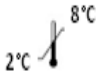
POTASSIUM REAGENT TEST (COLORIMETRIC METHOD)

IVD For *in vitro* diagnostic and professional use only



Store at (2-8˚C). CE

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.

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.

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.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. Preservatives and thickening agents.
- Potassium Standard: Equivalent to 4mEq/L.

MATERIALS REQUIRED BUT NOT PROVIDED

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

PRECAUTION

- Sodium Tetraphenylboron is a corrosive substance. Avoid skin contact or ingestion.
- DO NOT PIPETTE BY MOUTH. Flush with water if contact occurs.
- For *in vitro* diagnostic and professional use only.
- Protective clothing should be worn when handling the reagents.
- Wash hands and the test table top with water and soap once the testing is done.
- Do not use these reagents if the label is not available or damaged.
- Do not use the kit if damaged or the glass vials are broken or leaking and discard the contents immediately.
- Test materials and samples should be discarded properly in a biohazard container.

STORAGE AND STABILITY

All components of the kit are stored at (2-8˚C). 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 PRPARATION

1. Serum is recommended; to prepare serum sample, the whole blood sample could be collected using no anticoagulant tube.
2. To prepare plasma sample; the whole blood sample could be collected using EDTA and sodium citrate anticoagulants.

NOTE: Do not use anticoagulants containing Potassium.

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, 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 0.02 mL (20 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

1. Linearity: 2 - 7 mEq/L.
2. 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 = 1.06X - 0.4.
3. 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		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Fragile, handle with care		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry