A-Series

Urinalysis Reagent Strips User's Guide

Rev.12/2018

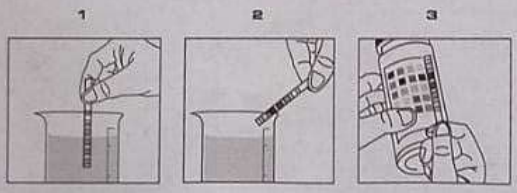
This User's Guide is to be used with the following products:
DIRUI A10/ 9 Items/8 Items/7 Items/5 Items/4 Items(glucose, protein, pH, blood)/4 Items (glucose, protein, pH, SG)/ 3 Items/ 2 Items (Protein-pH)/ 2 Items (bilirubin-Urobilinogen)/2 Items (Glucose-Ketone) /2 Items (Glucose-Protein) / Glucose/ Ketone/ Bilirubin/ Protein/ Blood/ Urobilinogen

General Summary:
This guide instructs the methods, reaction principles and points for attention for the use of DIRUI A Series of Reagent Strips.
DIRUI A Series of Reagent Strips are made for urinalysis of both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. It tests Leukocytes, Nitrite, Urobilinogen, Protein, pH, Blood, Specific Gravity, Ketone (acetoacetic acid), Bilirubin, and Glucose in urine. Please refer to the out-side box carton and bottle label for the specific test parameters of the product you are using.
The strips are for professional use only.
The results on the strips can be read visually and instrumentally.
You are required to read the User's Guide before taking use of the strips.

Collecting and Preparing Specimen
Collect fresh urine in a clean and dry container. Don't centrifuge the urine. Mix the sample well before taking the test. The urine test must be taken within two hours. All specimens must always be taken and kept under sanitary conditions.

Note: Water should not be used as negative control liquid. The preservatives will not prevent the deterioration of ketones, bilirubin or urobilinogen. The growth of bacteria in the long-term storage specimen may affect the test results on glucose, pH, nitrite and blood.

Visual Reading Technique
1. Immerse the reagent area of the strip in the urine specimen and take it up quickly and immediately.
2. Run the edge of the strip against the rim of the container to remove the excess urine.
3. Hold the strip up horizontally and compare the result on the strip with the colour chart on the bottle label closely. Make note of the result. For a semi-quantitative result, take the result according to the time specified on the colour chart.For a qualitative result, the strip should be read between 1-2 minute after dipping. If a positive result is obtained, repeat the test and compare with the colour chart at the specified time . Colour changes beyond 2 minutes are of no diagnostic value.



Instrumental Reading Technique
Follow the directions given in appropriate instrument-operating manual.

Storage Conditions and Validity
Storage Conditions: The product should be stored at 2℃~30℃ in a dry place (not in refrigerator). In order to protect the reagent activity, it should be protected from humidity, light and heat. Do not touch the reaction area of the strips.
Validity: When stored under seal at 2℃~30℃ in a cool and dry place, it is stable for 2 years, it will be stable for 1 month at 2℃~30℃ after opened.

REAGENT REACTIVITY. Deterioration may result in discoloration or darkening of the reagent area of the strip. If all these happen, or the test results are questionable or inconsistent with the expected results, check and make sure the strips are within the expiration date and also compare with the control urine. Please dispose the used strips as wastes according to Treatment Regulations Of Lab Biohazard Materials .

Limitation of Procedures
Like all the other laboratory tests, definitive diagnostic or therapeutic decisions should not be made or based on any single result or method.

Reaction Principles
Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium , which makes the colour changes.
Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce azo dyes in a strongly acid medium.
Ketone: The acetoacetate and sodium nitroprusside cause reaction in alkaline medium, which produces violet colour.
Specific Gravity: Electrolyte (M^+X^-) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid(-COOH),which are weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with pH indicator that causes the colour change.
Blood: Hemoglobin acts as peroxidase. It can cause peroxidase release neo-ecotypes oxide(O). (O) oxidizes the indicator and make the colour change subsequently.
pH: The method of pH indicator is applied.
Protein: This is based on the protein-error-of-indicator principle. Anion in the specific pH indicator attracted by cation on protein molecule makes the indicator further ionized, which changes its colour.
Urobilinogen: This test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a colour enhancer reacts with urobilinogen in a Strongly acid medium to produce a pink-red colour.
Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo(h) quinolin 3-phenol causes the colour change.
Leukocytes: Granulocyte leukocytes in urine contains esterases that catalyze the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy 5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple colour.

