ISE S.r.l. **Potassium** – Instructions for use

CUSTOMISED SOLUTIONS FOR YOUR LABORATORY

CE IVD

R1: 2x 12 mL R2: 2x3 ml **R3330000097** REF

Diagnostic reagent for quantitative in vitro determination of Potassium in human serum on photometric systems

TEST PARAMETERS

Method:	enzymatic, 2 Point Kinetic (fixed time)
Wavelength	380 nm (380 – 405 nm)
Temperature:	37°C
Sample:	Serum
Measuring range:	2.0 – 8.0 mmol/L

REAGENT COMPOSITION

COMPONENTS	CONCENTRATION
Reagent 1:	
LDH	< 50 kU/L
NADH-analogue	< 10 mmol/L
Substrate	
Azide	0.05 %
Reagent 2:	
Pyruvate kinase	< 50 kU/L
Azide	0.05 %

REAGENT PREPARATION

The reagents are ready to use.

REAGENT STABILITY AND STORAGE

Conditions: protect from light

close immediately after use
do not freeze!
do not mix reagents of different lots

Storage: at 2 – 8°C

Stability: up to the expiration date

SPECIMEN COLLECTING AND HANDLING

For use with non-hemolysed serum.
No special handling or pretreatment is necessary.
Serum samples should be collected such that testing is performed as soon as possible and within 5 days after the specimen collection.

MATERIALS REQUIRED BUT NOT PROVIDED

NaCl solution (9 g/L)
General laboratory equipment

INTERFERING SUBSTANCES

The assay is not interfered by the following substances at indicated concentrations:

Na^+	150 mM
NH_4^+	0.5 mM
Ca^{2+}	7.5 mM
P_i	2.0 mM
Ascorbic acid	10.0 mM
Zn^{2+}	0.5 mM
Fe^{3+}	0.5 mM
Cu^{2+}	0.5 mM
Triglycerides	1000 mg/dL
Haemoglobin	500 mg/dL
Conj. bilirubin	20 mg/dL
Unconj. bilirubin	15 mg/dL

ASSAY PROCEDURE

Wavelength: 380 nm
Second wavelength: 700 nm
→ Reagent 1: 200 µl
Sample: 5 µl
→ Incubation: 5 minutes
→ Reagent 2: 50 µl
→ 1st Reading: 1 minute after adding R2
→ 2nd Reading: 4 minutes after adding R2
(time between the 2 readings: 3 minutes)
Linear calculation with 2-point calibration (standard low and high)

REFERENCE RANGE [1]

3.5 – 5.1 mmol/L (13.7 – 19.9 mg/dL)

It is recommended that each laboratory should establish a range of normal values for the population in the country and region they serve.

DIAGNOSTIC IMPLICATION

Measurements of potassium in serum are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels. Small deviations from normal levels can have severe health consequences. Monitoring serum potassium concentration is important in both routine check and emergency rooms.

TEST PRINCIPLE

$$\text{Substrate} \xrightarrow[\text{pyruvate kinase}]{K^+} \text{Pyruvate}$$

$$\text{Pyruvate} + \text{NADH analogue} \xrightarrow{\text{LDH}} \text{Lactate} + \text{NAD}^+_{\text{analogue}}$$

Potassium is determined spectrophotometrically through a kinetic coupling assay system using potassium dependent pyruvate kinase [2,3]. Pyruvate generated is converted to lactate accompanying conversion of NADH analogue to NAD analogue. The corresponding decrease of optical density at 380 nm is proportional to the potassium concentratium in the serum.

ABBREVATIONS

LDH = Lactate dehydrogenase

PERFORMANCE CHARACTERISTICS

LINEARITY, SENSITIVITY

The assay is linear throughout the measuring range of 2.0 mmol/L – 8.0 mmol/L.
Detection limit: 0.87 mmol/L

ACCURACY

The potassium assay was tested on the Olympus AU400 instrument and results obtained were compared to an ISE method. A total of 52 serum samples ranging from 2.7 – 7.7 mM potassium and two sets of serum based controls were tested in both assays. The above described accuracy study showed that our method (y) had good correlation with existing ISE method (x):
$y = 1.07\ x - 0.30$ mmol/L; $R^2 = 0.98$

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PRECISION

The precision of the potassium assay was tested on the Olympus AU400 instrument over 20 days with two runs per day with our controls assayed in duplicate.

Within run precision, n = 80	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	4.62	0.052	1.12
Sample 2	6.96	0.084	1.20

Total precision, n = 80	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	4.62	0.081	1.77
Sample 2	6.96	0.123	1.77

QUALITY CONTROL

We recommend that each laboratory uses Potassium controls to validate the performance of the Potassium assay.
We recommend the our **Potassium Control Set (2 levels)**.

CALIBRATION

A 2-point calibration with a potassium calibrator or standard low and a potassium calibrator or standard high is recommended weekly.
For analysers that require a zero calibrator, saline can be used for that purpose, and the low and high potassium standards are used as calibrators 2 and 3, respectively.
We recommend the our **Potassium Standard Set (2 levels)**.

WARNINGS AND PRECAUTIONS

1. This reagent is for professional use only. Do not ingest. Avoid contact with skin and eyes.
2. The reagents contain lithium azide. Azide compounds may react with lead or copper plumbing to form potentially explosive compounds. Flush drains with copious amounts of water when disposing of this reagent.
3. Serum specimens and all materials coming in contact with them should be handled and disoposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory personal protective equipment attire.
4. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents.

WASTE MANAGEMENT

Please refer to local legal requirements.

REFERENCES

1. Wu, A.H.B., ed. Tietz clinical guide to laboratory tests, 4th edition, p.880. W.B. Saunders Company, St. Louis (2006).
2. Bergmeyer, H.U.., Gawehn, K., and Grassl, M. (1974) in *Methods of Enzymatic Analysis.* Second Edition, Volume I, 509-510, Academic Press, Inc., New York.
3. M.N. Berry, R.D. Mazzachi, M. Pejakovlc, and M.J. Peake, Enzymatic Determination of Potassium in Serum. Clin.Chem. 25/5, 817-820 (1989).

Symbols on labels and packaging

IVD = In vitro diagnostic medical device

REF = Catalog Number

LOT = Lot Number

= Manufacturer

= Expiration date

= Temperature limitation

= Instruction for use

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