

Instructions for Use

[Product Name] MC Urinalysis Strip		
[Package Specification] 50 strips/canister, 100 strips/canister		
	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, Vitamin C	
CA-12	Specific gravity, Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leukocytes, Glucose, pH, Vitamin C, Microalbumin	
CA-13	Specific gravity, Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leukocytes, Glucose, pH, Vitamin C, Microalbumin, Creatinine	
CA-14	Calcium, Specific gravity, Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leukocytes, Glucose, pH, Vitamin C, Microalbumin, Creatinine	

[Intended Purpose]
This product is intended for in vitro qualitative or semi-quantitative determination of calcium (Ca), specific gravity (SG), urobilinogen (UBG), bilirubin (BIL), ketones (KET), blood (BLD), protein (PRO), nitrite (NIT), leukocytes (LEU), glucose (GLU), pH,Vitamin C, microalbumin (MALB) and creatinine in human urine. This product is intended for use by healthcare professionals and laboratory personnel in medical institutions. Clinically, it is used as the auxiliary diagnosis of conditions related to renal diseases, diabetes mellitus, urinary tract infections, and hepatic/metabolic disorders. Results obtained from this product should not be used as the sole basis for confirming or excluding a diagnosis. Clinical evaluation should be performed in conjunction with the patient's symptoms, signs, and other diagnostic findings.

[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.
Ketone(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.
Vitamin C(VC): Ascorbic acid has a 1,2-enediol reductant group, which, under the condition of alkalinity, reduces the 2,6-DCIP 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 OCPG 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 OCPG
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: 7.7%w/v sodium nitroferricyanide
Blood:0.485% w/v tetramethylbenzidine
Protein:0.04% w/v tetraabromophenol 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
vitamin C:0.057% w/v2,6-DCIP
Microalbumin:0.028% w/v sulfophthalein dye
Creatinine:0.75% w/v 3,5-dinitrobenzoic acid
Materials required but not provided:

Product Name	Level	Specification	REF Code
MCC Control	Level 1	1×10mL	410102001
		4×10mL	410102008
		5×10mL	410102003

Product Name	Level	Specification	REF Code
MCC Control	Level 2	1×10mL	410102004
		4×10mL	410102011
		5×10mL	410102006
MCC Multiple Control	Level 1	1×10mL	410103001
		2×10mL	410103002
		4×10mL	410103003
MCC Multiple Control	Level 2	1×10mL	410103004
		2×10mL	410103002
		4×10mL	410103003
MC CMP Multiple Control	Level 1	1×10mL	410103013
		2×10mL	410103014
		4×10mL	410103015
MC CMP Multiple Control	Level 2	1×60mL	410103016
		1×10mL	410103017
		2×10mL	410103018
MC CM Multiple Control	Level 1	4×10mL	410103019
		1×60mL	410103020
		1×10mL	410102013
MC CM Multiple Control	Level 2	2×10mL	410102014
		4×10mL	410102015
		1×60mL	410102016
MCM Diluent	/	1×50mL	410106001
		4×50mL	410106002
MCC Cleaning	I	1×200mL	410107005
		4×200mL	410107006

[Storage Conditions and Shelf Life]
It should be stored in a dry place, sealed and protected from sunlight at 2-30°C, with a shelf life of 24 months.
After the first opening, it can be stable for 30 days when stored in a dry place, sealed and protected from sunlight at 2-30°C.

[Production Date and Expiration Date]
see the label.

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

[Sample Requirement]
1. Sample type: Fresh urine that has not been centrifuged.
2. Sample collection and processing: Collect urine samples using clean and dry containers. It is recommended to collect morning urine or random urine, and mid stream urine should be collected during sampling.
The sample should be thoroughly mixed before testing. After collection, it should be tested as soon as possible and it is not recommended to store it for a long time.
3. Not applicable samples: Samples that have deteriorated due to contamination or improper storage may affect the accuracy of test results. It is recommended to resample and test again.
4. Sample stability: The chemical composition of urine is unstable, and it is recommended to complete the test within 2 hours after sample collection. If it cannot be detected in a timely manner, it should be completed within the following time according to different storage conditions:
Storage at room temperature (15-30 °C): not exceeding 2 hours.
Refrigeration storage at 2-8 °C: not exceeding 24 hours.

