Sodium FS*

Diagnostic reagent for quantitative in vitro determination of sodium in serum or plasma on photometric systems

Order Information

Cat. No.
1 4808 99 10 021 R1 5 x 15 mL + R2 1 x 25 mL

Summary [1-4]

Sodium (Na^+) is the major positive ion in the extracellular fluid compartment (ECF) and is mainly responsible for the osmotic pressure in plasma. Its concentration in blood is regulated by adjusting the water content of the ECF and by maintaining total body sodium at a constant level within a narrow range. Sodium is excreted or resorbed by the kidneys, depending on the hormonal control of water homeostasis by aldosterone and antidiuretic hormone (ADH).
Measurement of Na^+ levels in serum is used for diagnosis of fluid and electrolyte imbalance, disorders of acid-base balance or excessive sodium intake. Furthermore, abnormal sodium values may indicate edema, renal diseases (e.g. diabetes insipidus), endocrine diseases like hypothyroidism and the syndrome of inappropriate antidiuretic hormone secretion (SIADH).

Method

Enzymatic photometric test

Principle

ß-galactosidase catalyzes the conversion of o-nitrophenyl-ß-D-galactopyranoside (ONPG) to o-nitrophenol and galactose. The activity of ß-galactosidase depends on the sodium concentration in the sample. The absorbance increase at 405 nm is proportional to the sodium concentration in the sample.

Reagents

Components and Concentrations

R1:	THAM buffer	pH 9.0	5.5%
	Chelator		0.15%
	ß-galactosidase		0.01%
R2:	THAM buffer	pH 8.8	0.2%
	o-nitrophenyl galactosidase		0.4%

Storage Instructions and Reagent Stability

The reagents are stable up to the end of the indicated month of expiry, if stored at 2 – 8 °C, protected from light and contamination is avoided. Do not freeze the reagents!

Warnings and Precautions

1. The sodium test is very susceptible to sodium contamination. The sole use of ultrapure glass ware and disposable material is strongly recommended.
2. In very rare cases, samples of patients with gammopathy might give falsified results [7].
3. Please refer to the safety data sheets and take the necessary precautions for the use of laboratory reagents. For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examinations and other findings.
4. For professional use only!

Waste Management

Please refer to local legal requirements.

Reagent Preparation

The reagents are ready to use.

Materials required but not provided

General laboratory equipment

Specimen

Serum or plasma (lithium heparin)
Stability [5]: 2 weeks at 20 – 25 °C
2 weeks at 4 – 8 °C
1 year at –20 °C
Discard contaminated specimens! Freeze only once!

Assay Procedure

Application sheets for automated systems are available on request.

Wavelength	405/660 nm (bichromatic)
Optical path	1 cm
Temperature	37 °C
Measurement	Against reagent blank

	Blank	Sample or calibrator
Sample or calibrator	-	40 µL
Dist. Water	40 µL	-
Reagent 1	900 µL	900 µL
Mix, incubate for 5 min. at 37 °C		
Reagent 2	300 µL	300 µL
Mix, incubate at 37 °C, read absorbance A1 after 1 min and start stopwatch. Read absorbance A2 after 1 and 2 min at 37 °C and calculate ΔA/min.		

Calculation

The concentration of sodium in unknown samples is derived from a linear calibration curve. It is obtained with the levels 1/2 and 3/4 of the electrolyte calibrator TruCal E.

Daily calibration is required.

Conversion factor

Sodium [mmol/L] = Sodium [mEq/L]
Sodium [mmol/L] x 2.30 = Sodium [mg/dL]

Calibrators and Controls

For calibration, DiaSys TruCal E calibrator is recommended. The assigned values of TruCal E have been made traceable to the NIST Standard Reference Material® SRM 956. DiaSys TruLab N and P controls should be assayed for internal quality control. Each laboratory should establish corrective action in case of deviations in control recovery.

