LiquiMAX Sodium (Na+) Potassium (K+)

(5 th Generation Dye Binding Na+ / Colorimetric K+)

ORDER INFORMATION:

Ref. No:	Pack Size	Presentation
AVNAK-30	30+30 T	Sodium (Mono Reagent, Mono Test Vials) Potassium (Mono Reagent)

INTENTED USE:

Kit for the Quantitative determination of SODIUM (Na^+) and POTASSIUM (K^+) in Human Serum.

PRODUCT FEATURES:

SODIUM:

1. Liquid Stable, Ready to use mono reagent (Mono Test Vials).
2. 5th Generation sodium specific dye incorporated
3. No precipitation of samples required.
4. Instant results can be taken (No incubation).
5. Results corelate with ISE, Direct / Indirect Potentiometry & Flame Photometry.
6. Aqueous standard provided (Standard Conc: Sodium 140 mMol/L).
7. Linearity Sodium : 200 mMol/L.
8. Measuring Wavelength for Sodium : 620 nm (600– 630 nm).
9. Serum is the only specimen
10. Available as multipurpose reagents

POTASSIUM:

1. Liquid Stable, Ready to use mono reagent.
2. 5 Minutes single step End Point reaction .
3. Results corelate with ISE, Direct/ Indirect Potentiometry & Flame Photometry.
4. Aqueous standard provided (Standard Conc: Potassium 5mMol/L
5. Linearity : 8 mMol/L
6. Measuring Wavelength for Potassium : 578 nm (570 – 620 nm)
7. Serum is the only specimen
8. Available as multipurpose reagents

CLINICAL SIGNIFICANCE:

This test is performed when symptoms of a sodium imbalance are present, or when disorders associated with abnormal sodium levels develop. Sodium (Na+) is the major positive ion in the fluids outside of cells. The concentration of sodium inside cells is only about 5 mEq/L compared with 140 mEq/L outside. The sodium content of the blood is a result of a balance between the amount in the food and beverages you consume, and the amount your kidneys excrete. (In addition, a small percent is lost through the stool and sweat.) Many factors affect sodium levels, including the steroid hormone aldosterone, which decreases loss of sodium in the urine. ANP (Atrial Natriuretic Protein) is a hormone secreted from the heart that increases sodium loss from the body. Despite the integral relationship between sodium and water, the body regulates them independent of each other if necessary. 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.

PRINCIPLE:

Sodium is estimated by the use of 5th Generation Dye which specifically binds with Sodium alone when the serum is added to the dye reagent. The intensity of the purple colour produced is directly proportional to the sodium concentration in the specimen and is measured photometrically at 620 nm(600-620).

Potassium is estimated by Turbidometric Method. Potassium Ions present in the specimen react with Sodium Tetra Phenyl Boron present in the potassium reagent to produce an insoluble Potassium Tetra Phenyl Boron resulting in a turbid suspension. The extent of turbidity is proportional to the potassium concentration and is measured photometrically at 578 nm (570-620).

STORAGE & STABILITY:

All the reagents must be stored at 2-8^{0}C and are stable till the expiry date mentioned on the labels.

KIT CONTENTS:

1. Sodium Dye Reagent (Mono Test Vials): 50 Nos (Filled with 1.0 ml Reagent)
2. Potassium Reagent 50 ml.
3. Standard 5 ml.

(Conc: Sodium 140 mMol/L, Potassium 5 mMol/L)

COMPOSITION:

	Sodium	Potassium	
Sodium Specific Dye	≥ 0.2 mMol/L	Sodium Hydroxide	≥ 40 mmol/L
Detergent	≥ 25 mmol/L	Sodium tetraphenyl Boron	≥ 50 mmol/L
Activators and Stabilizers		Activators and Stabilizers	

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

1. When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION

- Discard any turbid reagent if blank reagent absorbance exceeds 0.8 at 630 nm against distilled water.

WARNING & PRECAUTIONS

- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP

SPECIMEN: Unhemolysed Serum is the only specimen. Do not use Plasma Do not use lipaemic / turbid / icteric samples.

SYSTEM PARAMETERS	FOR SODIUM ASSAY	FOR POTASSIUM ASSAY
Reaction Type (Mode)	End Point	End Point
Wave Length	620 nm (600-620)	578 nm (570-620)
Flow Cell Temp	37° C	37° C
Sample Volume Sodium Dye Reagent	25 µl 1.0 ml	Sample Volume 50 µl Potassium Reagent 1.0 ml
Standard Concentration	150	5
Units	mMol/L	mMol/L
Low Normal	125	3.5
High Normal	155	5.5
Linearity	200	8.0
Blanking	Reagent	Distillied Water

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TEST PROCEDURE:

SODIUM

Take pre filled Mono Test Vials labelled as Blank (B), Standard (S) and Test (T).

