

FE Calibrator II

Instruction

[Product name] FE Calibrator II

[Package specification] 1×10 mL, 1×12 mL, 1×15 mL, 1×60 mL, 1×125 mL.

[Intended use] This product is used to calibrate Urine Sediment Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System to ensure test accuracy.

[Test principle] Flow cytometry imaging

[Main component] QC blood: 900 particles/µL~1,300 particles/µL;

Note: fixed values of different batches of formed elements analysis calibrator are different (see the label for details); and the traceability of fixed values is from internal reference methods of the company.

[Storage conditions and shelf life]

- 1. This product shall be sealed and kept in a dark place at the temperature of $2^{\circ}\text{C}\sim8^{\circ}\text{C}$. For shelf life refer to the label.
- 2. After being unsealed for the first time, it shall be sealed and kept in a dark place at the temperature of $2^{\circ}C^{\circ}$, and the shelf life is 7 days.

[Test method] Refer to the user manual of the applicable instrument.

[Product performance indices]

- 1. Accuracy: total particles: 900 particles/ μ L~1,300 particles/ μ L; relative bias shall be within the range of $\pm 10.0\%$.
- 2. Homogeneity: CV≤10.0%

[Cautions]

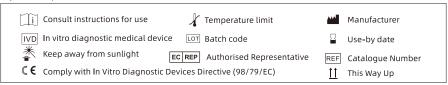
- 1. This product is used for in vitro diagnostics only.
- 2. Shake the product for 1~3min before use, and do not shake it violently. If it is not mixed well, the number of tested particles may be smaller, thus affecting the calibration result.
- 3. Freeze is prohibited.
- 4. To avoid or reduce relevant infection risks, please wear disposable gloves and eyes/face protection articles when using the product.

[References]

- 1. Ferris JA urine microscopy comparison & standard: Lab Med14: 659-662,1983.
- 2. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition.

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[Symbol Explanation]



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