

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

BACKGROUND

Potassium is the principle 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. 1,2

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

ASSAY 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.

EXPECTED VALUES

3.4- 5.3mEq/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

- R₁** Potassium standard 4.0 mEq/dl
- R₂** Sodium Tetraphenylboron 2.1 mM, preservatives and thickening agents.

• Reagent Preparation & Stability

All reagents are stable up to the expiry date given on label when stored at 15 - 25°C.

SPECIMEN

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 °C
Zero adjustment against reagent blank
Specimen Serum or plasma

	Blank	Standard	Specimen
R₂	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.

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

Serum potassium Concentration=

CALCULATION

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

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.

INTERFERING SUBSTANCES

• Bilirubin:

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

Drugs:

Young⁹ in 1990 has published a comprehensive list of drugs and substances, which may interfere with this assay.

• Haemoglobin:

Hemolyzed sera produce elevated results.

WARNING & PRECAUTION

Vitro Potassium Reagent Set is for "in vitro diagnostic use" only.

2- Sodium Tetraphenylboron is a corrosive substance. Avoid skin contact or ingestion. DO NOT PIPET BY MOUTH. Flush with water if contact occurs.

PERFORMANCE CHARACTERISTICS

Imprecision

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

	Within Run		Between Day	
	Level I	Level II	Level I	Level II
Control				
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

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 mEq/l.

LINEARITY










When run as recommended, the assay is linear up to 7.0 mEq/l.

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

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

ORDERING INFORMATION

REF	SIZE
1451	2 X 25 ml
1452	2 X 50 ml

Manufactured in Egypt by:
Vitro Scient
www.vitrosient.com

Technical Support:
+202 26439699
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orders:
+202 26439698
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