SPECTRUM

The Creative Approach to Bioscience

Sodium - single reagent

REF: 303 001 (2 x 25 ml) 50 test
REF: 303 002 (4 x 25 ml) 100 test
REF: 303 003 (2 x 100 ml) 200 test
REF: ZL-303 001 50 test

SYMBOLS IN PRODUCT LABELLING

EC REP	Authorised Representative		Use by/Expiration Date
IVD	For in-vitro diagnostic use		CAUTION. Consult instructions for use
LOT	Batch Code/Lot number		
REF	Catalogue Number		Manufactured by
	Consult instructions for use		(Xi) - Irritant
	Temperature Limitation		

Intended Use

Spectrum-Diagnostics Sodium reagent is intended for the in-vitro quantitative diagnostic estimation of sodium in human serum on manual systems.

Background

Sodium and Potassium are the major cations of extracellular and intracellular fluids respectively. Sodium maintains the normal distribution of water and the osmotic pressure in the various fluid compartments. Potassium influences the acid base balance and osmotic pressure including water retention. Increased sodium levels are found in severe dehydration and excessive treatment with sodium salts. Decreased levels are found in severe polyurea, metabolic acidosis, diarrhoea and renal insufficiency. Increased potassium levels are found in renal failure, dehydration, shock and adrenal insufficiency. Decreased levels are found in malnutrition, gastrointestinal fluid loss, and hyperactivity of the adrenal cortex.

Method

Colorimetric method.

Assay 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.

Reagents

Reagent **(R)** Color Reagent

Chromogen	0.03 gm/L
EDTA	25 mmol/L
Dimethyl sulfoxide (DMSO)	75 mmol/L
preservatives	0.05%
Antifoam	0.01 %
Standard **(S)** Sodium	150 mEq/l

Precautions and Warnings

Do not ingest or inhalate. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Reagent Storage and Stability

Reagents and standard are ready-to-use. When stored at 15 - 25°C; they are stable up to the expiry date stated on the label. Once opened, the reagent and standard are stable for 3 months at the specified temperature.

Deterioration

Failure to recover control values within the assigned range may be an indication of reagent deterioration.

Sample Preparation and Preservation

Serum and plasma
Freshly drawn non-hemolysed serum is the specimen of choice. Heparinised plasma can also be used.
Stability: Serum Sodium is stable for at least 24 hours at room temperature and two weeks at 2-8°C.
Urine
Urine diluted 1+1 with distilled water can be used for Sodium estimation.

System Parameters

Wavelength	630 nm
Optical path	1 cm
Assay type	colorimetric end-point
Direction	Increase
Sample: Reagent Ratio	1:100
e.g.: Reagent volume	1 ml
Sample volume	10 µl
Temperature	Room temperature
Zero adjustment	Against reagent blank
Sensitivity	55 mEq/l.
Linearity	180 mEq/l
Incubation	5 min.
Blank absorbance limit	1.2

Procedure

Pipette into clean test tubes:

	Blank	Standard	Sample
Reagent (**R**)	1 ml	1 ml	1 ml
Standard	.....	10 µl	.....
Sample	.....	.....	10 µl

Mix well, let stand for 5 minutes at R.T.
Read absorbances ,A standard and A sample against Reagent Blank at 630 nm.

Calculation

$$\text{Serum Sodium Conc.(mEq/l)} = \frac{A_{\text{Sample}}}{A_{\text{Standard}}} \times 150$$

Quality Control

Normal and abnormal control serum of known concentrations should be analyzed with each run

Performance Characteristics

Precision

Within run (Repeatability)

	Level 1	Level 2
n	20	20
Mean (mEq/L)	140	170
SD	0.72	1.44
CV%	0.51	0.84

Run to run (Reproducibility)

	Level 1	Level 2
n	20	20
Mean (mEq/L)	140	170
SD	0.76	1.58
CV%	0.54	0.93

Methods Comparison

A comparison between Spectrum Diagnostics Sodium reagent and a commercial reagent of the same methodology was performed on 20 human sera. A correlation of 0.979 was obtained.

Sensitivity

When run as recommended, the minimum detection limit of the assay 55 mEq/l.

Linearity

The assay is linear up to 180 mEq/l.

Interfering Substances

Hemoglobin and Lithium
Demonstrates positive interference

Lipemia
No significant interference

Other Ions
No adverse influence is exerted on the procedure by blood calcium, chloride and potassium levels of up to 3 times normal values. Hypermagnesemia may interfere with sodium assay.

Anticoagulants
Complexing Anticoagulants such as citrate and oxalate must be avoided.

Expected Values

Serum 135 – 150 mEq/l.

Note:
It is recommended for each laboratory to establish and maintain its own reference values. The given data are only an indication.

Spectrum Diagnostics does not interpret the results of a clinical laboratory procedure; interpretation of the results is considered the responsibility of qualified medical personnel. All indications of clinical significance are supported by literature references.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.
S56: dispose of this material and its container at hazardous or special waste collection point.
S57: use appropriate container to avoid environmental contamination.
S61: avoid release in environment. refer to special instructions/safety data sheets.

References

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)

ORDERING INFORMATION	
CATALOG NO.	**QUANTITY**
303 001	2 x 25 ml 50 Test
303 002	4 x 25 ml 100 Test
303 003	2 x100 ml 200 Test
ZL-303 001	50 Test

Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail:info@spectrum-diagnostics.com

EC REP **MDSS GmbH**
Schiffgraben 41
30175 Hannover, Germany

CE

TÜV SÜDWEST CERTIFIED ISO 13485:2016