LiquiMAX Sodium SLR

(5 th Generation Dye Binding Na+)

ORDER INFORMATION:

Ref. No.	Pack Size	Presentation
AVNA - 25	25 ml	25x1 ml
AVNA - 50	50 ml	50x1 ml

INTENDED USE:

LiquiMAX Sodium is an in-vitro diagnostic kit for the Quantitative determination of Sodium (Na^+) in Human Serum. This kit is a automated.

INTENDED USER:

Laboratory Technician

PRODUCT FEATURES:

Liquid Stable, Ready to use mono reagent (Mono Test Vials).

5th Generation sodium specific dye incorporated

No precipitation of samples required.

Results corelate with ISE, Direct / Indirect Potentiometry & Flame Photometry.

Aqueous standard provided (Standard Conc: Sodium 150 mMol/L).

Linearity Sodium : 200 mMol/L.

Measuring Wavelength for Sodium : 620 nm (600– 630 nm).

Serum is the only specimen

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.

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 630 nm(600-630).

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 Reagent
2. Sodium Standard : Concentration as stated on the label

COMPOSITION:

Sodium Specific Dye	≥ 0.2 mMol/L
Detergent	≥ 25 mmol/L

Activators and Stabilizers and Stabilizers

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

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 or blank reagent absorbance exceeds 1.1 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 COLLECTION AND STORAGE

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

SYSTEM PARAMETERS

Reaction Type (Mode)	End Point
Wave Length	630 nm (600-630)
Flow Cell Temp	37° C
Sodium Dye Reagent	1.0 ml
Sample Volume	25 µl
Standard Concentration	150
Units	mMol/L
Low Normal	125
High Normal	155
Linearity	200
Blanking	Reagent

TEST PROCEDURE:

Reagent	(B)	(S)	(T)
Sodium Reagent	1.0 ml	1.0 ml	1.0 ml
Standard (150 mMol/L)	-	25 µl	-
Serum Sample/ Control	-	-	25 µl

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

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 Photo colorimeter which is set at 630 nm (600- 630)

CALCULATIONS:

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

EXPECTED VALUE

Sodium - 125 – 155 mMol/L

It is recommended that laboratories should establish their own normal range.

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result. Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:

a) When using a new reagent or lot.

b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

For Sodium-Up to 200 mMol/L

2. Sensitivity/ Limit of Detection (LOD)
The lower limit of detection is 5 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

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

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

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

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 Pack

REF	Catalogue 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
	Contains sufficient no. of test		

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AVECON™ Healthcare Pvt. Ltd.
Transforming Research into Innovations
Plot No.: 338, Sector-2, Industrial Growth Centre, Saha, Ambala, Haryana (INDIA)-133104
E-mail : helpdesk@aveconhealthcare.com, Website : www.aveconhealthcare.com
Customer Care No. : +91 93065 12576, CIN No.: U24230HR2006PTC118875

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