Atlas Medical

CE

POTASSIUM REAGENT TEST (COLORIMETRIC METHOD)

IVD *For In-Vitro and professional use only*

Store at room temperature

INTENDED USE

For the colorimetric determination of potassium in serum and plasma.

INTRODUCTION

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 most 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.

PRINCIPLE

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 mEq/L.

MATERIALS

MATERIALS PROVIDED

- Potassium Reagent: Sodium Tetraphenylboron 2.1 mM
- Potassium Standard: Equivalent to 4mEq/L.

MATERIALS REQUIRED BUT NOT PROVIDED

- Spectrophotometer.
- Test tube/rack.
- Timer.

PRECAUTION

- Potassium Reagent Set is for "in vitro diagnostic use" only.
- Sodium Tetraphenylboron is a corrosive substance. Avoid skin contact or ingestion.
- DO NOT PIPETTE BY MOUTH. Flush with water if contact occurs.

STORAGE AND STABILITY

Both reagents are stored at room temperature. The reagents are stable until expiration date indicated on the package label.

REAGENT DETERIORATION

DO NOT USE IF:

- The reagent is very cloudy.
- The reagent fails to achieve assigned value on fresh control serum.

SPECIMEN COLLECTION AND STORAGE[1,2]

1. Serum is recommended.
2. Potassium in serum is stable for at least 2 weeks at 2 - 8°C.
3. Specimens for serum potassium analysis should be free from haemolysis 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

1. Label test tubes: standard, control, patients, etc. A blank is necessary.
2. Pipette 1.0 mL of Potassium Reagent to all tubes.
3. Add 0.01 mL (10 µl) of samples to respective tubes. Mix and let sit at room temperature for 3 minutes.
4. After 3 minutes, set the wavelength of spectrophotometer to 500 nm, zero spectrophotometer with reagent blank. Read and record the absorbance of all tubes.

NOTE

If the spectrophotometer being used required 2.5 mL reagent, use 0.025 mL (25 µl) of sample to 2.5 mL of reagent. Perform the test as described above.

LIMITATIONS

Our method has been found to be linear between 2 - 7 mEq/L. It is important to note that our method may not produce accurate results when used with potassium calibrator other than that provided by us. Other products contain preservatives that interfere with this procedure and tend to produce false elevated results. Samples with values above 7 mEq / L should be diluted 1:1 with normal saline, re-assayed and results multiplied by two.

CALCULATION

Abs. = Absorbance
STD = Standard

$$\frac{\text{Abs. of unknown}}{\text{Abs. of STD}} \times \text{Conc. of STD (mEq/L)} = \text{Potassium (mEq/L)}$$

Example: If the absorbance of the unknown = 0.200, the absorbance of the standard is 0.160 and standard concentration is 4 mEq/L, then

$$\frac{0.200}{0.160} \times 4 = 5 \text{ mEq/L}$$

QUALITY CONTROL

Serum controls with known normal and abnormal values should be run routinely to monitor the validity of the reaction.

EXPECTED VALUES

3.4- 5.3mEq/L.
It is strongly recommended that each laboratory establish its own normal range.

INTERFERENCE

Turbid or icteric samples produce falsely elevated results. Bilirubin above 40 mg / dl and Urea Nitrogen above 80 mg / dl will produce elevated results. Hemolyzed sera produce elevated results. Sera containing high levels of ammonia should be avoided.

PERFORMANCE

- Linearity: 2 - 7 mEq/L

- Sensitivity: Based on an instrument resolution of A = 0.001, the present method has a sensitivity of 0.006 mEq/L
- Comparison: A comparison study performed between our method and a similar method resulted in a correlation coefficient of 0.99 with a regression equation of Y = 1.06 - 0.37.
- Precision Study:

Within Run			Run To Run		
Mean*	S.D.	C.V.%	Mean*	S.D.	C.V.%
4.1	0.1	5	4.1	0.4	10
7.4	0.3	4	7.4	0.5	6

* (mEq/L)

REFERENCES

1. Henry, R.F. et. al., *Clinical Chemistry Principles and Technics*, 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).

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REF	Catalogue Number		Store at
IVD	For In-Vitro Diagnostic use		Caution
Σ	Number of tests in the pack		Read product insert before use
LOT	Lot (batch) number		Manufacturer
	Fragile, handle with care		Expiry date
	Manufacturer fax number		Do not use if package is **damaged**
	Manufacturer telephone		