

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_有形成分分析聚焦液II_说明书		
库存编码		版本号	20180919
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 Focus B II

Instruction

【Product name】 FE Focus B II

【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°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 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/μL~3,500 particles/μL;

2. Homogeneity: CV≤15.0%

【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 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】

 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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