

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工_阴性_说明书 | | |
|------|----------------------|-----|----------|
| 库存编码 | Х | 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 | | | |





FE Control II Negative Control

Instruction

[Product name] FE Control II Negative Control

[Package specification] Negative 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] Negative control: disodium hydrogen phosphate: 6.7 mmol/L.

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°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 number of negative control shall be ≤20/µL.
- 2. Homogeneity: negative control not being tested

[Cautions] 1. This product is used for in vitro diagnostics only.

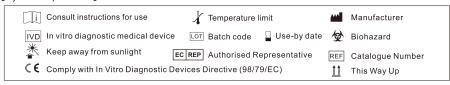
- 2. Shake the product for 1~3min before use, and do not shake it violently. If it is not mixed well, the number of tested particles may be smaller, thus affecting the QC result.
- 3. Refrigeration is prohibited.
- 4. To avoid or reduce relevant infection risks, please wear disposable gloves and eyes/face 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]



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