

**Quantitative determination of Sodium in human Serum / Plasma / other body fluids. Only for *In Vitro* Diagnostic use**

**ORDER INFORMATION**

REF	Pack Size
SODMONO 25	25 X 1 ml
SODMONO 50	50 X 1 ml
SOD 25	1 X 25 ml
SOD 50	1 X 50 ml
SOD 100	1 X 100 ml
SOD 1000	1 X 1000 ml
SOD 5000	1 X 5000 ml
SOD 10000	1 X 10000 ml

**CLINICAL SIGNIFICANCE**

Sodium plays a key role in your body. It helps maintain normal blood pressure, supports the work of your nerves and muscles, and regulates your body's fluid balance. Clinical diagnosis should not be made on a single test result; it should integrate clinical and other laboratory data.

**Method**

Colorimetric test

**PRINCIPLE**

The Present method is based on reaction of sodium with a selective chromogen producing a chromophore 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**

The Reagent is ready to use.

**REAGENT STORAGE AND STABILITY**

Reagent is stable till expiry when stored at RT  
Store protected from light.

**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.

**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 heparin plasma**

Separate at the latest 1h after blood collection from cellular contents.

7 days at 2 – 8°C

1 day at –20°C

Stability in serum (separated from cellular contents, hemolysis free) without adding a glycolytic inhibitor

8 h at 25°C

7 days at 2 – 8°C

Only freeze 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°C, prior to analysis.

AUTOMATED PARAMETERS	
Wavelength	630 nm
Reaction Type	End Point
Cuvette	1 cm light path
Reaction Temperature	RT
Reaction Type	Increasing
Measurement	Against Reagent Blank
Sample Volume	10µl
Reagent Volume	1000µl
Incubation	05 minutes
Blank Absorbance Limit	< 1.300
Low Normal at 37°C	135 mEq/l
High Normal at 37°C	155 mEq/l
Linearity at 37°C	180 mEq/l

**MANUAL ASSAY PROCEDURE**

**Pipette into Test Tubes**

	BLANK	STD	SAMPLE
Sample	-	-	10µl
Standard	-	10µl	-
Reagent	1000µl	1000µl	1000µl

Mix & Incubate for 05 min. at R.T. Measure absorbance of Sample (AT) and Standard (AS) against Reagent Blank at 630 nm.

**SAMPLE DILUTIONS**

- This method is linear up to a concentration of 180 mEq/l.
- Dilute samples above this concentration 1:1 with 0.9% saline.
- Repeat assay. Multiply the result by 2.

**CALCULATION**

Results are calculated, usually automatically by the instrument, as follows:

$$\text{Total Sodium (mEq/l)} = \text{AT/AS} \times \text{Conc. of Standard}$$

**CLIBRATORS AND CONTROLS**

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

The assigned values of this **Sodium Standard** have been made traceable to the reference method gas chromatography – isotope dilution mass spectrometry (GC-IDMS).

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 %
Randox 2	141.94	1.04	0.73%
Randox 3	151.92	1.03	0.68%

#### RUN TO RUN

Sample	Mean Concentration	SD	CV %
Randox 2	141.67	1.03	0.73%
Randox 3	152.34	1.07	0.70%

#### LINEARITY

The method is linear up to a concentration of 180 mEq/l. dilute samples above this concentration 1:1 with 0.9% saline solution and repeat assay. Multiply the result by 2.

**Limit of detection:** The limit of detection for Sodium is 3 mEq/l.

#### METHOD COMPARISON

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

#### REFERENCE VALUES

Serum/Plasma	135-155 mEq/l
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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

- Hemoglobin: No interference found up to 400 mg/dL.
- Bilirubin: No interference found up to 20mg /dL.
- Lipemia: No interference found up to 400 mg/dL.
- These characteristics have been obtained using an automatic analyzer. Results may vary if a different instrument or a manual procedure is used.

#### BIBLIOGRAPHY

- Tietz, N.W., Fundamentals of clinical Chemistry, W.b. Saunders Co. Phila, P.A. p. 874.
- Henry R.F., et, al, Clinical Chemistry Principles and Technics. 2nd Ed, Harper and Row, Harper and Row, Hargersein, M.D. (1974)
- Maruna RFL., Clin Chem. Acta. 2:581, (1958)
- Trinder, P:Analyst, 76:596, (1951)

#### GLOSSARY OF SYMBOL

	Consult Instruction for Use
	Catalog Number
	Store between
	Manufacturer
	Keep away from sunlight



Paramcare Life Sciences Private Limited, G/F-12/13, Evershine-2,  
Survey No. 307/3/1, Balitha N.H No 48, Vapi, Valsad, Gujarat, 396191.

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