mindray

Automatic Urinalysis System Reagent (EU-50)

Packing Specifications

5L×2

Intended Use

It is used for diluting samples before urine analysis and preparation of cell suspension.

Performance Specifications

- Appreance: The product is clear liquid without any precipitation, particles or flocs-cules.
- pH value: The pH value of the product at (25±1) ℃ should be between 7.0 to 11.0.
- Blank count results: The blank count results of the product tested on Automatic Urinalysis System should be less than 1 particle/μL.
- Electrical conductivity: The electrical conductivity value(ρ) of the product at (25±1)℃ should be between (16±5)mS/cm.

Test Principle

The diluent is used to prepare cell suspension which is needed during performance testing, or dilute high-value urine samples prior to the urine analysis to provide a stable solution environment for the analysis.

Major Components

Polyoxyethylene lauryl ether	0.1 g/L - 1.0 g/L
Sodium methyl parahydroxybenzoate	0.01 g/L - 1.0 g/L
NaCl	4.5 g/L - 11.5 g/L

Applicable Instruments

This product applies to Automatic Urinalysis System manufactured by Mindray: EU-3000, EU-3000 Pro, EU-5300, EU-5300 Pro, EU-5600, EU-5600 Pro.

Sample Requirements

Urine sample types include random urine, morning urine, catheter and suprapubic bladder puncture urine.
Note: For detailed sample requirements, refer to the Operator's Manual of the applicable instruments.

Sample Collection and Preparation

Refer to the Operator's Manual of the applicable instruments.

Material Required but Not Provided

The following materials are required but not provided with the product: Mindray-manufactured urianlysis instruments and matched reagents.

Test Methods

1. Open the external package of the product.
2. Restore the product to working temperature.
3. Connect the reagent cap assembly to the diluent inlet on the back panel of the analyzer. Note the inlet connector is of the same color of the reagent cap assembly.
4. Insert the pickup tube into the reagent container.
5. Screw the reagent cap assembly tightly, and follow the instruction in the Operator's Manual to use the product.

For detailed test procedure, refer to the Operator's Manual of the applicable instruments.

Storage Conditions and Stability

- The working temperature range of the product is consistent with that of its applicable instruments.
- Store the product in a well-ventilated environment, at 2 ºC to 40 ºC (35ºF to 104 ºF), and with relative humidity not exceeding 93%.
- Keep the product away from corrosive gas.

For the expiry date, see the product package or the label.

Stability	
Unopened under storage conditions	Two years
Open-vial vailidity	90 days

Reagent Preparation

The product is a ready-to-use reagent.

Result Elaboration

Not applicable.

Cut-off Value and Reference Interval

Not applicable.

Limitation

Not applicable.

Precautions and Warnings

- For ***in-vitro diagnostic use*** only. For laboratory professional use.
- Read the package inserts carefully before using this product. The product shall be used before the expiry date and disposed of properly when expired.
- Confirm the integrity of the package before use. Do not use the product if the package is damaged. Otherwise, the test results may not be accurate.
- Do not use expired products.
- Do not mix reagents of different lots.
- Avoid exposure to skin and mucous membranes. If the product accidentally spill on your skin, wash them off with plenty of water and go seek medical treatment if necessary.
- Avoid exposure to eyes. If you accidentally spill the product into your eyes, wash it off with plenty of water and go seek medical treatment if necessary.
- Do not take the product into your mouth. If you accidentally take the product into your mouth, go seek medical treatment.
- Dispose waste product, unused product and contaminated package in accordance with governmental requirements.
- The Material Safety Data Sheet (MSDS) is available upon request.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.

Symbols

LOT Batch code	Use-by date	Temperature limit	Consult Instruction for Use
IVD *In vitro* diagnostic medical device	Manufacturer	Humidity limitation	REF Catalogue number
EC REP Authorized representative in the European Community	CE European Conformity	UDI Unique device identifier	

REFERENCES

Not applicable.

Company Contact

Manufacturer	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address	Mindray Building Keji 12th Road South, High-tech Industrial Park, Nanshan, Shenzhen 518057, P.R. China.
Website	www.mindray.com
E-mail address	service@mindray.com
Tel	+86 755 81888998
Fax	+86 755 26582680

Authorized Representative in the European Community

EC-Representative	Shanghai International Holding Corp. GmbH(Europe)
Address	Eiffestraβe 80, 20537 Hamburg, Germany
Tel	0049-40-2513175
Fax	0049-40-255726

Approval Date of the Instruction for Use

2023-08

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Digitally signed by Poiata Vitalie
Date: 2025.07.29 17:37:06 EEST
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