URIT 14G Urine Reagent Strips

PLEASE CAREFULLY READ THIS PACKAGE INSERT BEFORE USE.
For In Vitro Diagnostic Use Only. For Instrument Use Only.

INTENDED USE

URIT 14G urine reagent strips provide tests for the semi-quantitative measurement of leukocytes, ketone, nitrite, urobilinogen, bilibrubin, glucose, protein, specific gravity, pH, blood, ascorbic acid, microalbumin, calcium and creatinine in urine. Use with the **URIT-50, 180, 500B, 500C, 330, 31, 560** urine analyzer.

SUMMARY

URIT 14G 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 LIMITATIONS

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 ($\geqslant$ 55mmol/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. Reactivity may also vary with temperature.
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 suggests 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 caused by organisms which do not contain reductase to convert nitrate to nitrite; when urine has not been retained in the bladder long enough (4hrs - 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 43μmol/L or less.
Urobilinogen: This test is based on the Ehrlich reaction.
This test area will detect urobilinogen in concentrations as low as 3μmol/L(approximately 0.2 Ehrlich unit/dL) in urine. 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°C- 26°C. 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 1.4mmol/L or greater may cause false negatives.
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 1.4mmol/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.
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 chlorhexidine are present in the urine vessel maybe lead to a false positive result.
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 $\geqslant$ 7.0 or pH $\leqslant$ 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.
pH: This test contains a mixed indicator which assures a marked change in colour between pH5.0 and pH9.
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 (Hemoglobin concentration of 150 μg/L - 620 μg/L is approximately equivalent to 5-15 intact red blood cells per microlitre). 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 of 1.4mmol/L or greater may cause false negatives at the trace levels.
Ascorbic Acid: The test involves the decolorization of Tillman's reagent. False positive reaction with other reducing agent.
Microalbumin: The albumin's reaction is more sensitive than the reaction of globulin、hemoglobin、Bence-Jones protein and mucin, thus the negative result does not rule out the existence of above mentioned proteins in urine. When the results is 20mg/L - 200mg/L, it is indicated as microalbuminuria, and when the results is beyond 200mg/L, it is indicated as clinical albuminuria. This action is few effect by creatinine and hemoglobin etc. High cushion of urine and alkaline urine may cause false positive result.
Calcium: The test is based on the calcium ion in urine react with OCPC to produce a color change.
A great number of magnesium ion in urine may affect the test.
Creatinine: The test is based on the creatinine in urine react with 3,5-Dinitrobenzoic acid to produce a color change.
Daily Creatinine excretion, related to muscle mass of the human body, is usually constant. Some compounds , physical properties and high-concentration yellow pigment that may affect the test result.
Microalbumin-to-Creatinine Ratio: For the MA, to combine with creatinine and get the ratio can reduce the stochastic error. Normally, the ratio is lower than 3.4mg/mmol, when the ratio is between 3.4 mg/mmol to 33.9mg/mmol, it is abnormal, and when it is beyond 33.9mg/mmol, it is highly abnormal.

SENSITIVITY

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

Leukocytes	(15-40) CELL/μL granulocyte	Ketone	(0.5-1.0) mmol/L acetoacetic acid
Nitrite	(18-33) μmol/L nitrite	Urobilinogen	(17-33) μmol/L urobilinogen
Bilirubin	(8.6-17) μmol/L	Glucose	(2.2-2.8) mmol/L
Protein	(0.1-0.3) g/L albumin	Blood	(0.15-0.3) mg/L hemoglobin
Ascorbic Acid	(0.6-0.85) mmol/L	Microalbumin	(20-30) mg/L albumin
Calcium	(2.0-2.5) mmol/L Calcium ion	Creatinine	(2.0-3.6) mmol/L

