URINE STRIPS

IN VITRO DIAGNOSTIC STRIPS DETERMINATION OF URINE PARAMETERS

GENUINE BIOSYSTEM

Kit name	Kit size	Cat. No
UROGB US-11	100 Strips	GB16DR

INTRODUCTION

UROGB US-11 urine reagent strips provide tests for the semi-quantitative measurement of leukocytes, ketone, nitrite, urobilinogen, bilirubin, protein, glucose, specific gravity, blood, pH and ascorbic acid in urine. For use with the **UROGB - 120 & UROGB - 520** urine analyzers. The test is intended for use by health care professionals

SUMMARY

UROGB US-11 urine reagent strips consist of a plastic strip affixed with reagent papers and a calibration pad. This feature facilitates measurement of multiple urine constituents and use for everyday diagnosis and group examinations. The calibration pad, which is not impregnated with reagents, allows instrumental correction interference from natural color of urine automatically and obtains accurate result.

TEST PRINCIPLES AND LIMITATION

Leukocytes: The test reveals the presence of granulocyte esterases. These esterases cleave an indoxyl ester, and the indoxyl so liberated reacts with a diazonium salt to produce a violet dye.

Leukocyte esterase results may be positive in the absence of observable cells if the leukocytes have lysed. Positive results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (55-110 mmol/L) or high specific gravity may cause decreased test results. The presence of cephalexin, cephalothin, tetracycline may cause decreased reactivity, and high levels of the drug may cause a false negative reaction. The test area does not react with lymphocyte.

Ketone: This test is based on the principle of Legal's test and is more sensitive to acetoacetic acid than to acetone.

The reagent area does not react with β-hydroxybutyric acid. Some high specific gravity/low pH urines may give reactions up to and including Trace. Normal urine specimens usually yield negative results with this reagent. False positive results (Trace) may occur with highly pigmented urine specimens or those containing large amounts or levodopa metabolites.

Nitrite: The test is based on the principle of Griess's test and is specific to nitrite. Any degree of uniform pink colour development should be interpreted as a positive.

Nitrite test suggesting the presence of 10^5 or more organisms per mL, but colour development is not proportional to the number of bacteria present. A negative result does not in itself prove that there is no significant bacteriuria. Negative results may occur when urinary tract infections are cause by organisms which do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (4-8hrs) for reduction of nitrate to occur; or when dietary nitrate is absent, even if organisms containing reductase are present and bladder incubation is ample. Ascorbic acid concentrations of 1.4mmol/L or greater may cause false negative results with specimens containing nitrite ion concentrations of 58μmol/L or less.

Urobilinogen: This test is based on the Ehrlich reaction.

The reagent area may react with interfering substances known to react with Ehrlich's reagent. Excreted pigments and medicaments that have a red intrinsic coloration in acidic medium may produce false positive results. This test is inhibited by elevated concentrations of formaldehyde. Strip reactivity increases with temperature; the optimum temperature is 22℃ to 26℃. The absence of urobilinogen cannot be determined with this test.

Bilirubin: This test is based on the coupling of bilirubin with diazonium salt in an acid medium.

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. Some urine constituents (medicines, urinary indicants) may produce a yellowish or reddish discoloration of the test paper that may interfere with interpreting the result. Ascorbic acid concentrations of 5.6mmol/L or greater may cause false negatives.

Protein: The test is based on the principle of the protein error of a pH indicator.

The reagent area is more sensitive to albumin. An elevated pH (up to 9) may affect the test. The residues of disinfectants containing quaternary ammonium groups or chlorohexidine are present in the urine vessel maybe lead to a false positive result.

Glucose: The test is based on the specific glucose oxidase/peroxidase reaction.

The test is specific for glucose, no substance excreted in urine other than glucose is known to give a positive result. Ascorbic acid of more than 2.52mmol/L and/or high Ketone concentrations (8mmol/L) may cause false negatives for specimens containing small amounts of glucose (5.5mmol/L). The reactivity of the glucose test decreases as the SG of the urine increases. False positive reactions may be caused by hypochlorite or peroxide (cleaning agents). Reactivity may also vary with temperature.

Specific Gravity: This test contains a detergent and Bromthymol blue that indicates the presence of ionic constituents in the urine by changing color from green to yellow.

The specific gravity test permits determination of urine specific gravity between 1.005 and 1.030. In general, it correlates within 0.005 with values obtained with the refractive index method. Strips are automatically adjusted for pH by the instrument when pH≥7.0 or pH≤5.0. Highly buffered alkaline urine may cause low readings relative to other methods. Elevated specific gravity readings may be obtained in the presence of moderate quantities (5g/L) of protein.

