

PDM签审页

PDM版本：

PDM编码：

产品名称	出口_尿有形成分分析仪应用试剂-鞘液_说明书_A类		
库存编码	1075795	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 Sheath

Instructions

[Product Name] Urine Sediment Analyzer Reagent Sheath

[Basic UDI-DI] 69257945W010106020302R0FD

[Package Specification] 1×5L, 1×10L, 1×15L, 1×20L, 1×28L, 1×30L

[Intended Use]

As automated reagent and auxiliary reagent, it is used to wrap the urine sample to form a sheath flow. The reagent itself has no diagnostic function.

[Test Principle]

Flat flow cell imaging principle

[Main Components]

6mM PBS buffer, 0.09% sodium chloride, 0.01% EDTA-2Na, 0.01% non-ionic surfactant

[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-100/200 Urine Sediment Analyzer, FUS-2000 Urinalysis Hybrid

[Usage 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. Conductivity: at (25±1)°C, conductivity is $\rho=(13.80\pm0.50)\text{mS/cm}$
5. Osmotic concentration: (275±10)mmol/L, i.e. (275±10)mOsm/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 shall be treated uniformly 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



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