



## 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°C~8°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°C~8°C, 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/μL~1,300 particles/μL; relative bias shall be within the range of ±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.

【Instruction Approved and Modified Date】 05/2023

【Symbol Explanation】



Consult instructions for use



Temperature limit



Manufacturer



In vitro diagnostic medical device



Batch code



Use-by date



Keep away from sunlight



Authorised Representative



Catalogue Number



Comply with In Vitro Diagnostic Devices Directive (98/79/EC)



This Way Up

**DIRUI INDUSTRIAL CO., LTD.**

95 Yunhe Street, New & High Tech.

Development Zone Changchun, Jilin 130012 P.R.China

Tel: +86 431 85100409 Fax: +86 431 85172581

E-mail: dirui@dirui.com.cn http://www.dirui.com.cn



Emergo Europe B.V. Westervoortsedijk 60  
6827 AT Arnhem The Netherlands