

URICHECK

Urine test strips

Reagent strips for the rapid visual determination of Urobilinogen, Glucose, Bilirubin, Ketones (Acetoacetic Acid), Specific Gravity, Blood, pH, Protein, Nitrite, Leukocytes and Ascorbic Acid in urine.

I. SUMMARY AND EXPLANATION

URICHECK reagent strips are dip-and-read test strips for *in vitro* diagnostic use only for testing above items in urine. Test result may provide information regarding the status of carbohydrate metabolism, kidney and liver function, acid-base balance, and urinary tract infection. It is measured by comparison of test paper attached to a plastic strip with the color chart blocks printed on the vial label. When tested visually, the directions must be followed exactly.

II. WARNING AND PRECAUTIONS

For *in vitro* diagnostic use only.

For professional use only.

III. CHEMICAL PRINCIPLES OF PROCEDURE AND INGREDIENTS

- **Urobilinogen:** The test is based on the Ehrlich's reaction. Color changes from light orange-pink to dark pink.

Ingredients: 4-Methoxybenzenediazonium 2.9 mg

- **Glucose:** Glucose oxidase catalyzes the oxidation of glucose to form hydrogen peroxide. The hydrogen peroxide thus formed then oxidizes a chromogen on the reaction pad by the action of peroxidase.

Ingredients: Glucose oxidase 430U, Peroxidase 200U, Potassium iodide 12 mg.

- **Bilirubin:** Azo-coupling reaction of bilirubin with a diazonium salt in an acid medium to form an azodye. Color changes from light tan to beige or light pink.

Ingredients: Sodium nitrite 0.733 mg, 2,4-dichlorobenzene diazonium 2.3 mg, Sulfosalicylic acid 25 mg

- **Ketones:** Legal's test-nitroprusside reaction. Acetoacetic acid in an alkaline medium reacts with nitroferricyanide to produce a color change from beige to purple.

Ingredients: Sodium nitroprusside 23.0 mg

- **pH:** Double indicator system. Indicator's methyl red and bromothymol blue are used to give distinct color changes from orange to green to blue. (pH 5.0 to 9.0)

Ingredients: Methyl red 0.05 mg, Bromothymol blue 0.5 mg

- **Blood:** The test is based on the Pseudo-peroxidase activity of the haem moiety of hemoglobin and myoglobin. The chromogen is oxidized by a hydroperoxide in the presence of haem and changes color from yellow to blue.

Ingredients: Cumene Hydroperoxide 12 mg, o-Toluidine 35 mg

- **Specific Gravity (SG):** Ionic solutes present in the urine cause protons to be released from a polyelectrolyte. As the protons are released, the pH decreases and produces a color change of bromothymol blue from blue-green to yellow-green.

Ingredients: Bromothymol blue 0.5 mg

Poly vinyl ether-ALT-maleic acid anhydrous 140.5 mg

- **Protein:** Protein "error of indicators." When pH is held constant by a buffer, indicator dyes release H⁺ ions because of the protein present and change color from yellow to blue-green.

Ingredients: Tetrabromophenol blue 0.34 mg

- **Nitrite:** The test is based on the diazotization reaction of nitrite with an aromatic amine to produce a diazonium salt. It is followed by an azo-coupling reaction of this diazonium salt with an aromatic compound on the reaction pad. The azo dye produced causes a color change from white to pink.

Ingredients: P-arsanilic acid 4.5 mg

- **Leukocyte:** This test pad contains an indoxyl ester and diazonium salt. It is followed by an azo-coupling reaction of the aromatic amine formed by leukocytes esterase with a diazonium salt on the reaction pad. The azo dye produced causes a color change from beige to violet.

Ingredients: Induced Indole amino acid ester 1.3 mg

- **Ascorbic acid:** The test field involves the decolorization of Tillmann's reagent. The presence of ascorbic acid causes the color of the test field to change from gray-blue to yellow.

Ingredients: 2,6-dichloro indophenol sodium salt 0.8 mg

IV. STORAGE AND HANDLING

Store in a cool, dry place at temperatures between +2°C and +30°C. Do not store the strips in a refrigerator or freezer. Store away from moisture and light. When stored in the original container, the product is stable up to the expiry date printed on the bottom of the container.

Replace the bottle cap immediately and tightly after removing test strips, and keep the vial tightly closed between tests.

Do not remove desiccant from bottle. Do not touch test areas of urine reagent strips. Do not open container until ready to use. After removing from the tube, the strip must be used within 30 minutes.

