BIOLABO
www.biolabo.fr
MANUFACTURER :
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SODIUM Enzymatic method

Reagent for quantitative determination Sodium in human serum or plasma.

REF 90085 **R1** 1x120 mL **R2** 1x60 mL **R3** 1x3 mL **R4** 1x3 mL

TECHNICAL SUPPORT AND ORDERS
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Latest revision: www.biolabo.fr

CE

IVD

Made In France

I: corresponds to significant modifications

INTENDED USE

This reagent is designated for professional use in laboratory (manual or automated method).
It allows the quantitative determination of sodium ions in human serum and plasma to determine if there is a problem with electrolyte balance.
As part of a routine health check-up, results may be used as help to diagnose, in conjunction with other clinical signs and laboratory data.

GENERALITIES (1) (2)

Hypernatremia is encountered in case of dehydration, diabetes insipidus, loss of gastrointestinal hypotonic fluids, salt poisoning, selective depression of the sense of thirst, loss of skin, burns, sudation, hyperaldosteronism, CNS disturbances; hyponatremia by dilution, depletion or delirium and syndrome of inappropriate antidiuretic hormone secretion (SIADH)

PRINCIPLE (1) (4)

The assay is based on the activation of β-galactosidase enzyme by the sodium present in the sample and the consequent enzymatic transformation of o-nitrophenyl-β- D-galactopiranoside (o-NPG) into o-nitrophenol and galactose, as shown in the following reaction scheme:

$$\text{o-nitrophenyl-β-D-galactopiranoside (o-NPG)} \xrightarrow[\text{β-galactosidase}]{Na^+} \text{o-nitrophenol} + \text{galactose}$$

The o-nitrophenol formed is kinetically measured at 405 nm.

REAGENTS

R1	**Sodium**	Reagent 1
Tampon de Good's	pH 8,5	
Cryptand	> 0,4	mmol/L
β-galactosidase	< 8	UI/L
Proclin 300	0,02	%

R2	**Sodium**	Reagent 2
Tampon de Good's	pH 6,5	
o-NGP	> 0,5	mmol/L
Proclin 300	0,02	%

Vial R1 and R2: EUH208 - Contains reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500- 7], and 2-methyl-2H - isothiazol-3-one [EC no. 220-239-6] (3:1), reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7], and 2-methyl-4-isothiazolin-3-one [EC no. 220- 239-6] (3:1) (Proclin 300). May produce an allergic reaction. EUH210 - Safety data sheet available on request.

R3	**Sodium**	Cal 1	Calibrator Level 1
Sodium Chloride	approx. 110	mmol/L	
Sodium Azide	< 0,1	%	

R4	**Sodium**	Cal 2	Calibrator level 2
Sodium Chloride	approx. 170	mmol/L	
Sodium azide	< 0,1	%	

Specific batch value indicated on the label of the vial.

According to 1272/2008/EC Regulation, these reagents are not classified as dangerous.

SAFETY CAUTIONS

- Refer to current Material Safety Data Sheet available on request or on www.biolabo.fr
- Verify the integrity of the contents before use.
- Waste disposal: Respect legislation in force in the country.
- All specimens or reagents of biological origin should be handled as potentially infectious. Respect legislation in force in the country.

Any serious incident that has occurred in connection with the device is notified to the manufacturer and the competent authority of the Member State in which the user and/or patient is based.

REAGENTS PREPARATION

Ready for use.

STABILITY AND STORAGE

Stored away from light, well caped in the original vial at 2-8°C, when stored and used as described, reagents are stable:

Unopened:

- Until expiry date stated on the label of the kit.

Once opened:

- at least 30 days.

SPECIMEN COLLECTION AND HANDLING (3)

Plasma (Lithium or ammonium héparinate).

Unhaemolysed serum:

✓ Centrifuge and test as soon as possible after collection.

LIMITES (5)

When Sodium and Potassium are requested together, sodium is assayed immediately before Potassium

For a more comprehensive review of factors affecting this assay refer to the publication of Young D.S.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Basic medical analysis laboratory equipment.
2. Spectrophotometer or Biochemistry Clinical Analyzer

QUALITY CONTROL

- REF 95010 BIOLABO EXATROL-N Level I
- REF 95011BIOLABO EXATROL-P Level II
- External quality control program

It is recommended to control in the following cases:

- At least once a run
- At least once within 24 hours
- When changing vial of reagent
- After maintenance operations on the instrument

If control is out of range, apply following actions:

1. Prepare a fresh control serum and repeat the test
2. If control is still out of range, use a new vial of fresh calibrator
3. If control is still out of range, use a new vial of reagent and reassay

If control is still out of range, please contact BIOLABO technical support or your local Agent.

