TOYO DIAGNOSTICS

URINALYSIS REAGENT STRIPS (11 PARAMETERS)

FOR PROFESSIONAL USE ONLY.

PRODUCT CODE: TUS02

INTENDED USE

Urinalysis Reagent Strips test for ascorbic acid, glucose, bilirubin, ketone, specific gravity, blood, pH, protein, urobilinogen, nitrite, leukocytes. The strips may be read visually or instrumentally, using the appropriate Urine Chemistry Analyzers.

SAMPLE COLLECTION AND PROCEDURE

1. To obtain accurate results, use fresh urine samples. If urine sample cannot be used immediately, samples should be stored at 4 °C for 2 hours. Prior to test, bring the samples to room temperature.
2. Remove one strip from the bottle and replace the cap tightly. Briefly (no longer than one second) immerse all reagent areas into the sample. Wipe off excess urine on the rim of the container. Furthermore, lightly dab off the residual urine with a piece of tissue paper at the rim of the strip. All patient samples should be handled as taking capable of transmitting disease into consideration.
3. Hold strip in horizontal position immediately. Refer to bottle label for specific reagent areas on the test strip. Compare the test areas with the color scale on the bottle label. Proper reading times are critical for optimal results. See each reagent time as indicated on bottle label.
4. Coloration appearing only along the edges of the test, or appearing after more than two minutes, has no diagnostic value.
5. The reagent strips must be kept in the bottle with tightly closed cap to maintain reagent activity. Please refer to bottle label for specific reading time for each reagent.

LIMITATION

As with all laboratory tests, definitive diagnostic or therapeutic decision should not be based on any single test result or method. For only in vitro diagnostic use. Each strip is for single use. Do not touch test areas.

STORAGE

Do not remove desiccants from the bottle. Store at 2 - 30°C (36-86°F). Test strips should be kept away from direct sunlight, moisture, heat and radiation sources. Do not use after expiry date.

REAGENT AREA INFORMATION (please refer to the ingredients on bottle label)

Leukocytes

Normal urine samples generally yield negative results; positive results are clinically significant. Individually observed "Trace" results may be questionable clinical significance; however "Trace" results observed repeatedly may be clinically significant. "Positive" results may occasionally be found with random samples from females due to contamination of the sample by vaginal discharge. Higher glucose concentration (166 mmol/L) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, or high concentrations of oxalic acid may also cause a false negative reaction. Nitro-furation gives a brown color to urine that may mask the color reaction on the reagent pad. Any substance that causes abnormal urine color may obscure the color reaction.

Nitrite

This test is specific for nitrite in urine. Pink spots or pink edges should not be interpreted as a positive result. Any degree of uniform pink color development should be interpreted as a positive nitrite test, suggesting the presence of 10^5 or more organisms per ml, but color development is not proportional to the number of bacteria present. A negative result does not prove that there are no significant bacteria in urine. Prolonged urinary retention in bladder (4-8 hours) is essential in order to obtain an accurate result; or test is reduced for urine with high specific gravity. 1,42 mmol/L or greater ascorbic acid concentrations may cause false negative results with samples containing small amounts of nitrite ion. (13 µmol/L or less)

Urobilinogen

This test area will detect urobilinogen as low as 3,3 µmol/L in urine. A result of 34 µmol/L represents the transition from normal to abnormal, and the patient and/or urine sample should be evaluated further. The reagent area may react with substances known to interfere with Erlich's reagent, such as p-aminosalicyclic acid and sulphonamides. Atypical color reactions may be obtained in the presence of high concentrations of p-aminosalicyclic acid. False negative results may be obtained if formalin is present. Highly colored substances, such as azo dyes and riboflavin may mask color development on the test area. Strip reactivity increases with temperature; optimum temperature is 22 - 26°C. The absence of urobilinogen can't be determined with the test.