[Test Method]
(1) When urinalysis strips are used in conjunction with a compatible urinalysis hybrid analyzer, the analyzer employs a dropper-dispensing mechanism to apply the sample onto the strips. For specific operating procedures, please refer to the user manual of the urinalysis hybrid analyzer.
(2) Testing environment requirements: At 20°C-30°C and relative humidity ≤80% RH. Balance the supporting controls to room temperature before the experiment.
(3) Sample pretreatment: Collect fresh urine using clean, dry containers. Gently invert and mix the sample before testing. The sample should be tested within 2 hours of collection; if refrigerated at 2-8°C, it may be stored for no more than 24 hours. Samples that are severely turbid, contaminated, or contain menstrual blood or secretions are not acceptable for use.
(4) Quality control procedures: Use commercially available urine controls, selecting at least two levels – normal and abnormal. Quality control must be performed whenever the strips' lot number is changed or after maintenance of the companion instrument. Control results must fall within acceptable ranges. If results are out of range, inspect the strips and controls for validity, verify the correctness of operating procedures, and retest after corrective action. If results remain unacceptable, suspend testing and investigate the cause.
(5) Calculation of test results: The instrument will automatically calculate the concentration of each specimen. Perform testing in accordance with the user manual of the companion instrument. To obtain accurate results, follow correct operating procedures and observe the specified measurement timing.

[Positive Judgement Value]		Reference Range / Expected Result	
Urobilinogen (UBG)		Normal	
Vitamin C (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	
Bilirubin (BIL)		Negative	
Ketones (KET)		Negative	
Blood / Occult Blood (BL)		Negative	
Protein (PRO)		Negative	
Nitrite (NIT)		Negative	
Leukocytes (LEU)		Negative	
Glucose (GLU)		Negative	

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(1) The reference range mentioned above come from the general healthy population, and may vary depending on age, gender, diet, physiological conditions, and the tested population. It's recommended that each lab establish its own reference range.
(2) The clinical interpretation of specific results should be combined with the patient's symptoms, signs, and other test results, and be comprehensively assessed by a doctor.

[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 vitamin C 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.

[Limitations of Test Method]
1. The test results of this product are used for auxiliary diagnosis of related diseases and cannot be used as the sole basis for determining or excluding diseases. Abnormal or suspicious results should be comprehensively judged based on the patient's clinical symptoms, signs, and other laboratory tests.
2. This product is a qualitative or semi quantitative test. Some test results are expressed as "negative, ±, 1+, 2+, 3+" levels, and some test results are expressed in quantitative concentration units, which reflect semi quantitative test results and cannot accurately reflect the true concentration of the analyte in urine.
3. Certain drugs or their metabolites, abnormal urine components, or high concentrations of test substances may interfere with the detection, leading to false positive or false negative results. For example, high-dose vitamin C may have negative interference (low or false negative results) on glucose (GLU), blood (BLD), nitrite (NIT) and other items; Strong oxidative pollutants may cause false positives in blood (BLD).
4. Any clinically significant test results should be consulted with professional medical personnel for comprehensive judgment, and clinical decisions should not be made solely based on these test results.