Discoloration or darkening of the test pads may indicate deterioration. If this is evident, or if test results are questionable or inconsistent with expected finding, confirm that the product is within its expiry date and is reacting properly, using known negative and positive control materials.

V. SPECIMEN COLLECTION AND PREPARATION

Collect urine in a clean, dry container that allows complete immersion of all the fields on the test strip. Do not add preservatives. Test the specimen as soon as possible, with the sample well mixed but not centrifuged. The use of fresh morning urine is recommended for optimal nitrite tests, as well as for the valid determination of bilirubin and urobilinogen, since these compounds are unstable when exposed to light.

If immediate testing is not possible, the sample should be stored in the refrigerator, but not frozen, and then brought to room temperature before used in the test. Unpreserved urine at room temperature may undergo pH changes due to microbial proliferation, which may interfere with protein determination.

If cleanly voided specimens are not collected from females, positive results for leukocytes may be found due to contamination from outside the urinary tract. Skin cleansers containing chlorhexidine may affect protein test results, if specimen contamination occurs.

VI. VISUAL TEST PROCEDURE

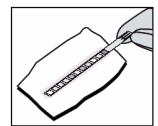
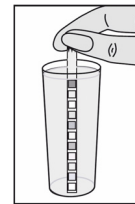
The procedure must be followed exactly to achieve reliable results.

a) Dip the strip into the urine up to the test area for no more than two seconds.

b) Draw the edge of the strip along the brim of the vessel to remove excess urine; at this time, don't make the test areas touch to the brim of the vessel.

c) Turn the strip on its side and tap once on a piece of absorbent material to remove any remaining urine; excessive urine on the strip may cause the interaction of chemicals between adjacent reagent pads, so that an incorrect result may occur.

d) After the proper time, compare the test results carefully with the color chart on the vial label, under good light. While comparing, keep the strip horizontally to prevent possible mixing of chemicals, when excessive urine is present.



VII. QUALITY CONTROL

For best results, performance of reagent strips should be confirmed by testing known negative and positive specimen or controls (e.g., Bio-Rad Level 1, Level 2 control solution) whenever a new bottle is first opened. Each laboratory should establish its own goals for adequate standards of performance. Each lab worker should ensure that it complies with government and local requirements.

VIII. PERFORMANCE CHARACTERISTICS

a) Sensitivity and Specificity

Performance characteristics are based on clinical and analytical studies and depend upon several factors: the variability of colour perception; the presence or absence of inhibitory and matrix factors typically found in urine; and the laboratory conditions in which the product is used (e.g., lighting, temperature and humidity). Each colour block represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between normal levels may give results at either level. Results will usually be within one level of the true concentration. The following list shows the generally detectable levels of the analytes in contrived urines; however, because of the inherent variability of clinical urines, lesser concentrations may be detected under certain conditions.

Test Pad and Sensitivity (Specificity)

Urobilinogen: 2 EU/dL (Urobilinogen)

Glucose: 100 mg/dL (Glucose)

Bilirubin: 0.5 mg/dL (Bilirubin)

Ketones: 5 mg/dL (Acetoacetic acid)

Blood: 10 RBC/ μ L (0.03mg/dL hemoglobin, Intact RBC)

Protein: 10-15 mg/dL (albumin)

Nitrite: 0.05 mg/dL (Nitrite ion)

Leukocytes: 20-25 WBC/ μ L (Intact and lysed WBCs)

Ascorbic acid: 20 mg/dL (Ascorbic acid)

b) Expected values

- **Urobilinogen:** The normal urobilinogen range is 0.1 to 1.0 Ehrlich unit /dl. If results exceed the concentration of 2.0 mg/dL, the patient and the urine specimen should be evaluated further.

- **Glucose:** The kidney normally excretes small amounts of glucose. Concentrations of 100 mg/dL may be considered as abnormal if found consistently.

- **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.

- **Ketones:** Ketone bodies should not be detected in normal urine specimens with this reagent.

- **pH:** Urine values generally range from pH 5 to 9.

- **Blood:** Normally, no hemoglobin is detectable in urine (0.010 mg/dL; 3 RBC/ μ L). When hemoglobin appears in urine, it indicates kidney disease or urinary tract disorder. Blood may often be found in the urine of menstruating females.

- **Specific Gravity (SG):** The normal SG of urine ranges from 1.001 to 1.035.

- **Protein:** Normal urine specimens ordinarily contain some protein (<20 mg/dL); therefore only persistent elevated levels of urine protein indicate kidney or urinary tract disease. The persistent results of trace level, or over, indicate significance proteinuria and thus further clinical testing is needed to evaluate the significance of results.

