CE IVD

Urea Reagent Kit-2 (Urease-GLDH Kinetic method)

Instructions for Use

REF CC1014

PRODUCT NAME

Urea Reagent Kit-2 (Urease-GLDH Kinetic method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×8 mL
R1: 1×40 mL	R2: 1×10 mL	R1: 1×60 mL	R2: 1×15 mL
R1: 2×30 mL	R2: 1×15 mL	R1: 2×35 mL	R2: 1×20 mL
R1: 2×40 mL	R2: 1×20 mL	R1: 2×60 mL	R2: 2×15 mL
R1: 2×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 1×35 mL
R1: 2×80 mL	R2: 1×40 mL	R1: 2×80 mL	R2: 2×20 mL
R1: 4×35 mL	R2: 2×20 mL	R1: 4×40 mL	R2: 2×20 mL
R1: 4×50 mL	R2: 2×25 mL	R1: 4×50 mL	R2: 3×20 mL
R1: 4×60 mL	R2: 2×30 mL	R1: 4×60 mL	R2: 2×35 mL
R1: 4×60 mL	R2: 4×15 mL	R1: 4×100 mL	R2: 2×50 mL
R1: 4×120 mL	R2: 2×60 mL	R1: 6×66 mL	R2: 6×16 mL
2×300 T (R1: 2×72 mL R2: 2×18 mL)			
12×60 T (R1: 12×16.8 mL R2: 12×4.2 mL)			
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is designed for *in vitro* quantitative determination of urea in human serum, plasma or urine. The urea concentration is widely used for complementary evaluation of renal function. For professional and laboratory use only.

TEST PRINCIPLE

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$2NH_3 + \alpha\text{-Ketoglutaric acid} + NADH + H^+ \xrightarrow{\text{GLDH}} \text{Glutamate} + NAD^+ + H_2O$$

340nm laser is used to measure the decrease rate of NADH and calculate the urea concentration according to standard equation.

MAIN COMPONENTS

Kit contents	Reagent components	Conc.
Reagent 1	Urease	10 KU/L
	Glutamate dehydrogenase	10 KU/L
	ADP	1.4 g/L
	Tris (pH7.8)	50 mmol/L
Reagent 2	NADH (I)	0.13 g/L
	α-Ketoglutaric acid	1.7 g/L
Calibrator (Optional)	Urea, Aqueous Matrix	6-8 mmol/L

As for multi-component kit, the components are not exchangeable.
Calibrator traceability: Traceable to international Standard Reference Material (SRM) 909c.

STORAGE AND SHELF LIFE

The validity period of sealed reagents and calibrators is 18 months at 2-8°C light-proof. Once opened, reagents are stable for 42 days when stored at 2-8°C. Opened calibrators are stable for 15 days when stored at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE DEVICES

The kit is applicable to the following instruments: fully automatic biochemistry analyzers from Hitachi High-Tech (Shanghai) International Trading Co., Ltd., models: 7100, 7170, 7180, 7600, LABOSPECT 008 AS, 3100, 3500; fully automatic biochemistry analyzers from Beckman Coulter Commercial Enterprise (China) Co., Ltd., models: DXC800, AU480, AU680, AU5800; fully automatic biochemistry analyzers from Canon Medical Systems (China) Co., Ltd., models: TBA-120FR, TBA-2000FR, TBA-FX8; fully automatic biochemistry analyzers from Shenzhen Mindray Bio-Medical Electronics Co., Ltd., models: BS-420, BS-490, BS-600, BS-800, BS-820, BS-2000; fully automatic biochemistry analyzers from Dirui Industrial Co., Ltd., models: CS-400, CS-600B, CS-1200; fully automatic biochemistry analyzers from Siemens Healthineers Diagnostics (Shanghai) Co. Ltd., models: 1800, 2400, ADVIA Chemistry XPT; fully automatic biochemistry analyzers from Roche Diagnostics (shanghai) Co., Ltd., models: cobas 6000 c 501, cobas 8000 c 502, 701, 702; clinical chemistry analyzers from Getein Biotech, Inc, models: CM-400, CM-430, CM-480, CM-600, CM-630, CM-680, CM-800, CM-830, CM-880, CM-2000, CM-1600, CM-1200, CM-1000; automatic biochemical analyzers from Changchun Blaser Medical Technology Co., LTD, models: BBA-400, BBA-300, BBA-480. If you need the application parameters of the fully automatic biochemistry analyzers, please contact our company.

