BIOLABO
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POTASSIUM Enzymatic method

Reagent for quantitative determination of potassium ions in human serum or plasma.

REF K1084	**R1**	2x16 mL	**R2**	1x8 mL	**R3**	1x3 mL	**R4**	1x3 mL
REF K2084	**R1**	2x32 mL	**R2**	2x8 mL	**R3**	1x3 mL	**R4**	1x3 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).
It allows the quantitative determination of potassium ions in human serum and plasma to determine if there is a problem with electrolyte balance. As part of a routine health check-up, results may be used as a screening test, in conjunction with other clinical signs and laboratory data.

GENERALITIES (1)

Disturbances in concentration of kalium may be encountered in case of hypokalaemia (metabolic alkalosis, metabolic acidosis, and abnormal acid-base balance), hyperkalaemia (over-administration of potassium, acidosis or crush injuries), kidneys damage, Addison disease or other diseases involved in electrolytes imbalance.

PRINCIPLE (1) (2)

Potassium is determined spectrophotometrically through a kinetic coupling assay system using potassium dependent pyruvate kinase. Pyruvate generated is converted to lactate accompanying conversion of NADH in $NAD^+ + H^+$. The corresponding decrease of optical density at 380 nm is proportional to the potassium concentration in the serum.

REAGENTS

R1	**POT**	Reagent 1		
LDH			< 50	KU/L
NADH analog substrate			< 10	mmol/L
Sodium Azide			0.05	%
R2	**POT**	Reagent 2		
Pyuvate Kinase			< 50	KU/L
Sodium Azide			0.05	%
R3	**Potassium**	**Cal 1**	Calibrator Level 1	
Potassium Chloride			approx. 3	mmol/L
Sodium azide			< 0.1	%
R4	**Potassium**	**Cal 2**	Calibrator Level 2	
Potassium Chloride			approx. 7	mmol/L
Sodium azide			< 0.1	%

Specific batch value indicated on the label of the vial.

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the

kit. Once opened:

- Reagents are stable for at least 30 days.

SPECIMEN COLLECTION AND HANDLING (3) (4)

Plasma (Lithium héparinate)

✓ Do not use plasma from blood that has been stored in ice water
✓ Remove from cells promptly and test as soon as possible after collection.

Unhaemolyzed serum:

✓ Separate from cells as soon as possible after collection.

LIMITES (5)

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Biochemistry Clinical Analyzer KENZA One, KENZA 240TX/ISE or KENZA 450TX/ISE

REFERENCE INTERVAL (3) (4)

Serum or plasma	mEq/L	[mmol/L]
Premature, cord	5.0-10.2	[5.0-10.2]
Premature, 48h	3.0-6.0	[3.0-6.0]
New born, in cord	5.6-12.0	[5.6-12.0]
New Born	3.7-5.9	[3.7-5.9]
Infant	4.1-5.3	[4.1-5.3]
Child	3.4-4.7	[3.4-4.7]
Thereafter	3.5-5.1	[3.5-5.1]
Men	3.5-4.5	[3.5-4.5]
Women	3.4-4.4	[3.4-4.4]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

On automatic analyser AU400, at 37°C, 380 nm
Linearity Range: between 2 mmol/L and 8 mmol/L
Precision:

Within-run N = 20	*Low level*	*Normal level*
Mean (mmol/L)	4.62	6.96
S.D. mmol/L	0.052	0.084
C.V. %	1.1	1.2

Between run N = 20	*Low level*	*Normal level*
Mean (mmol/L)	4.62	6.96
S.D. mmol/L	0.081	0.122
C.V. %	1.8	1.8

Analytical Sensitivity (manual method):
approx. 0.100 abs / 1mmol/L (380 nm, 1 cm path length, 37°C)

Interferences (less than 5% deviation for listed concentrations):

Interference	Concentration	Interference	Concentration
Ascorbic acid	10 mmol/L	NH4+	0,5 mmol/L
Triglycerides	1000 mg/dL	Ca2+	7,5 mmol/L
Hemoglobin	500 mg/dL	Pi (inorganic phosphorous)	2 mmol/L
Conjugate bilirubin	20 mg/dL	Fe3+	0,5 mmol/L
Bilirubin	15 mg/dL	Cu2+	0,5 mmol/L
Na+	150 mmol/L	Zn2+	0,5 mmol/L

Other substances may interfere (see § Limits)

Comparison studies with commercially available reagent:
Automated analyzer (specimens n=56) from 2.5 to 7.8 mmol/L

y =1,0703 x – 0,3042 r = 0,9902

On the board stability: 2 separate reagents are stable 30 days.

Calibration Frequency: 15 days

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

CALIBRATION (6)

- Cal1 and Cal 2 (Vial R3 and R4) traceable *to SRM956*

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

QUALITY CONTROL

- REF 95010 EXATROL-N Level I
- REF 95011 EXATROL-P Level II
- External quality control program

It is recommended to control in the following cases:
- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:
1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the KENZA Analyzer used

CALCULATION

The analyzer provides directly final result.
Refer to the instruction of use of KENZA analyzer.

REFERENCES

(1) 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.

(2) *M.N. Berry ,R. D. Mazzachi, M. Pejakovlc, and M. J. Peake Enzymatic Determination of Potassium in Serum. CLIN. CHEM. 35/5, 817-820 (1989*).

(3) TIETZ N.W. Text book of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1058, 1101—1104.

(4) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 880.

(5) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-476 à 3-486

(6) SRM: Standard Reference Material®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with