

[Product Name]

MCC Control

[Package Specification]

Level 1 1×10mL; 4×10mL; 5×10mL
Level 2 1×10mL; 4×10mL; 5×10mL

[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 and calcium of urine test strip and the dry chemical analyzer.

[Test Principle]

Used for dry chemical analysis, the control can objectively measure and evaluate the methods and technologies used in the laboratory.

[Main Component]

Product Model	Main component
Level 1	Sodium chloride, ascorbic acid
Level 2	Anhydrous glucose, urea, creatinine, calcium chloride, albumin, hemoglobin, esterase, naphthylamine 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 under 2℃ - 8℃.

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 User Manual.

[Expected Operator]

Used by trained technicians, nurses and physicians.

[Interpretation of Test Results]

The test result of the quality control material for the project shall be within the target value range. If the quality control result is not within the target value range, the material needs to be retested or replaced with a new bottle of quality control material for retest.

[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]

Accuracy: the test results of urobilinogen, bilirubin, ketone, blood, protein, nitrite, leukocytes, glucose, specific gravity, pH, ascorbic acid, microalbumin, creatinine and calcium 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 Model	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. Homogeneity: the consistency of test results of all items is 100%.

[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

[Symbol Explanation]

Symbol	Explanation	Symbol	Explanation
	Consult instructions for use		Manufacturer
	Batch code		Date of manufacture
	Use-by date		In vitro diagnostic medical device
	Keep away from sunlight		Temperature limit
	Comply with In Vitro Diagnostic Medical Device Directive (98/79/EC)		Authorized representative in the European Community
	Country of Manufacture (China)		Catalogue number

[Manufacturer]

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[EMDN Code] W0101050207

[Basic UDI-DI] 697423503UCA0002ER

[Catalogue Number]

Catalogue Number	Model	Specification
410102007	Level 1	1×10mL
410102008	Level 1	4×10mL
410102009	Level 1	5×10mL
410102010	Level 2	1×10mL
410102011	Level 2	4×10mL
410102012	Level 2	5×10mL

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