SAMPLE REQUIREMENTS

1. Sample type: fresh non-hemolyzed serum, heparin anticoagulated plasma, fresh urine.
2. Sample collection: Routine venous blood collection of about 3 mL, placed in a test tube, after sample collection, immediately sealed and sent to the test. Routine urine should be 10 mL, placed in a test tube and immediately sealed for testing.
3. Blood should be separated in time after collection to avoid hemolysis; after urine collection, strictly avoid contamination. The test results for serum and plasma will not change for 7 days at 15-25°C, for 7 days at 2-8°C and for 1 year at -20°C. The urine is stable for 2 days at 15-25°C, for 7 days at 2-8 °C and for 1 month at -20°C.

TEST PROCEDURE

1. Preparation: Use directly (duo reagents);
2. Conditions: (different parameters to be set on the machine can be obtained according to different testing instruments)

Main/sub wavelength	340 nm/415 nm	**Calibration type**	Linear
Sample/R1/R2	6/240/60 μL	**Time of Mixture of Serum and R1**	3-5 min
Method	Kinetic rate	**Reaction time after addition of R2**	3 min
Calibration Method	Two-point calibration	**Direction**	Downward

Test steps:

Substance Added	Blank tube	Test tube
R1	240 μL	240 μL
Sampel	-	6 μL
ddH_2O	6 μL	-
Mixed, incubated at 37˚C for 3-5min,		
R2	60 μL	60 μL
Mixed, incubated at 37˚C for 90 s and keep monitoring for 180s calculate ΔA/min		

3. Calibration: A calibrator from Getein is recommended, and a calibration serum from Randox can also be used.
4. Quality control: Randox QC serum are recommended. QC value should be within the range of the preset value. If not, please follow the below steps to check:
   4.1 Check whether the parameter setting and light source are correct;
   4.2 Check whether the cuvettes and the sample probe are contaminated;

4.3 Check whether the ddH_2O are polluted, because bacterial growth cause incorrect results;
4.4 Check the reaction temperature;
4.5 Check the expiration date of the kit.
5. Calculation of results:
C_{urea}(mmol/L) = ($\triangle A_{measurement}$ / min) / ($\triangle A_{standard}$ / min) × standard urea concentration

REFERENCE RANGE

Serum, plasma: 1.43-7.14 mmol/L (5-20 mg/dL).
Urine: 1st morning urine 141–494 mmol/L (847–2967 mg/dL) ; 24 h urine 170–580 mmol/24 h (10000–35000 mg/24 h), equivalent to 110–390 mmol/L (670–2300m g/dL) (assuming the 24-hour urine volume is 1.5 L) .
The reference range is for reference purposes only. The uric acid concentration may change due to geography, race, gender and age. It is recommended to set its own reference range in each laboratory.

EXPLANATION OF TEST RESULTS

Hemolysis interferes the assay and should be avoided as much as possible during the operation. The duration of sample storage also affects the assay results.

LIMITATIONS

When hemoglobin ≤ 500 mg/dL, vitamin C ≤ 200 mg/dL, bilirubin ≤ 40 mg/dL, there is no interference to the assay.

