

## PDM签审页

PDM版本：

PDM编码：

产品名称	出口_尿有形稀释液_说明书_A类		
库存编码	1075772	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			



# Urine Sediment Analyzer Reagent Diluent

## Instructions

**[Product Name]** Urine Sediment Analyzer Reagent Diluent

**[Basic UDI-DI]** 69257945W010106020302R0FD

**[Package Specification]** 1×500mL, 1×50mL

**[Intended Use]**

As a non-automated reagent and auxiliary reagent, it is used to dilute urine samples, and then the samples are tested by DIRUI FUS Series Urinalysis Hybrid, MUS Series Urinalysis System, FUS Series Urine Sediment Analyzer.

**[Test Principle]**

The diluent has suitable osmotic pressure and conductivity to ensure that various components in the diluted urine sample are complete and not destroyed.

**[Main Components]**

disodium hydrogen phosphate: 0.84%, potassium chloride: < 0.01%, potassium dihydrogen phosphate: 0.73%

**[Storage Conditions]**

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

**[Shelf Life]**

The shelf life is 12 months if stored at 2-30°C and in seal. The shelf life is 30 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, MUS Series Urinalysis System, FUS Series Urine Sediment Analyzer.

**[Test Method]**

Diluent is used to directly dilute the sample according to the test needs, and the diluted sample is directly tested on the applicable instrument according to the instrument operation interface.

**[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 sediment, particles or floccules
2. Net weight: no lower than the nominal value
3. pH value: at (25±1)°C, pH is 6.30±0.20
4. Conductivity: at (25±1)°C, (16.00±0.50)mS/cm
5. Osmotic concentration: (310±10) mmol/L (310±10mOsm/kg)
6. Between-batch difference:

Test item	Between-batch difference
pH value	≤0.40
Conductivity	≤1.00mS/cm
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 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