Points for attention
Glucose
The test is for specificity of glucose. There is no false positive result occurred in reagent strip, caused by any substance in urine.
When the ascorbic acid concentration ≥2.8mmol/L or acetoacetic acid concentration ≥1.0mmol/L, the sample of glucose concentration is 3~7mmol/L may occur false negative result.

Bilirubin
Normally, even the most sensitive method can't detect bilirubin in urine. It is abnormal to have little bilirubin in urine, which requires further inspection. Medicines that dyes urine red and anything that shows red itself in an acid medium e.g., phenazopyridine may affect the test result. High concentration of the ascorbic acid may cause false negative result.

Ketone
The reagent strip reacts with acetoacetic acid in urine. It doesn't do with acetone or β-hydro butyric acid. Normal urine specimens usually conduct negative results in the test. False positive results may occur in highly pigmented urine or those containing a large amount of levodopa metabolites.

Specific Gravity
The reagent strip for Specific Gravity allows the urine specimens specific gravity between 1.000 and 1.030.In general, the mean error between the

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results of the strip test and those from the refractive index method is only 0.005. To make it more accurate, 0.005 may be added to readings from urines with pH equal or greater than 6.5.Urine reading instrument can automatically make these adjustments in strip-readings. The urine nonionic constituents such as glucose or radiopaque dye won't make any changes in the test. Highly buffered alkaline urines may cause the low readings comparing with the other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein(1g/L-7.5g/L)

Blood

'Trace' reaction may vary among the patients. Clinical judgments are required for individual cases. The presence of green spots (intact erythrocytes) or green colour (haemoglobin/myoglobin) on the reagent area within 60 seconds indicates for further diagnostic check. Blood is often found in the urine of the menstruating females. Haemoglobin 150 μ g/L-620 μ g/L is approximately equivalent to 5-15 cells/ μ L intact erythrocytes.

The reagent strip is highly sensitive to haemolobin and thus can be used as a supplementary to the microscopic examination. The sensitivity of the strip might be reduced in urine with a large amount of specific gravity. The strips are equally sensitive to myglobin as to haemoglobin. Certain oxidizing contaminants, such as hypochlorite, may lead to false positive results. Microbial peroxidase associated with urinary tract infection may also produce a false positive result.Ascorbic acid less than 5.0mmol/L in urine may not influence the result of the test.

pH

The strip tests for pH values are generally in the range of 5.0-8.5 visually and 5.0-9.0 instrumentally.

Protein

The reagent area is more sensitive to albumin than to globulins, haemoglobin, Bence-Jones protein and mucoprotein. So a 'Negative Result' is not good enough to indicate that these proteins don't exist in urine. Normally no protein is detectable in urine with conventional methods, although a minute amount of protein is excreted through a normal kidney. It shows the protein in urine when the colour is darker than mark on the chart. False positive results may be obtained in highly buffered alkaline urines. Urine specimens contaminated with quaternary ammonium compounds and cleansers containing chlorhexidine may also produce false positive results.

Urobilinogen

The reagent strips can detect urobilinogen in low amount as 3 μ mol/L (approximately 0.2 Ehrlich unit/dL) in urine. A result of 33 μ mol/L in urine indicate the critical value, representing the transition from normal to abnormal, which requires further check on patients and specimens. The negative results are not final to determine the absence of urobilinogen.

Nitrite

Gram-negative bacteria in urine converts nitrate(derived from foods)into nitrite.The reagent strip is essential to nitrite and won't react with the other substances in urine. Pink spots or edges on the strip should not be interpreted as positive result, but any degrees of uniform pink colour development should be taken as positive result. The degrees of colour development the numbers of bacteria are not in direct proportion. The negative result doesn't mean the existence of bacteria in a large amount. Negative result may occur (1) when urine doesn't contain organism that caused the conversion from nitrate to nitrite. (2)when urine has not remained in the bladder long enough(four hours up)to let the nitrate covert into nitrite.(3) the nitrate in the foods is absent. Large High volume of specific gravity in urine may reduce the sensitivity of the test. 1.4mmol/L ascorbic acid or less won't interfere the test result.

LEUKOCYTES

Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine specimens generally yield negative result; positive results (+ or greater) are clinically significant. Individually observed 'Trace' results may be of questionable clinical significance; however 'Trace' results observed repeatedly may be clinically significant. 'Positive' results may occasionally be found with random specimens from females due to contamination of the specimen by vaginal discharge. Elevated glucose concentrations (160mmol/L) or high specific gravity may cause decreased test results.

