

[Product Name] MC Urinalysis Strip	
[Package Specification] 50 strips/bottle, 100 strips/bottle	
Model	Test Items
CA-1 (GLU)	Glucose
CA-1 (KET)	Ketone
CA-1 (PRO)	Protein
CA-2 (GLU , KET)	Glucose、Ketone
CA-2 (GLU , PRO)	Glucose、Protein
CA-3 (GLU , KET , PRO)	Glucose、Ketone、Protein
CA-3 (GLU , PRO , pH)	Glucose、Protein、pH
CA-4 (GLU , PRO , pH , SG)	Glucose、Protein、pH、Specific gravity
CA-4 (GLU , PRO , pH , BLD)	Glucose、Protein、pH、Blood
CA-5 (GLU , PRO , pH , BLD , KET)	Glucose、Protein、pH、Blood、Ketone
CA-8	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Glucose、pH
CA-9	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Glucose、pH
CA-10	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Leukocytes、Glucose、pH
CA-11	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Leukocytes、Glucose、pH、Ascorbic acid
CA-12	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Leukocytes、Glucose、pH、Ascorbic acid、Microalbumin
CA-13	Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Leukocytes、Glucose、pH、Ascorbic acid、Microalbumin、Creatinine
CA-14	Calcium、Specific gravity、Urobilinogen、Bilirubin、Ketone、Blood、Protein、Nitrite、Leukocytes、Glucose、pH、Ascorbic acid、Microalbumin、Creatinine

[Intended Use]
It is used for in vitro qualitative or semi-quantitative determination of calcium, specific gravity, urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, pH, ascorbic acid, microalbumin and creatinine in the urine. Clinically, it is mainly applied to auxiliary diagnosis of nephropathy, diabetes, urinary infection and other diseases (such as liver metabolism).

[Test Principle]
Glucose (GLU): Glucose generates gluconic acid and hydrogen peroxide under the action of glucose oxidase, and hydrogen peroxide oxidizes potassium iodide under the action of peroxidase, leading to a change in color.
Bilirubin (BIL): Direct bilirubin is conjugated with dichloroaniline diazonium salt under the condition of strong acidity, generating azo dyes.
Ketnone (KET): Acetoacetic acid reacts with sodium nitroferricyanide under the condition of alkalinity, forming a purplish red compound.
Specific gravity (SG): Methyl vinyl ether-maleic acid copolymer is a weakly acidic (—COOH group) ion permutoid. The M⁺ cations (mainly Na⁺) in the electrolyte (M⁺X⁻) existing in the form of salts in the urine react with the ion permutoid to displace hydrogen ions, which then react with the acid-base indicator, resulting in a color change.
Blood (BLD): Hemoglobin has peroxidase-like activity which can catalyze the oxidation indicator of peroxides, causing a change in the color of indicator.
pH: Acid-based indicator method is applied.
Protein (PRO): Indicator protein error method. In a constant pH environment, a specific pH indicator combines with the protein, resulting in further ionization of the indicator followed by a change in color.
Urobilinogen (UBG): Urobilinogen is conjugated with diazonium salt to generate purplish red dyes under strong acidic conditions.
Nitrite (NIT): The diazotization reaction of nitrite and sulfonamide produces diazo compounds, which are conjugated with tetrahydrobenzoquinolin-3-phenol to generate red azo dyes.
Leukocytes (LEU): Indoxyl esters, under the hydrolysis of neutrophil esterase, generate free phenols which are then conjugated with phenyl diazonium salts to produce purple azo dyes.
Microalbumin (MALB): Indicator protein error method; sulfonphthalein dye with high sensitivity to albumin is used.
Ascorbic acid (VC): Ascorbic acid has a 1,2-enediol reductive group, which, under the condition of alkalinity, reduces the 2,6-DCPIP dye with the oxidation state being blue to colorless 2,6-dichlorodifluoromethane-phenolamine.
Creatinine (CRE): Creatinine reacts with 3,5-dinitrobenzoic acid under strong alkaline conditions to generate a colored compound.
Calcium (Ca): The reaction between calcium ions and OCPC produces a purplish red color, the shade of which is directly proportional to the concentration of calcium ion.