Blood: Hemoglobin and myoglobin catalyze the oxidation of the indicator by means of organic hydroperoxide contained in the test paper.

This test is highly sensitive to hemoglobin and thus complements the microscopic examination. The sensitivity of this test may be reduced in urine with high specific gravity. The test is equally sensitive to myoglobin as to hemoglobin. Captopril and Lodine may also cause decreased reactivity. Blood is often found in the urine of menstruating females. Certain oxidizing contaminants, such as hypochlorite, may produce false positive results. Microbial peroxidase associated with urinary tract infection may cause a false positive reaction. Ascorbic acid concentrations greater than 1.4mmol/L may cause false negatives at the trace levels.

pH : This test contains a mixed indicator which assures a marked change in colour between pH4.5 and pH92.

Microalbuminurea: Based on the protein deviation method, utilizing the sulfonepthalein dyestuff only specific to microalbumin.

SENSITIVITY

Sensitivity is dependent upon the presence or absence of interfering specimens.

Urobilinogen	17-33μmol/L
Blood	0.15-0.3mg/L hemoglobin (about 5-10Ery/μL)
Bilirubin	8.6-17μmol/L
Ketone	0.5-1.0mmol/L acetoacetic acid
Leukocytes	15-40 cells/μL granulocyte
Glucose	2.2-2.8 mmol/L
Protein	0.1-0.3g/L
pH	----
Nitrite	18-26μmol/L
Specific gravity	-------
microalbuminurea	0.08-0.15 gl/L

REAGENTS COMPOSITION

Based on the dry weight content of each areas of 100 strips:

Leukocytes: indoxyl ester 1.4mg;diazonium salt 0.7mg.

Ketone : sodium nitroprusside 30.0mg.

Nitrite : sulfanilamide 0.65mg;N-(naphthyl)-ethylenediammonium dihydrochloride 0.45mg.
Urobilinogen: fast blue B salt 1.2mg.
Bilirubin : 2,4-dichlorobenzene diazonium 14.3mg.
Protein : tetrabromphenol blue 0.36mg.
Glucose : glucose oxidase 800 I.U.; peroxidase 200 P.U.;4-aminoantipyrine 2.0mg.

Specific Gravity : bromthymol blue 0.4mg.
Blood : cume hydroperoxide 35.2mg, 3,3',5,5'-Tetramethylbenzidine 15.0mg.
pH : bromxylenol blue 3.3mg; bromocresol green 0.2mg.
Microalbuminurea : 2.2% w/w sulphonephthalein dyestuff; 96% w/w buffer, 1.8% w/w non-reactive ingredients

TESTING PROCEDURE
Please refer to the User's manual of the UROGB urine analyzer.

PRECAUTIONS
1. HANDLING

Use only clean vessels to collect urine. False-positive readings for blood and glucose can result from residues of strongly oxidizing disinfectants in the specimen collection vessel. Do not add preservatives to the urine. Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially low results for these two paraments.

2. OPERATION

Incorrect results may be obtained when you shake the strip in specimen container. The dipping time is too short or too long may result in a negative error.

HANDLING CARE

Improper storage may cause insufficient performance of test strips. Return to room temperature before use. Do not use deteriorated, discolored or blackened test strips. Avoid contamination by volatile chemicals. Do not touch test papers of reagent strips.

PLEASE NOTE
On principle, diagnosis or therapy should not be based on one test result alone but should be established in the contest of all other medical findings. Knowledge of the effects of drugs or their metabolites upon the individual tests is not yet complete. In doubtful cases, it is therefore advisable to repeat the test after discontinuing a particular drug. Large amounts of ascorbic acid in the urine can produce artificially low to false-negative results for glucose, blood, nitrite and bilirubin.

STORAGE AND STABILITY
Store at temperatures between 2℃ to 30℃ avoiding humidity, direct sunlight or heat. Store only in original bottle. Do not remove desiccants. Do not remove strip from the bottle until immediately before it is to be used for testing. Replace cap immediately and tightly after removing reagent strip. Unused strips that remain in the original capped container are stable within 3 month. Do not use reagent strips after expiry date printed on the label of the vial.

AVAILABILITY
100 strips per container.

IVD CE

Genuine Biosystem Private Limited
Plot No.97 & 98, kattabomman street,
Parvathy Nagar Extension,
Old Perungalathur, Chennai - 600063, India.
Ph: +91-44-48681845
Email: genuinebiosystem@gmail.com
website: www.genuinebiosystem.com

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