FUS-Ⅱ Urinalysis Strips

In order to provide reliable results, please read the user's guide carefully before use.

Rev:08/2018

[Product Name] FUS-Ⅱ Urinalysis Strips
[Specification] 150 strips/bottle, 100 strips/bottle, 50 strips/bottle, 30 strips/bottle

[Product Model]

Products Type	Test Item
FUS-10 Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH
FUS-10 Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH
FUS-11 Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH, ascorbic acid
FUS-11 Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH, ascorbic acid
FUS-11MA Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, pH,nitrite, leukocyte, glucose, specific gravity, microalbumin
FUS-11MA Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, pH,nitrite, leukocyte, glucose, specific gravity, microalbumin
FUS-12MA Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH, microalbumin, ascorbic acid
FUS-12MA Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH, microalbumin, ascorbic acid
FUS-13Cr Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, pH, specific gravity, nitrite, glucose, leukocyte, ascorbic acid, microalbumin, creatinine
FUS-13Cr Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, pH, specific gravity, nitrite, glucose, leukocyte, ascorbic acid, microalbumin, creatinine
FUS-14Ca Ⅱ(N)	urobilinogen, bilirubin, ketone, blood, protein, pH, specific gravity,nitrite, glucose, leukocyte, ascorbic acid, microalbumin, creatinine, Ca
FUS-14Ca Ⅱ	urobilinogen, bilirubin, ketone, blood, protein, pH, specific gravity,nitrite, glucose, leukocyte, ascorbic acid, microalbumin, creatinine, Ca

[Intended Use]
FUS-Ⅱ Urinalysis Strips is used for qualitative or semi-quantitative test of urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocyte, glucose, specific gravity, pH, ascorbic acid, microalbumin, creatinine, Ca.

[Testing Principle]
Urobilinogen: In strong acidic conditions, urobilinogen is coupled with the diazonium salt to generate purple red dye.
Bilirubin: Direct bilirubin is coupled with dichloroaniline diazonium salt under acidic conditions to produce azo dyes.
Ketone: Acetoacetate reacts with sodium nitroprusside under basic conditions to form a purple red compound.
Creatinine: Creatinine reacts with 3,5-dinitrobenzoic acid under strong alkaline conditions to form a colored complex.
Blood: Hemoglobin has a peroxidase-like activity that allows the peroxide to decompose and release new oxygen [O], [O] oxidizes the indicator and make the color change.
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 color.
Microalbumin: Depend on protein error principle, use sulfone phthalein dye only sensitive to albumin.
Nitrite: Nitrite and sulfonamide have diazotization reaction, and form diazo compounds. Diazo compounds couple with tetrahydrobenzo quinolin-3-phenol to generate red azo dyes.
Leukocyte: In the neutrophil esterase hydrolysis, indole phenol ester produces free phenol. Free phenol couples with diazonium salt to generate purple azo dyes.
Glucose: Glucose produces gluconic acid and sodium hydroxide under the action of glucose oxidase. Sodium hydroxide releases neo-oxygen under the action of peroxidase [O]. [O] oxidizes potassium iodide and undergoes a color change.
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 color change.
pH: The method of pH indicator is applied.
Ascorbic Acid: Ascorbic acid, with 1,2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2,6-dichloroindophenolate into colorless N-(p-phenol)-2,6- dichloro-P-amine phenol.
Ca: Ca reacts with o-cresolphthalein complexone produce purple red, the color shade is proportional to Ca concentration.

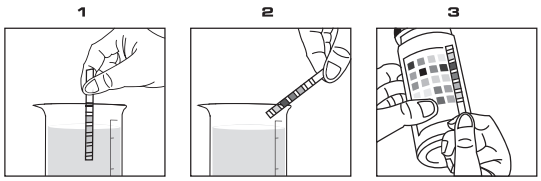
[Main Ingredients]
Urobilinogen: 0.2% w/w fast blue B salt; 99.8% w/w phosphate buffer.
Bilirubin: 0.6% w/w 2,4-dichloroaniline diazonium salt; 67.3% w/w salicylic acid buffer; 32.1% w/w caffeine.
Ketone: 5.7%w/w sodium nitroprusside; 94.4% w/w TAPS buffer.
Creatinine: 4.8% w/w 3,5-dinitrobenzoic acid; 95.5% w/w Tris buffer.
Blood: 26.0% w/w cumyl hydroperoxide; 1.5% W/W tetramethyl benzidine; 72.5% w/w phosphate buffer.
Protein: 0.1% w/w tetrabromophenol blue; 99.9% w/w citrate buffer.
Microalbumin: 2.2% w/w sulfone phthalein dye; 97.8% w/w citrate buffer.
Nitrite:1.3% w/w p-arsanilic acid; 0.9% w/w tetrahydrobenzo quinolin-3-phenol; 97.8% w/w glycine buffer.
Leukocyte: 4.3% w/w pyrrole phenol ester; 0.4% w/w phenyl diazonium salt; 95.3%w/w phosphate buffer.
Glucose: 1.7% w/w glucose oxidase (123U); 0.2% w/w peroxidase (horseradish, 203U); 0.1% w/w potassium iodide; 98%w/w citrate buffer.
Specific Gravity: 4.8% w/w bromothmol blue; 90.2%w/wpoly (methyl vinyl ether-maleic anhydride); 5.0% w/w sodium hydroxide.
pH: 3.3% w/w methyl red; 55.0% w/w bromothmol blue; 41.7% w/w polyethylene glycol.
Ascorbic Acid: 0.8% w/w 2, 6-dichlorophenol indophenol sodium; 99.2%w/w phosphate buffer.
Ca: 2.5% w/w o-cresophthalein complexon; 97.5% w/w sodium hydroxide buffer.
Material contents may be slightly different due to different batches.