Protein

The test area is more sensitive to albumin than globulin, hemoglobin, Bence-Jones protein and mucoprotein; a "negative result" does not rule out the presence of other proteins. Normally no protein is detectable in urine by conventional methods although a small amount is excreted by the normal kidney. A color matching with any block greater than "Trace" indicates significant protein in urine. For urine with high specific gravity, highly buffered or alkaline urine, the test area may most closely match with "Trace" color block even though only normal concentrations of protein are present. Further evaluation is needed for "Trace" results. False positive results may also be obtained by contamination of the urine sample with quaternary ammonium compounds or chlorhexidin based disinfectants.

pH

The pH area measures pH value range of 5 - 8,5 visually. If proper procedure is not followed and excess urine remains on the strip, a phenomenon known as 'runover' may occur in which the acid buffer from the protein reagent will run onto the pH area, causing a falsely low pH result.

Blood

The significance of the "Trace" reaction may vary among patients, and clinical judgment is required for assessment in each individual case. Development of green spots or green color on the reagent area within 60 seconds indicates the need for further investigation. Blood is often found in the urine of menstruating females. This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The test is equally sensitive to myoglobin as to hemoglobin. Higher specific gravity or captopril may reduce the reactivity of the blood test. Certain oxidizing contaminants, such as hypochlorite or microbial peri-oxidase associated with urinary track infection may result in false positive. Levels of ascorbic acid normally found in urine do not interfere with the test.

Specific Gravity

This test reflects the ion concentration of urine and correlates well with the refractometric method. If pH is equal or greater than 6.5 then add 0.005 to SG obtained. Instrumental readings are automatically adjusted for Ph by the instrument. The test is affected neither by certain nonionic urine constituents such as glucose nor by the presence of radiopaque dye. Highly buffered alkaline urines may cause low readings relative to other methods. Higher specific gravity readings may be obtained in the presence of moderate quantities (1 - 7.5 g/L) of protein.

Ketones

The test reacts with acetoacetic acid in urine. It does not react with acetone or ßhydroxybutyric acid. Some high specific gravity / low pH urine may give reactions up to and including "Trace". Clinical judgment is needed to determine "Trace" results. Normal urine samples usually yield negative results. Detectable levels of ketone may occur in urine during physiological stress conditions such as fasting, pregnancy and frequent strenuous exercise. In ketoacidosis, starvation or with other abnormalities of carbohydrate or lipid metabolism, ketones may appear in the urine in large amounts before serum ketone is elevated. False positive results (Trace) may occur with highly pigmented urine samples or those containing large amounts of levodopa metabolites. Compounds such as Mesna that contain sulfhydryl groups may cause false positive results or an atypical color reaction.

Bilirubin

Normally no bilirubin is detected in the urine by even the most sensitive methods. Even trace amounts of bilirubin in urine are sufficiently abnormal and it is required further investigation. Atypical colors may indicate that bilirubin derived bile pigments are present in urine sample and may be masking the bilirubin reaction. These colors may indicate the urine sample should be tested further. Indican (indoxyl sulfate) can produce a yellow-orange to red color response which may interfere with the bilirubin reading. Ascorbic acid concentrations of 1,4 mmol/L or greater may cause false negatives.

Glucose

The test is specific for glucose. In dilute urines, containing less than 0.3 mmol/L ascorbic acid, as little as 2.2 mmol/L of glucose, may produce a color change that might be interpreted as positive. Ascorbic concentrations of 3 mmol/L or greather and/or high ketone concentrations (4 mmol/L) may give false negative for samples containing small amounth of glucose (4-7 mmol/L).
The reactivity may also vary with temperature. Small amount of glucose is normally excreted by the kidney. These amounts are usually below the sensitivity of this test, but on occasion may produce a color between the "Negative" and the 6 mmol/L color blocks.

Ascorbic Acid

The test is based on the principle of Tillman's reagent. Ascorbic acid can reduce indicator and cause color changing from blue to orange. This test can be used to determine ascorbic acid concentration in sample and decide ascorbic acid's interference.

SPECIFIC CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical samples, the sensitivity depends on several factors: the variability of color perception, specific gravity, pH, and the lighting conditions when the product is read visually. Each color block or instrumental display value represents a range of values. Because of sample and reading variability, samples with analytic concentrations that fall between two levels may give results at either level.