REAGENTS COMPOSITION

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

Leukocytes: indoxyl ester 1.4mg;diazonium salt 0.7mg.
Ketone: sodium nitroprusside 30.0mg.
Nitrite: arsanilic acid 0.7mg;N-(naphthyl)-ethylenediammonium dihydrochloride 0.5mg.
Urobilinogen: fast blue B salt 1.2mg.
Bilirubin: 2,4-dichlorobenzene diazonium 14.3mg.
Glucose: glucose oxidase 800 I.U; peroxidase 200 I.U;4-aminoantipyrine 0.1mg.
Protein: tetrabromphenol blue 0.4mg.
Specific Gravity: bromthymol blue 0.4mg;sodium poly methyl vinyl acetate maleic 16.0mg.
pH: bromocresol green 0.2mg; bromxylenol blue 3.3mg.
Blood: cumene hydroperoxide 35.2mg; 3,3',5,5'-tetramethylbenzidine 2.0mg.
Ascorbic acid: 2,6-dichloroindophenol sodium salt 0.5mg.
Microalbumin: fluorescein dye 0.4mg.
Calcium: O-Cresolphthalein complexone 2.5mg.
Creatinine: 3,5-Dinitrobenzoic acid 5.0mg.

TESTING PROCEDURE

1.Additional materials required: **URIT-50,180, 500B, 500C, 330, 31, 560** urine analyzer.
2.Completely immerse the pads into fresh, well mixed urine, and the sample tube of urine should be higher than 88mm. make sure that all pads are wetted. Remove the strip after 2 seconds. The drip method also permitted.
3.While removing the strip, dragging the edge of the strip against the rim of the urine container to remove excess urine. Blot the strip on length-wise edge, on absorbent paper. Avoid running over contamination from adjacent reagent pads.
4.When interpreting the result by urine analyzer, please follow the respective operating manual.

PRECAUTIONS

1.The test is intended to use by health care professionals.
2.The strip does not apply for visual test, labels on color piece is for reference only, not for test judging.
3.Collect a fresh urine specimen in a clean, dry container. Do not expose urine specimens to sunlight as this induces oxidation of bilirubin and urobilinogen and hence leads to artificially lower results for these two parameters.
4.No touching with hand, the reaction block of reagent strips should keep clean to avoid contamination.
5.Do not remove desiccants. Replace cap immediately and tightly after removing reagent strip, a long time (more than 5 minutes) exposing to moist air can easily lead to inaccurate test results.
6.Do not use reagent strips after expiry date, and do not use deteriorated, discolored or blackened test strips.
7.Return to room temperature before use.
8.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. Avoid contamination by volatile chemicals.
9.The used test strip can not be reused, but should be disposed as general medical waste.

BIOLOGICAL REFERENCE INTERVALS

Leukocytes	0 CELL/μL	Specific Gravity	1.010-1.025
Ketone	0 mmol/L	pH	5.5-7.0
Nitrite	0μmol/L	Blood	<10CELL/μL
Urobilinogen	(3.2-16) μmol/L	Ascorbic Acid	0mmol/L
Bilirubin	0μmol/L	Microalbumin	<20mg/L
Glucose	<2.8mmol/L	Calcium	(1.5-9.0) mmol/L
Protein	<0.15g/L	Creatinine	(2.0-22.0) mmol/L

MEASURING INTERVAL

Leukocytes	(15-500) CELL/μL	Specific Gravity	1.005-1.030
Ketone	(0.5-8.0) mmol/L	pH	5.0-9.0
Nitrite	+	Blood	(10-200) CELL/μL
Urobilinogen	(33-131) μmol/L	Ascorbic Acid	(0.6-5.6) mmol/L
Bilirubin	(8.6-100) μmol/L	Microalbumin	(20-150) mg/L
Glucose	(2.8-55)mmol/L	Calcium	(1.0-10) mmol/L
Protein	(0.15-3.0) g/L	Creatinine	(0.9-26.4) mmol/L

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 room temperature between 2 °C to 30 °C. Store only in original bottle, avoiding humidity, direct sunlight or heat.

EXPIRY

Valid for 18 months. Unused strips that remain in the original capped container are stable within 3 months after it is opened.

AVAILABILITY

100 strips per container.

EXPLANATIONS FOR SYMBOLS ON THE LABEL

IVD In vitro diagnostic medical device
Temperature limit
Do not re-use
Consult instructions for use
LOT Batch-code
Use-by date
Manufacturer
Date of manufacture
Keep away from sunlight
Keep dry
EC REP Authorized Representative in the European Community
CE This product fulfils the requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

EC REP
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