

Intended Use:

Potassium Test reagent/kit is a medical device intended for estimation of Potassium in serum or plasma.

Clinical Significance

Potassium is the principle cation of the intra-cellular fluid. It is also an important constituent of the extra-cellular fluid due to its influence on muscle activity. Its intra-cellular function parallels that of its extra-cellular function, namely influencing acid-base balance and osmotic pressure, including water retention.

Principle

The amount of potassium is determined by using sodium tetraphenylboron in a specifically prepared mixture to produce a colloidal suspension. The turbidity of which is proportional to potassium concentration in the range of 2-7 mEq/L.

Tetraphenyl Boron + K⁺ → White Turbidity

Reagent Composition

R1 Potassium Reagent	Sodium tetraphenylboron ≥ 50 mmol/L Sodium hydroxide ≥ 30 mmol/L
Std Conc	5 mmol/L

Working Reagent Preparation

Reagent is ready to use.

Stability and Storage

Store at 2-8°C

All the kit contents are stable until the expiry date stated on the label. Do not use reagents over the expiration date. Store the vials tightly closed protected from light and prevent contaminations during the use.

Materials required

- Photometer or spectrophotometer with a thermostat cell compartment set at 25/30/37°C, capable of reading at 620nm.
- Stopwatch, strip-chart recorder or printer.
- Cuvettes with 1-cm path length
- Pipettes to measure reagent and samples.

Sample and Stability

Serum or plasma

Serum or heparinized plasma free of hemolysis.

Potassium reported to be stable in serum or plasma for at least 2 weeks at 2-8°C.

Assay Procedure

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

Addition Sequence	Std	Test
R1 Potassium Reagent	1000µl	1000µl
Standard (S)	50µl	-
Sample	-	50µl

Mix and allow it to stand at room temperature for 5 min. read & record the absorbance at 620 nm of all tubes.

Calculation

$$\text{Potassium (mmol/L)} = \frac{\text{Abs.of Test}}{\text{Abs.of Std}} \times 5$$

Quality Control

To ensure adequate quality control (QC), each run should include a set of controls (normal and abnormal) with assayed values handled as unknowns.

If the values are found outside of the defined range, check the instrument, reagents and procedure.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable results.

Linearity

The procedure is linear up to 8mmol/L. If values exceed this limit, dilute the sample with distilled water and repeat the assay. Calculate the value using the proper dilution factor.

Reference Values

Serum, Plasma : 3.4 - 5.3 mmol/L

It is recommended that each laboratory establishes its own normal range representing its patient population.

General System Parameters

Mode	End Point
Reaction	Increasing
Wavelength	620 nm
Blank with	Reagent
Sample Volume	50µl
Reagent Volume	1000µl
Std Conc.	5mmol/L
Incub. Temp.	R.T.
Incub. Time	5 min.
Normal Range	3.4 – 5.3 mmol/L
Linearity	Up to 8mmol/L
Unit	mmol/L

Notes

1. Turbid or icteric samples produced falsely elevated results. Bilirubin above 40 mg/dl, Urea nitrogen above 80 mg/dl and hemolyzed sera will produce elevated results. Sera containing high levels of ammonia should be avoided.
2. Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

Reference

1. Henry RF et al. Clinical Chemistry Principles and Technics, 2nd Ed., Harper and Rox, Hagerstown, M.D. (1974).
2. Tietz NW. Fundamentals of Clinical Chemistry WB Saunders Co., Phila, PA, P.874.
3. Terri AE and Sesin PG, Am. J.Clin. Path., 29:86 (1958).

For *in vitro* Diagnostic use only.