Reagent	(B)	(S)	(T)
1. Sodium Dye Reagent (Mono Test Vial)	1.0 ml	1.0 ml	1.0 ml
3. Standard (Conc: Sodium 150 mMol/L)	-	25 µl	-
Serum Sample	-	-	25 µl

Mix well and Incubate at 37° C for 5 Minutes then measure the absorbance of Standard (S) and Test (T) against Reagent Blank on a Photocolorimeter which is set at 620 nm (600-630)

POTASSIUM

Pipette into two clean dry test tubes labelled Standard (S) and Test (T).

Reagent	(S)	(T)
2. Potassium Reagent	1.0 ml	1.0 ml
3. Standard (Conc: Potassium: 5 mMol/L)	50 µl	-
Serum	-	50 µl

Mix well, incubate at room temperature for 5 minutes and read the absorbance of Standard (S) and Test (T) against distilled water on a Photocolorimeter at 578 nm (570-620) within 10 minutes.

CALCULATIONS:

$$\text{Sodium in mMol/L} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 150$$

$$\text{Potassium in mmol/L} = \frac{\text{Abs. of Test}}{\text{Abs. of Standard}} \times 5$$

EXPECTED VALUE

Sodium - 125 – 155 mMol/L
Potassium - 3.5– 5.5 mMol/L
It is recommended that laboratories should establish their won normal range.

PERFORMANCE CHARACTERISTICS

1. Linearity

For Sodium - Up to 200 mMol/L
For Potassium - Up to 8 mMol/L

2. Sensitivity/ Limit of Detection (LOD)

For Sodium - 5 mMol/L
For Potassium - 1 mMol/L

3. Interferences

No significant interference was observed from Bilirubin up to 20 mg/dl (Both conjugated and unconjugated Bilirubin) Hemoglobin up to 50 mg/dl,Lipemia as Triglycerides up to 2000 mg/dl, Ascorbic acid up to 50 mg/dl.

4. PRECISION:

Intra-Assay (For Sodium)

Sample	Mean mMol/L	SD mMol/L	CV%
Control serum 1	133.5	0.13	1.59
Control serum 2	145.6	0.32	2.15
Control serum 3	155.2	0.58	1.95

Inter-Assay (For Sodium)

Sample	Mean mMol/L	SD mMol/L	CV%
Control serum 1	133.8	0.033	1.49
Control serum 2	145.9	0.035	1.32
Control serum 3	155.6	0.031	0.80

Intra-Assay (For Potassium)

N=20	Mean mMol/L	SD mMol/L	CV%
Control serum 1	4.5	0.11	2.58
Control serum 2	6.70	0.176	2.54

Inter-Assay (For Potassium)

N=20	Mean mMol/L	SD mMol/L	CV%
Control serum 1	4.15	0.152	4.11
Control serum 2	6.70	0.19	2.23

5. Method Comparison:

A comparison of the LiquiMAX Sodium - SLR (y) with a commercial obtainable assay (x) gave the following result : $y = 1.113x - 0.278$; $r = 0.990$

LIMITATIONS

Measuring range: 5-200 mMol/L. Determine samples having higher concentrations manually dilute with 0.9% NaCl or distilled/deionized water (e.g. 1 + 1). Multiply the result by the appropriate dilution factor (e.g. 2).

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

NOTES:

1. Sodium Assay is performed in Mono Test Vials. Do not pipette the reagent in to other test tubes.
2. All glassware and cuvettes should be washed with good quality distilled water before use for Potassium Test

REFERENCE

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)
4. ISO 15223 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied.
5. Young DS. Effects of drugs on Clinical Lab. Tests, 4th ed AACC Press, 1995.
6. Young DS. Effects of disease on Clinical Lab. Tests, 4th ed AACC 2001.

Symbols Used on Avecon's Labels

REF	Catalog Number		Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
	Do Not Reuse		Contains sufficient no. of test

Manufactured in India by :
AVECON Healthcare Pvt. Ltd.
Transforming Research into Innovations
Plot No.: # 338, Sector-2, Industrial Growth Centre, Saha (Haryana) India-133104.
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com
Customer Care No. : +91 93065 12576

Ver. : 03
Date : 05/2023

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