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SODIUM – Single Reagent

Diagnostic reagent for the in-vitro quantitative determination of Sodium in human serum, plasma, CSF and urine on both manual and automated systems.

REF: BS.1/NA02.025.0050	50 test	REF: BS.1/NA02.050.0100	100 test
REF: BS.1/NA04.025.0100	100 test	REF: BS.1/NA02.100.0200	200 test

CLINICAL SIGNIFICANCE

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 polyuria, metabolic acidosis, diarrhea 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 PRINCIPLE

The Present method is based on reaction of sodium with a selective chromogenic producing a chromosphere whose absorbance varies directly as the concentration of sodium in the test specimen.

REAGENT COMPOSITION

R1: Standard	150 mEq/l
R2: Reagent	
Chromogen	0.03 gm/L
EDTA	25 mmol/L
Dimethyl Sulfoxide	75 mmol/L
preservatives	0.05%
Antifoam	0.01%

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- 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.
- Respect country requirement for 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.

For further information, refer to the sodium reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien sodium reagents are supplied ready-to-use. All reagents are stable until expiration date stated on label when stored at 2-8°C.

Deterioration

The ***BioScien*** sodium reagent is normally clear, do not use reagent if it is turbid.

SPECIMEN COLLECTION AND PRESERVATION

Serum or heparinized plasma, CSF & Urine.
Freshly drawn non hemolysed serum is the specimen of choice. Serum Sodium is stable for at least 24 hours at room temperature and two weeks at 2-8°C.
Urine diluted (1+1) with distilled water can be used for Sodium estimation. Sodium is stable for 7 days at 2-8°C.

SYSTEM PARAMETERS

Wavelength	630 nm
Optical path	1 cm
Assay type	End-point
Direction	Increase
Sample Reagent Ratio e.g.: Reagent volume Sample volume	1:100 1 ml 10 µl
Temperature	15-25°C
Incubation time	5 min at 15-25°C
Zero adjustment	Reagent blank
Sensitivity	22 mEq/l
Linearity	175 mEq/l

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes, automatic pipet
- Centrifuge and spectrophotometer

ASSAY PROCEDURE

	Blank	*Standard*	*Specimen*
Reagent	1.0 ml	1.0 ml	1.0 ml
Standard		10 µl	
Specimen			10 µl

Mix, incubate for 5 minutes at room temp. Measure absorbance of specimen and standard against reagent blank. The color is stable for at least 30 minutes.

CALCULATION

$$\text{Sodium concentration (mEq/l)} = \frac{\text{Abs. specimen}}{\text{Abs. standard}} \times 150$$

QUALITY CONTROL

To ensure adequate quality control, it is recommended that normal and abnormal commercial control serum of known concentrations included in each run. If control values are found outside the defined range, check the instrument calibration, and reagent for problems. If control still out of range please contact ***BioScien*** technical support.

PERFORMANCE CHARACTERISTICS

Precision	Within run (Repeatability)		Run to run (Reproducibility)	
	Normal level	High level	Normal level	High level
n	40	40	40	40
Mean mg/dl	127	147	139	148
SD.	4	7	14	5
CV. %	3	5	10	4

The results of the performance characteristics depend on the analyzer used.

Accuracy (Methods Comparison)
Result obtained from ***BioScien*** sodium reagent compared with commercial reagent of the same methodology performed on 20 human sera give a correlation of 0.92.

Sensitivity
When run as recommended, the minimum detection limit of the assay is 22 mEq/l.

Linearity
The reaction is linear up to concentration of 175 mEq/l. Specimens showing higher concentration should be diluted 1+1 using physiological saline and repeat the assay (result×2).

INTERFERING SUBSTANCES

Haemoglobin
No significant interference up to 300 mg/dl.

Icterus
No significant interference up to a bilirubin level of 20 mg/dl.

lipemia
No significant interference up to 1000 mg/dl.

Drugs
For further information on interfering substances refer to Young DS

Others
Blood contain calcium, magnesium, potassium, iron, zinc, copper may interfere.

EXPECTED VALUES

135 – 155 mEq/l.

DYNAMIC RANGE

22 – 175 mEq/l.

REFERENCES

1- Tietz, N.W., Fundamentals of clinical Chemistry, W.b. Saunders Co. Phila, P.A. p. 874.
2- Young DS. Effects of Drugs on Clinical Laboratory Tests. 5th ed. Volume 1 and 2. Washington, CD: The American Association for Clinical Chemistry Press 2000.
3- Henry R.F., et, al, Clinical Chemistry Principles and Technics. 2nd Ed, Harper and Row, Harper and Row, Hargersein, M.D. (1974).
4- Maruna RFL., Clin Chem. Acta. 2:581, (1958).
5- Trinder, P: Analyst, 76:596, (1951).

SYMBOLS IN PRODUCT LABELLING

IVD	For in-vitro diagnostic use	Σ	Number of <n> test in the pack
LOT	Batch Code/Lot number		Caution
REF	Catalogue Number		Do not use if package is damaged
	Temperature Limitation		Consult Instruction for use
	Expiration Date		
	Manufactured by		

EC REP

Medical Device Safety Service
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30175 Hannover, Germany

CE