

POTASSIUM (2–8°C)

(TETRAPHENYLBORON SINGLE REAGENT)

CATALOGUE NUMBER	KIT SIZE (ML)
MPRKTB2	2x50ml / 1x5ml

Intended Use:

For *In Vitro* diagnostic use by trained professionals only.
 Potassium single reagent is intended for the quantitative determination of Potassium in serum and plasma.

Clinical Significance:

Potassium is an intracellular cation, helping in the communication between nerves and muscles. It helps in the movement of nutrients into the cells. Low levels of potassium can lead to irregular heartbeat and high levels can cause decreased heart muscle activity.

Test Principle:

Sodium tetraphenylboron reacts with potassium in the sample to produce a fine turbidity of potassium tetraphenylboron. The intensity of turbidity is directly proportional to the concentration of potassium in the sample and can be measured spectrophotometrically.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Potassium Reagent 1	Sodium Tetraphenylboron	0.2 mol/l
	Sodium Hydroxide	2.2 mol/l
	Preservative	0.1%
Potassium Standard	Potassium	5.0 mmol/l

Reagent Preparation and Stability:

Potassium Reagent R1: Liquid, ready to use.
 Potassium Standard R2: Liquid, ready to use.
 R1 and R2 are stable to the expiry date when stored unopened at 2 - 8°C.
 Exercise the normal precautions associated with the handling of laboratory reagents and dispose of carefully according to local guidelines.

Sample Collection, Preparation and Stability:

Collect serum and heparin plasma by standard venepuncture technique. Potassium is stable in serum and plasma up to 24 hours when stored at 15 - 25°C and up to 2 weeks at 2 - 8°C.
 Note: Separate serum from the red cells as soon as possible, at least within one hour, after collection. Red cells contain potassium at very high concentration and immediate separation will prevent falsely elevated results.

Assay Procedure:

WAVELENGTH	630nm (620-650nm)
TEMPERATURE	15 - 30°C
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	20 µl
Standard	-	20 µl	-
TPB Reagent	1000 µl	1000 µl	1000 µl

Mix and incubate 5 minutes at assay temperature. Read absorbance of Sample/Standard against the Reagent Blank.

Calculation:

Potassium Concentration (mmol/l) = $\frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times \text{Concentration of Standard}$

Performance Characteristics:

Measuring range:
 0.1 – 7.0 mmol/l

Intra-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Pool 1	4.23	0.08	1.89
Pool 2	6.32	0.13	2.05

Inter-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Pool 1	4.32	0.09	2.058
Pool 2	6.41	0.14	2.18

Reference Range:

Serum	3.60 – 5.50 mmol/l
Plasma	4.00 – 4.80 mmol/l

Each laboratory should establish its own mean reference range according to the population.

Quality Control and Calibration Material:

It is recommended that a laboratory uses reference control sera to verify the reagent performance. Results obtained should fall within the specified ranges. If results fall outside these ranges actions should be taken in line with the laboratory's internal quality procedures.

Prestige Diagnostics recommend the following controls
 Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
 Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

Limitation:

The result from this test should not be used as the sole criteria for diagnosis, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.

References:

- Hillman G, Beyer G, Z. Clin Biochem. 5, 93.
- Henry R.J., Clin Chem, Harper & Row, New York, Sec Edit 646 (1974)
- Tietz, N.W. Fundamentals of Clinical Chemistry, Saunders Philadelphia, Sec Edition.1976.

REF	Catalogue number	LOT	Temperature limitation
	Consult instructions for use		Batch code
	<i>In vitro</i> diagnostic medical device		Use by Date
	Manufacturer		

