Potassium Assay Kit (K)

Method: Enzymatic

Cat .No.	Size	Instrument
GB4K	R1:3×60 ml R2:3×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GS4K	R1:3×60 ml R2:3×20 ml	For Hitachi917 & Olympus AU640/400/600
GB4K/S	R1:1×60 ml R2:1×20 ml	For Hitachi 717 & Shimadzu CL7200/8000
GS4K/S	R1:1×60 ml R2:1×20 ml	For Hitachi 917 & OlympusAU640/400/600
Calibrator 1	1×3 ml	
Calibrator 2	1×3 ml	

INTENDED USE

For the *in vitro* quantitative determination of potassium in serum or plasma.

ASSAY PRINCIPLE[1]

Potassium is determined enzymatically via potassium-dependant pyruvate kinase activity using phosphoenolpyruvate as substrate. The pyruvate formed reacts with NADH in the presence of LDH to form Lactate and NAD. The corresponding decrease in absorbance at 340nm is proportional to the potassium concentration.

$$PEP + ADP \xrightarrow[PK]{K^+} Pyruvate + ATP$$

$$Pyruvate + NADH + H^+ \xrightarrow{LDH} lactate + NAD^+$$

SAMPLE COLLECTION AND PREPARATION

Serum, plasma treated with lithium heparinate.

REAGENT COMPOSITION

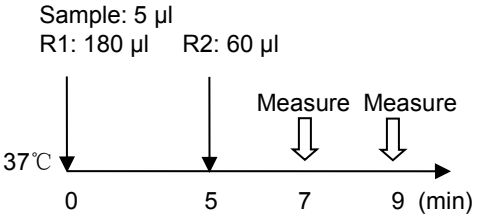
Contents	Concentration of Solutions
R1. Buffer/Enzymes	
Tris buffer	250 mmol/L , PH8.2
Cryptand	12 mmol/L
PET	≥3.3 mmol/L
ADP	≥3.15 mmol/L
α-oxoglutarrte	≥1.2 mmol/L
NADH	≥0.35 mmol/L
GLDH	≥11 U/mL
PK	≥1.2 U/mL
R2. Enzyme	
LDH	≥65 U/mL
Calibrator 1	3 mmol/L
Calibrator 2	7 mmol/L

STABILITY AND PREPARATION OF REAGENTS

All reagents are ready to use.
Stable up to the expiry date when stored at 2-8℃.

ASSAY PROCEDURE

Test Procedure for Analyzers (HITACHI 7170/917)
Assay Mode: 2 Point Rate 20-26
Wave Length (main/sub): 340 nm/405 nm



1. Mix 5 µl sample with 180 µl R1 and incubate at 37℃ for 5 minutes.
2. Add 60 µl R2 into cuvette, mix and incubate for 2 minutes at 37℃.
3. Read initial absorbance and start timer simultaneously, read again after 1 and 2 minutes.
4. Calculate absorbance change per minute (ΔA/min)

CALIBRATION

1. This assay should be calibrated using the enclosed two level calibrators.
2. Construct the calibration curve according to the different absorbance change and concentration of the two level calibrators.
3. The sample concentration is read from the calibration curve with its absorbance.
4. It is recommended that this assay should be calibrated daily.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range. If these values fall outside the range and repetition excludes error the following
steps should be taken:

1. Check instrument settings and light source.
2. Check reaction temperature.
3. Check expiration date of kit and contents.
4. Check the quality of the water used for reagents reconstitution.

NORMAL VALUE[2]

3.5 -5.1 mmol/L (13.7 -19.9 mg/dL)
It is recommended that each laboratory establish its own reference range to reflect the
age, sex, diet and geographical location of the population.

SPECIFIC PERFORMANCE CHARACTERISTICS

LINEARITY

This method is linear up to 10 mmol/L. If the sample above this concentration should be diluted with 0.9% NaCl and reassay. Multiply the result by dilution factor.

PRECISION

The CV of the test should be less than 5%.

Intra assay precision		
N=20	Level1	Level 2
Mean	4.04	6.14

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CE For professional use

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SD	0.04	0.04
CV	0.93%	0.59%
Inter assay precision		
N=5	Level1	Level 2
Mean	3.98	6.05
SD	0.04	0.05
CV	0.96%	0.83%

SENSITIVITY
The minimum detectable concentration of potassium with an acceptable level of precision was determined as 0.379 mmol/L.

INTERFERENCE
The following analytes were tested up to the levels indicated and found not to interfere:
Introlipid: 1000mg/dl
Bilirubin: 30 mg/dl
Hemoglobin: 100 mg/dl
VC: 40 mg/dl
NH_4^+: 1mM
Ca^{2+}: 10 mM
Fe^{3+}: 200 μM
Mg^{2+}: 10 mM
Cu^{2+}: 100 μM
Zn^{2+}: 100 μM

CORRELATION
This method (Y) was compared with another commercially available method (X) and the following linear regression equation obtained:
Y=0.388X+0.2688, and a correlation coefficient of r^2 =0.9231; 330 patient samples were analysed with values spanning the range 2.54 mmol/L to 5.83 mmol/L.

PROCEDURE NOTES
When sodium and potassium are requested together, sodium is assayed immediately before potassium.

SAFETY PRECAUTIONS AND WARNINGS
1. For *in vitro* diagnostic use only. Do not pipette by mouth. Exercise the normal precautions required for handing laboratory reagents.
2. All specimens used in this test should be considered potentially infectious. Universal Precautions, as they apply at your facility, should be used for handling and disposing of materials during and after testing.

REFERENCES
1. Berry, M. N. et al., (1988) Clin. Chem.35:817
2. Tietz, N. W. (1986). textbook of clinical Chemistry, p.1841. W. B. Saundres Company, Philadelphia.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

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