[Storage Conditions and Shelf Life]
Storage Conditions: The strips must be stored in dry place at the temperature between 2℃-30℃, sealed and protected from direct sunlight and chemical reagents.
Shelf Life: Stored in a dry place, sealed and protected from sunlight, with the temperature between 2℃-30℃, the sealed shelf life is 2 years; After opened, cover the tap closely, stored in dry, protected from sunlight with the temperature between 2℃-30℃, the shelf life is 1 month.

[For Instrument]
FUS series urinalysis hybrid and MUS series urinalysis system

[Sample Requirements]
Collect fresh urine in a clean and dry container. Don't centrifuge the urine. Mix the sample well before the test. The urine test must be taken within two hour. All samples must always be taken and kept under sanitary conditions.
Note: 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 of glucose, pH, nitrite and blood.

[Test Methods]
Room temperature for test:(25±5)℃
Visual Reading:
1. Immerse the reagent area of the strip in urine sample and take it out 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 color chart on the bottle label closely. Make note of the result. For a semi-quantitative result, take the result according to the specified time on the color chart. For a qualitative result, the strip should be read within 1-2 minutes after dipping. If a positive result is obtained, repeat the test and compare with the color chart at the specified time. Color changes beyond 2 minutes are of no diagnostic value.



Instrumental Reading:
Follow the directions given in appropriate instrument user manual.

[Result Explanation]
Urobilinogen
The reagent strips can detect urobilinogen in low amount as 3μmol/L (approximately 0.2 Ehrlich unit/dL) in urine. The normal content of Urobilinogen is 3μmol/L-16μmol/L. A result of 33μmol/L in urine indicate the critical value, representing the transition from normal to abnormal, which requires further check on patients and samples. The negative results are not final to determine the absence of urobilinogen.
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 acetone reacts with acetoacetic acid of urine. It doesn't do with acetone or β-hydro butyric acid. Normal urine sample usually shows negative results in the test. False positive results may occur in highly pigmented urine or those containing a large amount of levodopa metabolites.
Creatinine
Normal urine creatinine concentration of adult is 0.6-2.0g/24h (about 4.4-17.7 mmol/L by test strip). High deviation exists on the test results of random urine sample creatinine, with the range from 0.9mmol/L to 26.5mmol/L. Concentrated and morning urine have higher level of creatinine (maybe more than 17.7mmol/L tested by test strip). The concentration of the component required to test can be diluted due to over-ingestion of water or other substance, will result in typical low concentration

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urine (the tested result ≤50mg/dL). Visible hematuria(≥5mg/dL) or Cimitidine may result in creatinine testing result spurious rising.

Albumin-Creatinine Ratio

Urine albumin content of adult is less than 30 mg albumin/g creatinine (3.4 albumin/mmol creatinine). A ratio of 30-300mg/g (3.4-33.9mg/mmol) indicates microalbuminuria. A ratio of more than 300mg/g (＞33.9mg/mmol) indicates albuminuria.

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. Vitamine in urine may not influence the result of the test.

Protein and Microalbumin

Albumin concentration in normal adult urine is less than 20 mg/L. A result of 20-200 mg/L indicates clinical microalbumin. A result of higher than 200 mg/L indicates clinical albuminuria. A albumin discharge rate of 30-300 mg/24 hour indicates a warning of urine microalbumin symptom. A albumin discharge rate of higher than 300 mg/24 hour indicates a warning of urine albumin symptom. Urine albumin discharge may be elevated by temporary sport, urinary tract infection or acute fever disease.

Microalbumin strip is intended for detecting urine microalbumin, and is sensitive to microalbumin. Its sensitivity for other protein is 9 times lower than microalbumin. 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 (≥5 mg/dL) may cause falsely elevated results.