	Cat. No.	Kit size
TruCal E	1 9310 99 10 079	4 x 3 mL
TruLab N	5 9000 99 10 062	20 x 5 mL
	5 9000 99 10 061	6 x 5 mL
TruLab P	5 9050 99 10 062	20 x 5 mL
	5 9050 99 10 061	6 x 5 mL

* fluid stable

Performance characteristics

Measuring range

The test has been developed to determine sodium concentrations within a measuring range from 100 to 180 mmol/L.

Specificity/Interferences

Interfering substance	Interferences < 3.0 %	Sodium [mmol/L]
Ascorbate	up to 50 mg/dL	127
	up to 50 mg/dL	147
Conjugated bilirubin	up to 20 mg/dL	133
	up to 60 mg/dL	147
Unconjugated bilirubin	up to 55 mg/dL	133
	up to 60 mg/dL	155
Lipemia (triglycerides)	up to 1000 mg/dL	122
	up to 1000 mg/dL	153
Hemoglobin	up to 500 mg/dL	125
	up to 300 mg/dL	148
Calcium	from 2 to 7.7 mmol/L	139
	from 2 to 8.0 mmol/L	147
Copper	up to 60 µmol/L	124
	up to 60 µmol/L	141
Iron	up to 260 µmol/L	127
	up to 200 µmol/L	155
Lithium	up to 3.7 mmol/L	134
	up to 3.3 mmol/L	150
Magnesium	up to 15 mmol/L	135
	up to 15 mmol/L	154
Potassium	from 3 to 13 mmol/L	122
	from 3 to 13 mmol/L	153
Zinc	up to 80 µmol/L	127
	up to 80 µmol/L	145
For further information on interfering substances refer to Young DS [6].		

Limit of Detection

The lower limit of detection is 22 mmol/L.

Precision

Intra-assay n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	130	1.24	0.95
Sample 2	144	0.989	0.69
Sample 3	150	0.885	0.59

Inter-assay n = 20	Mean [mmol/L]	SD [mmol/L]	CV [%]
Sample 1	130	1.82	1.40
Sample 2	143	2.03	1.42
Sample 3	149	2.49	1.67

Method comparison

A comparison of DiaSys Sodium FS (y) with Flame Atomic Emission Spectrometry ((x) FAES) using 122 samples in the range of 121 – 162 mmol/L showed deviations between –9.55 and 2.44% to the comparison method.

A comparison of DiaSys Sodium FS (y) with ion-selective electrode ((x) ISE respons®920) using 122 samples in the range of 121 – 162 mmol/L showed deviations of –6.52 and 4.77% to the comparison method.

Reference Range [1]

Adults:	135 – 145 mmol/L
Children:	
0 – 7 days	133 – 146 mmol/L
7 – 31 days	134 – 144 mmol/L
1 – 6 month(s)	134 – 142 mmol/L
6 months – 1 year	133 – 142 mmol/L
> 1 year	134 – 143 mmol/L

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Literature

1. Thomas L. Clinical Laboratory Diagnostics. 1st ed. Frankfurt: TH-Books Verlagsgesellschaft; 1998. p. 287–295.
2. Scott MG, LeGrys VA, Klutts JS. Electrolytes and blood gases. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry. 4th ed. St. Louis: W.B Saunders Company; 2006. p. 983–1018.
3. Delaney MP, Price CP, Newman DJ, Lamb E. Kidney disease. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry. 4th ed. St. Louis: W.B Saunders Company; 2006. p. 1671–1745.
4. Demers LM, Vance ML. Pituitary Function. In: Burtis CA, Ashwood ER, Bruns DE editors. Tietz Textbook of Clinical Chemistry. 4th ed. St. Louis: W.B Saunders Company; 2006. p. 1967–2002.
5. Guder WG, Zawta B et al. The Quality of Diagnostic Samples. 1st ed. Darmstadt: GIT Verlag; 2001; p. 44-5.
6. 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.
7. Bakker AJ, Mücke M. Gammopathy interference in clinical chemistry assays: Mechanisms, detection and prevention. Clin Chem Lab Med 2007; 45(()): 1240–1243.

Manufacturer

IVD CE

DiaSys Diagnostic Systems GmbH
Alte Strasse 9 65558 Holzheim Germany