DIRUI 迪瑞

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_有形成分分析质控液II_阳性_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 Control Ⅱ Positive Control

Instruction

【Product name】FE Control Ⅱ Positive Control

【Package specification】Level 1 of positive control: 1×20 mL, 1×22 mL, 1×25 mL, 1×60 mL, 1×125 mL;
Level 2 of positive control: 1×20 mL, 1×22 mL, 1×25 mL, 1×60 mL, 1×125 mL;
Level 3 of positive control: 1×20 mL, 1×22 mL, 1×25 mL, 1×60 mL, 1×125 mL;

【Intended use】This product is used for QC of test process of Urine Sediment Analyzer, FUS series urinalysis hybrid and MUS series urinalysis system.

【Test principle】Flow cytometry imaging

【Main components】Level 1 of positive control: QC blood: 50 particles/μL~300 particles/μL;
Level 2 of positive control: QC blood: 300 particles/μL~700 particles/μL;
Level 3 of positive control: QC blood: 900 particles/μL~1,300 particles/μL;
Note: control range varies with the batch (see the label for fixed values of each batch).

【Storage conditions and shelf life】

1. This product shall be sealed and kept in a dark place at the temperature of 2℃~8℃. 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℃~8℃, 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: Level 1 of positive control: relative bias shall be within the range of ±25.0%;
Level 2 of positive control: relative bias shall be within the range of ±15.0%;
Level 3 of positive control: relative bias shall be within the range of ±15.0%;
2. Homogeneity: Level 1 of positive control: CV≤15.0%;
Level 2 of positive control: CV≤10.0%;
Level 3 of positive control: 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 QC 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
IVD In vitro diagnostic medical device	LOT Batch code	Use-by date	Biohazard
Keep away from sunlight	EC REP Authorised Representative		REF Catalogue Number
CE Comply with In Vitro Diagnostic Devices Directive (98/79/EC)			This Way Up

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