



BIOLABO
www.biolabo.fr
MANUFACTURER :
BIOLABO SAS,
 Les Hautes Rives
 02160, Maizy, France

SODIUM Enzymatic method

Reagent for the quantitative determination of sodium ions
 in human serum or plasma.

I REF	K1085	R1	2x16 mL	R2	2x8 mL	R3	1x3 mL	R4	1x3 mL
REF	K2085	R1	2x30 mL	R2	2x15 mL	R3	1x3 mL	R4	1x3 mL



Made In France

I: corresponds to significant modifications

TECHNICAL SUPPORT AND ORDERS

Tel: (33) 03 23 25 15 50

support@biolabo.fr

Latest revision: www.biolabo.fr

INTENDED USE

This reagent is designated for professional use in laboratory (automated method).

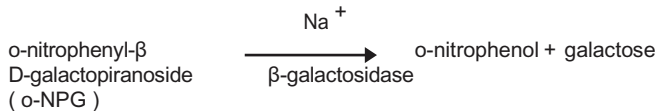
It allows the quantitative determination of sodium ions in human serum and plasma to determine if there is a problem with electrolyte balance. As part of a routine health check-up, results may be used as help to diagnose, in conjunction with other clinical signs and laboratory data.

GENERALITIES (1)

Hyponatremia 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-galactopyranoside (o-NPG) into o-nitrophenol and galactose, as shown in the following reaction scheme:



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

REAGENTS

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

R2	SOD	Reagent 2
Good's buffer	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 capped 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.

LIMITS (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.

MATERIAL REQUIRED BUT NOT PROVIDED

- Basic medical analysis laboratory equipment.
- Biochemistry Clinical Analyzer KENZA One, KENZA 240TX/ISE or KENZA 450TX/ISE

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 717 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	Between run N = 20	Low level	Normal level
Mean (mmol/L)	129	156	Mean (mmol/L)	129	156
S.D. mmol/L	1.6	1.7	S.D. mmol/L	2.01	2.6
C.V. %	1.2	1.1	C.V. %	1.6	1.7

Analytical Sensitivity:

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

Interferences:

Interference	Concentration	Interference	Concentration
Ascorbic acid	10 mmol/L	NH ₄ ⁺	1,5 mmol/L
Triglycerides	1000 mg/dL	Ca ²⁺	7,5 mmol/L
Haemoglobin	500 mg/dL	Pi (inorganic phosphorous)	2 mmol/L
Conjugate bilirubin	40 mg/dL	Fe ³⁺	0,5 mmol/L
Bilirubin	40 mg/dL	Cu ²⁺	0,5 mmol/L
K ⁺	10 mmol/L	Zn ²⁺	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.

QUALITY CONTROL

- REF 95010 BIOLABO EXATROL-N Level I
- REF 95011 BIOLABO 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 re-assay
- If control is still out of range, please contact BIOLABO technical support or your local Agent.

PROCEDURE

Refer to validated application of the KENZA Analyzer used













CALCULATION

The analyzer provides directly final result.

Refer to the instruction of use of KENZA analyzer.

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