[Main Component]
Calcium: 0.049% w/v OCPC
Specific gravity: 0.096% w/v bromothymol blue
Urobilinogen: 0.078% w/v diazonium salt
Bilirubin: 0.175% w/v phenylamine diazonium salt; 6.557% w/v caffeine
Ketone : 7.76% w/v sodium nitroferricyanide
Blood: 0.488% w/v tetramethylbenzidine
Protein: 0.04% w/v tetrabromophenol blue
Nitrite: 0.030% w/v sulfonamide; 0.050% w/v tetrahydrobenzoquinolin-3-phenol
Leukocytes: 0.090% w/v indoxyl ester; 0.060% w/v phenyl diazonium salt
Glucose: 0.083% w/v glucose oxidase; 0.033% w/v peroxidase; 0.958% w/v potassium iodide
pH: 0.003% w/v methyl red; 0.132% w/v bromothymol blue
Ascorbic acid: 0.057% w/v 2,6-DCPIP
Microalbumin: 0.028% w/v sulfophthalein dye
Creatinine: 0.75% w/v 3,5-dinitrobenzoic acid

[Storage Conditions and Shelf Life]
This product should be stored in a dry and dark place at 2-30°C.
After the first opening, it should be stored in a dry and dark place at 2-30°C with its lid sealed, the validity period of which is then 30 days.
Shelf Life 24 months

[Applicable Instruments]
It is applicable to CA series Urine Analyzer and CM series Urinalysis System produced by Zhejiang Medicside Medical Technology Co., Ltd.

[Sample Requirement]
The fresh urine should be collected in a clean and dry container without centrifugation, and should be mixed before the test. The test should be carried out within 2 hours.
Note: Preservatives cannot prevent the deterioration of ketone, urobilinogen, and bilirubin, for which urine samples stored for a long time may affect the test results of glucose, pH, nitrite and blood owing to bacteria growth.

[Test Method]
For accurate results, please follow the correct operation method and measurement time. Test environment temperature: 25±5°C

[Visual test]
1. Take out enough test strips from the bottle as needed and then cover with a cap immediately.
2. Fully immerse the urine test strip in the fresh and well-mixed urine for 2 seconds.
3. Sweep the mouth wall of the sample bottle with the edge of the test strip to remove excess urine.
4. Keep the test strip level to prevent urine from spilling over and interfering with each other.
5. Perform the visual test according to the reaction time of the color code on the test strip bottle and the chromatogram.

[Instrument test]
1. Preparation: take a proper amount of test strips, and put them in the test strip chamber of the applicable instrument;
2. Place the test samples on the instrument sample rack;
3. Click the test start button on the instrument, and the instrument will automatically select the test strips and test the samples;
4. After the test is completed, the instrument will automatically output the test results;
5. Check User Manual for the instrument operation.

[Expected Operator]
Used by trained technicians, nurses and physicians.

[Interpretation of Test Results]
Glucose:
Small amounts of glucose can be detected in normal urine with a concentration of 2-20 mg/dL and a daily excretion of 40-85 mg. When the urine ascorbic acid concentration is ≥2.8mmol/L or the acetoacetic acid concentration is ≥1.0mmol/L, false negative results may emerge in samples with a glucose concentration of 3-7mmol/L.

Protein and microalbumin:
The concentration of albumin in normal urine of adults is less than 20 mg/L. The test result of 20-200mg/L indicates a clinical microalbuminuria, while the result greater than 200mg/L indicates a clinical proteinuria.

Due to physiological changes, small amounts of protein may be detected in healthy individuals. Large amounts of protein may appear in the urine owing to excessive exercise, stress or unbalanced meat diet. Additionally, premenstrual periods and hot baths may also see high protein. When protein results are too high or too low, other diagnostic results should be referred to.
Urobilinogen:
Positive results may arise from exercise, alcohol consumption, fatigue or constipation. Healthy individuals excrete small amounts of urobilinogen. The test strip results cannot detect a decrease in urobilinogen, indicating that the test strip cannot be zero.

