

PDM签审页

PDM版本：

PDM编码：

| | | | |
|------|------------------------------|-----|----------|
| 产品名称 | 出口_尿液分析用鞘液II_FUS-1000_说明书_A类 | | |
| 库存编码 | 1075774 | 版本号 | 20230712 |
| 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 | | | |



FUS Series Urinalysis Hybrid Sheath II

Instructions

[Product Name] FUS Series Urinalysis Hybrid Sheath II

[Basic UDI-DI] 69257945W010106020302R0FD

[Package Specification]

5L/barrel, 10L/ barrel, 15L/ barrel, 20L/ barrel, 28L/ barrel, 30L/ barrel

[Intended Use]

It is used for wrapping the sample to form a sheath flow to count formed elements in urine.

[Test Principle]

Flat flow cell imaging principle

[Main Components]

22mmol/L Tris buffer, 0.02% EDTA-2Na

[Storage Conditions]

Stored at 2-30°C in a dry place, protected from sunlight and in seal.

[Shelf Life]

1. The shelf life is 18 months if stored at 2-30°C and in seal.
2. The shelf life is 60 days after being opened if stored at 2-30°C.

[Date of Manufacture & Expiry Date] See the label

[Applicable Instrument] DIRUI FUS-1000/1000PLus Urinalysis Hybrid

[Test Method]

Use and install the reagent according to user manual of applicable instrument.

[Sample Requirements]

The sample type is fresh urine sample without centrifugation, placed at room temperature, and the urine should be tested within 2 hours.

[Sample Processing]

The sample does not require special treatment and can be used directly for testing.

[Product Performance Indices]

1. Appearance: colorless transparent liquid without sediments, particles or floccules
2. Net weight: no lower than the nominal value
3. pH value: at (25±1)°C, pH is 7.55±0.20
4. Osmotic concentration: (275±10)mmol/L, i.e. (275±10)mOsm/kg
5. Between-batch difference:

| Test item | Between-batch difference |
|-----------------------|--------------------------|
| pH value | ≤0.40 |
| Osmotic concentration | ≤20mmol/L (20mOsm/kg) |

[Warnings and Precautions]

1. The product is only for in vitro diagnosis and professional use.
2. Avoid contact with eyes and skin.
3. Rinse eyes with the flow of warm water for a few minutes if the product splashes into eyes, ensure that the eyes are open. Seek medical care immediately if pain or swelling happens. Once in contact with the skin, rinse with soap water and then rinse with water.
4. The test waste liquid should be treated in accordance with the medical waste management regulations.
5. If any adverse events occur during use, please report to the competent authority of the Member State where the manufacturer is located.

Safety precautions:

Hazard pictograms: No hazard pictogram is used.

Signal word(S): No signal word is used.

Preventive measure: Not applicable.

Emergency measure: Not applicable.

For information about the safety technical manual, contact your local supplier or customer service representative.

[References]

1. Ferris JA Comparison and Standards of Urine Microscopy Lab Med 14: 659-662, 1983.
2. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline-Second Edition.

[Symbol Explanation]

| | | |
|---|-----------------------------|-----------------------|
| Please read Instructions | Storage temperature | Manufacturer |
| Catalogue number | Lot No. | Expiry date |
| Authorized representative | In vitro diagnostic reagent | County of manufacture |
| European in Vitro Diagnostic Medical Device Regulation(EU) 2017/746(IVDR) | | |

[Instructions Approved & Modified Date] 2023-07



DIRUI INDUSTRIAL CO., LTD.

95 Yunhe Street, New & High Tech.

Development Zone Changchun, Jilin 130012 P.R.China

Tel: +86 431 85100409 Fax: +86 431 85172581

E-mail:dirui@dirui.com.cn http://www.dirui.com.cn



SUNGO Europe B.V. Fascinatio Boulevard 522,
Unit 1.7, 2909VA Capelle aan den IJssel,
The Netherlands