

[Product Name]

MCC Cleaning

[Package Specification]

- I 1x200mL 4x200mL
II 1x500mL 4x500mL
III 1x50mL 4x50mL

[Intended Use]

It is used to clean the reaction system during test, which facilitates the in vitro test on the substance to be tested. It does not contain the Cleaning used solely for instrument cleaning.

[Test Principle]

I, II: It's used to flush the pipeline based on the surfactant decontamination principle.

III: It is used to clean the pipeline and probe of the instrument based on the principle of sodium hypochlorite cleaning.

[Main Component]

- I: Brij-35 0.16%W/V
II: Tris buffer 7.2%W/V, Brij-35 3.2%W/V
III: Sodium hypochlorite 0.5% W/V

[Storage Conditions and Shelf Life]

It shall be dried and sealed for preservation (away from light) at 2°C-30°C.

Shelf Life 12 months.

[Production Date and Used-by Date]

See label.

[Applicable Instrument]

I,II: It is applicable to CA series Urine Analyzer, CM series Urinalysis System produced by Zhejiang Medicside Medical Technology Co., Ltd., FUS series Urinalysis System, MUS series Urinalysis System, H-800 Urine Analyzer, H-1600 Urine Analyzer, HC-900 Urine Analyzer produced by DIRUI Industrial Co., Ltd.

III: It is applicable to MA series Urine Sediment Analyzer, CM series Urinalysis System produced by Zhejiang Medicside Medical Technology Co., Ltd., FUS series Urinalysis System, MUS series Urinalysis System produced by DIRUI Industrial Co., Ltd.

[Test Method]

- Dilution: I and purified water are diluted in the ratio of 1:49 before use. II and purified water are diluted in the ratio of 1:19 before use. The operation should follow the suitable analyzer user manual.
- III is directly used following the suitable analyzer user manual.

[Expected Operator]

Used by trained technicians, nurses, and physicians.

[Product Performance Indices]

- Cleaning shall be in liquid form, there may be insoluble particles which not impacting the measurement.
- The net volume should not be less than the indicated value.
- The pH value of the Cleaning I and II is 7.0±1.0 at (22±1)°C, of cleaning III is 11.5±1.0 at (22±1)°C.
- Between-batch deviation of I,II, III pH: after dilution, $\Delta pH \leq 1.0$.













[Precautions]

- This product is used for in vitro diagnosis only.
- Do not use expired products.
- Used fluid shall be handled in reference to the laboratory method for biohazardous material treatment.
- If the fluid 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]

- Mei Min, Liang jieling, Li Haizhu, etc.. Clinical significance of electrical conductivity in urine analysis[J].Laboratory and clinical medicine,2006,17(2)
- Zhang Dongqing.Urinary routine parameters and their significance,Chinese medical journal. 2010,45(8):83-84.

[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 Regulation ((EU) 2017/746)		Authorised representative in the European Community
	Country of Manufacture(China)		Catalogue number

[Manufacturer]

Changchun Medicside Medical Technology Co.,Ltd

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SRN:NL-AR-000000444

[EMDN Code]W01019001

[Basic UDI-DI]697423503UCA0006EZ

[Catalogue Number]

Catalogue Number	Model	Specification
410107005	I	1×200mL
410107006	I	4×200mL
410107007	II	1×500mL
410107008	II	4×500mL
410205003	III	1×50mL
410205004	III	4×50mL

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