

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_有形成分分析校准液II_说明书		
库存编码	x	版本号	20180820
成品尺寸	140×190mm	单位	mm
印刷色	单色	允差	±2mm
材质	80g胶版纸		
备注			
设计			
审核			
批准			

DIRUI[®]

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. Refrigeration 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】 08/2018

【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

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