REFERENCE INTERVAL (3)

Serum or plasma	mEq/L	[mmol/L]
Premature, cord	116-140	[116-140]
Premature, 48h	128-148	[128-148]
Newborn, in cord	126-166	[126-166]
New Born	133-146	[133-146]
Infant	139-146	[139-146]
Child	138-145	[138-145]
Thereafter	136-145	[136-145]
> 90 years	132-146	[132-146]

Each laboratory should establish its own normal ranges for the population that it serves.

PERFORMANCES

Performances studies on Hitachi 917 Analyzer at 405 nm, 37°C:
Linearity Range: between 80 mmol/L and 180 mmol/L
Detection limit: 16 mmol/L

Precision:

Within-run N = 20	*Low level*	*Normal level*
Mean (mmol/L)	129	156
S.D. mmol/L	1.6	1.7
C.V. %	1.2	1.1

Between run N = 20	*Low level*	*Normal level*
Mean (mmol/L)	129	156
S.D. mmol/L	2.01	2.6
C.V. %	1.6	1.7

Analytical Sensitivity (Manual method):
approx. 0.035 abs / 10mmol/L (405 nm, 1 cm path length, 37°C)

Interferences:

Interference	Concentration
Ascorbic acid	10 mmol/L
Triglycerides	1000 mg/dL
Haemoglobin	500 mg/dL
Conjuguate bilirubin	40 mg/dL
Bilirubin	40 mg/dL
K+	10 mmol/L

Interference	Concentration
NH4+	1,5 mmol/L
Ca2+	7,5 mmol/L
Pi (inorganic phosphorous)	2 mmol/L
Fe3+	0,5 mmol/L
Cu2+	0,5 mmol/L
Zn2+	0,5 mmol/L

Other substances may interfere (see § Limits)

Comparison studies with Sodium ISE:
Automated Analyzer (specimens n=50) from 80 to 180 mmol/L

y =1,0881x -9,9478 r = 0,9814

CALIBRATION (6)

- Cal1 and Cal 2 (Vial R3 and R4) traceable *to SRM909*

The calibration frequency depends on proper instrument functions and on the preservation of reagent.

Make a new calibration when changing reagent batch, if quality control results are found out of the established range and after maintenance operations.

PROCEDURE

Manual method

Let stand reagent and specimens at room temperature.

Reagent 1	600 µL
Blank, Standards, control or specimen	24 µL
Mix well. Let stand for 5 minutes at 37°C. Add:	
Reagent 2	300 µL
Mix well. Read at 405 nm absorbance A1 after 120 sec and A2 after 240 sec Calculate ΔA = (Abs A2 – Abs A1) for Blank, Standards and Assays	

1- Performances with manual procedure should be validated by user.
2- KENZA applications and other applications proposal are available on request.

CALCULATION

Serum or plasma:

$$\frac{\Delta Abs\ (Assay) - \Delta Abs\ (Blank)}{\Delta Abs\ (Standard) - \Delta Abs\ (Blank)}$$

Interpolate obtained ΔA in the Calibration Curve

REFERENCES

(1) BERRY, M. N. et al., (1988) Clin. Chem. 34,2295
(2) TIETZ N.W. Textbook of clinical chemistry, 3rd Ed. C.A. Burtis, E.R. Ashwood, W.B. Saunders (1999) p. 1057, 1098-1101.
(3) Clinical Guide to Laboratory Test, 4th Ed., N.W. TIETZ (2006) p. 992.
(4) R. Quiles, J.M. Fernandez Romero, CLIN. CHEM. 39/3, (1993) p.500-503
(5) YOUNG D.S., Effect of Drugs on Clinical laboratory Tests, 4th Ed. (1995) p. 3-531 à 3-541
(6) SRM: Standard Reference Material®

Manufacturer	Expiry date	In vitro diagnostic	Storage temperature	Dematerialized water	Biological risk
Product Reference	See Insert	Batch number	Store away from light	Sufficient for	Dilute with