Bilirubin:
Even small amounts of bilirubin detected in the urine shall be taken seriously.
Nitrite:
This reaction is only specific to nitrite rather than any other normal excretion in urine. Besides this reaction is only based on bacteria containing nitrate reductase, for which a negative result does not rule out the possibility of bacteriuria.

pH:
A normal urine sample is weakly acidic, with a pH around 6.0, which ranges from 5 to 9 depending on the diet.

Specific gravity:
The normal urine specific gravity is 1.000~1.030, which often varies with water intake, urine output, dietary properties and some other factors.

Blood:
The generation of blue-green spots on the test strip indicates the presence of non-hemolytic red blood cells. The test strip, extremely sensitive to hemoglobin, can complement each other with the microscopic examination. It has the same sensitivity to myoglobin. Urine containing heat-labile enzymes or bacteriuria can result in false positives.

Ketone:
Ketones are rarely seen in normal human urine. It may only appear due to hunger or strenuous exercise.

Leukocytes:
Test strips react with esterases in the urine white blood cells (neutrophils)

Ascorbic acid:
This reaction zone is used to detect ascorbic acid in urine, through which the level of ascorbic acid in the human body can be understood and the impact of ascorbic acid on the test strip results of glucose, bilirubin, blood and nitrite can be evaluated. The containing of oxidizing agents (such as potassium permanganate, hypochlorite, etc.) in the urine may affect the sensitivity of this test.

Creatinine:
The normal urine creatinine concentration of adults is 0.6-2.0 g/24 hours, and creatinine test results of random urine samples vary widely, from 0.9 mmol/L to 26.5 mmol/L. Concentrated urine and morning urine have higher levels.
Albumin-creatinine ratio

The content of albumin in normal urine of adults is less than 30mg of albumin/g of creatinine (3.4mg of albumin/mmol of creatinine). For that reason, the microalbuminuria can be concluded if the ratio in the sample is 30-300mg/g (3.4~33.9mg/mmol), and the albuminuria can be concluded if the ratio is >300 mg/g (33.9 mg/mmol).

Calcium:
A large amount of magnesium ions (greater than 10 mmol/L) can cause the urinary calcium test result to be slightly higher.

[Limitations of Test Method]
This is used for in vitro diagnosis only.
As with all laboratory tests, the determination of diagnostic results and treatment plans cannot build on any single diagnostic method.
The application of test strips is based on clinical analysis and research. For clinical urine samples, the detection limit depends on the following factors: variability of color identification, pH, specific gravity, medication use, changes in lighting conditions during visual test and so forth. Visual test results or instrument printout results actually represent a range. Due to the variability of urine samples and readings, the measured values of concerned analytes may deviate from the actual values to some extent. For protein, glucose, ketone and urobilinogen tests, the deviation of positive values above the second positive is usually within one "+". Given the inherent light-sensing difference between the eye and optical system, the visual test results and instrumental test results may not match completely.

[Reference Range]
Urobilinogen (UBG): Normal, ascorbic acid (VC): 0 mmol/L, creatinine (CRE) : 0.9-26.5 mmol/L, Calcium (Ca): 1.0-10 mmol/L, pH: 5.0-9.0, specific gravity (SG): 1.000-1.030. microalbumin (MALB): 10 mg/L, and negative for measured values of all other items. Due to the differences in geography, race, gender and age, it is recommended that each laboratory establish its own reference range.

[Performance Indices]

Detection Limit:			
Item	Unit	Detection Range	Detection Limit
UBG	μmol/L	Normal ~ 135	34
BIL	μmol/L	Neg ~ 100	17
KET	mmol/L	Neg ~ 16	0.5
CRE	mmol/L	0.9 ~ 26.5	0.9
BLD	cells/μL	Neg ~ 200	10
PRO	g/L	Neg ~ 20	0.15
MALB	mg/L	10 ~ 150	10
NIT	mg/dL	Neg ~ 0.25	0.125
LEU	cells/μL	Neg ~ 500	15
GLU	mmol/L	Neg ~ 56	2.8
pH	—	5.0 ~ 9.0	—
SG	—	1.000 ~ 1.030	—
VC	mmol/L	0 ~ 5.7	0.6
Ca	mmol/L	1.0 ~ 10	1.0





Accuracy: The test result of the test strip for each concentration of the reference solution for all the test items and the marked value of the corresponding reference solution shall not differ by more than one order of magnitude in the same direction, and reversed deviation shall not appear. Positive reference solution shall not be negative, while negative reference solution shall not be positive










Repeatability: The test strip repeatedly tests the positive samples, with the consistency of the test results no less than 90%.