PERFORMANCE CHARACTERISTICS

1.Appearance
Reagent 1 in the kit is a colorless clear liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a colorless or light-yellow liquid, which may contain a small number of insoluble particles that do not affect determination.
2.Blank Test
2.1 Reagent blank absorbance
Then blank absorbance of reagent A_{340nm}≥1.000.
2.2 The change rate of the blank absorbance
The change rate of reagent blank absorbance $|A_{340nm}|$/min ≤ 0.04.
3. Accuracy
The relative deviation should not exceed ±15.0%。
4. Linear range
a）Linear correlation coefficient (r) should be ≥ 0.990 in the range of [0.9, 35.7] mmol/L;
b) In the range of [0.9, 3.0] mmol/L, the linear deviation should less than ±1.5 mmol/L;
In the range of (3.0, 35.7] mmol/L Comparative linear deviation should less than 10%.
5. Analytical sensitivity
The rate of change of absorbance per unit concentration should be ≥ -0.350.
6. Precision
6.1 Repeatability (with-in run precision)
When repeat test sample using same kit，the CV should not be greater than 5%
6.2 Between-run precision
When repeat test sample using same kit，the CV should not be greater than 10%.

PRECAUTIONS

1. General Precautions
1.1 For *in vitro* diagnosis only.
1.2 When used for clinical diagnosis, please make comprehensive judgment based on the assay results, clinical symptoms and other examination results, etc.
1.3 Please use this product according to the IFU.
1.4 The assay results of the kit are only used as a clinical aid for the diagnosis of various diseases. The clinical diagnosis and treatment of patients should be considered in conjunction with their symptoms/signs, medical history, other laboratory examinations and their response to treatment.
2. Precautions for operation
2.1 Please dispose of the specimen as if it were a hazardous substance that may be infected with HIV, HBV, HCV, etc. To avoid or reduce the risk of infection, please use disposable gloves.
2.2 In case of accidental contact with the eyes or mouth, or with the skin, rinse immediately and thoroughly with water and seek medical advice if necessary.
3. Precautions for use
3.1 Please store the reagents according to the storage method and avoid freezing. The quality of reagents may change after freezing, please do not use them.
3.2 Please do not use reagents that have expired. The results of expired reagents may be inaccurate.
3.3 Please avoid adding reagents halfway through the test.
3.4 Please avoid direct sunlight during operation.
3.5 Do not use if the reagent is turbid.
4. Precautions for waste disposal
Samples and waste fluids are potentially biologically infectious. Operators should comply with laboratory safety regulations and dispose of waste fluids according to local regulations for medical waste, infectious waste, and industrial waste.
5. Other precautions
5.1 On automated biochemistry analyzers, the linearity range is related to the ratio of sample volume used to reagent volume and the time of measurement.
5.2 The volume of reagents and samples can be changed proportionally according to the requirements of different instruments.
5.3 Do not use the reagent bottles for other purposes.
5.4 The result of calculation with k-value is not as reliable as that using the calibration measurement value of standard substance.
5.5 Do not mix reagents of different batches.

REFERENCE

H. Shang., *et. al.*: National Clinical Test Operation Procedures (4th ed.). People's Health Publishing House. 2015: 307-309.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on Urea Reagent Kit-2 (Urease-GLDH Kinetic method) are the most common ones appearing on medical devices and their packaging. They are explained in more details in the European Standard EN ISO 15223-1:2021.

Key to symbols used					
	Manufacturer		Use-by date	REF	Catalogue number
	Date of manufacture	LOT	Batch code		Temperature limit
IVD	*In vitro* diagnostic medical device		Keep away from sunlight		Biological risks
	Consult *instructions for use* or consult electronic *instructions for use*		Do not use if package is damaged and consult *instructions for use*	EU REP	Authorized representative
CE	CE mark		This way up		Do not re-use

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DN: C=VN, CN=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, L=Huyện Đông Anh, O=CÔNG TY TNHH XUẤT NHẬP KHẨU VÀ THƯƠNG MẠI ROKO VIỆT NAM, ST=Hà Nội, UID=MST:0106416199