CE IVD

UA Reagent Kit-2 (Uricase Method)

Instructions for Use

REF CC1081

PRODUCT NAME

UA Reagent Kit-2 (Uricase Method)

PACKAGE SPECIFICATION

R1: 1×20 mL	R2: 1×10 mL	R1: 1×40 mL	R2: 1×20 mL
R1: 1×60 mL	R2: 1×30 mL	R1: 2×60 mL	R2: 2×30 mL
R1: 2×30 mL	R2: 2×15 mL	R1: 2×40 mL	R2: 2×20 mL
R1: 2×50 mL	R2: 1×50 mL	R1: 2×60 mL	R2: 1×60 mL
R1: 2×60 mL	R2: 3×20 mL	R1: 2×65 mL	R2: 1×65 mL
R1: 2×65 mL	R2: 1×70 mL	R1: 2×80 mL	R2: 1×80 mL
R1: 2×120 mL	R2: 2×60 mL	R1: 3×20 mL	R2: 3×10 mL
R1: 3×40 mL	R2: 3×20 mL	R1: 4×40 mL	R2: 4×20 mL
R1: 4×50 mL	R2: 2×50 mL	R1: 4×55 mL	R2: 2×55 mL
R1: 4×60 mL	R2: 2×60 mL	R1: 4×60 mL	R2: 4×30 mL
R1: 4×60 mL	R2: 6×20 mL	R1: 4×65 mL	R2: 2×65 mL
R1: 4×65 mL	R2: 2×70 mL	R1: 4×100 mL	R2: 2×100 mL
R1: 4×64 mL	R2: 4×278 mL		
12×72 T (R1: 12×16.8 mL + R2: 12×8.4 mL)			
Calibrator (Optional): 1×1 mL			

INTENDED USE

This test kit is designed for *in vitro* quantitative measurement of serum, plasma, and urine uric acid in human. The uric acid concentration was mainly used for complementary evaluation of hyperuricemia clinically. For professional and laboratory use only.

PRINCIPLE

$$\text{L-Ascorbic Acid Sodium Salt} + O_2 \xrightarrow{\text{Ascorbate Oxidase}} \text{Dehydroascorbic acid} + H_2O$$

$$\text{Uric Acid} + 2H_2O + O_2 \xrightarrow{\text{Uricase}} \text{Allantoin} + CO_2 + H_2O_2$$

$$H_2O_2 + \text{4-AAP+TOOS} \xrightarrow{\text{Peroxidase}} \text{Quinone} + H_2O$$

COMPONENTS

Kit contents	Reagent components	Concentration
Reagent 1	Piperazine-1,4-bis(2-ethanesulfonic acid) (pH 7.0)	11 g/L
	N-Ethyl-N-(2-hydroxy-3-propylsulfonyl)-3-methylaniline	0.5 g/L
	Potassium Ferrocyanide	0.03 g/L
	Ascorbate Oxidase	2 KU/L
	Peroxidase	1 KU/L
Reagent 2	4-Aminoantipyrine	0.3 g/L
	Uricase	0.5 KU/L
Calibrator (Optional)	Uric acid, aqueous matrix	300-400 μmol/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

Unopened reagents should be stored at 2°C-8°C away from light, with a shelf life of 18 months. Opened reagents are stable for 42 days when stored at 2°C-8°C.
Please refer to the label on the reagent kit for the production date and expiration 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

Serum and plasma with heparin anticoagulant are recommended. Sample should be separated in time after collection to avoid hemolysis. Serum and plasma are stable for 3 days at 15-25°C, for 7 days at 4-8°C and for 6 months at -20°C. Urine is stable for 4 days at 15-25°C. To prevent urate precipitation in urine specimens after collection, add a sufficient volume of sodium hydroxide to bring the pH between 8 and 9.

TEST PROCEDURE

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

Primary/secondary wavelength	546 nm/700 nm	**Calibration type**	linear
Sample/R1/R2	6/200/100 μL	**Time of mixing Sample and R1**	3-5 min
Method	Two-point end assay	**Reaction time of mixing after adding R2**	5 min
Calibration Method	Two-point calibration	**Direction**	Upward

(The absorbance A read by the device = $A_{\text{Primary wavelength}}$ - $A_{\text{Secondary wavelength}}$)
Test steps:

Substance Added	Blank tube	Test tube
R1	200 μL	200 μL
Sampel	-	6 μL
ddH_2O	6 μL	-
Mixed, incubated at 37˚C for 3-5 min, read Absorbance A_0;		
R2	100 μL	100 μL
Mixed, incubated at 37˚C for 5 min, read Absorbance A_1, $\Delta A=A_1-A_0$		

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:
   $UA_{\text{concentration}}=UA_{\text{standard concentration}} \times A_{\text{assay}} / A_{\text{standard}}$

REFERENCE RANGE

Serum, plasma: Male 200 - 420 μmol/L; Female 170 - 390 μmol/L
Urine: 1st morning urine 2200–5475 μmol/L, 24 h urine 1200–5900 μmol/24 h, equivalent to 773–3986 μmol/L （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.

RESULT INTERPRETATION

Hemolysis interferes the assay and should be avoided as much as possible during the operation.

LIMITATIONS

When hemoglobin ≤ 100 mg/dL, bilirubin ≤ 10 mg/dL, triglyceride ≤ 2000 mg/dL, there is no interference to the assay.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Both R1 and R2 are colorless or light-yellow clean solution. There are possibly small amount of undissolved particles in the solution that will not affect the test.
2. Reagent Blank Absorbance
   Then blank absorbance of reagent A_{546nm} ≤ 0.200.
3. Accuracy
   The relative deviation should not exceed ±10.0%.
4. Linear Range
   a）Linear correlation coefficient (r) should be ≥ 0.990 in the range of [12, 1190] μmol/L;
   b）In the range of [12, 50] μmol/L, the linear deviation should not exceed ±10 μmol/L;
   In the range of (50, 1190] μmol/L, Comparative linear deviation should not exceed ±10%.
5. Analytical sensitivity
   The absorbance of 297 μmol/L sample (△A) should not exceed 0.130
6. Precision
   6.1 Repeatability (within-run precision)
   When repeat test sample using same kit, the CV should not exceed 4.0%.
   6.2 Between-run precision.
   When repeat test sample using same kit, the CV should not exceed 6.0%.

PRECAUTIONS

1. General Precautions
   1.1 For *in vitro* diagnosis only.
   1.2 For clinical diagnosis, please make a comprehensive judgment based on the measurements, clinical symptoms and other findings.
   1.3 Please use this product according to the IFU.
   1.4 The test results of the kit should be used solely as an auxiliary basis for clinical diagnosis of various diseases. Clinical decision-making for patients must be interpreted in conjunction with their symptoms/signs, medical history, other laboratory tests, and treatment response, integrated into a comprehensive evaluation.
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 amount 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. 2015:312-313.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on UA Reagent Kit-2 (Uricase 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

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn
overseas@getein.com.cn
Website: www.getein.com

EU REP CMC Medical Devices & Drugs S.L.
Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.
Tel: +34951214054