[Performance Indices]
1.Summary of Performance Analysis Research:
Limit of detection:
Randomly select 20 test strips from the same batch and test the first non negative level of each test item. The limit of detection of each item is:

Item	Unit	Detection Range	Limit of Detection
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

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

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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).
vitamin C:
This reaction zone is used to detect vitamin C 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.
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Accuracy: Repeat the detection of the reference solution at each concentration level for all items three times using strips, and calculate the difference in magnitude between the detection results and the labeled values of the reference solution.The test result of strips 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 reverse deviation shall not appear. Positive reference solution shall not be negative, while negative reference solution shall not be Positive.
Repeatability: Randomly select 20 strips from the same batch number, test the same positive sample separately, and calculate the consistency of the test results for each item. The strips repeatedly tests the positive samples, with the consistency of the test results no less than 90%.
Analysis specificity: Randomly select 3 strips from the same batch and use them to detect the concentration of anti vitamin C interference reference solution. When the VC concentration ≤1.4mmol/L, there will be no interference with the nitrite test results at 0.25mg/dL .
2.Summary of clinical performance evaluation: A comparative study was conducted between this product and a domestically marketed product of the same variety (Urinalysis Strips, model FUS-14Call). A total of 400 clinical urine samples were collected and tested using synchronous blind method. The positive coincidence rate of each item is 92.86% to 100.00%, the negative coincidence rate is 93.98% to 100.00%, the total coincidence rate is 95.00% to 99.75%, the false negative rate is 0.00% to 2.00%, the gradient coincidence rate is 94.25% to 100.00%, and the Kappa coefficient is all greater than 0.75, indicating good consistency. The clinical performance meets the expected usage requirements.

Instructions for Use

[Warnings and Precautions]
1.This product is for professional operation only and is exclusively applicable to in vitro diagnosis. It is not intended for self-testing or near-patient testing.
2.The strips must be sealed and stored in its original packaging, and the desiccant must not be removed. Avoid freezing, direct sunlight, and isolate moisture and heat sources in the environment.
3. If taken out of the refrigeration equipment, it should be restored to room temperature before opening the outer packaging to prevent condensation from affecting the performance of the strips.
4. Do not use strips that have exceeded their expiration date. If the test results do not match clinical expectations, it is necessary to confirm whether the strips are within the validity period and use the matching control for testing. Water cannot undergo negative quality control.
5. The container for collecting urine should be clean. If there are residues of detergent or disinfectant, it may interfere with the measurement results.
6. During the testing process, it is necessary to strictly follow the operating steps specified in the instructions and relevant laboratory standards. Any deviation in operation may affect the accuracy of the results.
7. Each strip can only be used once. Please read the instructions for use carefully before use.
8. Do not touch the reaction zone of the test strip with your hands to protect the reactivity of the test strip.
9. All patient samples and post use strips should be considered as potential infectious biohazards and must be disposed of in accordance with the laboratory biohazard waste disposal procedures of the institution.
10. Any serious incident relating to the device shall be reported to the manufacturer and to the competent authority of the Member State where the user and/or the patient is established.

[Symbol Explanation]					
Symbol	Explanation	Symbol	Explanation	Symbol	Explanation
	Consult Instructions for Use		Manufac-turer		Batch code
	Date of Manufacture		Use-by date		In vitro diagnostic medical device
	Do not re-use		Tempera-ture limit		CE Mark, certified by BSI
	Authorized representative in the European Union		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 Information]
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Manufacturer Address: Room 701-707, Building 7, Changxinchuanggu, West of Beiyuanda Street and south of Longhu Road, Beihu Science and Technology Development Zone, Changchun, Jilin 130052, P.R.China
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Model	Specification	Catalogue Number	UDI-DI
CA-14	100strips/barrel	410101277	06974235031891
CA-13	100strips/barrel	410101276	06974235031938
CA-12	100strips/barrel	410101275	06974235031976
CA-11	100strips/barrel	410101274	06974235032010
CA-10	100strips/barrel	410101273	06974235032058
CA-9	100strips/barrel	410101160	06974235032096
CA-8	100strips/barrel	410101158	06974235032133
CA-5(GLU, PRO, pH, BLD, KET)	100strips/barrel	410101156	06974235032171
CA-4(GLU, PRO, pH, BLD)	100strips/barrel	410101154	06974235032218
CA-4(GLU, PRO, pH, SG)	100strips/barrel	410101152	06