

PDM签审页

PDM版本:

PDM编码:

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产品名称	出口_有形成分分析聚焦液工_说明书		
库存编码		版本号	20180919
成品尺寸	140×190mm	单位	mm
印刷色	単色	允差	±2mm
材质	80g胶版纸		
备注			
设计			
审核			
批准			





FE Focus B II

Instruction

[Product name] FE Focus BII

[Package specification] 1×20 mL, 1×22 mL, 1×25 mL, 1×60 mL, 1×125 mL.

[Intended use]

This product is used to determine position of focal plane of microscopic imaging system for Urine Sediment Analyzer, FUS Series Urinalysis Hybrid and MUS Series Urinalysis System.

[Test principle] Flow cytometry imaging

[Main component] QC blood: 2,500 particles/µL~3,500 particles/µL;

Note: fixed values of different batches of formed elements analysis focus are different (see the label for details).

[Storage conditions and shelf life]

- 1. This product shall be sealed and kept in a dark place at the temperature of $2^{\circ}\text{C} 8^{\circ}\text{C}$. 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 open-vial shelf life is 30 days.

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

[Product performance indices]

- 1. Accuracy: total particles: 2,500 particles/µL~3,500 particles/µL;

[Cautions]

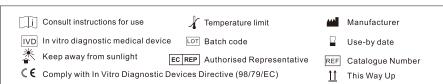
- 1. This product is used for in vitro diagnostics only;
- 2. Shake the product for 1~3min before use, and do not shake it violently. If it is not being mixed well, the tested number of particles may be smaller, which will affect the focus effect.
- 3. Refrigeration is prohibited.
- 4. To avoid or reduce 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] 09/2018

[Symbol Explanation]



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