The following table lists the generally detectable levels of analyses in contrived urine; however, concentrations may be detected under certain conditions:

Reagent Area	Sensitivity	Visual Range
Glucose(Glucose)	4-7 mmol/L	0-111 mmol/L
Bilirubin(Bilirubin)	7-14 µmol/L	0-100 µmol/L
Ketone(Acetoacetic Acid)	0.5-1.0 mmol/L	0-16 mmol/L
Blood(Hemoglobin Or Red Cell)	105-450 µg/L 5-15 cells/µL	0-200 cells/µL
Protein(Albumin)	0.15-0.30 g/L	0-20.0 g/L
Urobilinogen(Urobilinogen)	3.3-16 µmol/L	3.3-131 µmol/L
Nitrite(Nitrite Ion)	13-22 µmol/L	(-)(+)
Leukocytes(White Cell)	5-15 cells/µL	0-500 cells/µL
pH	N/A	5.0-8.5
Specific Gravity	N/A	1.000-1.030
Ascorbic Acid	0.5-0.6 mmol/L	0.5-5.0 mmol/L

INGREDIENTS (100 Strips) :

Glucose	Glucose oxidase	3.50 mg
	Peroxidase	0.60 mg
	Potassium iodide	6.50 mg
Bilirubin	2,4-Dichloroaniline diazonium sal	2.20 mg
Ketone	Sodium nitroprusside	25.0 mg
Specific Gravity	Bromothymol blue	0.30 mg
	Poly (methly vinyl ether maleic acid sodium salt)	15.0 mg
pH	Methy red	0.05 mg
	Bromothymol blue	1.00 mg
	Isopropylbenzene hydroperoxide	18.0 mg
Blood	3,3'-Dimethylbenzidine	5.50 mg
	Tetrabromphenol blue	0.30 mg
Protein	p-Dimethylaminobenzaldehyde	1.50 mg
Urobilinogen	p-Arsanilic acid	6.80 mg
Nitrite	N-(1-Naphthyl) Ethylenediamine	2.40 mg
Leukocytes	3-Indoly-phenol ester	6.00 mg
	Benzendiazonium salt	0.40 mg
Ascorbic Acid	2,6-dichrophenol-indophenole	16.5mg

REFERANCES

1. Ahmed Z, Lee J. Asymptomatic urinary abnormalities. Hematuria and proteinuria. Med Clin North Am 1997; 81:641-52.
2. Eidelman Y,Raveh D, Yinnoh AM, Ballin J, Rudensky B, Gottehrer NP. Reagent strip diagnosis of UTI in a high risk population. Am J Emerg Med 2002;20:112-3.
3. Hanno PM, Wein AJ, Malkowicz SB., Clinical manual of urology. 3rd ed. New York: McGraw Hill, 2001.
4. Lammers RL, Gibson S, Kovacs D, Sears W, Strachan G,. Comparison of Test Characteristics of urine dipstick and urinalysis at various test cut off points. Ann Emerg med. 2001; 38:505-12.
5. Rabinovitch A. Urinalysis and collection, transportation and preservation of urine specimens: approved guideline. 2nd ed. Wayne Pa.: National Committee For Clinical Laboratory Standards, 2001. NCCLS document GP 16-A2.

TURKLAB TIBBİ MALZ. TİC. A.Ş.
i.A.O.S.B. 10040 Sok. No: 20 35620 Çiğli - İzmir - TURKEY
Phone : +90.232.376 80 81 pbx Fax: +90.232.376 80 40 www.turklab.com.tr e-mail: info@turklab.com.tr

EC REP **GESAN PRODUCTION s.r.l.** Via Einaudi, 19-91021
TRE FONTANE - Campobello di Mazara (TP) ITALY

Manufacturer | Attention, see instruction for use | IVD *In vitro* diagnostic medical device | For single use only

EC REP Authorized European Representative | Consult instruction for use | Σ_n Number of test | Storage temperature

CE | LOT Lot number | REF Catalog number | Expiry date

Exp. Date : Please refer to expiry date on the bottle or package.

Instruction for use preparation date: 25.12.2009 Rev.: 1

C08.TUS.03