SPECIFIC PERFORMANCE CHARACTERISTICS

Specific performance characteristics are based on clinical and analytical studies. In clinical specimens, the sensitivity depends upon several factors; the variability of colour perception, the presence or absence of inhibitory factors typically found in urine, specific gravity, pH, and the lighting conditions when the product is read visually. Each colour block or instrumental display value represents a range of values. Because of specimen and reading variability, specimens with analyte concentrations that fall between nominal levels may give results at either level. Results at levels greater than the second positive level for the Protein, Glucose, Ketone, and Urobilinogen tests will usually be within one level of the true concentration. Exact agreement between visual results and instrumental results might not be found because of the inherent differences between the perception of the human eye and the optical system of the instruments.

Notes

This product is used for invitro diagnosis.

The strips must be kept in the original bottle. Never use the products after the expiration date. Each strip can be used only once. Do not remove the desiccant(s). If strips are removed from the bottle, they must be used immediately. Cap the bottle immediately and tightly after taking out the strips.The strips should be stored in a dry place at the temperature between 2℃-30℃. Do not store the strips in refrigerator and keep them away from direct sunlight.Do not touch the reagent area of the strip. Protection against ambient moisture, light and heat is essential to guard against altered reagent reactivity. Deterioration may result in discoloration or darkening of the reagent area of the strip. If this happens, or the test results are questionable or inconsistent with the expected results, check and make sure the strips are within the expiration date and also run a control. Please dispose the used strips as waste according to Treatment Regulations of Lab Biohazard Materials.

SENSITIVITY AND TEST RANGE OF URINALYSIS STRIPS

Item	Sensitivity	Instrumental test range	Visual test range
Glucose(mmol/L)	2.8-5.5	Neg.-55	Neg.-110
Protein(g/L)	0.15-0.3	Neg.-3.0	Neg. -20.0
Ketone(acetoacetic acid) (mmol/L)	0.5-1.0	Neg.-7.8	Neg.-16
Blood (cells/ μ L)	5-15	Neg.-200	
Bilirubin (μ mol/L)	3.3-17	Neg.- Large	
Nitrite(μ mol/L)	13-22	Neg.- Pos.	
Leukocytes (cells/ μ L)	5-15	Neg.-500	
Urobilinogen (μ mol/L)	3.2-16	3.2-131	3.2-128
PH	——	5.0-9.0	5.0-8.5
Specific Gravity	——	1.005-1.030	1.000-1.030

REACTIVE INGREDIENTS
(based on dry weight at time of impregnation)

Protein	tetrabromphenol blue buffer nonreactive ingredients	0.1% w/w 97.4% w/w 2.5% w/w
Blood	diisopropylbenzene dihydro peroxide tetramethylbenzidine buffer nonreactive ingredients	26.0% w/w 1.5% w/w 35.3% w/w 37.2 %w/w
Glucose	glucose oxidase (microbial.123U) peroxidase(horseradish. 203U) potassium iodide buffer nonreactive ingredients	1.7% w/w 0.2 % w/w 0.1% w/w 71.8% w/w 26.2% w/w
Ketone	sodium nitroprusside nonreactive ingredients buffer	5.7% w/w 29.9% w/w 64.4% w/w
Leukocytes	pyrrole amino acid ester diazonium salt buffer nonreactive ingredients	4.3% w/w 0.4% w/w 92.6% w/w 2.7% w/w
Nitrite	p-arsanilicacid-N-(1-Naphthol) -ethylenediamine tetrahydroquinoline buffer nonreactive ingredients	1.3% w/w 0.9%w/w 89.6% w/w 8.2% w/w
Specific Gravity	bromthymol blue poly(methyl vinyl ether co maleic anhydride) sodium hydroxide	4.8%w/w 90.2%w/w 5.0% w/w
pH	methyl red bromthymol blue nonreactive ingredients	3.3% w/w 55.0% w/w 41.7% w/w
Bilirubin	2,4-dichloroaniline diazonium salt buffer nonreactive ingredients	0.6%w/w 57.3%w/w 42.1%w/w
Urobilinogen	p-diethylamino benzaldehyde buffer nonreactive ingredients	0.2%w/w 98.0%w/w 1.8%w/w

Notes on symbols and marks

LOT	Batch code		Use by
	Single use	IVD	In Vitro Diagnostic Use
	Manufactured by		Store at
	Please read package insert	CE	These test strips conform to the directive 98/79/EC(IVD-directive)
EC REP	Authorised Representative	REF	Catalogue number

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