Microalbumin in urine may lead to:

(1) Occasionally presented urine microalbumin may be functional albuminuria or postural proteinuria caused by physiological albuminuria, such as diet, sport, mental stress, etc.

(2) Continuously presented urine microalbumin, microalbumin and glucose, or microalbumin and blood are with great clinical significance.

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 color 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. High specific gravity urine may reduce the sensitivity of the test. 1.4mmol/L ascorbic acid or less won't interfere with the result.

Leukocyte

Test area react with esterase in leucocytes (granulocytic leukocytes). Normal urine sample 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 sample from females due to contamination of the sample by vaginal discharge. Elevated glucose concentrations (160mmol/L) or high specific gravity may cause decreased test results.

Glucose

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

Specific Gravity

The reagent strip for Specific Gravity allows the urine sample 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 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).

pH

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

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)present in the urine.

Ca

A great deal of Mg(more than 10mmol/L) will cause urine Ca rising.

Result Table

Routine system of units and international system of units can be selected in urine analyzer test.

Test Item	Ab.	Print or Display Result			
		Routine System of Units		International System of Units	
Microalbumin	MA	10 mg/L	80 mg/L	10 mg/L	80 mg/L
		30 mg/L	150 mg/L	30 mg/L	150 mg/L
Creatinine	Cr	10 mg/dL	200 mg/dL	0.9 mmol/L	17.7 mmol/L
		50 mg/dL	300 mg/dL	4.4 mmol/L	26.5 mmol/L
		100 mg/dL		8.8 mmol/L	
Albumin-Creatinine Ratio	A: C	＜30 mg/g(normal)		＜3.4 mg/mmol(normal)	
		30-300 mg/g(abnormal)		3.4-33.9 mg/mmol(abnormal)	
		＞300 mg/g(highly abnormal)		＞33.9 mg/mmol(highly abnormal)	

Remark: shaded area indicates abnormal result.

[Limitation of Test Method]

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

The application of the reagent strips is based on the study of clinical analysis. For the clinical urine samples, the sensitivity depends on the following factors: color variability, SG, pH, lighting condition, etc. Visual reading and instrumental reading represent a range of values. Because of urine sample and reanding variability, there is a deviation between the value of tested analyte and actual value. For the tests of protein, glucose, ketone and urobilinogen, the deviation of positive value above the second positive level should be within a "+". Because of the inherent difference of sensitization between eyes and optical system, visual reading and instrumental reading might not coincide completely.

[Product Performance Index]

Urinalysis Strip LOD & Test Range

Item	LOD	Instrumental Test Range	Visual Test Range
Urobilinogen(μmol/L)	3.4	3.4-135	
Bilirubin(μmol/L)	17	Neg.-103	
Ketone(mmol/L)	0.5	Neg.-16	
Creatinine(mmol/L)	0.9	0.9-26.5	
Blood(cells/μL)	10	Neg.-200	
Protein(g/L)	0.2	Neg.-20.0	
Microalbumin 1 (g/L)	0.15	0-0.15	
Nitrite(mg/dL)	0.125	Neg.-16	
Leukocyte(cells/μL)	15	Neg.-500	
Glucose(mmol/L)	2.8	Neg.-56	
Specific Gravity	—	1.005-1.030	1.000-1.030
pH	—	5.0-9.0	5.0-8.5
Ascorbic Acid(mmol/L)	0.6	0-5.7	
Ca(mmol/L)	1.0	1.0-10	
Microalbumin 2 (mg/L)	10	10-150	

Notes:

Microalbumin 1 is used for FUS-11MAⅡ, FUS-12MAⅡ Urinalysis Strip.
Microalbumin 2 is used for FUS-13CrⅡ, FUS-14CaⅡ Urinalysis Strip.

Specificity

Detect the Anti-VC Standard Solution presented in the following table using the strips, the test results should not be negative.

Item	Anti-VC Standard Solution Concentration	VC Concentration
NIT	36μmol/L	1.4mmol/L
GLU	14mmol/L	2.8mmol/L

[Points for Attention]

1.In vitro diagnosis for professional only.
2.Reagent strips must be stored in original bottle, do not take out strips except use them immediately. Do not remove the desiccants, cap the bottle immediately and tightly after taking out strips.
3.The expired strip should not be used, please make sure whether the strip is over the life, and test it by quality control if the deterioration of strips occurs, which leads color shallower or deeper, or any question occurs with the unexpected results.
4.Water can not be used as negative control.
5.Each strip can be used only once.
6.Please read the User's Guide carefully before use.
7.Please dispose of the used strips according to Treatment Regulations of Lab Biohazard Materials.
8.Do not place them in the refrigerator, however they should be stored in dry place and protected from direct sunlight, do not touch the reactive area of strip, ambient moisture, light and heat must be prevented in order to protect the reactivity of the strips.

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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