Specific Gravity

The reagent strip for Specific Gravity measures. urine specific gravity between 1.000 and 1.030.In general, the mean error between the results of the strip test and those from the refractive index method in only 0.005. To make it more accurate, 0.005 may be added to readings from urines with pH equal to or greater than 6.5. Urine reading instruments can automatically make these adjustments when reading strips. The urine nonionic constituents such as glucose or radiopaque dye won't make any changes in the test. Highly buffered alkaline urines may cause low readings compared with other methods. Elevated specific gravity readings may occur in the presence of moderate quantities of protein (1g/L - 1.75g/L).

Blood

'Trace' reactions may vary among patients. Clinical judgment is required for each case. The presence of green spots (intact erythrocytes) or green colour (hemoglobin/myoglobin) on the reagent area within 60 seconds is an indication for further diagnostics. Blood id often found in the urine of menstruating females. A hemoglobin of 150-620 μ g/L is approximately equivalent to 5-15 cells/ μ L of intact erythrocytes.

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

pH

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

Urobilinogen

The reagent strips can detect urobilinogen in amounts as low as 3 μ mol/L (approximately 0.2 Ehrlich unit/dL) in urine. The normal range is 3-16 μ mol/L. A result of 33 μ mol/L in urine indicates the transition from normal to abnormal, which requires further diagnostics on the patient or specimen. The negative results do not necessarily mean the absence of urobilinogen.

Nitrite

Gram-negative bacteria in urine converts nitrate (derived from foods) into nitrite. The reagent strip only reacts with nitrite and won't react with the other substances in urine. Pink spots or edges on the strip should not be interpreted as a positive result, but any degree of uniform pink colour development should be taken as a positive result. The degree of colour development is not proportional to the numbers of bacteria present. A negative results doesn't mean bacterial are not present in large amounts. A negative result may occur (1) when urine doesn't contain organisms that convert nitrate to nitrite. (2) when urine has not remained in the bladder long enough (up to four hours) to allow nitrate conversion into nitrite. (3) nitrate in the food is absent. High specific gravity in urine may reduce the sensitivity of the test. 1.4mmol/L ascorbic acid or less won't interfere with the test result.

Leukocytes

The test area reacts with esterase in leukocytes (granulocytic leukocytes). Normal urine specimens generally yield a 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.

Ascorbic Acid

The reagent area is for Ascorbic Acid determination which can provide information of internal Ascorbic Acid level and used to evaluate its influence to glucose, bilirubin, blood and nitrite test. Oxidant in urine (such as potassium permanganate and hypochlorite) may influence the sensitivity of testing.

The common question for microalbumin testing

1.The reason for the testing of microalbumin

The assay of microalbumin has the early detection for several diseases.

1.) Practical value for patient of high blood pressure: the excretion rate of microalbumin for high blood pressure patient is obviously higher than one for normal person. The increasing microalbumin is the important forecast parameter for cardiovascular disease.

2.) Microalbumin can forecast the development of diabetic nephropathy and early detection. Because the earliest clinic signal for diabetic nephropathy is the presence of microalbumin in urine, it is very helpful for diabetes patients to take earlier measures to protect the function of kidney.

3.) The assay of microalbumin is the sensitive indicator for diabetic complication of micro vessel.

2. Clinic significance of positive result of microalbumin

1) If the strips has the positive result on microalbumin, it is necessary to test urine sample consecutively for several days. If microalbumin is casually present , it could be physical proteinuria.for example, it might be caused from diet, exercise or stress.

2) If the positive result is consecutively present, or the positive result on blood and microalbumin simultaneously or positive result on glucose and microalbumin simultaneously, it is suggested that the result of microalbumin should be confirmed by the method of immuno turbidimetry.

Notes

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 of used strips as waste according to Treatment Regulations of Lab Biohazard Materials.

SENSITIVITY AND TEST RANGE URINALYSIS STRIPS OF H-800

Item	Sensitivity	Instrumental test range	Visual test range
Glucose(mmol/L)	2.8-5.6	Neg.-56	
Protein(g/L)	0.2-0.3	Neg.-3.0	Neg. -20.0
Microalbumin (g/L)	0.08-0.15	Neg.-0.15	Neg.-0.15
Ketone(acetoacetic acid) (mmol/L)	0.5-1.0	Neg.-7.8	Neg.-16
Blood (Ery/ μ L)	5-25	Neg. -200	
Bilirubin (μ mol/L)	8.6-17	Neg.- 103	
Nitrite(μ mol/L)	9 -18	Neg- Pos.	
Leukocytes (Leuko/ μ L)	5-15	Neg.-500	
Urobilinogen (μ mol/L)	3.4-17	3.4-135	
Ascorbic Acid (mmol/L)	0.6-1.4	0-5.7	
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) tetramethylbenzidine 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 buffer nonreactive ingredients	5.7% w/w 29.9% w/w 64.4% w/w
Leukocytes	pyrrole amino acid 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-dichlorbenzene amine diazonium salt buffer caffeine nonreactive ingredients	0.6%w/w 57.3%w/w 32.1%w/w 10.0%w/w
Urobilinogen	fast blue B salt buffer nonreactive ingredients	0.2%w/w 98.0%w/w 1.8%w/w
Microalbumin	sulfone phthalein buffer nonreactive ingredients	2.2%w/w 96.0%w/w 1.8%w/w
Ascorbic Acid	2,6-dichlorophenol indophenol buffer nonreactive ingredients	0.8%w/w 40.7%w/w 58.5%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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H-800 Series

Urinalysis Reagent Strips User's Guide

Rev:09/2013

General Summary

This guide describes the methods, reaction principles and important points for the use of specific DIRUI Reagent Strips of H-800.

