[Product Name]
MCC Multiple Control

[Package Specification]
Level 1 1×10mL; 2×10mL; 4×10mL
Level 2 1×10mL; 2×10mL; 4×10mL

[Intended Use]
It is used for the quality control of urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, specific gravity,pH, ascorbic acid, microalbumin, creatinine, calcium, color, turbidity and conductivity of the dry chemical analyzer and urine test strip.

[Test Principle]
Dry chemical items refer to dry chemical analysis method; conductivity refers to Ohm's law; Turbidity refers to infrared scattering principle (90°light measurement) ; SG refers to refraction principle; color refers to reflection principle.

[Main Component]
Level 1:Ascorbic acid
Level 2:Indole derivative, nitro cobalt salt, anhydrous, glucose, urea, creatinine,calcium chloride, albumin,hemoglobin,esterase,naphthy lamine salt.
Note: See the target value table for the specific target value range.

[Storage Conditions and Shelf Life]
It shall be dried and sealed for preservation (away from light)under 2°C-8°C.

Shelf Life
12 months; After opened, the reagent shall be sealed and stored in a dry place at 2℃-8℃, and kept away from sunlight. The opening shelf life is 30 days.

Production Date and Used-by Date
See label.

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

[Test Method]
1.Balance the reagent to room temperature.
2.Turn the reagent bottle over slightly to make the reagent fully mixed.
3.After the bubble disappears, pour the reagent into the test tube.
4. Place the test tube containing reagent in the test-tube rack of applicable instrument in the order of low level to high level.
5. Put the test-tube rack into the instrument testing area for quality control.
6. For instrument operation, please refer to the User Manual.

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

[Interpretation of Test Results]
QC test result of each item shall be within the target value range. If not, the item should be retested by the same QC or new one.

[Limitations of Test Method]
The test results are affected by the method, instrument, operation technology and reagent type, so the test shall be carried out in strict accordance with the reagent specification and instrument user manual.

[Product Performance Indices]
1.Accuracy:the test results of urobilinogen, bilirubin, ketone , blood, protein, nitrite, leukocytes,glucose, specific gravity,pH,ascorbic acid ,microalbumin, creatinine, calcium, color,turbidity and conductivity should be within the target value range.
The deviation between the average value of the test results of specific gravity, pH, glucose and albumin and the nominal value meets the requirements in the following table.

Product Mode	Specific Gravity	pH	Glucose	Albumin
Level 1	≤0.005	≤0.2	≤1.0mmol/L	≤0.05g/L
Level 2	≤0.005	≤0.2	Relative deviation ≤5%	Relative deviation ≤15%

2. Uniformity: degree of consistency of all items from one strip is 100%.
Conductivity: CV≤10%; SG: CV≤2%; Turbidity: CV≤10%.
Note: Uniformity of Level 1 turbidity is not calculated.

[Precautions]
1.This product is used for in vitro diagnosis only.
2. Invert the bottle several times before use for even mixing.
3.After use, the bottle should be covered with the cap in time to avoid pollution.
4.Please do not pour the remaining quality control materials back into the original reagent bottle.
5.If the reagent accidentally enters the eyes or mouth, or comes into contact with the skin, please rinse with water immediately, and seek medical attention if necessary.

[References]
1.By Xiao Ying. Analysis of clinical urine routine test, Chinese medical innovation, 2009,6(25) : 1.
2.Yin Tao. The clinical significance of routine urine examination, basic medicine forum, 2012,16(35) : 4727

MEDICSIDE Instruction For Use

[Symbol Explanation]

Symbol	Explanation	Symbol	Explanation
	Consult instructions for use		Manufacturer
LOT	Batch code		Date of manufacture
	Use-by date	IVD	In vitro diagnostic medical device
	Keep away from sunlight		Temperature limit
CE	Comply with In Vitro Diagnostic Medical Device Directive(98/79/EC)	EC REP	Authorised representative in the European Community
CN	Country of Manufacture(China)	REF	Catalogue number
	Danger Causes severe skin burns and eye damage		

[Catalogue Number]

Catalogue Number	Model	Specification
410103007	Level 1	1×10mL
410103008	Level 1	2×10mL
410103009	Level 1	4×10mL
410103010	Level 2	1×10mL
410103011	Level 2	2×10mL
410103012	Level 2	4×10mL

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[Manufacturer]
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