LiquiMAX Potassium (K+) - SLR

(TURBIDOMETRIC METHOD)

ORDERING INFORMATION

Ref. No.	Pack Size	Presentation
AVPOT- 25	25x1 ml	Mono Reagent
AVPOT- 50	50x1 ml	

INTENDED USE:

LiquiMAX Potassium(K+) is an in-vitro diagnostic kit is use for the quantitative determination of potassium (K+) in Human Serum .

PRODUCT FEATURES

1. Liquid Stable, Ready to use Mono Reagent
2. 5 Minutes single step end point reaction (Potassium)
3. Results corelate with ISE, Direct/ Indirect Potentiometry & Flame Photometry.
4. Aqueous Potassium standard provided (Standard Conc: 5mMol/L
5. Linearity : 8 mMol/L
6. Measuring Wavelength: 578 nm (570 – 620 nm)
7. Serum is the only specimen

CLINICAL SIGNIFICANCE :

Potassium (K+) is the major positive ion within cells and is particularly important for maintaining the electric charge on the cell membrane. This charge allows nerves and muscles to communicate and is necessary for transporting nutrients into cells and waste products out of the cell. The concentration of potassium inside cells is about 30 times that in the blood and other fluids outside of cells. Potassium levels are mainly controlled by the steroid hormone aldosterone. Aldosterone is secreted from the adrenal gland when levels of potassium increase. Aldosterone, in turn, causes the body to rid itself of the excess potassium. Metabolic acidosis (for example, caused by uncontrolled diabetes) or alkalosis (for example, caused by excess vomiting) can affect blood potassium. In normal people, taking potassium supplements or potassium-containing drugs is of no consequences, because the kidneys efficiently dispose of excess potassium.

PRINCIPLE

Potassium is estimated by Turbidometric Method. Potassium Ions present in the specimen react with Sodium Tetra Phenyl Boron (Boron Reagent) to produce an insoluble Potassium Tetra Phenyl Boron resulting in a turbid suspension. The extent of turbidity is proportional to the potassium concentration and is measured photometrically at 578 nm (570-620).

STORAGE & STABILITY:

All the reagents must be stored at 2-8ºC and are stable till the expiry date mentioned on the labels.

KIT CONTENTS:

1. Potassium Reagent
2. Potassium Standard :Concentration as stated on the label

COMPOSITION:

Sodium Hydroxide	≥ 90 mMol/L
Sodium tetraphenyl Boron	≥ 60 mMol/L
Activators and Stabilizers	

Aqueous Potassium Standard:
Potassium Chloride as active potassium Ions : Equivalent to 5 mMol/L

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

Discard any turbid reagent or blank reagent absorbance exceeds 1.5 at 578 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN:

Unhemolysed Serum is the preferred specimen. Do not use Plasma Do not use lipaemic / turbid / icteric samples.

SYSTEM PARAMETERS

Reaction Type (Mode)	: End Point
Wave Length	: 578 nm (570-620)
Flow Cell Temp:	: 37ºC
Sample Volume	: 50 µl
Potassium Reagent Volume	: 1.0 ml
Standard Concentration	: 5
Units	: mMol/L
Low Normal	: 3.5
High Normal	: 5.5
Linearity	: 8.0
Blanking	: Distilled Water

TEST PROCEDURE

Pipette into two clean dry test tubes labeled Standard (S) and Test (T)

Reagent	(S)	(T)
Potassium Reagent	1.0 ml	1.0 ml
Potassium Standard(Conc:5 mMol/L)	50 µl	-------
Serum	-------	50 µl

Mix well, incubate at room temperature for 5 minutes and read the absorbance of Standard (S) and Test (T) against distilled water on a Photo colorimeter at 578 nm (570-620) within 10 minutes.

CALCULATIONS:

$$\text{Potassium in mMol/L} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 5$$

EXPECTED VALUE

Potassium - 3.5–5.5 mMol/L

It is recommended that laboratories should establish their own normal range.

QUALITY CONTROL & CALIBRATION

To ensure adequate quality control, the use of commercial reference control serum is recommended with each assay batch. Use of Quality Control material checks both, the instrument and the reagent functions.

PERFORMANCE CHARACTERISTICS

1. Linearity
Linearity : 8 mMol/L

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 1 mMol/L

3. Interferences
No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl,Lipemia as Triglycerides up to 1000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. Precision:
Intra-Assay (N=20)

Sample	Mean mMol/L	SD mMol/L	CV%
Control serum 1	4.5	0.11	2.58
Control serum 2	6.70	0.176	2.54

Inter-Assay (N=20)

Sample	Mean mMol/L	SD mMol/L	CV%
Control serum 1	4.15	0.152	4.11
Control serum 2	6.70	0.19	2.23

5. Method Comparison:
A comparison of the LiquiMAX Pottasium - SLR (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113\,x - 0.278$; $r = 0.990$

LIMITATIONS

From detection limit of 2 mMol/L to linearity limit of 7 mMol/L. If the results obtained were greater than linearity limit, dilute the sample 1 : 2 with NaCl 9 g/L and multiply the result by 2

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES:

1. All glassware and cuvettes should be washed with good quality distilled water before use.
2. As red blood cells contain about 25 times the amount of potassium, they have to be separated from the serum within one hour after blood collection. Otherwise, falsely elevated potassium concentrations will be found.
3. Traces of detergents produce turbidity which leads to falsely elevated potassium concentrations.
   They therefore have to be avoided.

REFERENCE

1. Hillmann, G., Beyer, G., Z. Klin. Chem. Klin. Biochem. 5, 93 (1967)
2. Henry, R.J., Clin. Chem., Harper & Row, New York, Sec. Edit. 646 (1974)
3. Tietz, N.W., Fundamentals of Clinical Chemistry, Saunders, Philadelphia, Sec. Edit., 876 (1976)
4. ISO 15223 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.
5. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
6. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001

Symbols Used on Pack

REF	Catalogue Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Contains sufficient no. of test		

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