ACCUCARE®

POTASSIUM

COLORIMETRIC METHOD

Quantitative determination of Potassium in serum / Plasma
Only for *In Vitro* Diagnostic use

ORDER INFORMATION

REF	Cont.
KM 50	50 X 1 mL
KM 100	2 X 50 mL

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

Method

Photometric test with endpoint determination

PRINCIPLE

Potassium ions in a protein-free alkaline medium react with sodium tetraphenylboron to produce a finely dispersed turbid suspension of potassium tetraphenylboron. The turbidity produced is proportional to the potassium concentration and read photometrically.

REAGENT

Reagent I : Potassium reagent
Phosphorus standard : 5.0 mEq/L

REAGENT PREPARATION

All Reagents are ready to use

REAGENT STORAGE AND STABILITY

When stored at recommended storage temperature stated on label, reagent is stable until the expiration date stated on the bottle and kit box label

WARNING AND PRECAUTIONS

- For in vitro diagnostic use.
- Do not use components beyond the expiration date.
- Do not mix materials from different kit lot numbers.
- Exercise the normal precautions required for handling all laboratory reagents.
- The reagent contains preservative. Do not swallow. Avoid contact with skin and mucous membranes.
- For detailed information refer Material Safety Data Sheet.
- Proceed carefully with this product because due to its nature it can get contaminated easily.
- Most of the detergents and water softening products used in the laboratories contain chelating agents. A defective rinsing will invalidate the procedure.

WASTE MANAGEMENT

Please refer to local legal requirements.

MATERIALS REQUIRED BUT NOT PROVIDED

- NaCl solution 9 g/L
- General laboratory equipment

SAMPLE COLLECTION AND PRESERVATION

Serum or plasma (lithium heparin)
Separate from cellular contents immediately after blood collection.
Stability: at least one year at –20°C in case of immediate freezing.
7 days at 4 – 8°C
Freeze only once! Discard contaminated specimens!

ASSAY PROCEDURE

Operating Instructions

- Check reagent inventories at least daily to ensure that quantities are sufficient for the planned work load.
- Bring all reagents, standard and samples to room temperature 18 – 28 ºC, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	630 nm (620-650 nm)
Cuvette 1 cm	1 cm
Reaction Temperature R.T.	R.T.
Measurement Against	Reagent blank
Reaction type	End Point
Sample Volume	20 µl
Reagent Volume	1000 µl
Incubation 5 mins.	5 mins.
Blank Absorbance Limit	< 0.100
Low Normal	3.6 mEq/l
High Normal	5.5 mEq/l
Linearity	7.0 mEq/l

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STANDARD	TEST
Reagent	1 ml	1 ml	1 ml
Standard	-	20 µl	-
Serum /Plasma	-	-	20 µl

Mix & Incubate for 5 min. at R.T. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 630 nm.

SAMPLE DILUTIONS

- This method is linear upto a concentration of 7 mEq/L.
- Dilute samples above this concentration 1:1 with DI Water
- Repeat assay. Multiply the result by 2.

CALCULATION

$$\text{Potassium Conc. in Serum / Plasma (mEq/L)} = \frac{\text{Abs Sample}}{\text{Abs Standard}} \times \text{Concentration of Standard}$$

CALIBRATORS AND CONTROLS

For the calibration of automated photometric systems the commercially available suitable multi-calibrator is recommended.

The assigned values of **Potassium standard** have been made traceable to the NIST Standard Reference Material® SRM 956.

It is recommended to run a normal and a pathological control serum which is commercially available to verify the performance of the measured procedure. The value of controls should fall within the established limit.

Each laboratory should establish corrective action in case of deviations in control recovery.

PERFORMANCE CHARACTERISTICS

WITHIN RUN

Sample	Mean Concentration	SD	CV %
Norm	3.26	0.12	3.73%
Path	4.38	0.16	3.67%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm	3.30	0.10	3.01%
Path	4.41	0.15	3.35%

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LINEARITY

This method is linear upto a concentration of 7 mEq/L.
Dilute samples above this concentration 1:1 with DI Water and Repeat assay. Multiply the result by 2.

Limit of detection: The limit of detection for Potassium is 1 mEq/L.

METHOD COMPARISON

A comparison of Accucare Potassium with a commercially available assay (x) using 20 samples gave following results: $R^2 = 0.9800$

REFERENCE VALUES

Serum	: 3.60 – 5.50 mEq/L
Plasma	: 4.00 – 4.80 mEq/L

The reference values are to be considered as indicative only. Every laboratory should establish its own normal range.

LIMITATION OF THE PROCEDURE

- For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

INTERFERENCE

- Bilirubin: No interference found upto Bilirubin 50mg/dl.
- Hemoglobin: No interference found upto 500mg/dl.
- Ascorbic Acid: No interference found upto 60mg/dl.
- Lipemia: No interference found upto 1000mg/dl.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

BIBLIOGRAPHY

1. Hillmann, G., Beyer, G., Z. Klin. Chem. Klin. Biochem. 5, 93 (1967)
2. Henry, R.J., Clin. Chem., Harper & Row, New York, Sec. Edit. 646 (1974)
3. Tietz, N.W., Fundamentals of Clinical Chemistry, Saunders, Philadelphia, Sec. Edit., 876 (1976)

GLOSSARY OF SYMBOL

	Consult Instruction for Use	LOT	Lot Number
REF	Catalog Number		Date of Manufacturing
	Store between		Use By or Expiration Date
	Manufacturer	IVD	For *in vitro* Diagnostic use only
	Keep away from sunlight	CONT	Content of the kit

LAB-CARE DIAGNOSTICS (INDIA) PVT. LTD.
C1 Type, Shed No.: 3225, Chemical Zone,
GIDC Sarigam – 396155, Dist. Valsad, Gujarat, India.
Tel.: +91 22 2554 2109 /1558
Email: accucare@labcarediagnostics.com;
Website: www.labcarediagnostics.com

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