POTASSIUM

INTENDED USE

Vitro potassium reagent is intended for the determination of potassium in human serum and plasma on both automated and manual systems.

METHOD

Tetraphenylborate method without deproteinization.

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.

Potassium is the principal cation of the intracellular fluid. It is also an important constituent of the extracellular fluid due to its influence on muscle activity. Its intracellular function parallels that of its extracellular function, namely influencing acid-base balance and osmotic pressure, including water retention. [1, 2].

Elevated potassium levels (hyperkalemia) are often associated with renal failure, dehydration shock or adrenal insufficiency. Decreased potassium levels (hypokalemia) are associated with malnutrition, negative nitrogen balance, gastrointestinal fluid losses and hyperactivity of the adrenal cortex. [1].

ASSAY PRINCIPLE

In previously described colorimetric methods for determination of potassium or sodium, prior deproteinization of serum or plasma specimen was required. Our improved method is the direct spectrophotometric measurement of potassium in blood or plasma.

The amount of potassium is determined by using sodium tetraphenylboron in a specifically prepared mixture to produce a colloidal suspension.3 The turbidity of which is proportional to potassium concentration in the range of 2 - 7 mmol/L (mEq/L)

EXPECTED VALUES

Serum: 3.4- 5.3 mmol/L (mEq/L)

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary, determine its own reference range.

REAGENTS

R_1	Potassium standard	4.0	mmol/L (mEq/L)
R_2	Sodium Tetraphenylboron. Preservatives and thickening agents.	2.1	mM

SPECIMEN

Reagent Preparation & Stability

All reagents are stable up to the expiry date given on label when stored at 15 – 25^{0}C.

Serum is recommended.

1. Potassium in serum is stable for at least 2 weeks at 2 - 8°C.

2. Specimens for serum potassium analysis should be free from hemolysis since the high concentration of potassium released from red cells significantly increase the serum levels and this invalidates the test results. Blood specimens should also be separated from the red cells shortly after collection to prevent any leakage of potassium from the intracellular into the extracellular fluid. Plasma from anticoagulants not containing potassium is also suitable.

PROCEDURE

- **Manual Procedure**

Wavelength	500 nm
Cuvette	1 cm light path
Temperature	20 - 25 ^{0}C
Zero adjustment	against reagent blank
Specimen	Serum or plasma

	Blank	Standard	Specimen
R_2	1.0 ml	1.0 ml	1.0 ml
Standard	……	10 µl	……
Specimen	……	……	10 µl

Mix, and Incubate for 10 minutes at room temperature Measure the absorbance of specimen ($A_{specimen}$) and standard ($A_{standard}$) against reagent blank.

The color is stable for 30 minutes.

- **Automated Procedure**

User defined parameters for different auto analyzers are available upon request.

CALCULATION

Calculate the potassium concentration in serum by using the following formulae:

Serum potassium Concentration=

$$\frac{\text{Absorbance of Specimen}}{\text{Absorbance of Standard}} \times \text{Standard value}$$

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QUALITY CONTROL

It is recommended that controls (normal and abnormal) be included in:

- Each set of assays, or
- At least once a shift, or
- When a new bottle of reagent is used, or
- After preventive maintenance is performed or a clinical component is replaced.

Commercially available control material with established potassium values may be routinely used for quality control.

Failure to obtain the proper range of values in the assay of control material may indicate:

- Reagent deterioration,
- Instrument malfunction, or
- Procedure errors.

The following corrective actions are recommended in such situations:

- Repeat the same controls.
- If repeated control results are outside the limits, prepare fresh control serum and repeat the test.
- If results on fresh control material still remain outside the limits, then repeat the test with fresh reagent.
- If results are still out of control, contact Vitro Technical Services.

PERFORMANCE CHARACTERISTICS

	Within Run		Between Day	
Control	Level I	Level II	Level I	Level II
Number of samples	40	40	40	40
Mean (mg/dl)	4.1	7.4	4.1	7.4
SD (mg/dl)	0.1	0.3	0.4	0.5
CV (%)	5	4	10	6

Imprecision

Reproducibility was determined using in an internal protocol. The following results were obtained.

Method Comparison

Comparison studies were carried out using another commercially available potassium reagent as a reference. Normal and abnormal human serum samples were assayed in parallel and the results compared by least squares regression. The following statistics were obtained.

Correlation coefficient 0.979

Sensitivity

The sensitivity is defined as the change of analytical response per unit change in analyte concentration at a pathlength of 1 cm.

When run as recommended the sensitivity of this assay is 2 mmol/L (mEq/L)

LINEARITY

When run as recommended, the assay is linear up to 7.0 mmol/L (mEq/L)

If result exceeds 7.0 mmol/L (mEq/L), specimen should be diluted with 0.9% NaCl solution and reassayed. Multiply the result by the dilution factor.

INTERFERING SUBSTANCES

Bilirubin:

Bilirubin above 40 mg/dl and Urea Nitrogen above 80 mg/dl will produce elevated results.

Drugs:

Young[9] in 1990 has published a comprehensive list of drugs and substances, which may interfere with this assay.

Hemoglobin:

Hemolyzed sera produce elevated results.

WARNING & PRECAUTION

1. Vitro Potassium Reagent Set is for *"in vitro* diagnostic use" only.
2. Sodium Tetraphenylboron is a corrosive substance. Avoid skin contact or ingestion.
3. DO NOT PIPET BY MOUTH. Flush with water if contact occurs.

BIBLIOGRAPHY

1. Henry, R.F. et. al., Clinical Chemistry Principles and Techniques, 2nd Ed., Harper and Row, Hagerstown, M.D., (1974).
2. Tietz, N.W, Fundamentals of Clinical Chemistry, W.B., Saunders Co., Philadelphia, PA, p. 874.
3. Terri, A.E. and Sesin, P.G., Am. J Clin. Path., 29:86 (1958).

SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

REF	SIZE
14501	2 X 25 ml
14502	2 X 50 ml
14503	2 X 100 ml

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