Dry Chemistry Urine analysis Control Instruction

【Product Line】

Dry Chemistry Urine analysis Control

【Package】

Model	Quality Control item	Specification
NO.I	Ca、Cr、SG、MA、KET、GLU、LEU、pH、BLD、VC、PRO、BIL、URO、NIT	4mL/bottle, 15 bottles/box
NO.II	Ca、Cr、SG、MA、KET、GLU、LEU、pH、BLD、PRO、BIL、URO、NIT	4mL/bottle, 15 bottles/box
NO.III	VC	4mL/bottle, 15 bottles/box
Remark: In addition to pH, SG, Ca and Cr, the quality control NO.I can perform negative tests on each item; NO.II can perform positive tests on corresponding item; NO.III can perform positive test only for VC.		

【Intended Use】

Internal quality control (IQC) for Keyu serial Urine analyzer and Urine Reagent Strips manufactured by Zhuhai Keyu Biological Engineering Co., Ltd.

【Main Components】

Model	Component
NO.I	Composed of urea, sodium chloride and buffer, etc.
NO.II	Composed of bovine serum albumin, bovine hemoglobin, glucose, nitrite, creatinine, calcium chloride, etc.
NO.III	Composed of ascorbic acid and buffer, etc.

【Storage and shelf life】

1. The control shall be stored at 2℃ - 8℃ and kept away from light.
2. Valid for 18 months. Do not use beyond the expiration date.
3. Stored at 2℃ - 8℃ and kept away from light after opened, it will be valid for 1 month.

【Applicable instruments】

Instrument Name	Model
Dry Chemistry Urine Analyzer	KU-500, KU-U200
Urinalysis System	KU-2800

【Sample requirement】

None.

【Test method】

1. Take out the dry chemical urine analyzer quality control and equilibrate to room temperature.
2. Mix the QC by inverting up and down.
3. Pour the QC into a clean tube, place it in the sample holder and run the QC procedure according to the instrument.
4. The QC used can not be reused.
5. Compare the test results with the target values provided by the manufacturer.

【Target values and quality control range】

The target values and quality control ranges of the products are shown in the table of target values.

【Result Interpretation】

1. All the test results should be within the quality control range.
2. If the test result are not within the quality control range, a thorough analysis of the test system is required to fine the cause.

【Limitation】

Some items of the dry chemical urine analyzer quality control are replaced with mimics, so the reaction color may differ from that of the clinical sample.

【Precautions】

1. This product is for in vitro diagnostic use only.

2. Avoid contact with eyes and skin when using; if contact is accidental, please rinse with water immediately.

3. Please do not use quality control beyond the validity period.

4. User should not touch the reagent part of the urinalysis strips used for QC with their hands. The dry chemistry urine analyzer and automatic urine analysis system should have clean test strip slots to prevent the reagent block from being contaminated and affecting the QC results.

5. The urine test strips should be placed in the correct position in the reagent strip slot during testing to avoid bias in the test results.

6. The used QC should be discarded after the test is completed, which should not be stored in the test tube or poured back into the bottle for storage.

【Index of symbol】

IVD	In vitro diagnostic medical device	Σ	Contains sufficient for <n> tests
	Consult instructions for use		Do not re-use
	Date of manufacture		Manufacturer
LOT	Batch code		Use-by date
	This way up		Temperature limit
	Keep away from sunlight		Biological risks
	Fragile, handle with care		
CE	CE marked according to IVD Medical Devices Directive 98/79/EC		
EC REP	Authorized representative in the European Community		

【References】

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