Analysis performance specificity: When the VC concentration ≤1.4mmol/L, there will be no interference with the 0.25mg/dL nitrite test results.

[Precautions]
1. This product is for professional operation only and is exclusively applicable to in vitro diagnosis.
2. The test strip shall be kept in the original test strip bottle; the test strip shall not be taken out from the bottle except for immediate use; the cap of the bottle shall be tightened immediately after taking out the test strip; the desiccant shall not be taken out.
3. Test strips beyond the expiry date shall not be used. In case of inconsistency between test results and expected ones, please confirm whether the test strip has expired and test it with the quality control liquid.
4. Water cannot be used as the negative quality control liquid.
5. Each test strip can be used only once.
6. Please read the Instructions carefully before the use.
7. Used test strips shall be handled in reference to the laboratory method for biohazardous material treatment.
8. This product shall not be stored in the refrigerator; it shall be protected against direct sunlight; the reaction zone of the test strip shall not be touched; in order to protect the reactivity of the reagent, it shall be isolated from moisture, light and heat in the surrounding environment.

[Symbol Explanation]

Symbol	Explanation	Symbol	Explanation
	Consult instructions for use		Manufacturer
	Batch code		Date of manufacture

	Use-by date		In vitro diagnostic medical device
	Do not re-use		Temprature limit
	Comply with In Vitro Diagnostic Medical Device Directive (98/79/EC)		Authorised representative in the European Community
	Country of Manufacture (China)		Catalogue number
	Keep away from sunlight		

[References]
1. Zhang Dongqing. Urinary routine parameters and their significance, Chinese medical journal, 2010, 45(8) : 83 -84.
2. Xu Wenjuan, Wang Shipping. Urine routine test and its clinical significance, China Health Industry, 2012, 08: 185 -186.

[Manufacturer]
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[EMDN Code] W0101060205
[Basic UDI-DI] 697423503UCA0001EP

Catalogue Number	Model	Specification
410101277	CA-14	100strips/bottle
410101276	CA-13	100strips/bottle
410101275	CA-12	100strips/bottle
410101274	CA-11	100strips/bottle
410101273	CA-10	100strips/bottle
410101160	CA-9	100strips/bottle
410101158	CA-8	100strips/bottle
410101156	CA-5 (GLU、PRO、pH、BLD、KET)	100strips/bottle
410101154	CA-4 (GLU、PRO、pH、BLD)	100strips/bottle
410101152	CA-4 (GLU、PRO、pH、SG)	100strips/bottle
410101150	CA-3 (GLU、PRO、pH)	100strips/bottle
410101148	CA-3 (GLU、KET、PRO)	100strips/bottle
410101146	CA-2 (GLU、PRO)	100strips/bottle
410101144	CA-2 (GLU、KET)	100strips/bottle
410101142	CA-1 (PRO)	100strips/bottle
410101140	CA-1 (KET)	100strips/bottle
410101138	CA-1 (GLU)	100strips/bottle
410101169	CA-14	50strips/bottle
410101167	CA-13	50strips/bottle
410101165	CA-12	50strips/bottle
410101163	CA-11	50strips/bottle
410101161	CA-10	50strips/bottle
410101159	CA-9	50strips/bottle
410101157	CA-8	50strips/bottle
410101155	CA-5 (GLU、PRO、pH、BLD、KET)	50strips/bottle
410101153	CA-4 (GLU、PRO、pH、BLD)	50strips/bottle
410101151	CA-4 (GLU、PRO、pH、SG)	50strips/bottle
410101149	CA-3 (GLU、PRO、pH)	50strips/bottle
410101147	CA-3 (GLU、KET、PRO)	50strips/bottle
410101145	CA-2 (GLU、PRO)	50strips/bottle
410101143	CA-2 (GLU、KET)	50strips/bottle
410101141	CA-1 (PRO)	50strips/bottle
410101139	CA-1 (KET)	50strips/bottle
410101137	CA-1 (GLU)	50strips/bottle

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