- **Nitrite:** Normally no nitrite is detectable in urine.

- **Leukocyte:** Normally no leukocytes are detectable in urine.

- **Ascorbic acid:** The average daily intake ranges from 30-80 mg, with an output of 20-30 mg/day.

IX. LIMITATIONS OF PROCEDURE

As with all laboratory tests, definitive diagnostic or therapeutic decisions should not be based on any single result of method. Substances that cause abnormal urine color may affect the readability of test pads in urine reagent strips.

- **Urobilinogen:** The absence of urobilinogen in the specimen cannot be determined. The test area will react with interfering substances known to react with Ehrlich's reagent, such as p-aminosalicylic acid (\geq 1125mg/dL). Drugs containing azo gantrisin ($>$ 100mg/dL) may give a masking golden color. The test is not a reliable method for the detection of porphobilinogen.

- **Glucose:** High SG ($>$ 1.030) with high pH ($>$ 9) urine and ascorbic acid (more than 40 mg/dL) may cause false negative result at the low level of glucose. Ketones reduce the sensitivity of the test. Moderately high ketone level ($>$ 40 mg/dL) may cause a false negative for specimen containing small amount of glucose (100 mg/dL). Reactivity may be influenced by urine SG and temperature.

- **Bilirubin:** Metabolites of drugs, such as selenium ($>$ 200mg/dL) which give a color at low pH, may cause false positives. Indican (indoxyl sulfate) can produce a yellow-orange to red color response, which may interfere with the interpretation of negative or positive bilirubin readings. Ascorbic acid ($>$ 30 mg/dL) may cause false negative result.

- **Ketones:** Positive results (trace or less) may occur with highly pigmented urine specimens. Formaline (\geq 1000mg/dL) may cause false negative result. Low pH ($<$ 5) urine may give false positive result. Phenylpyruvic acid ($>$ 100mg/dL) may cause false positive result.

- **pH:** If excessive urine remains on the strip because of improper test procedure, it is possible that the acidic buffer in protein portion comes out and affect the pH portion, then pH result may be decreased than the actual. This phenomenon is called "run-over effect."

- **Blood:** Elevated specific gravity or protein in urine may reduce the reactivity of the blood test portion. Microbial peroxidase associated with urinary tract infection may cause false positive results. Ascorbic acid concentrations ($>$ 30 mg/dL) may cause false negatives at the low level of blood. Nitrofurantion (\geq 200mg/dL) may cause false positive result.

- **Specific Gravity (SG):** High-buffered alkaline urine may cause diminished result, whereas high-buffered acidic urine may cause slightly elevated result.

- **Protein:** False positive results may be found in strongly basic urine (pH 9). The interpretation of results is also difficult in turbid urine specimens.

- **Nitrite:** Ascorbic acid (\geq 40 mg/dL) may cause false negative result with low level of nitrite containing ($<$ 0.03 mg) urine. The negative result does not always mean that the patient is free from bacteriuria. Pink spots or pink edges should not be interpreted as a positive result. Negative result may occur when urinary tract infections are caused by organism which do not contain nitrate reductase; when urine has not been retained in the bladder long enough (four hours or more) for reduction of nitrate to nitrite occur; or when dietary nitrate is absent.

- **Leukocyte:** The test result may not always be consistent with the leukocyte cell number by the microscopic examination. High concentration of glucose (\geq 2000mg/dL), high specific gravity ($>$ 1.030), high level of albumin ($>$ 1000mg/dL), high concentration of formaldehyde (\geq 150mg/dL) or presence of blood may cause decreased test results. Urobilinogen (\geq 9mg/dL) may cause false positive. False positive results may occasionally be due to contamination of the specimen by vaginal discharge.

- **Ascorbic acid:** No interferences are known.

X. BIBLIOGRAPHY

1- **NCCLS (National Committee for Clinical Laboratory Standard)** GP 16-A/ Routine urinalysis and collection transportation and preservation of urine specimens; Approved Guideline VOL 12-NO 26, EC.1992

2- **B.Berg, K.Hellsing, R.Jagenburg & A.Kallner.** Guidelines for evaluation of reagent strips. Scand. J. Clin. Lab. Invest. 1989;49;689-699.

3- **Kaplan L. A. and Pesce A.J.,** Clinical Chemistry Theory, Analysis and correlation, C.V.MOSBY. PP. 1004 –1007 (1984).



Temperature limitation



Consult operating instructions



Do not re-use



In vitro diagnostic use



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