1(++) mmol/L

The glucose and blood test must be repeated if the ascorbic acid reaction is positive, however, at the earliest 10 hours after the last vitamin C intake, because an ascorbic acid content of as little as 5 mg/dL can disturb the glucose and blood assay in low concentrations.

Glucose: Pathological glucose concentrations are indicated by a colour change from green to bluish green. Yellow or greenish test fields should be considered negative or normal. The colour 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

Larger amounts of ascorbic acid which may be present in urine after a high intake of vitamin C (e.g. vitamin tablets, antibiotics or fruit juices) can lead to lower or falsely negative results. In addition 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 colour 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. Urines from adults 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 urines specific gravity in dependence on glucose concentrations of > 1000 mg/dL (> 56 mmol/L) cannot be demonstrated by the strips. Elevated specific gravity readings may be obtained in the presence of moderate quantities of protein. Highly buffered alkaline urines may cause low readings.

Leucocytes: The test records values starting from approx. 10 leucocytes/µL urine. Changes in colour that can not be assigned to the negative reference field and faint violet colours after 120 seconds must be evaluated as positive. The colour reference fields correspond to the following leucocyte concentrations:

negative (normal), 25, 75, 500 leucocytes/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. Boric acid used as preservative decreases the sensitivity of the reaction. Excretion of bilirubin, nitrofruantoin or other strongly-coloured compounds may disguise the colour 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	59 µg	sulfanilic acid	80 µg	methyl red	2.8 µg
cumene hydroperoxide	253 µg	quinoline derivative	25 µg	bromothymol blue	10 µg
Urobilinogen:		**Ketones:**		**Specific Gravity:**	
diazonium salt	28 µg	sodium nitroprusside	116 µg	bromothymol blue copolymer	12 µg 295 µg
Bilirubin:		**Ascorbic Acid:**		**Leucocytes:**	
diazonium salt	26 µg	2.6-dichlorophenolindophenol	7.5 µg	carboxylate diazonium salt	10.6 µg 4.4 µg
Protein:		**Glucose:**			
tetrabromophenol blue	7.5 µg	glucose	3.2 U		
		peroxidase	0.2 U		
		o-tolidine	65 µg		

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 medicaments or their metabolic products on the test is not known in all cases. In case of doubt it is recommended not to take the medicaments and then repeat the test.

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 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 colour charts on the bottle label. HOLD STRIP CLOSE TO COLOUR BLOCKS-MATCH CAREFULLY.
5. Some colours 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. Colour changes that take place after more than 7 minutes are of no significance.

QUALITY CONTROL

For best results, the performance of the reagent strips should be confirmed by use of commercially available positive and negative control materials. Positive and negative controls should be analyzed on each day of testing, whenever a new bottle of strips is opened, whenever a new lot of strips is started, and every 30 days to check storage conditions. Each laboratory should establish its own goals for adequate standards of performance, and should question handling and testing procedures if these standards are not met.

RESULTS

Results with test strips are obtained in clinically meaningful units directly from the colour chart comparison.

STORAGE AND STABILITY HANDLING

Urispec® 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.

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