POTASSIUM (K) Multi-Purpose (MPR) Liquid Reagent

Glenbio
Diagnostics & Research Laboratory Solutions

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
GL1118K	4 x 40ml	R1	2-8°C
	4 x 10ml	R2	
	1 x 5ml	Low Calibrator	
	1 x 5ml	High Calibrator	

INTENDED USE:

In Vitro Diagnostic reagent for the quantitative determination of Potassium in human serum.

SUMMARY AND EXPLANATION:

In healthy individuals, an extracellular fluid level of potassium is regulated to maintain at 3.5 - 5.1 mM. Small deviations from normal levels can have severe health consequences. Monitoring serum potassium concentration is important in both routine checks and emergency rooms. Measurements obtained by this device are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.

PRINCIPLE OF THE TEST:

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 analog to NAD analog. The corresponding decrease of optical density at 380 nm is proportional to the potassium concentration in the serum.

WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only
Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

Safety precautions:
Do not pipette by mouth. Exercise the normal precautions required for handling laboratory reagents. These reagents contain lithium azide. Azide compounds may react with lead or copper plumbing to form potentially explosive com-pounds. Flush drains with copious amounts of water when dispos-ing of this reagent.

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.

INSTRUMENTS:

Instrument applications are available upon request.

COMPONENT COMPOSITION:

Component	*Ingredients*	
Reagent 1	Azide	0.05%
	NADH analog	< 20 mmol/L
	LDH	< 50 KU/L
	Substrate	--
	Stabilisers	--
Reagent 2	Azide	0.05%
	Pyruvate kinase	< 50 KU/L
	Stabilisers	--

REAGENT PREPARATION AND STABILITY:

Reagents are ready to use
Stable up to the expiry date when stored at 2-8°C
Stable when stored at 2-8°C until the expiration date on the label. Do not freeze.

TYPE OF SPECIMEN:

The assay is formulated for use with non-hemolysed serum. No special handling or pretreatment is needed.

Serum samples should be collected such that testing is per-formed as soon as possible and within 5 days after the specimen collection.

Note: Serum specimens and all materials coming in contact with them should be handled and disposed as if capable of transmitting infection. Avoid contact with skin by wearing gloves and proper laboratory personal protective equipment (PPE) attire.

TEST PROCEDURE:

Materials required but not supplied:

Description	*Catalogue No.*	*Description*	*Catalogue No.*
Potassium Calibrator	Low and High Calibrator (enclosed)	Photometer	N/A
General Chemistry Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Level 2	GL932		

Assay procedure:
Wavelength: λ: 380 nm
Temperature: 37°C
Optical path: 1 cm light path.

	Blank	**Calibrator**	**Sample**
Reagent 1	800 µl	800 µl	800 µl
Sample	----	----	20 µl
Calibrator	----	20 µl	----
Gently mix and Incubate at 37°C Measure the Optical Density (OD1) after 5 minutes.			
Reagent 2	200 µl	200 µl	200 µl
Gently mix and Incubate at 37°C Measure the Optical Density (OD2) after 4 minutes.			

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

Quality Control:
All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.
Controls should be assayed:
- Prior reporting patient results.
- Following any maintenance procedure on the photometer used.
- At intervals established by the Laboratory's QC programme.

RESULTS:

Potassium results are printed out in mmol/L.

EXPECTED VALUES:

Healthy subjects have Potassium levels in the range of 3.5 - 5.1 mM (13.7 - 19.9 mg/dL).
Each laboratory should establish its own expected values. The Potassium results should always be reviewed with the patient's medical examination

PERFORMANCE CHARACTERISTICS:

Interference:
The assay is not interfered by the following substances at indicated concentrations: Na+ 150 mM, NH4+ 0.5 mM, Ca2+ 7.5 mM, Pi 2.0 mM, ascorbic acid 10.0 mM, Zn2+ 0.5 mM, Fe3+ 0.5 mM, Cu2+ 0.5 mM, triglycerides 1000 mg/dL, hemoglobin 500 mg/dL, conjugated bilirubin 20 mg/dL and unconjugated bilirubin 15 mg/dL.

Linearity:
This method is linear through-out the measuring range of 2.0 mmol/L - 8.0 mmol/L.

Precision:

Within Run Precision

	4.46 mM K+ (20 days, n=80)	6.86 mM K+ (20 days, n=80)
Mean	4.62 mM	6.96 mM
CV %	1.12 %	1.20 %

Total

	4.46 mM K+ (20 days, n=80)	6.86 mM K+ (20 days, n=80)
Mean	4.62 mM	6.96 mM
CV %	1.77 %	1.77 %

Sensitivity:
The Lowest Detectable Level is 0.87 mM K+.

BIBLIOGRAPHY:

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4. 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.
5. M.N. Berry,R. D. Mazzachi, M. Pejakovlc,and M. J. Peake Enzymatic Determina-tion of Potassium in Serum. CLIN. CHEM. 35/5, 817-820 (1989).

SYMBOLS:

The following symbols are used in the labelling of Glenbio systems:

IVD	In Vitro Diagnostics	REF	Catalogue No
LOT	Batch Code	CONT	Content
REAG	Reagent	Ab	Antibody
CAL	Calibrator	SUBS	Substrate
BUF	Buffer	STD	Aqueous Standard
	Storage temperature	→	Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

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