

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_尿液分析用鞘液 (Fus-3000Plus) _说明书_A类		
库存编码	1075797	版本号	20230712
成品尺寸	140×190mm	单位	mm
印刷色	单色	允差	±2mm
材质	胶版纸		
备注			
设计			
审核			
批准			

Sheath

Instructions

[Product Name] Sheath

[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]

23mmol/L Tris buffer, 0.6% sodium chloride

[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 Series Urinalysis Hybrid (Except FUS-2000), MUS Series Urinalysis System, Urine Sediment Analyzer (Model:FUS-360) .

[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