

## Potassium Estimation Kit

# High-Q Potassium (K<sup>+</sup>) - ML

### (Colorimetric Method)

#### Intended Use:

Kit for the quantitative determination of potassium (K<sup>+</sup>) in Human Serum.

#### Summary and Clinical Significance :

Potassium (K<sup>+</sup>) 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 and Stability:

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

#### Specimen:

Unhemolysed Serum is the preferred specimen. Do not use Plasma

Do not use lipaemic / turbid / icteric samples.

#### Kit Contents:

1. Potassium Reagent                    4 x 25 ml
2. Potassium Standard                5 ml.  
(Conc : 5 mMol/L)

#### Reagent Composition:

##### Boron Reagent:

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

#### 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:

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

#### Linearity:

For Potassium - Upto 8 mMol/L

#### System Parameters:

Reaction Type (Mode)	: End Point
Wave Length	: 578 nm (570-620)
Flow Cell Temp:	: 37°C
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

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#### Quality Control

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.

#### Normal Range:

**Potassium - 3.5–5.5 mMol/L**

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

#### Performance Characteristics

**Measuring range:** 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.

#### Precision:

intra- assay (n=20)		inter- assay (n=20)		
Mean (mmol/L)	4.5	6.70	4.15	6.70
SD	0.11	0.176	0.152	0.19
CV (%)	2.58	2.54	4.11	2.23

**Sensitivity:** 1 mMol/L

#### Accuracy:

Results obtained using High-Q Potassium (K<sup>+</sup>) - ML reagents did not show any systematic differences when compared with other commercial reagents. The results of the performance characteristics depend on the analyzer used.

#### Notes:

1. Disposable test tubes must be used for testing. Use always fresh test tubes for Potassium Estimation.
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 detergent in the glassware produces turbidity which leads to falsely elevated potassium results. They therefore have to be avoided.

#### Bibliography:

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
















#### Ordering information:

Ref./Cat. No.	Pack Size	Presentation
P-POT- 50	50 Tests	Mono Reagent
P-POT- 100	100 Tests	

### Product Features

- **Liquid Stable, ready to use mono reagent**
- **5 Minutes single step end point reaction (Potassium)**
- **Results correlate with ISE, Direct/Indirect Potentiometry & Flame Photometry.**
- **Aqueous Potassium standard provided (Standard Conc: 5mMol/L)**
- **Linearity : 8 mMol/L**
- **Measuring Wavelength: 578 nm (570 – 620 nm)**
- **Serum is the only specimen**
- **Available as multipurpose reagents**

#### Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

eIFU Indicator



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