CE IVD

K Reagent Kit (Enzymatic Method)

Instructions for Use

REF CC1050

PRODUCT NAME

K Reagent Kit (Enzymatic Method)

PACKAGE SPECIFICATION

R1: 1×15 mL	R2: 1×5 mL	R1: 1×30 mL	R2: 1×10 mL
R1: 1×30 mL	R2: 1×12 mL	R1: 1×33 mL	R2: 1×13 mL
R1: 1×45 mL	R2: 1×15 mL	R1: 1×60 mL	R2: 1×20 mL
R1: 2×15 mL	R2: 1×10 mL	R1: 2×30 mL	R2: 1×20 mL
R1: 2×30 mL	R2: 2×10 mL	R1: 2×45 mL	R2: 2×15 mL
R1: 2×45 mL	R2: 2×20 mL	R1: 2×55 mL	R2: 2×20 mL
R1: 2×60 mL	R2: 1×40 mL	R1: 2×60 mL	R2: 1×45 mL
R1: 2×60 mL	R2: 2×20 mL	R1: 2×90 mL	R2: 1×60 mL
R1: 2×90 mL	R2: 2×30 mL	R1: 2×120 mL	R2: 2×40 mL
R1: 3×40 mL	R2: 3×15 mL	R1: 3×45 mL	R2: 3×15 mL
R1: 3×60 mL	R2: 1×60 mL	R1: 3×60 mL	R2: 3×20 mL
R1: 4×30 mL	R2: 2×20 mL	R1: 4×45 mL	R2: 2×30 mL
R1: 4×45 mL	R2: 4×15 mL	R1: 4×55 mL	R2: 4×20 mL
R1: 4×60 mL	R2: 2×40 mL	R1: 4×60 mL	R2: 2×45 mL
R1: 4×60 mL	R2: 4×20 mL	R1: 4×90 mL	R2: 2×60 mL
R1: 4×651 mL	R2: 4×230 mL	R1: 6×13.5 mL	R2: 6×4.3 mL
R1: 6×54 mL	R2: 6×20 mL	R1: 6×250 mL	R2: 6×97 mL
R1: 8×60 mL	R2: 8×20 mL	R1: 12×4.2 mL	R2: 6×2.9 mL
R1: 24×3.8 mL	R2: 12×2.6 mL	150 T（R1: 1×20 mL R2: 1×6 mL）	
2×100 T（R1: 2×15 mL R2: 2×5 mL）			
2×260 T（R1: 2×65 mL R2: 2×21 mL）			
2×260 T（R1: 2×70 mL R2: 2×21 mL）			
6×52 T（R1: 6×16.8 mL R2: 6×5.8 mL）			
12×52 T（R1: 12×16.8 mL R2: 12×5.8 mL）			

INTENDED USE

This reagent kit is intended for the *in vitro* quantitative determination of potassium concentration in human serum.
Clinically, it is mainly used for the auxiliary diagnosis of potassium metabolism disorders.
For professional and laboratory use only.

TEST PRINCIPLE

Potassium is detected through the enzymatic kinetic reaction of the substrate phosphoenolpyruvate (PEP) catalyzed by potassium-dependent pyruvate kinase. Its product, pyruvate, reacts with NADH under the action of lactate dehydrogenase (LDH) to form NAD+. The rate of absorbance change at 340 nm is proportional to the concentration of potassium.

MAIN COMPONENTS

Kit composition	Reagent components	Content
Reagent 1	Tris(hydroxymethyl)aminomethane	250 mmol/L, pH8.2
	4,7,13,16,21-Pentaoxa-1,10-diazabicyclo[8.8.5]tricosane	12 mmol/L
	Phosphoenolpyruvic acid	3.3 mmol/L
	Adenosine diphosphate	3.15 mmol/L
	α-ketoglutaric acid	1.2 mmol/L
	β-Nicotinamide adenine dinucleotide reduced (NADH)	0.35 mmol/L
	Glutamate dehydrogenase	11 U/mL
	Pyruvate kinase	1.2 U/mL
Reagent 2	Lactate Dehydrogenase	65 U/mL

The components in different batches of a multi-component kit are not interchangeable.

STORAGE AND SHELF LIFE

The unopened reagents are stable for a shelf life of 18 months when stored away from direct sunlight at 2-8°C. Opened reagents are stable for 30 days when stored away from direct sunlight at 2-8°C.
Refer to the label on the reagent kit for the manufacturing date and the expiry date.

APPLICABLE INSTRUMENTS

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.
2. Sample collection: Collect approximately 3 mL of venous blood, placing it in a test tube. After collection, the sample should be sealed and sent for testing immediately.
3. Serum should be separated promptly after blood collection to avoid hemolysis.
4. Interference: Samples containing substances that can interfere with the absorbance, such as hemolyzed and lipemic samples, may affect the test results. In such cases, a new sample collection is recommended. There is no interference with the test when bilirubin in the sample is ≤ 665μmol/L, Hb is ≤ 1 g/L, and TG is ≤ 24.2 mmol/L.
5. Serum samples can remain stable for 48 hours when stored at 4°C.

