H-Series

Urinalysis Strips User's Guide

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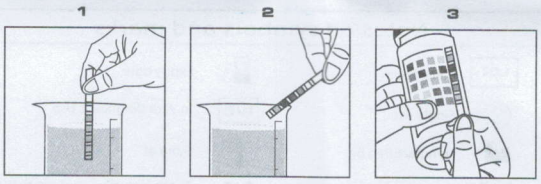
Intended Purpose:
This guide instructs the methods, reaction principles and points for attention for the use of DIRUI H Series Urinalysis Strips.
DIRUI H Series Urinalysis Strips are made for urinalysis both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. The strips are 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.
The following chart tells the type of strips and the items tested.

Products Type	Test Item
H11	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH and Ascorbic Acid
H10	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite,Leukocytes,Glucose,Specific Gravity and pH
H8	Urobilinogen, Bilirubin, Ketone (acetoacetic acid), Blood, Protein, Nitrite,Glucose and pH

Sample Collecting and Preparation
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 2 hours. All samples 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 sample may affect the test results on glucose, pH, nitrite and blood.

Test Method
Room temperature for test:(25±5)℃
Visual Reading
1.Promptly replace cap after taking out strip.
2.Immerse the reagent area of the strip in the urine 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 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 significance.



Instrumental Reading
Follow the directions given in the instrument user 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℃.Protect it from direct sunlight and chemical reagents.
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.

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: 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 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.
Ascorbic Acid: Ascorbic acid, with 1,2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2,6-dichloroindophenolate into colourless N-(p-pheno)-2,6- dichloro-P-amine phenol.

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(1-7.5g/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 color (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 150μg/L-620μg/L is approximately equivalent to 5-15 cells/μL 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. Normal Vitamine 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 color 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 3μmol/L (approximately 0.2 Ehrlich unit/dL) in urine. A result of 34μmol/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 color 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.

Ascorbic Acid

The test area can detect the ascorbic acid in urine. Through the ascorbic acid detection, we will know the level of ascorbic acid in the body and the effect degree that the ascorbic acid bring to the test on glucose, bilirubin, blood and nitrite. It will reduce the sensitivity when the oxidant (such as potassium permanganate, hypochlorite) in the urine.

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

SENSITIVITY AND TEST RANGE OF H SERIES URINALYSIS STRIPS

Item	Sensitivity	Instrumental test range	Visual test range
Glucose (mmol/L)	2.8-5.6	Neg.-56	
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 (Ery/μL)	5-15	Neg. -200	
Bilirubin (μmol/L)	8.6-17	Neg.-103	
Nitrite(μmol/L)	13-22	Neg.- Pos.	
Leukocytes (leuko/μL)	5-15	Neg.-500	
Urobilinogen (μmol/L)	3.4-17	3.4-135	
Ascorbic Acid(mmol/L)	0.6-1.4	0-5.7	0-6.0
pH	——	5.0-9.0	5.0-8.5
Specific Gravity	——	1.005-1.030	1.000-1.030

REACTIVE INGREDIENTS

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	bromcresol green 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	fast B blue buffer nonreactive ingredients	0.2%w/w 98.0%w/w 1.8%w/w
Ascorbic acid	2,6-dichloroindophenolate hydrate buffer nonreactive ingredients.	0.8%w/w 40.7%w/w 58.5%w/w

Notes on symbols and marks

LOT	Batch code		Expiry date
	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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