Specific DIRUI Reagent Strips of H-800 are used for the determination of kidney failure, diabetes or related kidney damage, serious infection, liver and gall function failure.

The determination of microalbumin has significant value to inspecting post kidney transplant, distinguishing glomerulitis and canaliculitis, diabetes-related kidney damage.

The amount of albumin excreted reflects the degree of change of glomerular permeability and in clinic microalbumin test has been used as an indicator of glomerular damage.

Specific DIRUI Reagent Strips of H-800 provide qualitative and semi-quantitative results.

The strips are for in vitro use and for professional use only.

The results on the strips can be read either visually or instrumentally. To achieve a more reliable result you are required to read the User's Guide carefully before use.

The following chart describes the types of strips and the items tested.

Product	Test Item
H10-800	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, and pH.
H11-800	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid.
H11-800MA	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Microalbumin.
H12-800MA	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, Ascorbic Acid, and Microalbumin.

Specimen Collection and Preparation

Collect fresh urine in a clean and dry container. Don't centrifuge the urine. Mix the sample well before testing. The urine must be tested within two hours of collection. Collect and store all specimens under sanitary conditions.

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

Test Method

Visual Reading

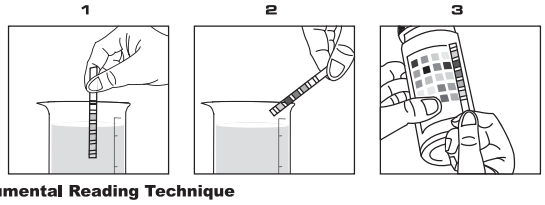
Romm temperature for test:(25±5)℃

1.promptly replace cap after taking out strip

2.Immerse the reagent area of the strip in the urine specimen and remove quickly.

3.Run the edge of the strip against the rim of the container to remove the excess urine.

4.Hold the strip horizontally and compare the result on the strip with the colour chart on the bottle label . Make note of the result. For a semi-quantitative result, read the result according to the time specified on the colour chart. For a qualitative results, the strip should be read between 1-2 minutes after dipping. If a positive result is obtained, repeat the test and compare with the colour chart at the time specified. Colour changes beyond 2 minutes are of no diagnostic value.



Instrumental Reading Technique

Follow the directions given in the instrument-operating manual.

Limitation of Test Method

Like all lab tests, diagnosis result and therapeutic schedule can not be made according to any single diagnosis method.

Reagent strips' application is based on clinical analysis. In clinical sample, the sensitivity depends upon several factors: the variability of color perception, specific gravity, pH, and the lighting conditions change when the product is read visually. Each colour block or instrumental display value represents a range of values. Because of sample and reading variability, sample 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.

Storage Condition and Validity

Storage Condition: The strips must be stored in dry place at the temperature between 2℃-30℃, and do not keep in the refrigerator; Avoid direct sunlight and do not touch the reaction area of the strip; As to protect the activity of the reagent, must eliminate the humidity, sunlight and heat from the ambience environment.

Validity: Stored in dry place and avoid sunlight, with the temperature between 2℃-30℃, the sealed validity is 2 years; After opened seal, cover the tap closely, stored in dry, avoid sunlight with the temperature between 2℃-30℃, the validity is 1 month.

For Instrument

DIRUI H-800 Automatic Urine Analyzer

Reaction Principles

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and hydrogen peroxide. Hydrogen peroxide releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes tetramethylbenzidine, which makes the colour changes.

Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce azo dyes in a strongly acid medium.

Ketone: The acetoacetic acid 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.

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: Urobilinogen and diazonium produce pink azo dyes under the function of strong acid medium.

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 contain esterases that catalyze the hydrolysis of the pyrrole amino change. acid ester to liberate 3-hydroxy 5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple colour.

Microalbumin: Sulfone phthalein dye have high sensitivity to microalbumin by the method of protein error.

Ascorbic Acid: In alkaline medium, blue oxidized 2,6-dichlorophenol-indophenol dye is changed into colorless.

Points for Attention

Protein and Microalbumin

The Microalbumin test can accurately and specifically determine albumin. A strip result of 15 mg/dL is indicative of clinical albuminuria. The test is not affected by other proteins at concentrations at least nine times greater than the excretion rate considered to be abnormal.

The Protein test pad is not specific for a particular protein, and proteins other than albumin can cause a positive response. The test is less sensitive to mucoproteins and globulins, which are generally detected at levels of 60 mg/dL or higher.

A visibly bloody urine (≥5mg/dL) may cause falsely elevated results.

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 a little bilirubin in urine, this 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 ascorbic acid may cause false negative results.

Ketone

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

DIRUI® DIRUI INDUSTRIAL CO.,LTD.

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