ACCUCARE®

SODIUM

COLORIMETRIC METHOD

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

ORDER INFORMATION

REF	Cont.
SODM 50	50 X 1 mL

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.

Method

Photometric test with endpoint determination

PRINCIPLE

The Present method is based on reaction of sodium with a selective chromogen (phosphonazo III) changing a colour from violet to blue in the presence of chealating agent whose absorbance varies directly as the concentration of sodium in the test specimen.

REAGENT

Reagent I : Sodium reagent
Sodium standard : 150 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)
Reaction Type	End Point
Cuvette 1 cm	1 cm
Reaction Temperature R.T.	R.T.
Reaction Type	Increasing
Measurement Against	Reagent blank
Sample Volume	10 µl
Reagent Volume	1000 µl
Incubation	5 mins.
Low Normal	135 mEql/l
High Normal	155 mEql/l
Linearity	180 mEql/l

MANUAL ASSAY PROCEDURE

Pipette into Test Tubes

	BLANK	STANDARD	TEST
Reagent	1000 µl	1000 µl	1000 µl
Standard	-	10 µl	-
Serum /Plasma	-	-	10 µl

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

SAMPLE DILUTIONS

- This method is linear upto a concentration of 180 mEq/L.
- Dilute samples above this concentration 1:1 with DI Water
- Repeat assay. Multiply the result by 2.

CALCULATION

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

CALIBRATORS AND CONTROLS

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

The assigned values of **Sodium 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 Control	115.39	2.85	2.47%
Path Control	165.92	4.73	2.85%

RUN TO RUN

Sample	Mean Concentration	SD	CV %
Norm Control	116.38	2.93	2.52%
Path Control	165.75	3.64	2.20%

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Revision No.: 01

LINEARITY

This method is linear upto a concentration of 180 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 Sodium is 22 mEq/L.

METHOD COMPARISON

A comparison of Accucare Sodium with a commercially available assay (x) using 59 samples gave following results: $R^2 = 0.9800$

REFERENCE VALUES

Serum / Plasma	135 - 155 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 40mg/dl.
- Hemoglobin: No interference found upto 500mg/dl.
- Ascorbic Acid: No interference found upto 50mg/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. Tietz, N.W., Fundamentals of clinical Chemistry, W.b. Saunders Co. Phila, P.A. p. 874.
2. Henry R.F., et, al, Clinical Chemistry Principles and Technics. 2nd Ed, Harper and Row, Harper and Row, Hargersein, M.D. (1974)
3. Maruna RFL., Clin Chem. Acta. 2:581, (1958)
4. Trinder, P:Analyst, 76:596, (1951)

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;
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