TEST PROCEDURE

1. The dual reagent is ready for use directly.
2. Test conditions:

Primary Wavelength	340 nm	**Sample**	5 μL
Secondary Wavelength	405 nm	**Reagent 1**	180 μL
Temperature	37°C	**Reagent 2**	60 μL
Optical Path of Cuvette	1 cm	**Method**	Two-point rate assay
Calibration Method	Two-point calibration	**Direction**	Downward

3. Operating procedures:

Substances Added	Calibration Tube	Test Tube
Reagent 1	180 μL	180 μL
Calibrator	5 μL	-
Sample	-	5 μL
Mix well, incubate at 37°C for 5 min		
Reagent 2	60 μL	60 μL
Mix well, incubate at 37°C for 1 min, and read the absorbance A_1. Incubate at 37°C for 2 min, read the absorbance A_2, and calculate the rate of absorbance change △A/min.		

4. Calibration procedure:
   Use the calibrator from Getein and compare the measured value with that of Randox's calibrator. Calibration should be conducted on a daily basis.
5. Quality control procedure:
   Use the quality control product that comes with the reagent kit, and its measured value should be within the range of its label claim.
6. Result calculation

$$\text{Sample concentration} = \frac{\text{Sample } \triangle A/\text{min}}{\text{Calibration } \triangle A/\text{min}} \times \text{Calibration concentration}$$

REFERENCE RANGE

3.5-5.1 mmol/L
The provided reference range is for reference only, and it is recommended that each laboratory establish its own reference range.

RESULT INTERPRETATION

Test results will be reviewed by the professionals. These results may be affected by the age, gender, diet and region of the individual being tested. Under normal circumstances, if the result is within the reference range, it is considered normal; if it exceeds the reference range, a retest should be conducted. If the test results are inconsistent with, or even contradict, clinical symptoms, the cause should be analyzed and investigated.

LIMITATIONS

There is no interference with the measurement when bilirubin is ≤ 665 μmol/L, hemoglobin is ≤ 1 g/L and triglycerides is ≤ 24.2 mmol/L.

PERFORMANCE CHARACTERISTICS

1. Appearance
   Reagent 1 in the kit is a colorless transparent liquid, which may contain a small number of insoluble particles that do not affect determination. Reagent 2 is a slightly yellow clear liquid, which may contain a small number of insoluble particles that do not affect determination.
2. Reagent blank
   2.1 Reagent blank absorbance
   Reagent blank absorbance $A_{340nm} \geq 1.000$.
   2.2 Rate of change in reagent blank absorbance
   Rate of change in reagent blank absorbance $|\triangle A_{340nm}|/\text{min} \leq 0.200$.
3. Accuracy
   The deviation between the measured value and the labeled value of the test reference material should be within ±15.0%.
4. Linear range
   Linear correlation coefficient (r) should be ≥ 0.990 in the range of [2,10] mmol/L.
   Within the range of [2,10] mmol/L, the linear deviation should not exceed ±10%.
5. Analytical sensitivity
   When testing a 7mmol/L sample, the unit absorbance change rate should be between -0.0857 and -0.0143.
6. Precision
   6.1 Within-run precision
   Within-run precision should not be greater than 5.0%.
   6.2 Between-run precision
   Between-run precision should not be greater than 10.0%.

PRECAUTIONS

1. General precautions
   1.1 This product is for *in vitro* diagnostic use 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 user manual.
2. Precautions for operation
   2.1 Treat the samples as dangerous materials that may cause infection with HIV, HBV, HCV, etc. Please use disposable gloves to avoid or reduce the associated risk for infection.
   2.2 If the reagents get into the eyes or mouth, or touch the skin, rinse them quickly and thoroughly with water, and receive medical treatment from a doctor when necessary.
   2.3 Hemolysis should be avoided during the operation procedure.
3. Precautions for use
   3.1 Please store the reagents according to the storage method, and avoid freezing. Please do not use frozen reagents whose quality may change.
   3.2 Please do not use expired reagents whose test results may be inaccurate.
   3.3 Please avoid adding reagents halfway during a test.
   3.4 Please avoid direct sunlight during operation.
   3.5 Avoid using the reagent if it displays any signs of turbidity.
4. Precautions for waste disposal
   Samples, waste liquids, etc. are potentially biologically hazardous. Operators should comply with the SOP for laboratory safety and dispose of waste liquids in accordance with local regulations for medical waste, infectious waste, industrial waste, etc.
5. Other precautions
   5.1 On a fully automatic biochemistry analyzer, the linearity range is related to the ratio of the amount of a sample to the amount of a reagent and the time of measurement.
   5.2 The amounts of the reagent and sample can be changed proportionally according to the requirements of different instruments.
   5.3 Please do not use the reagent bottles for other purposes.
   5.4 A result calculated with the k value is not as reliable as that obtained using the calibration result.
   5.5 Please do not mix reagents in different batches.

REFERENCE

1.Berry, M.N. et al (1989) Clin. chem. 35:817.
2.Tietz, N.W. (1986). Textbook of Clinical Chemistry, p.1841. W.B. Saunders Company, Philadelphia.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in or found on K Reagent Kit (Enzymatic 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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